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A sell unit for the parenteral application, a device for carrying out the parenteral application as well as a refill unit for the above mentioned sell unit

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The present invention is directed to a sell unit for the parenteral application of liquid pharmaceutical products, to a device for carrying out this parenteral application and to a refill unit for the afore mentioned sell unit, respectively device.

Parenterally applicable liquid pharmaceutical products, meaning such products that are subcutaneously applied by means of a syringe, nowadays are applied mainly by correspondingly trained professional staff, as for example by doctors or nursing staff. Hereby a usual syringe is used which is filled with the corresponding liquid pharmaceutical product before the parenteral application or which is filled already as a one-way syringe with the liquid pharmaceutical product. However, this means that the respective user has to submit himself to a medical treatment which involves high expenses particularly when, for the therapy of the respective disease, a given amount of a liquid pharmaceutical product has to be injected subcutaneously each day for a given limited time period.

The present invention has the object of elaborating a possibility by which the respective user can parenterally and preferably subcutaneously apply a liquid pharmaceutical product

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particularly easily.

According to the invention, this object is realised by a sell unit with the characteristics of patent claim 1, by a device with the characteristics of patent claim 11, as well as, if necessary, by a refill unit with the characteristics of patent claim 33 completing the sell unit according to patent claim 1, respectively the device according to patent claim 11.

The inventive sell unit for the parenteral application of a liquid pharmaceutical product by the user for the required therapy period is based on the main thought that the user can dispose, during the medically prescribed treatment period, of all necessary parts, so that the user is able to parenterally and preferably subcutaneously apply himself the required liquid pharmaceutical product without the help of medical staff. For that reason, the inventive sell unit comprises at least one cannula, one device for emitting a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel filled with the liquid pharmaceutical product, whereby the vessel can be set in the device and emptied by means of the device and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product. In other words, the user only needs to provide the device for emitting a given liquid amount, the device being arranged within the unit, with a cannula also arranged within the unit and, furthermore, to put the vessel filled with the liquid pharmaceutical product in the emitting device, so that immediately hereafter the user can parenterally and preferably subcutaneously apply himself the

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single dose of the liquid pharmaceutical product prescribed by the doctor.

The inventive sell unit has a range of advantages. Conditioned by the fact that the inventive sell unit comprises all parts that the user needs and that are required for the parenteral application in a single sell unit, it is firstly to be noted that, on one hand, these parts can be commonly stored in the sell unit by the user himself during the treatment and that, on the other hand, it is made particularly easy for the prescribing doctor to prescribe this sell unit as a whole. Since the emitting device of the sell unit forcibly determines, as a result of its construction, the given amount of the liquid pharmaceutical product for each single dose, the liquid pharmaceutical product cannot be underdosed or overdosed in the inventive sell unit, so that hereby the parenteral application of the liquid pharmaceutical product by the user is particularly safe. Moreover, the user can dispose of the parts required for the parenteral application in a well and clearly-arranged way, whereby the acceptance of the inventive sell unit is essentially improved for the user. Furthermore, the inventive sell unit avoids a soiling of its parts, particularly during their use for the user, and makes the expedition and the storing easier since it is formed as a unit, which is particularly advantageous for the use in the trade.

A first embodiment of the inventive sell unit is characterized in that the unit comprises a number of cannulas that corresponds to a number of the single doses of the pharmaceutical product.

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Hereby the user can exchange the used cannula by a corresponding sterile cannula after each parenteral application of the liquid pharmaceutical product, whereby the risk of an infection is avoided. The cannulas provided in the sell unit are preferably constructed in that way that the actual needle of the cannula is protected by a solid plastic jacket, whereby this solid plastic jacket, on one hand, guarantees the sterility of the needle and, on the other hand, keeps the user from unintentionally hurting himself with the needle. Such an embodiment of the sell unit particularly comprises ten of the afore described cannulas, whereby then the vessel being provided in the sell unit and being filled with the liquid pharmaceutical product makes it possible to correspondingly apply ten single doses of the product to be parenterally applied.

In order to make it again easier for the user to operate the inventive sell unit during the parenteral application, a further advantageous development is directed to a sell unit that comprises a number of cannulas that corresponds to a number of sponges, whereby these sponges are moistened with a disinfectant, as for example a low alcohol, ethanol, propanol. In order to avoid on the sponges an undesired evaporation of the disinfectant, the sponges moistened with a disinfectant are wrapped singly in corresponding foils, preferably plastic foils and more preferably compound plastic foils, so that, for the parenteral application, the user removes just one sponge from the wrapping and disinfects herewith the spot chosen for the injection.

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In another embodiment of the inventive sell unit, the unit additionally comprises a section serving to take up the used cannulas and/or used sponges. Hereby this section to take up the used cannulas, respectively the used sponges, is formed in the way that the used cannulas, respectively sponges, cannot fall out of the sell unit while being used, so that the section is formed particularly as a separately closable section. If in the sell unit this section is formed as a section being detachable from the sell unit, as for example as a closable box, the used cannulas and, if necessary, the sponges can be separately wasted, as for example by the special trade, as far as this is required by legal prescriptions.

The inventive sell unit can comprise basically each vessel containing the multitude of single doses of the liquid pharmaceutical product, as far as it is guaranteed that this vessel is formed in that way that it can be set into the device and emptied in single doses by means of the device. However, it is particularly suitable to fill the liquid pharmaceutical product to be parenterally applied by the user in single doses in a cylindrical or cylinder-like glass carpule (glass syringe cylinder), whereby such a glass carpule holds particularly between about 1,5 ml and about 8 ml, preferably between about 2 ml and about 6 ml, of the liquid pharmaceutical product.

A particularly advantageous development of the afore described glass carpule is characterized in that in the inventive sell unit such a glass carpule is arranged which is closed, at its bottom side, by a piercable membrane and, at its top side, by a

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plug being formed in that way that it can be axially shifted within the glass carpule in the direction of the piercable membrane when the liquid level is descending. This special development of the glass carpule has the particular advantage that the bottom section of the plug is located in the immediate proximity of the liquid level or even contacts the liquid level, so that there is no air puffer above the respective liquid level when the liquid level is descending because of the single doses emitted. On one hand, this avoids an undesired oxidative modification of the respective liquid pharmaceutical product and, on the other hand, the special forming of the plug effectively avoids the formation of a vacuum in the glass carpule when the liquid amount is decreasing, whereby such a vacuum would have a negative effect on the exactness of the liquid amount emitted in single doses.

In order to ensure the required tightness between the plug and the inner walling of the glass carpule, according to the afore described embodiment of the glass carpule which disposes of the afore described plug being axially shiftable in the direction of the piercable membrane, a further development of the inventive sell unit is characterized in that the plug comprises on its jacket surface at least one, preferably two to five, disk-like sections directing radially to the outside. Hereby these disk-like sections can be deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid-tightens and air-tightens the inner surface of the carpule. The disk-like sections directing to the outside are preferably dimensioned in that way that an end section of the

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disk-like sections is elastically deformed by the axial shifting of the plug in the glass carpule opposite to the shifting direction with the formation of a correspondingly larger dimensioned sealing surface. In respect to the material that the plug consists of, it is to be noted that herefore preferably an elastic, chemically resistant plastic material or rubber material is chosen, whereby herefore a halogenbutyl-caoutchouc proved to be particularly suitable.

When the afore described plug can be axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N, it is particularly guaranteed that the above described advantages occur in a particularly reproducible way.

By using the inventive sell unit, basically all liquid pharmaceutical products being stable in storage can be parenterally applied by the user himself. Hereby the term liquid pharmaceutical products means all such products which, as actual product, are liquid or from which stable solutions, stable dispersions or stable emulsion can be manufactured in an organic or inorganic, physiologically safe liquid. The afore described vessel or the afore described and particularly used glass carpule preferably comprise an aqueous solution of a heparin, preferably an aqueous solution of a low-molecular heparin, and particularly an aqueous solution of an enoxaparin-sodium. Such a sell unit is then used by such users who, because of their syndrome and from the medical point of view, have to apply the heparin daily in constant single doses for a longer time period,

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in order to prevent, for example, the risk of a thrombosis after having discharged the patient from the hospital. A further preferred employment of the inventive sell unit is the regular parenteral application of a given and constant amount of a growth hormone, whereby, for this case of application, the vessel and particularly the afore described glass carpule is filled with a solution of the growth hormone, preferably an aqueous solution of the growth hormone. Within the scope of the present invention, the term water does not only mean deionized or distilled water, but all aqueous systems, particularly physiological salt solutions or buffer solutions.

The present invention is furthermore directed to a device for emitting a given liquid amount of a pharmaceutical product in single doses, whereby the inventive device comprises a section arranged within a casing, the section taking up the vessel filled with the liquid pharmaceutical product. Moreover, the inventive device contains an outlet section for the single dose of the pharmaceutical product, whereby the outlet section directs into the direction of the user when he parenterally and particularly subcutaneously applies the single dose of the pharmaceutical product. According to the inventive device, the vessel containing the multitude of the single doses, can be connected with the outlet section by an intermediate reservoir in such a way that, when the vessel is set into the inventive device, the given liquid amount of each single dose can be drained firstly from the vessel into the intermediate reservoir and then from the intermediate reservoir into the outlet section. The amount of the liquid pharmaceutical product emitted

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with each single dose can be determined, according to the inventive device, by the volume of the intermediate reservoir. In other words, the amount of the single dose being parenterally applicable is variable in the inventive device by varying the volume of the intermediate reservoir, whereby the volume of the intermediate reservoir is chosen in that way that each single dose of the liquid pharmaceutical product to be applied has a volume of between 0,1 ml and 1 ml, particularly between 0,2 ml and 0,6 ml and preferably between 0,2 ml and 0,4 ml.

The inventive device shows a number of advantages. First of all it is to be noted that it has a relatively simple and unproblematical construction and that it is very easy to handle since for the use of the inventive device by the user, it is only necessary to arrange the vessel containing the multitude of single doses of the liquid pharmaceutical product within the section for taking up the vessel located in the inventive device and to fix it there, if necessary, so that subsequently within the inventive device the vessel is connected with the intermediate reservoir which is then connected with the outlet section. In other words, when the respective user, contrarily to the initially described procedure of parenterally applying a liquid pharmaceutical product by a doctor or the medical staff, uses the inventive device, he does not have to transmit the respective product to be applied from the ampoule into the syringe and to measure the exact amount to be injected since in the inventive device this procedure takes places inevitably because of the construction of the inventive device. This essentially simplifies the use of the inventive device, so that

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by using the inventive device even sick and/or old users are able to inject themselves the required single dose of the product to be parenterally applied without depending on the help of others.

In order to form in the inventive device the afore mentioned connection between the vessel being set into the device and the intermediate reservoir in a particularly simple way, a further development of the inventive device is characterized in that at least one connecting conduct is located between the set in vessel filled with the multitude of the single doses of the liquid pharmaceutical product and the intermediate reservoir. Hereby an end section of this connecting conduct preferably protrudes into the section being arranged within the casing of the inventive device and taking up the vessel filled with the pharmaceutical product, so that, when the vessel has to be put in, this end section simplifies the connecting of the intermediate reservoir and the set in vessel. If hereby the glass carpule, which is described above in connection with the inventive sell unit and which comprises particularly at its top end the afore mentioned piercable membrane, is used as a vessel, it is suitable to form this end section of the connecting conduct as a correspondingly pointed end section or preferably as hollow needle, so that by this pointed end section, respectively by this hollow needle, then the piercable membrane can be pierced and so that thus the afore mentioned connection between the content of the glass carpule and the intermediate reservoir can particularly easily be realised. Such a piercing of the piercable membrane can also be simplified by providing

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the pointed end section, respectively the hollow needle, with a stopping element for the carpule, whereby this stopping element preferably fixes the carpule shaft and thus the whole carpule in its position. If hereby this stopping section is formed as a thread or as a bayonet catch, meaning that the thread, respectively the bayonet catch, can receive the correspondingly formed section of the carpule shaft, the carpule forcibly moves axially in the direction of the connecting conduct when the carpule is screwed in, respectively fixed, so that hereby the end section formed as pointed end section, respectively as hollow needle, penetrates the piercable membrane and so that thus the liquid pharmaceutical product can flow from the glass carpule into the intermediate reservoir.

A further development of the afore described embodiment of the inventive device is characterized in that the connecting conduct comprises a valve avoiding a backflow of the liquid from the intermediate reservoir into the glass carpule. In other words, this embodiment of the inventive device thus comprises a connecting conduct being provided with a reflux valve, so that the liquid to be parenterally applied can superfuse the connecting conduct only in one single direction, meaning from the vessel into the intermediate reservoir.

In respect to the formation of the afore mentioned valve avoids a backflow of the liquid pharmaceutical product from the intermediate reservoir into the vessel, as this is already described above, there are several possibilities. This upper section can be formed, for example, as a usual ball-containing

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reflux valve. However, it is particularly suitable when the reflux valve is formed as a membrane valve, whereby a valve sheet, preferably consisting of a rubber-elastic material, can be moved between a first position in which the valve sheet covers the partial conduct section of the connecting conduct, whereby the partial conduct section is directed to the vessel, and between a second position in which the valve sheet is displaced in the direction of the intermediate reservoir and makes possible the liquid flow from the vessel into the intermediate reservoir. In order to prevent an adhesion of the disk-shaped valve sheet in the first position and to avoid thus a disturbance of the functioning of the reflux valve, it is suitable to provide a ring-shaped distancing element which gets in contact with the valve sheet when the valve sheet is in the first position, so that in all the sealing surface is decreased by the ring-shaped distancing element, as this is subsequently described in detail in a example.

For filling the intermediate reservoir in the inventive device with the single dose of the liquid pharmaceutical product from the vessel, the content of the vessel can flow into the intermediate reservoir and thus fill it for gravitation reasons. It is particularly suitable, however, when a piston being axially shiftable in the direction of the outlet section is arranged within the intermediate reservoir, whereby, with such an axial shifting in the direction of the outlet section, the piston then effectuates the flow of a single dose of the liquid pharmaceutical product, the single dose being located in the intermediate reservoir, in the direction of the outlet section.

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According to an axial shifting in the opposite direction hereof, a vacuum is generated in the intermediate reservoir if the connection between the intermediate reservoir and the outlet section is closed air-tight, so that a connecting conduct extending through the piston, the connecting conduct being located between the vessel and the intermediate reservoir, fills the intermediate reservoir with the liquid from the vessel filled with the liquid pharmaceutical product. Such a filling of the intermediate reservoir has the particularly advantage that hereby a reproducibly and exactly given liquid amount drains from the vessel into the intermediate reservoir, so that correspondingly the single dose of the liquid pharmaceutical product from the intermediate reservoir which is applied by the user can be formed in a particularly exact and reproducible way.

In order to obtain in the inventive device the air-tight blocking which is required before for the filling and which blocks the conduct located between the intermediate reservoir and the outlet section, there a several possibilities. For example, a valve , particularly a reflux valve, can be arranged also in this conduct, whereby this valve does not allow an air flow or a liquid flow from the outlet section into the intermediate reservoir, but only a liquid flow from the intermediate reservoir into the outlet section. It is particularly suitable, however, when the conduct comprises a closing element being operable from the outside, as for example a corresponding valve.

An embodiment of the inventive device which is particularly easy

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to handle by the respective user for a long time period is characterized in that the already afore mentioned closing element by which the conduct connecting the outlet section with the intermediate reservoir can be closed air-tight is formed as detachable closing element being located at the conduct. Hereby a sealing section of the closing element air-tightens the outer conduct outlet located at the outlet section. This closing element is preferably formed as a closing element which can be screwed onto the device in the outlet section or which can be fixed by a bayonet catch in such a way that it is detachably connectable with outlet section and/or the casing of the device. If in this embodiment of the inventive device it is desired to fill the intermediate reservoir with the single dose of the liquid pharmaceutical product in the afore described manner, which means that an air flow from the conduct outlet of the outlet section into the intermediate reservoir is avoided and that thus the vacuum required for the filling of the intermediate reservoir is generated, this closing element is screwed onto the outlet section, respectively onto the corresponding zone of the casing, so that the sealing section located at the closing element gears in with the conduct outlet. After filling the intermediate reservoir, the closing element is detached from the outlet section, respectively from the zone of the device casing, so that the single dose of the liquid pharmaceutical product, the single dose being located in the intermediate reservoir, can be drained out of the inventive device by axially shifting the piston in the direction of the outlet section and the consequently opened conduct.

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A particularly high reproducibility in respect to the liquid pharmaceutical product amount emitted with each single dose can be obtained in such an embodiment of the inventive device, when it is guaranteed that the intermediate reservoir can be completely emptied by axially shifting the piston being arranged in the intermediate reservoir in the direction of the outlet section.

Such a complete emptying furtherly avoids an undesired crystallisation or the deposition of residues of the pharmaceutical product on the intermediate reservoir wallings and/or the piston wallings, whereby, on one hand, the exactness of dosing each single dose and, on the other hand, the function of the inventive device would be endangered.

A particularly embodiment of the inventive device which makes it possible to emit single dose from the intermediate reservoir in an reproducible and untroubled way, is characterized in that the intermediate reservoir is formed in a cylindrical way and comprises a subsequent end section being conically shaped and directing to the outlet section, whereby the end section is connected with the outlet section by the afore described conduct. In this development the form of the piston moreover corresponds to the form of the afore described intermediate reservoir, so that correspondingly the piston comprises a cylindrical piston section and an end section being conically formed and being connected with the cylindrical piston section. If in this embodiment of the inventive device additionally the connecting conduct being located between the vessel and the

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intermediate reservoir extends through the piston section up to the conical piston point, not only the complete emptying is guaranteed to a high degree in such a development of the inventive device, but also the reproducible filling of the intermediate reservoir.

In respect to the formation of the conical end section, there are several possibilities. This conical piston end section can, for example, consist of the same material as the rest of the piston, whereby, however, in a particularly advantageous embodiment the conical piston end section can be formed by a conically extending jacket tube being closed at its end which is located opposite to the piston section. The connecting conduct then extends almost over the whole axial length of the jacket tube, whereby the connecting conduct is located between the vessel and the intermediate reservoir, and whereby the conically shaped jacket tube comprises outlets for the liquid advanced from the vessel on its jacket surface. Hereby it is guaranteed that the intermediate reservoir is impeccably filled with the single dose of the liquid pharmaceutical product coming from out of the vessel.

The inventive device basically makes it possible to parenterally apply the single dose of the liquid pharmaceutical product being located in the intermediate reservoir directly over the outlet section connected with the intermediate reservoir by means of the conduct by submitting the single dose of the liquid pharmaceutical product to a high pressure. It is particularly suitable, however, when the outlet section comprises a mounting

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section for the detachable fixing of a cannula in such a way that the conduct can be connected with the cannula in a liquid-tight manner. In this embodiment of the inventive device, the mounting section thus holds a cannula which can be detachably fixed and which, during the application of the liquid pharmaceutical product, penetrates the body zone chosen by the user and then effectuates the parenteral application of the product.

A further embodiment of the inventive device is characterized in that additionally the afore described closing element which effectuates a closing of the conduct being located between the intermediate reservoir and the outlet section during the filling of the intermediate reservoir can be detachably fixed at the mounting section. Depending on the formation of the mounting section and the closing element, the closing element and the cannula can either be fixed at the same time at the mounting section or the closing element and the cannula can be fixed optionally at the mounting section, whereby the latter mentioned possibility is preferred since hereby the risk of getting hurt by removing the closing element is avoided by cannula still being fixed at the mounting section.

Another embodiment of the inventive device is characterized in that moreover the mounting section comprises a protecting element, whereby this protecting element then covers a cannula fixed at the mounting section at least partially or completely. This protecting element protecting the respective user from an undesired hurting by the cannula can hold the closing element or

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additionally support the fixing of the closing element at the mounting section, so that hereby a handle section is formed which the user touches while preparing the inventive device for the application.

A further particularly suitable embodiment of the inventive device comprises first cylinder being located in the casing and a second cylinder surrounding the first cylinder, whereby the first cylinder and the second cylinder are axially shiftable relative to the casing. The section for taking up the vessel, particularly the afore described carpule, is arranged within the first cylinder, whereas the intermediate reservoir being connected with the vessel is arranged within the second cylinder. In this embodiment of the inventive device, the first cylinder and the second cylinder can be axially shifted from a first position in which the cannula being fixable to the mounting section protrudes over the afore described protecting element, respectively the device casing, and in which the intermediate reservoir is emptied over the conduct and the cannula following hereafter, and a second position in which a cannula being fixable to the mounting section is covered by the protecting element and in which the intermediate reservoir is filled with the single dose, and vice-versa.

The afore described embodiment of the inventive device permits a parenteral application of the corresponding single dose of the liquid pharmaceutical product in a particularly simple way. Herefore it is only necessary to transmit the first cylinder and the second cylinder from a first position in which the

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intermediate reservoir is empty into a second position by axially shifting the cylinders relatively to the casing. This axial shifting leads to the fact that the intermediate reservoir is filled with the liquid being drained out of the vessel. After attaching a corresponding cannula at the mounting section, the penetration of the cannula into the body zone of the user and the emptying of the intermediate reservoir is carried out by axially shifting both cylinders in the direction of the mounting section, whereby as a consequence the single dose is parenterally applied. Both cylinders are preferably formed in that way that they additionally can be axially shifted relatively to each other, so that there is a time difference between the actual penetration procedure of the cannula into the body zone of the user and the emptying of the intermediate reservoir, whereby it is made possible to apply the liquid pharmaceutical product in a corresponding time retardation.

In order to cause the afore described axial shifting of both cylinders from the first position into the second position and from the second position into the first position, these axial shiftings can be realised manually in both directions. This means, however, that, when the respective user transmits both cylinders from the second position into the first position in the afore mentioned way, the penetration of the cannula into the body zone has to be carried out manually by the user himself, which the user considers to be extremely unpleasant and invincible. For that reason a particularly advantageous development of the afore described embodiment of the inventive device is characterized in that the first cylinder and the

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second cylinder comprise each a spring in such a way that in the second position of the cylinders both springs are tensioned and that in the first position of the cylinders the springs are released.

In order to fix both cylinders in their second position being tensioned by the corresponding springs, each cylinder in the inventive device can comprise a corresponding locking element. By releasing the locking of the second cylinder, the second cylinder is then transmitted from the second position into the first position caused by the spring power of the spring located at the second cylinder, which causes an inevitable penetration of a cannula being fixed at the mounting section into the chosen body zone of the user, whereby the user has no influence on this. Subsequently the locking being provided for the first cylinder is released, whereby the first cylinder is axially moved in the direction of the outlet section by the spring being provided for the first cylinder, whereby the intermediate reservoir is emptied, so that the corresponding single dose of the liquid pharmaceutical product is parenterally applied.

According to a particularly suitable and easy to handle development of the embodiment of the inventive device, both cylinders are fixable in the second position by a single locking element. This means that the user has to release only one locking element in order to commonly transmit both spring-tensioned pistons being fixed in the second position into the first position, whereby the penetration procedure of the cannula into the body zone and the injection of the single dose takes

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place.

In order to obtain in the afore described embodiment of the inventive device that firstly the penetration of the cannula into the body zone takes place and hereafter the injection of the single dose, a particularly suitable development of this embodiment is characterized in that it comprises springs corresponding to each other in respect to their characteristic spring line. Hereby the spring provided for the second cylinder has a steeper characteristic spring line than the spring being located at the first cylinder, so that the already afore mentioned time retardation between the penetration of the cannula and the subsequent injection can be regulated by accommodating the characteristic spring lines to each other in a high range.

A further advantageous embodiment of the inventive device is directed to a first cylinder and a second cylinder surrounding the first cylinder being arranged within the casing, whereby the first cylinder and the second cylinder are axially shiftable relatively to the casing. The section for taking up the vessel, preferably the afore mentioned glass carpule, is arranged within the first cylinder, whereas the intermediate reservoir connected with the vessel is arranged within the second cylinder in such a way that the first and the second cylinder can be commonly and axially shifted from a first position in which the cannula being fixable to the mounting section protrudes over the protecting element, respectively the casing, and in which the intermediate reservoir is emptied, into a second position in which a cannula

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being fixable to the mounting section is covered by the protecting element, and vice-versa. For filling the intermediate reservoir the first cylinder can be axially shifted into a third position in the direction of the vessel relatively to the second position of the second cylinder.

In other words, this afore described and particularly advantageous development of the inventive device is characterized in that it provides also a third position, contrarily to the afore described embodiments of the inventive device in which the cylinders can only be arranged in a first and a second position.

In order to use the inventive device, firstly both cylinders are transmitted from the first position into the second position, which causes that a cannula being fixed at the mounting section is covered by a protecting element. At this time the intermediate reservoir is not yet filled with the single dose of the liquid pharmaceutical product. Subsequently the first cylinder is axially shifted into a third position relatively to the second cylinder which remains in the second position, whereby the intermediate reservoir is completely filled with the liquid pharmaceutical product being drained out of the vessel by the connecting conduct. As the first cylinder is moved from the second position into the third position, the conduct connecting the cannula with the intermediate reservoir is blocked in an air-tight way by one of the afore described valves or by the also afore mentioned closing element. A vacuum causing the liquid flow from the vessel into the intermediate reservoir is

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thus generated in the intermediate reservoir.

Hereafter the ready-to-operate device is brought into contact with the chosen body zone, so that then the user moves the second cylinder from the second position into the first position, whereby the penetration procedure of the cannula into the body zone is manually effectuated. Hereafter the user moves the first cylinder from the third position into the first position, whereby the corresponding injection of the single dose of the liquid pharmaceutical product from the intermediate reservoir into the body is caused.

As it is, however, mentioned above, some user have the problem with this application that they have to carry out themselves the corresponding injection of the single dose of the liquid pharmaceutical product from the intermediate reservoir into the body. In order to avoid this, a further development of the afore described embodiment of the inventive device is characterized in that each cylinder (first cylinder, second cylinder) comprises a spring, whereby a first spring pre-tensions the arrangement of the cylinder in the third position and a second spring pre-tensions the arrangement of the second cylinder in the second position. Moreover, the first cylinder is fixable in the third position by first locking and the second cylinder is fixable in the second position by a second locking in such a way that this fixing is caused by corresponding lockings can preferably be released by a single release button.

In order to apply such a device, the respective user transmits

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the second cylinder into the second position against the power of the corresponding second spring, whereby such an axial shifting of the second cylinder is realised preferably by a shifting element arranged at the outside of the casing. Concurrently to operating this shifting element, the first cylinder is shifted into its second position against the power of the first spring, whereby then the second locking fixes the second cylinder in the second position. When the shifting element is furtherly operated, the first cylinder is axially shifted relatively to the second cylinder from the second position into the third position against the power of the corresponding first spring and is then fixed in the third position by the first locking.

By operating the common release button both cylinders are axially shifted from the third position (first cylinder), respectively from the second position (second cylinder), into the first position as a result of the spring power of the first and the second spring, whereby the penetration of the cannula into the body zone and the injection of the single dose from the intermediate reservoir is forcibly effectuated without being influenced by the user.

A further development of the afore described embodiment is preferably characterized in that, by operating the release button, firstly the second locking fixing the second cylinder in the second position is released and then the first locking fixing the first cylinder in the third position is released in a corresponding time retardation.

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the afore described inventive device are particularly used in the initially discussed inventive sell unit, whereby, however, the inventive device can be traded on the market independently from the sell unit.

Furthermore, the present invention is directed to a refill unit to be employed in the initially described inventive sell unit or in the afore discussed inventive device.

Hereby this inventive refill unit comprises at least one cannula as well as at least on vessel filled with the liquid pharmaceutical product, whereby the vessel can be arranged within the afore described inventive device and emptied in single doses by means of this device.

The inventive refill unit has the essential advantage of being perfectly adjusted to the afore described sell unit as well as to the inventive device in respect to its constructive features, so that the user of the afore described inventive sell unit or of the afore discussed inventive device can apply the inventive refill unit when a longer parenteral application of the liquid pharmaceutical product is required from the medical point of view and when the vessel being filled with the liquid pharmaceutical product and being provided in the afore described inventive sell unit is emptied.

A first development of the inventive refill unit is characterized in that a detaching element to remove the emptied

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vessel from the inventive device for emitting a given liquid amount in single doses is arranged in the refill unit. The detaching element is formed correspondingly to the respective form of the section for taking up the vessel filled with the liquid pharmaceutical product, this section being located within the casing of the inventive device, whereby this detaching element preferably comprises a grip section so that the user can grip the detaching element and a fixing section for the form-fit and/or non-positive fixing of the emptied vessel.

As already described above in the inventive sell unit, a first embodiment of the inventive refill unit is characterized in that the unit comprises a number of cannulas that corresponds to a number of the single doses of the pharmaceutical product. Hereby the user can exchange the used cannula by a corresponding sterile cannula after each parenteral application of the liquid pharmaceutical product, whereby the risk of an infection is avoided. The cannulas provided in the refill unit are preferably constructed in that way that the actual needle of the cannula is protected by a solid plastic jacket, whereby this solid plastic jacket, on one hand, guarantees the sterility of the needle and, on the other hand, keeps the user from unintentionally hurting himself with the needle. Such an embodiment of the refill unit particularly comprises ten of the afore described cannulas, whereby then the vessel being provided in the refill unit and being filled with the liquid pharmaceutical product makes it possible to correspondingly apply ten single doses of the product to be parenterally applied.

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In order to make it again easier for the user to operate the inventive refill unit during the parenteral application, a further advantageous development is directed to a refill unit that comprises a number of cannulas that corresponds to a number of sponges, whereby these sponges are moistened with a disinfectant, as for example a low alcohol (ethanol, propanol). In order to avoid on the sponges an undesired evaporation of the disinfectant, the sponges moistened with a disinfectant are wrapped singly in corresponding foils, preferably plastic foils and more particular compound plastic foils, so that, for the parenteral application, the user removes just one sponge from the wrapping and disinfects herewith the spot chosen for the injection.

In another embodiment of the inventive refill unit, the unit additionally comprises a section serving to take up the used cannulas and/or used sponges. Hereby this section to take up the used cannulas, respectively the used sponges, is formed in the way that the used cannulas, respectively sponges, cannot fall out of the refill unit while being used, so that the section is formed particularly as a separately closable section. If in the refill unit this section is formed as a section being detachable from the refill unit, as for example as a closable box, the used cannulas and, if necessary, the sponges can be separately wasted, as for example by the special trade, as far as this is required by legal prescriptions.

The inventive refill unit can comprise basically each vessel containing the multitude of single doses of the liquid

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pharmaceutical product, as far as it is guaranteed that this vessel is formed in that way that it can be set into the device and emptied in single doses by means of the device. However, it is particularly suitable to fill the liquid pharmaceutical product to be parenterally applied by the user in single doses in a cylindrical or cylinder-like glass carpule, whereby such a glass carpule holds particularly between about 1,5 ml and about 8 ml, preferably between about 2 ml and about 6 ml, of the liquid pharmaceutical product.

A particularly advantageous development of the afore described glass carpule is characterized in that in the inventive refill unit such a glass carpule is arranged which is closed, at its bottom side, by a piercable membrane and, at its top side, by a plug being formed in that way that it can be axially shifted within the glass carpule in the direction of the piercable membrane when the liquid level is descending. This special development of the glass carpule has the particular advantage that the bottom section of the plug is located in the immediate proximity of the liquid level or even contacts the liquid level, so that there is no air puffer above the respective liquid level when the liquid level is descending because of the single doses emitted. On one hand, this avoids an undesired oxidative modification of the respective liquid pharmaceutical product and, on the other hand, the special forming of the plug effectively avoids the formation of a vacuum in the glass carpule when the liquid amount is decreasing, whereby such a vacuum would have a negative effect on the exactness of the liquid amount emitted in single doses.

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In order to ensure the required tightness between the plug and the inner walling of the glass carpule, according to the afore described embodiment of the glass carpule which disposes of the afore described plug being axially shiftable in the direction of the piercable membrane, a further development of the inventive refill unit is characterized in that the plug comprises on its jacket surface at least one, preferably two to five, disk-like sections directing radially to the outside. Hereby these disk-like sections can be deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid-tightens and air-tightens the inner surface of the carpule. The disk-like sections directing to the outside are preferably dimensioned in that way that an end section of the disk-like sections is elastically deformed by the axial shifting of the plug in the glass carpule opposite to the shifting direction with the formation of a correspondingly larger dimensioned sealing surface. In respect to the material that the plug consists of, it is to be noted that herefore preferably an elastic, chemically resistant plastic material or rubber material is chosen, whereby herefore a halogenbutyl-caoutchouc proved to be particularly suitable.

When the afore described plug can be axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N, it is particularly guaranteed that the above described advantages occur in a particularly reproducible way.

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By using the inventive refill unit in connection with the inventive device of the inventive sell unit, basically all liquid pharmaceutical products being stable in storage can be parenterally applied by the user himself. Hereby the term liquid pharmaceutical products means all such products which, as actual product, are liquid or from which stable solutions, stable dispersions or stable emulsion can be manufactured in an organic or inorganic, physiologically safe liquid. The afore described vessel or the afore described and particularly used glass carpule preferably comprise an aqueous solution of a heparin, preferably an aqueous solution of a low-molecular heparin, and particularly an aqueous solution of an enoxaparin-sodium. Such a refill unit is then used by such users who, because of their syndrome and from the medical point of view, have to apply the heparin daily in constant single doses for a longer time period, in order to prevent, for example, the risk of a thrombosis after having discharged the user from the hospital. A further preferred employment of the inventive refill unit is the regular parenteral application of a given and constant amount of a growth hormone, whereby, for this case of application, the vessel and particularly the afore described glass carpule is filled with a solution of the growth hormone, preferably an aqueous solution of the growth hormone.

The inventive sell unit, the inventive device as well as the inventive refill unit will be described in detail by embodiments in connection with drawings as follows. The figures show:

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Figure 1 a perspective view of an embodiment of the sell unit;

Figure 2 a perspective, schematical view of the device for emitting a given liquid amount in single doses;

Figure 3 an explosion drawing of figure 2;

Figure 4 an enlarged schematical sectional view of a closing element;

Figure 5 an sectional explosion view of the axially shiftable cylinder;

Figure 6 a sectional view of a first embodiment with emptied intermediate reservoir;

Figure 7 as figure 6, but with filled intermediate reservoir;

Figure 8 an enlarged schematical sectional view of a reflux valve;

Figure 9 a sectional view of a second embodiment of the device with filled intermediate reservoir; and

Figure 10 a perspective view of an embodiment of the refill unit.

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In the figures 1 to 10 the same parts are designated with the same reference numbers.

A sell unit collectively designated with 1 and shown in figure 1 comprises a device 3 for emitting a given liquid amount of the pharmaceutical product, a multitude of cannulas 2 being provided with a corresponding cannula protector 45 (figure 3) for the sterile storing, a glass carpule designated with 8 serving as vessel being filled with the liquid pharmaceutical product. Moreover, the sell unit 1 comprises a number of sponges 5 moistened with an disinfectant, whereby the number of sponges 5 corresponds to the number of the cannulas 2. The sell unit 1 furthermore contains a section 6 taking up used cannulas, whereby, according to the embodiment shown in figure 1, this section can be closed by a cover which is not shown. This section 6 is collectively arranged at the sell unit 1 in a detachable way, so that, after taking up the used cannulas, this section 6 can be separately wasted, as far as this is legally prescribed or desired. The sell unit 1 usually comprises 10 cannulas 2, so that correspondingly the glass carpule 8 contains the liquid amount for 10 cannulas. Usually the liquid amount emitted each in single doses varies between 0,1 ml and 1 ml, so that correspondingly the glass carpule contains between 1 ml and 10 ml of the liquid pharmaceutical product. In order to avoid an evaporation of the disinfectant of the sponges 5, each sponge 5 is separately wrapped by a corresponding plastic foil in an air-tight way. The sell unit 1 taking up the afore described parts is collectively closed by a cover (not shown) or is arranged in the usual plastic wrapping, if necessary even in a sterile way.

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The device 3 for emitting a given liquid amount of the liquid pharmaceutical product, the device 3 being shown in detail in figure 2, comprises a protecting element 22, whereby this protecting element 22 consists of a outer cylinder 22 a and inner cylinder 22 b being concentrically arranged relative to the outer cylinder 22 a which are manufactured from a transparent plastic material and which can cover a cannula 2 fixed at the device 3, as this is shown, for example, in figure 3. Furthermore, the device 3 comprises a casing 4, whereby an upper grip section 33, a window 34, a counting device 35, a second grip section 33 a, a cover 36 being detachable from the casing, a release button 37, a shifting element 38 being fixed by a corresponding slot 39, as well as a deepening 40 are arranged at the casing 4.

In the device 3 shown in figure 2 furthermore a closing element 18 is fixed at the casing 4, whereby the closing element 18 is subsequently described in detail in connection with figure 4. The user can thus easily hold the device 3 at the grip sections 33 and 33 a as well as at the closing element 18. The afore mentioned counting device 35 serves to count the single doses of the liquid pharmaceutical product emitted by means of the device 3, whereas the window 34 arranged in the casing makes it possible to control the liquid level in the glass carpule 8, as far as the glass carpule 8 is taken up by the device 3, whereby the cover 36 is removed in order to arrange the glass carpule 8, as this is shown in figure 3.

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Figure 3 schematically shows the insertion of the glass carpule 8 into the device 3 and the arrangement of the closing element 18 as well as the arrangement of a cannula 2. During the insertion of the glass carpule the cover 36 is firstly removed in order to open the section 41 taking up the vessel filled with the liquid pharmaceutical product, whereby this section 41 is located within the casing 4. When the glass carpule 8 has been inserted into the section 41, the corresponding opening is closed with the cover 36. At its bottom side the cover 36 comprises an axially extending lengthening pin 42 ending in an end section 42 a, whereby the lengthening pin 42 and the end section 42 a can be axially shifted together with the cover 36.

In a further, not shown and preferably used embodiment the lengthening pin 42 and the section 42 a are axially shiftable in the direction of the arrow 51 relative to the cover 36 so that after fixing the cover 36 on the casing 4 an axial shifting of the lengthening pin 42 and the section 42 a can be reached by a manuel operation done by the user independent of the kind in which the cover 36 is fixed on the casing 4. This axially shifting is done by the user by forcing a section of the lengthening pin 42 protruding over the cover 36 when the cover is fixed.

This end section 42 a can gear into a deepening being correspondingly carved into a plug 10, whereby the glass carpule 8 can be submitted to a power being axially directed downward can be, as soon as the glass carpule 8 is arranged in the section 41 and the cover 36 is screwed onto the corresponding

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opening or fixed by means of a bayonet closing. At its bottom side the glass carpule 8 filled with the liquid pharmaceutical product is closed by a piercable membrane 9 being fixed by a bead in connection with a metal strap 44 in a usual way. A cannula 2 or the closing element 18 can be optionally fixed at a mounting section 21 (for example a shown in figure 7) by a corresponding weight, as these options are shown in figure 3. Hereby the cannula 2 is surrounded by a cannula protector 45 which makes it possible for the user not to hurt himself when he operates the cannula 2. The cannula protector 45 can be clamped onto the base section 2 a of the cannula 2 and, if necessary, fixed at the base section 2 a by a thread.

The cylindrical closing element 18 (figure 4) comprises a sealing element 18 a which can contact a conduct outlet 19 (figure 5 and 6) and which can close the conduct outlet in an air-tight and liquid-tight way, as soon as the closing element 18 is fixed at the mounting section 21 by a corresponding thread 18 b. Moreover, the closing element 18 comprises a slot section 18 c to take up the walling of the inner cylinder 22 b of the protecting element 22.

The schematical explosion view of figure 5 shows the essential interior parts of the device 3. These are a first, inner cylinder 23, a second, outer cylinder 24, whereby the second cylinder 24 end with its bottom side in the mounting section 21 to which a cannula 2 or the closing element 18 can be optionally fixed. In this section the protecting element 22 is detachably mounted at the casing 4 which is only partially shown in figure

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5. The first cylinder 23 is provided with a first spring 25 and the second cylinder 24 is provided with a second spring 26, whereby the first spring 25 extends between an upper section 23 a of the first cylinder 23 and a ring element 46 being fixed at the second cylinder 24, whereas the second spring 26 is supported by an lower bearing 24 a being located at the second cylinder 24 and an upper bearing 23 b being located at the casing 4. The shifting element 38 is formed as on piece with the first cylinder 23.

Furthermore, the first cylinder 23 comprises a bottom plate 23 c being provided with a projection 23 d at its bottom side. The shaft 47 of a piston 16 can be connected with this projection 23 d, so that the piston 16 is fixed at the first cylinder 23 and moved together with the first cylinder 23. A connecting conduct 14 extends within the shaft 47 and within the piston 16, whereby this connecting conduct 14 is guided also by the bottom plate 23 c and the projection 23 d and ends in a hollow needle 48.

If then the glass carpule 8 filled with the liquid pharmaceutical product is set into the inner space of the first cylinder 23, the inner space forming the section 41 taking up the vessel, and if hereby the glass carpule 8 is submitted to a pressure in the direction of the mounting section 21 by means of the plug and the lengthening pin 42, respectively the end section 42 a, the hollow needle 5 pierces the piercable membrane 9 of the glass carpule 8, so that the connecting conduct 14 is connected to the content of the glass carpule 8. Hereby the connecting conduct 14 is provided with a reflux valve 15 in the

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section connecting the shaft 47 with the projection 23 d, whereby this reflux valve 15 is shown enlarged in figure 8.

This reflux valve 15 comprises, according to figure 8, a disk-like, round sealing membrane 49 being held by a ring bearing 50. A section which is superfused by the liquid and which enlarges the conduct inlet 14 a of the connecting conduct 14 is arranged underneath the sealing membrane 49. If the liquid flows in the direction of the arrow 51, as this is required in the conduct 14 for the filling of the intermediate reservoir, the sealing membrane 49 is lifted from the ring bearing 50 and does thus not block the flow of the liquid. Hereby this movement of the sealing membrane 49 is limited by four radially arranged linking elements 52, so that it is avoided that the sealing membrane 49 closes the enlarged conduct inlet 14 a. If the liquid flows in the opposite direction of the arrow 51, the sealing membrane 49 is brought into a position in which it seals the ring bearing 50, so that hereby a flow in the opposite direction of the arrow 51 is avoided without risking an adhesion of the sealing membrane 49.

I the figures 6 and 7 the same embodiments are shown, however, in different operating situations. Hereby figure 6 shows the device in a situation in which the intermediate reservoir 13 is empty, whereby in this situation the single dose of the liquid pharmaceutical product has thus been parenterally applied, and in which the respective user finds the device in order to then prepare it for the next single dose. In figure 7 the intermediate reservoir 13 is filled with a single dose of the

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liquid pharmaceutical product being supplied from the glass carpule 8 over the conduct 14. In the operating situation shown in figure 7 a cannula 2 is furthermore fixed at the mounting section 19, so that figure 7 as a whole shows the device in an operating situation occurring immediately before the parenteral application of the single dose of the liquid pharmaceutical product by the user.

The parts shown in figure 5 and described above are provided as well in the figures 6 and 7 and designated with the same reference numbers.

In the first cylinder 23 the glass carpule 8 is arranged in the adequate section 41, whereas the second cylinder 24 forms the intermediate reservoir 13 in its bottom section 24 c (also figure 5).

Starting from the operating situation shown in figure 6 in which the closing element 18 is fixed at the mounting section 21 and in which the closing element 18 a closes the conduct outlet 19 a of the conduct 19 which connects the intermediate reservoir with the conduct outlet, the first cylinder 23 and the second cylinder 24 were commonly transmitted from a first position not shown, in which the spring 25 is released and in which the second cylinder 24 contacts a casing section 53 by means of the recessing section 24 b (figure 5), into a second position as this is shown in figure 6, whereby this transmitting was realised by axially shifting both cylinders in the opposite direction of the arrow 51 and relatively to the casing 4. In

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this second position the spring 25 being released in the first position of both cylinders is thus tensioned, whereby a fixing of this second position is realised by a second locking 27 gearing in at the recessing section 24 b.

This common axial shifting of both cylinders 23 and 24 is caused by manually operating the shifting element 38 arranged at the outside of the casing, whereby this axial shifting of the shifting element 38 is guided through a slot 39 (figure 3) located in the casing 4.

In order to fill the intermediate reservoir 13 in this second position with a single dose of the liquid pharmaceutical product supplied by the glass carpule 8 arranged within the first cylinder 23, the first cylinder 23 is shifted into the third position in the opposite direction of the arrow 51 and relatively to the casing 4 and to the second cylinder 24 remaining in the second position, whereby this shifting is realised by means of the shifting element 38 against the power of the second spring 26, and whereby this third position is axially shifted in the opposite direction of the arrow 51, which is shown in figure 7.

In this third position of the first cylinder, the first cylinder 23 is fixed by a first locking 28 (figure 7).

Conditioned by the fact that the closing element 18 avoids a ventilation of the intermediate reservoir 13 by means of the conduct 19 as a result of the fluid-tight contacting of the

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sealing element 18 a with the conduct outlet 19 a, a vacuum is generated in the intermediate reservoir 13 when the first cylinder 23 is axially shifted from the second position into the third position. This depends on the fact that concurrently with the shifting of the first cylinder 23 the piston 16 which is fixed to the first cylinder 23 by piston shaft 47 is axially shifted in the opposite direction of the arrow 51. This vacuum generated in the intermediate reservoir 13 then causes a complete filling of the intermediate reservoir with exactly one single dose of the liquid pharmaceutical product being supplied from the glass carpule 8 by means of the connecting conduct 14 and the opened reflux valve 15 which is arranged in the projection 23 d of the first cylinder 23 and which is shown in figure 8.

This axial shifting of the first cylinder from the second position into the third position relatively to the casing and to the second cylinder is made possible by providing the walling of the second cylinder with a slot-like guidance 39 a through which a section of the shifting element 38 extends, whereby the shifting element 38 is formed in one piece with the first cylinder 23.

The closing element 18 is then replaced by a cannula 2, whereby the cannula 2 is gripped by user at the cannula protector 45 and the cannula 2 is screwed onto the mounting section 21. Hereafter the user removes the cannula protector 45, whereby the device is prepared to apply the single dose of the liquid pharmaceutical product.

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With this object the respective user chooses a body zone and brings the bottom zone of the inner cylinder 22 b of the protecting element 22 in contact with this body zone. By operating the release button 37 the second locking 27 is shifted in the direction of the arrow 54 against the spring power 27 a, so that the first cylinder 23 and the second cylinder 24 are commonly and axially shifted relatively to the casing 4 in the direction of the arrow 51 by means of the spring 26. This leads to the fact that the point of the cannula 2 penetrates the chosen body zone of the user. During the common axial shifting of both cylinders 23 and 24, a projection 27 b being located at the second locking 27 gets in contact with a projection 28 a being located at the first locking 28, whereby this causes a shifting of the first locking 28 also in the direction of the arrow 54 against the spring power of the spring 28 b located at the first locking 28. Hereby the first cylinder 23 is released from its third position, so that it is also axially shifted in the direction of the arrow 51 by means of the spring 25. This again leads to the fact that the piston 16 being connected with the first cylinder 23 by the shaft 47 is axially shifted in the direction of the arrow 51 and that thus the single dose of the liquid pharmaceutical product located in the intermediate reservoir 13 is injected into the body zone by the cannula 2. The axial shifting of the first cylinder 23 is terminated by the recessing section 24 b of the second cylinder 24 and by the axial movement of the second cylinder 24 through the casing section 53.

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After the parenteral application the user pulls the cannula 2 out of the body zone by means of the device, attaches the cannula protector 45 on the cannula 2, unscrews the cannula 2 from the mounting section 21 and screw the closing element 18 onto the mounting section 21. Independently of the power performed hereby by the user, the first cylinder and the second cylinder remain either in the first position or both cylinders are transmitted into a position as it is shown in figure 6.

The second embodiment of the device, the embodiment being shown in figure 9, presents the device in such an operating situation in which the intermediate reservoir 13 is filled with the single dose of the liquid pharmaceutical product. The embodiment shown in figure 9 is thus ready to operate meaning that is ready to inject. Contrarily to the embodiment described above in figures 6 and 7, the embodiment shown in figure 9 is characterized in that both cylinders 23 and 24 can be axially shifted in the direction of the arrow 51 and vice-versa only between a first position (not shown) in which the first cylinder 23 contacts the recessing section 24 b and the recessing section 24 b contacts the casing section 53 and in which the intermediate reservoir 13 is emptied, and a second position as this is shown in figure 9 and in which the intermediate reservoir 13 is filled with the single dose. Moreover, the embodiment shown in figure 9 provides only a single locking 29 which fixes the first cylinder 23 and the second cylinder 24 in the second position and which can be released by means of the release button 37.

In order to make it possible in the embodiment shown in figure 9

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to cause the time retardation between the penetration procedure of the cannula into the body zone of the user and hereafter the emptying of the intermediate reservoir 13 and thus the actual parenteral application of the single dose of the liquid pharmaceutical product, the characteristic spring lines of the springs 25 and 26 are adjusted to each other in such a way that the characteristic spring line of the spring 26 is steeper than the characteristic spring line of the spring 25. By operating the release button 37 the locking 29 is shifted in the direction of the arrow 54 against the spring power of the spring 29 a, so that the locking 29 is released and that thus the first cylinder 23 and the second cylinder 24 can be commonly and axially shifted in the direction of the arrow 51 relatively to the casing. Caused by the steeper characteristic spring line of the spring 26, the second cylinder 24 projects, during the axial shifting, relatively to the first cylinder 23 the spring 25 of which has a more levelled characteristic spring line, over the first cylinder 23, so that the cannula 2 firstly penetrates the body zone and that then the first cylinder 23 and thus also the piston 16 connected with the first cylinder 23 by the shaft 47 transmits the single dose of the liquid pharmaceutical product from the intermediate reservoir 13 into the body zone of the user.

In order to guarantee in the afore described embodiment of the inventive device a complete emptying of the intermediate reservoir, the intermediate reservoir 13 comprises a cylindrical section 13 b and a subsequent conical section 13 a (figure 9), whereby the outlet of the conical section 13 a opens into the

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conduct 19, as this can be seen perfectly in figure 9. The piston 16 being axially shiftable within the intermediate reservoir 13 correspondingly comprises a cylindrical piston section and conical piston section 16 a directed to the conduct 19, whereby this conical piston section is formed by a corresponding conically-shaped jacket tube surrounding the outlet of the connecting conduct 14. This jacket tube is closed at its bottom side and it comprises outlets on its conical surface, so that by these outlets the liquid supplied by the conduct 14 is transported into the intermediate reservoir. When the piston is axially lowered in the direction of the arrow 51, the conical piston section 16 a displaces the liquid located in the intermediate reservoir 13 in that way that the conical piston section 16 a enters the conical cylinder section 13 a and thus fills it completely.

It is even possible to provide an intermediate reservoir 13 which dos not comprises the afore described and especially in figure 9 shown conical section 13 a or which comprises a conical section 13 a having restricted length. In other words in this embodiment the cylindrical section 13 b of the intermediate reservoir empties directly into the conduct 19, or the cylindrical section 13 b is connected with the conduct via a correspondingly restricted conical section 13 a. Appropriate to that the plug 16 located inside of the intermediate reservoir 13 is adapted to such a formed intermediate reservoir 13 whereby preferably a sealing provided to the piston skirt and more preferably an O-formed flexible piston ring makes a safe use sure.

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In all afore described embodiments the plug 10 arranged within the glass carpule 8 is also axially shifted in the direction of the arrow 51 as a result of the descending liquid level in the glass carpule 8. Hereby it is avoided that a vacuum is generated in the glass carpule or that a gas puffer is formed above the liquid level. In order to furthermore guarantee a complete emptying of the glass carpule 8, the front surface 10 a (figure 9) of the plug 10 tapers, so that it contacts the shaft section of the glass carpule 8 a (figure 9) when the liquid is completely descended.

In this state, the completely emptied glass carpule 8 can be removed from the device together with the detaching element 101 shown in figure 10. For this purpose, the detaching element comprises a grip section 102 for handling the detaching element 101 as well as a fixing section which can gear non-positively into a deepening 10 b (figure 9) being provided in the plug 10 when the plug 10 is removed.

Moreover the refill unit shown in figure 10 comprises a multitude of cannulas 2 being provided with a corresponding cannula protector 45 (figure 3) for the sterile storing, a glass carpule designated with 8 serving as vessel being filled with the liquid pharmaceutical product. Moreover, the refill unit 100 comprises a number of sponges 5 moistened with an disinfectant, whereby the number of sponges 5 corresponds to the number of the cannulas 2. The refill unit 100 furthermore contains a section 6 taking up used cannulas, whereby, according to the embodiment

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shown in figure 10, this section can be closed by a cover which is not shown. This section 6 is collectively arranged at the refill unit 100 in a detachable way, so that, after taking up the used cannulas, this section 6 can be separately wasted, as far as this is legally prescribed or desired. The sell unit 1 usually comprises 10 cannulas 2, so that correspondingly the glass carpule 8 contains the liquid amount for 10 cannulas. Usually the liquid amount emitted each in single doses varies between 0,1 ml and 1 ml, so that correspondingly the glass carpule contains between 1 ml and 10 ml of the liquid pharmaceutical product. In order to avoid an evaporation of the disinfectant of the sponges 5, each sponge 5 is separately wrapped by a corresponding plastic foil in an air-tight way. The refill unit 100 taking up the afore described parts is collectively closed by a cover (not shown) or is arranged in the usual plastic wrapping, if necessary even in a sterile way. The afore described detaching element 101 is arranged in the refill unit 100.

The used term piercable membrane several times repeated means a flexible sealing disc being fixed at the carpule 8 by a flared flange, preferably by a metallic flared flange, as it is clearly shown in the drawings.

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Patent claims

1. A sell unit for the parenteral application of liquid pharmaceutical products by the user, characterized in that the unit (1) comprises at least one cannula (2), a device (3) to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel (8) filled with the pharmaceutical product, the vessel (8) being arranged within the device (3) and emptied in single doses by means of the device (3), whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

2. The sell unit according to claim 1, characterized in that the unit (1) contains a number of cannulas (2) corresponding to the number of single doses.

3. The sell unit according to claim 1 or 2, characterized in that the unit (1) comprises a number of sponges (5) being moistened with a disinfectant, whereby the number of sponges (5) corresponds to the number of cannulas (2).

4. The sell unit according to one of the preceding claims, characterized in that the unit (1) comprises a section (6) for taking up the used cannulas (2).

5. The sell unit according to one of the preceding claims, characterized in that the vessel (8) filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule (8).

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6. The sell unit according to claim 5, characterized in that the glass carpule (8) is closed, at its bottom side, by a piercable membrane (9) and, at its top side, by a plug (10) being formed in that way that it can be axially shifted within the glass carpule (8) in the direction of the piercable membrane (9) when the liquid level is descending.

7. The sell unit according to claim 5 or 6, characterized in that the plug (10) has, on its jacket surface, at least one, preferably two to five, disk-like sections radially directing to the outside, whereby these sections are deformed when the plug (10) is inserted into the glass carpule (8) with the formation of a sealing surface which liquid- or air-tightens the inner surface of the carpule (8).

8. The sell unit according to one of the claims 6 to 8, characterized in that the plug (10) is axially shifted within the glass carpule (8) by a power of less than 10 N, preferably by a power of between 4 N and 8 N.

9. The sell unit according to one of the preceding claims, characterized in that the vessel (8) is filled with an aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

10. The sell unit according to one of the preceding claims, characterized in that the vessel (8) is filled with a solution

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of a growth hormone, preferably an aqueous solution of a growth hormone.

11. A device for emitting a given liquid amount of a pharmaceutical product, characterized in that the device (3) for emitting a given liquid amount in single doses comprises a section (41) for taking up the vessel (8) being located within a casing (4) and being filled with the liquid pharmaceutical product, as well as an outlet section for the single dose of the pharmaceutical product, and in that the vessel (8) can be connected with the outlet section by an intermediate reservoir (13) in that way that, when the vessel (8) is set in, the given liquid amount of each single dose can firstly be drained from the vessel (8) into the intermediate reservoir (13) and then from the intermediate reservoir (13) into the outlet section, whereby the amount of the drained liquid can be determined for each single dose by the volume of the intermediate reservoir (13).

12. The device according to claim 11, characterized in that a connecting conduct (14) is arranged between the inserted vessel (8) and the intermediate reservoir (13).

13. The device according to claim 12, characterized in that the connecting conduct (14) comprises a valve (15) which avoids a liquid backflow from the intermediate reservoir (13) into the vessel (8).

14. The device according to one of the claims 11 to 13,

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characterized in that the intermediate reservoir (13) comprises a piston (16) for the transporting of each single dose of the liquid pharmaceutical product in the direction of the outlet section, whereby the piston (16) is located within the intermediate reservoir (13) and axially shiftable in the direction of the outlet section.

15. The device according to one of the claims 11 to 14, characterized in that the intermediate reservoir (13) is to fill with a single dose of the pharmaceutical product by an axial shifting of the piston (16) in the direction of the vessel (8).

16. The device according to claim 15, characterized in that, by axially shifting the piston (16), a vacuum is produced in the intermediate reservoir (13) for the transport of a single dose of the liquid pharmaceutical product from the vessel (8) into the intermediate reservoir (13).

17. The device according to claim 16, characterized in that the intermediate reservoir (13) is connected with the outlet section by a conduct (19) and that this conduct (19) can be air-tightened by a closing element (18).

18. The device according to claim 16 or 17, characterized in that the closing element (18) is formed as a detachable closing element located at the conduct (19) in that way that a sealing section (18 a) of the closing element (18) air-tightens the conduct outlet (19 a).

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19. The device according to one of the claims 14 to 17, characterized in that, by axially shifting the piston (16) within the intermediate reservoir (13) in the direction of the outlet section, the intermediate reservoir (13) is completely emptied.

20. The device according to one of the claims 11 to 19, characterized in that the intermediate reservoir (13) is formed in a cylindrical way and comprises a conically-shaped end section (13 a) following hereafter and directing to the outlet section, whereby the end section (13 a) is connected with the outlet section by the conduct (19), and that the piston (16) has a corresponding shape.

21. The device according to one of the claims 11 to 20, characterized in that the outlet section comprises a mounting section (21) for the detachable fixing of a cannula (2) in that way that the conduct (19) is connected with the cannula (2) in a fluid-tight way.

22. The device according to claim 17, 18 or 21, characterized in that a closing element (18) is fixed at the mounting section (21) in such a way that the conduct section (19 a) directing to the outside can be fluid-tightened by the closing element (18).

23. The device according to one of the claims 11 to 22, characterized in that the mounting section (21) comprises a protecting element (22) which covers at least a part of a cannula (2) being fixed at the mounting section (21).

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24. The device according to one of the claims 11 to 23, characterized in that a first cylinder (23) and a second cylinder (24) surrounding the first cylinder (23) are arranged within the casing (4), that the first cylinder (23) and the second cylinder (24) are shiftable axially relative to the casing (4), that the section (41) to take up the vessel (8) is situated within the first cylinder (23) and the intermediate reservoir (13) connected with the vessel (8) is located within the second cylinder (24), in such a way, that the first and the second cylinder (23; 24) are axially shiftable from a first position in which the cannula (2) being fixable to the mounting section (21) protrudes over the protecting element (22) and in which the intermediate reservoir (13) is emptied over the conduct (19) and the subsequent cannula (8), and a second position in which a cannula (2) being fixable to the mounting section (21) is covered by the protecting element (22) and in which the intermediate reservoir (13) is filled with the single dose, and vice-versa.

25. The device according to claim 24, characterized in that, by axially moving the first and the second cylinder (23; 24) relatively to the casing (4) from the first position into the second position, the intermediate reservoir (13) is filled with a single dose of the liquid pharmaceutical product.

26. The device according to claim 25, characterized in that the first and the second cylinder (23; 24) comprise each a spring (25; 26) in such a way that, in the second position of the

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cylinders (23; 24), the springs (25; 26) are tensioned and that, in the first position of the cylinders (23; 24), the springs (25; 26) are released.

27. The device according to one of the claims 24 to 26, characterized in that both cylinders (23; 24) are fixed in the second position by a locking element (29).

28. The device according to one of the claims 26 or 27, characterized in that the spring (26) of the second cylinder (24) has a steeper characteristic spring line than the spring (25) of the first cylinder (23).

29. The device according to one of the claims 11 to 23, characterized in that a first cylinder (23) and second cylinder (24) surrounding the first cylinder (23) are arranged within the casing (4), that the first cylinder (23) and the second cylinder (24) are shiftable axially relative to the casing (4), that the section (41) to take up the vessel (8) is situated within the first cylinder (23) and the intermediate reservoir (13) connected with the vessel (8) is located within the second cylinder (24), in such a way, that the first and the second cylinder (23; 24) are axially shiftable from a first position in which the cannula (2) being fixable to the mounting section (21) protrudes over the protecting element (22) and in which the intermediate reservoir (13) is emptied, into a second position in which the cannula (2) being fixable to the mounting section (21) is covered by the protecting element (22), and vice-versa, that for filling the intermediate reservoir (13), the first

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cylinder (23) is axially shiftable into a third position in the direction of the vessel (8) relatively to the second position of the second cylinder (24).

30. The device according to claim 29, characterized in that each cylinder (23; 24) contains a spring (25; 26), whereby a first spring (25) pre-tensions the position of the first cylinder (23) in the third position and a second spring (26) pre-tensions the position of the second cylinder (24) in the second position, and that the first cylinder (23) is fixable in the third position by a first locking (28) and the second cylinder (24) is fixable in the second position by a second locking (27).

31. The device according to claim 29 or 30, characterized in that, by operating a common release button (37), firstly the second locking (27) is released and then the first locking (28) is released in a corresponding time retardation.

32. The device according to one of the claims 11 to 31 for the use in a sell unit (1) according to one of the claims 1 to 10.

33. A refill unit for the use in the sell unit or the device according to one of the preceding claims, characterized in that the refill unit (100) comprises at least one cannula (2) as well as at least vessel (8) filled with the liquid pharmaceutical product, whereby the vessel (8) is insertable in the device (3) and emptied in single doses by means of the device (3).

34. The refill unit according to claim 33, characterized in that

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a detaching element (101) for the removal of an emptied vessel (8) out of the device (3) for emitting a given liquid amount in single doses is arranged within the refill unit (100).

35. The refill unit according to claim 33 or 34, characterized in that the refill unit (100) comprises the number of single doses corresponding to a number of cannulas (2) and/or sponges (5) moistened with disinfectant.

36. The refill unit according to one of the claims 33 to 35, characterized in that the refill unit (100) comprises a section (6) that takes up the used cannulas (2).

37. The refill unit according to one of the claims 33 to 36, characterized in that the vessel (8) filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule (8).

38. The refill unit according to claim 37, characterized in that the glass carpule (8) is closed, at its bottom side, by a piercable membrane (9) and, at its top side, by a plug (10) being formed in that way that it is axially shiftable within the glass carpule (8) in the direction of the piercable membrane (9) when the liquid level is descending.

39. The refill unit according to claim 37 or 38, characterized in that the plug (10) has, on its jacket surface, at least one, preferably two to five, disk-like, lip-tight sections radially directing to the outside, whereby these sections are deformable

when the plug (10) is inserted into the glass carpule (8) with the formation of a sealing surface liquid-tightening the inner surface of the carpule (8).

40. The refill unit according to one of the claims 37 to 39, characterized in that the plug (10) is axially shiftable within the glass carpule (8) by a power being lower than 10 N, preferably by a power of between 4 N and 8 N.

41. The refill unit according to one of the claims 33 to 40, characterized in that the vessel (8) is filled with am aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

42. The refill unit according to one of the claims 33 to 40, characterized in that the vessel (8) is filled with a solution of a growth hormone, preferably an aqueous solution of a growth hormone.

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* C L M S *

Abstract

A sell unit for the parenteral application of liquid pharmaceutical products by the user is describes, whereby the unit (1) comprises at least one cannula (2), a device (3) to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel (8) filled with the pharmaceutical product, the vessel (8) being arranged within the device (3) and emptied in single doses by means of the device (3), and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

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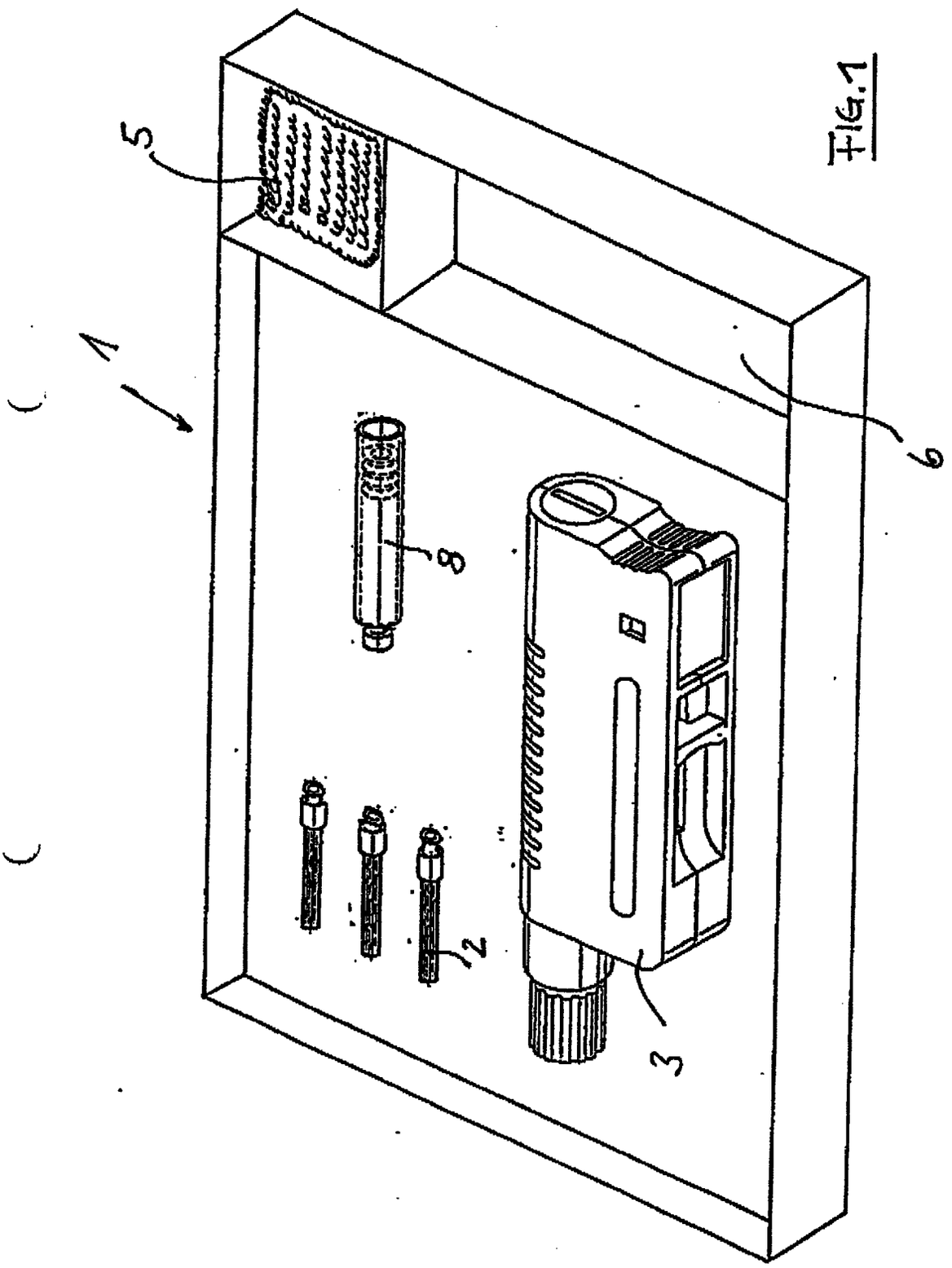


FIG.1

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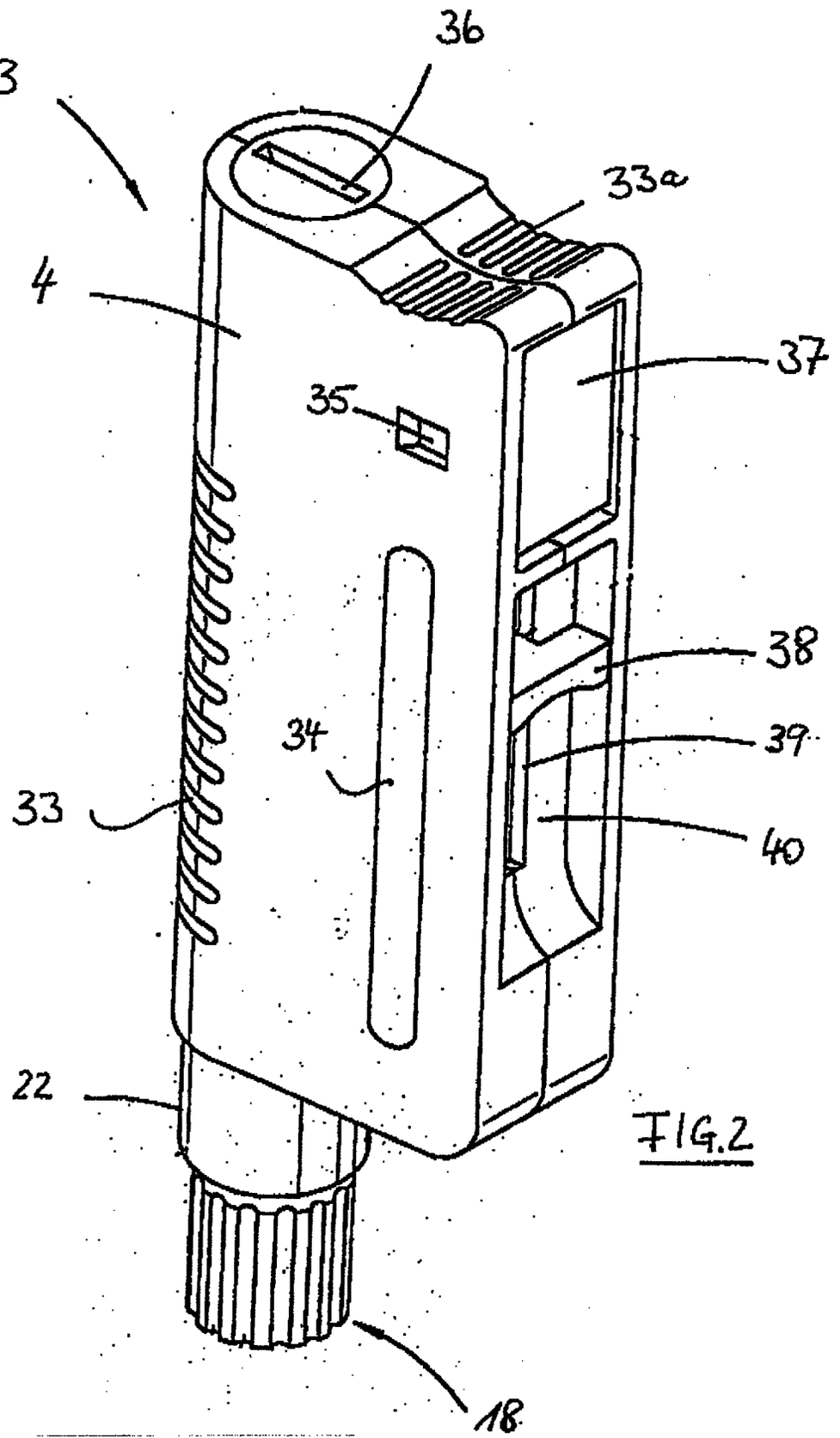


FIG.2

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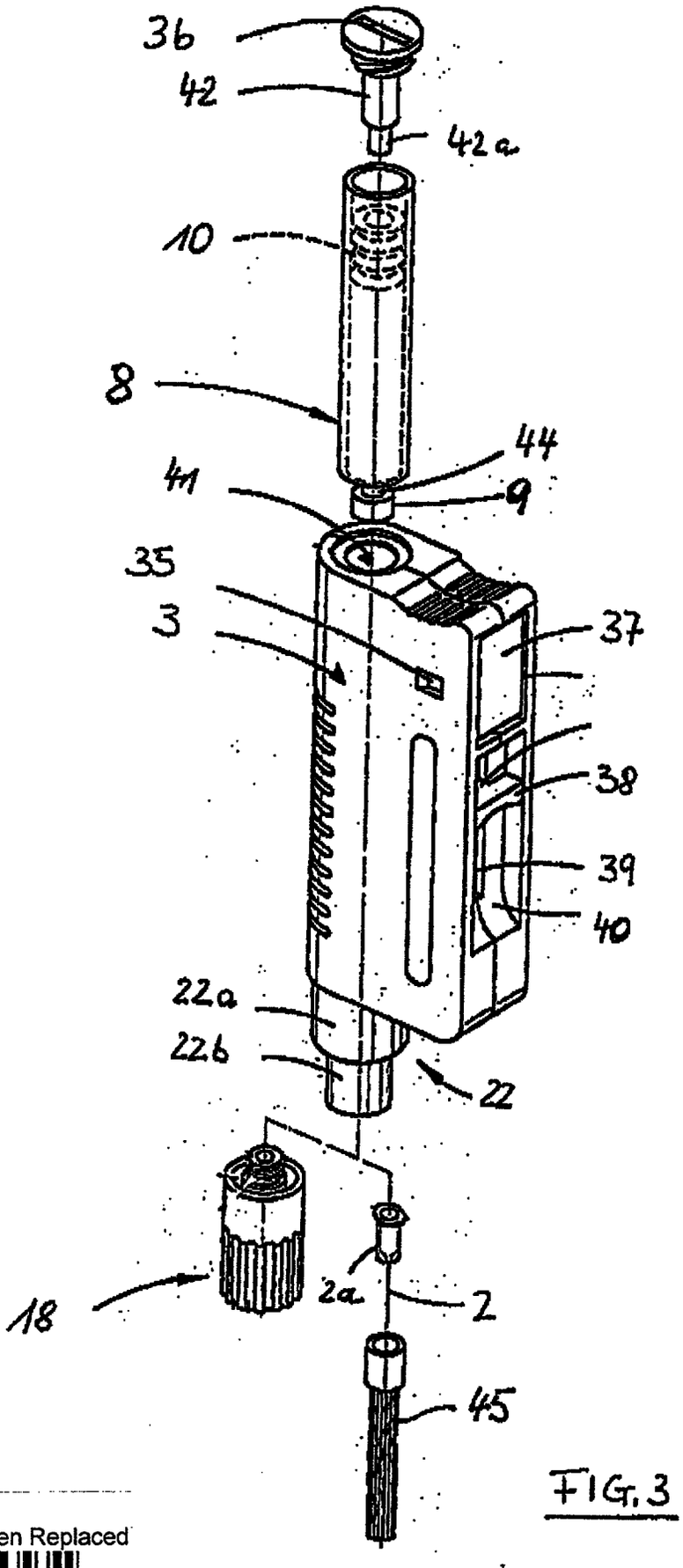


FIG. 3

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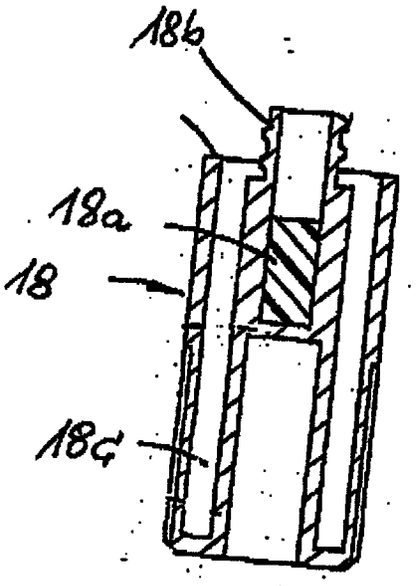


FIG.4

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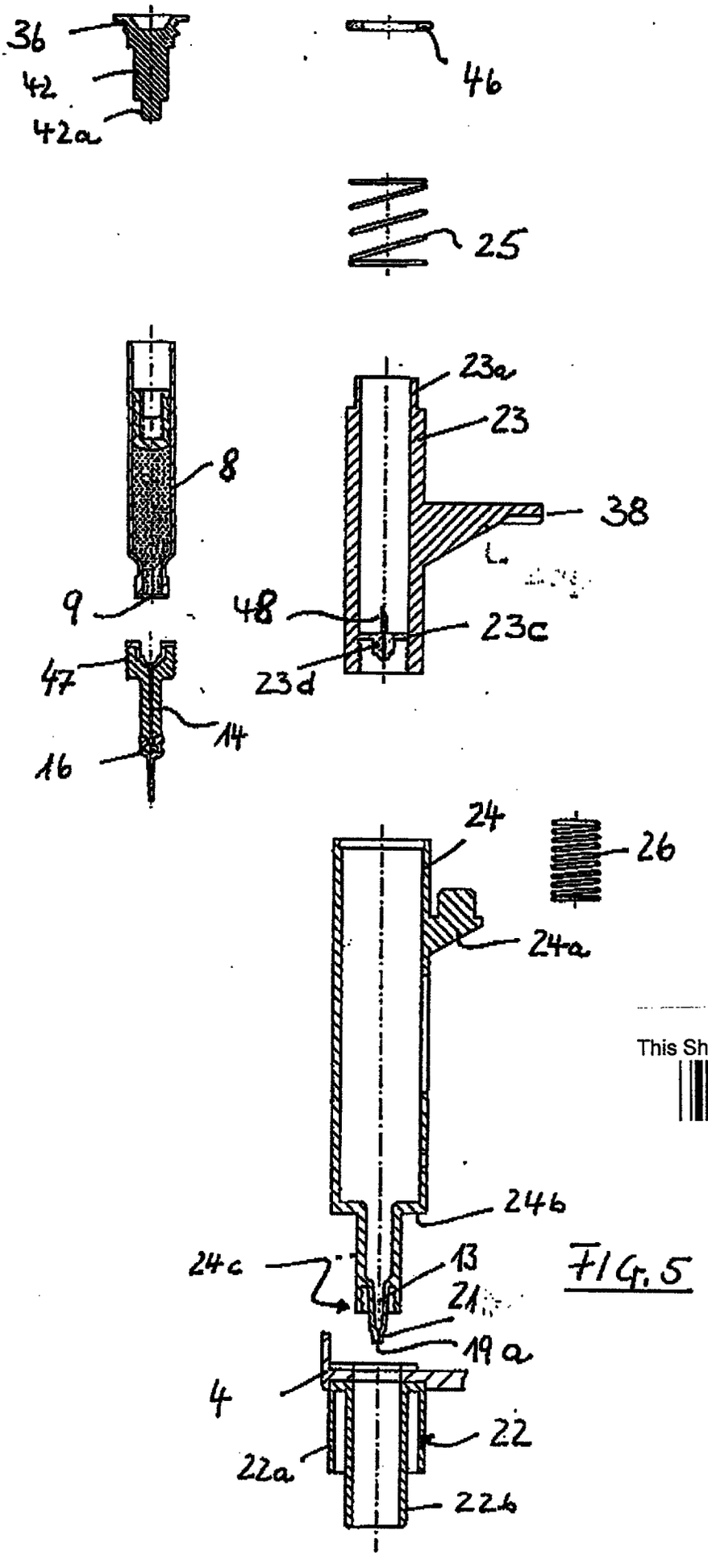


FIG. 5

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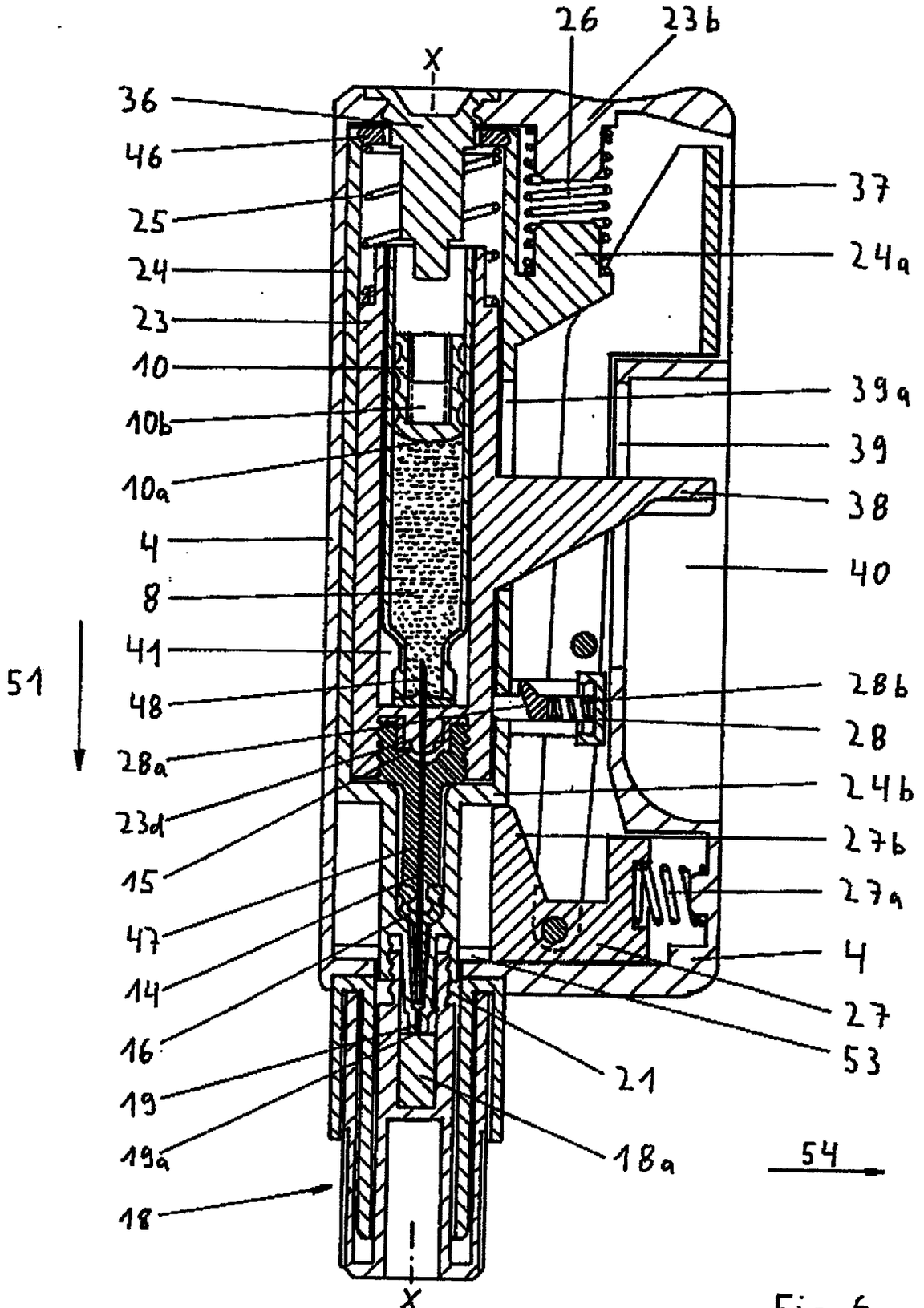


Fig. 6

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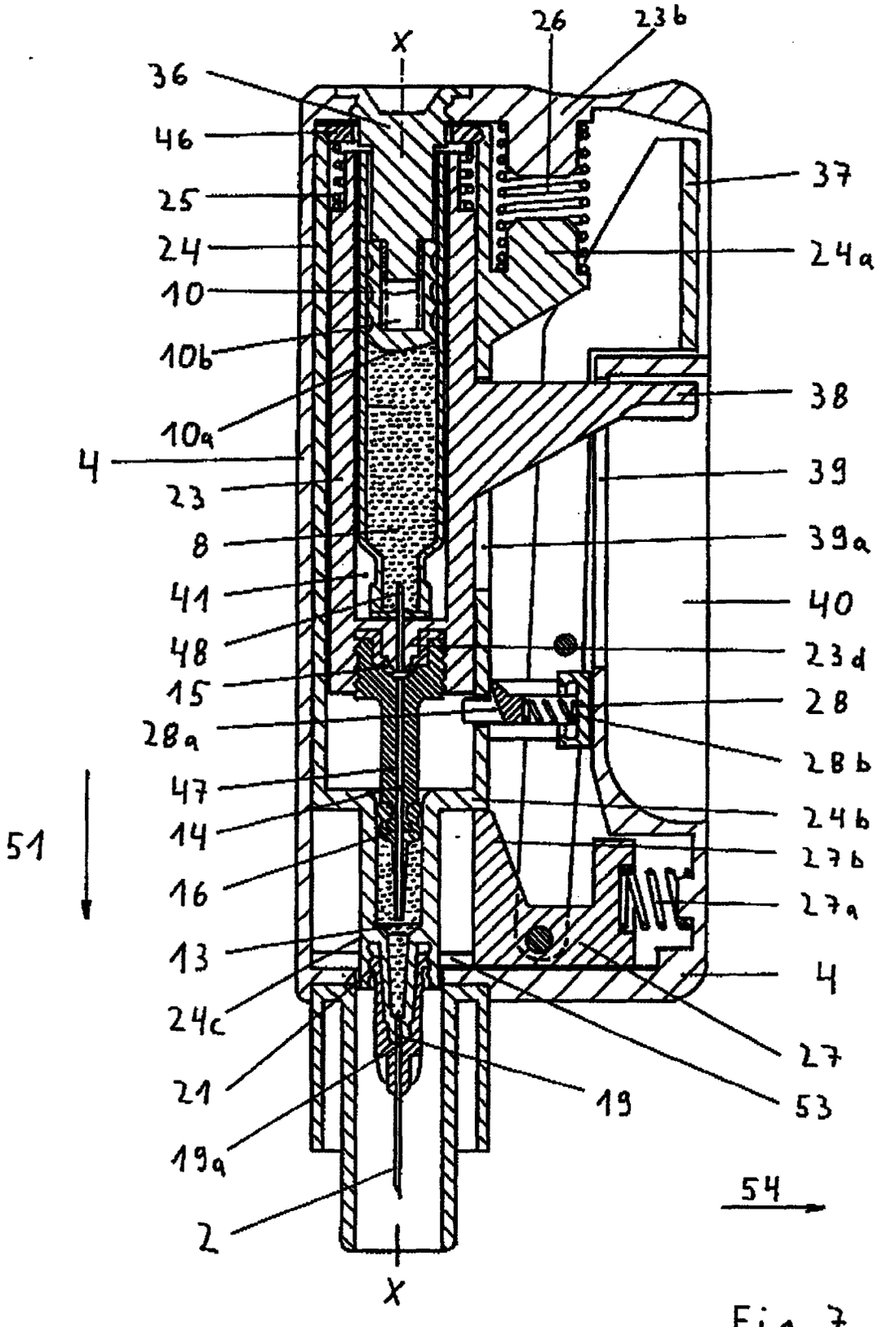


Fig. 7

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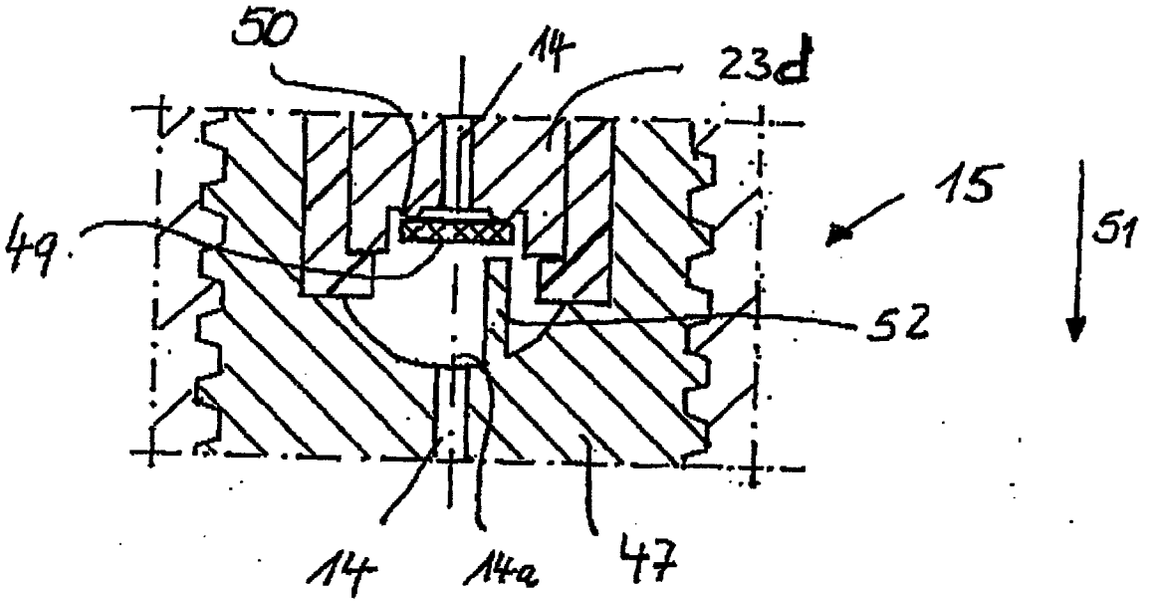


FIG.8

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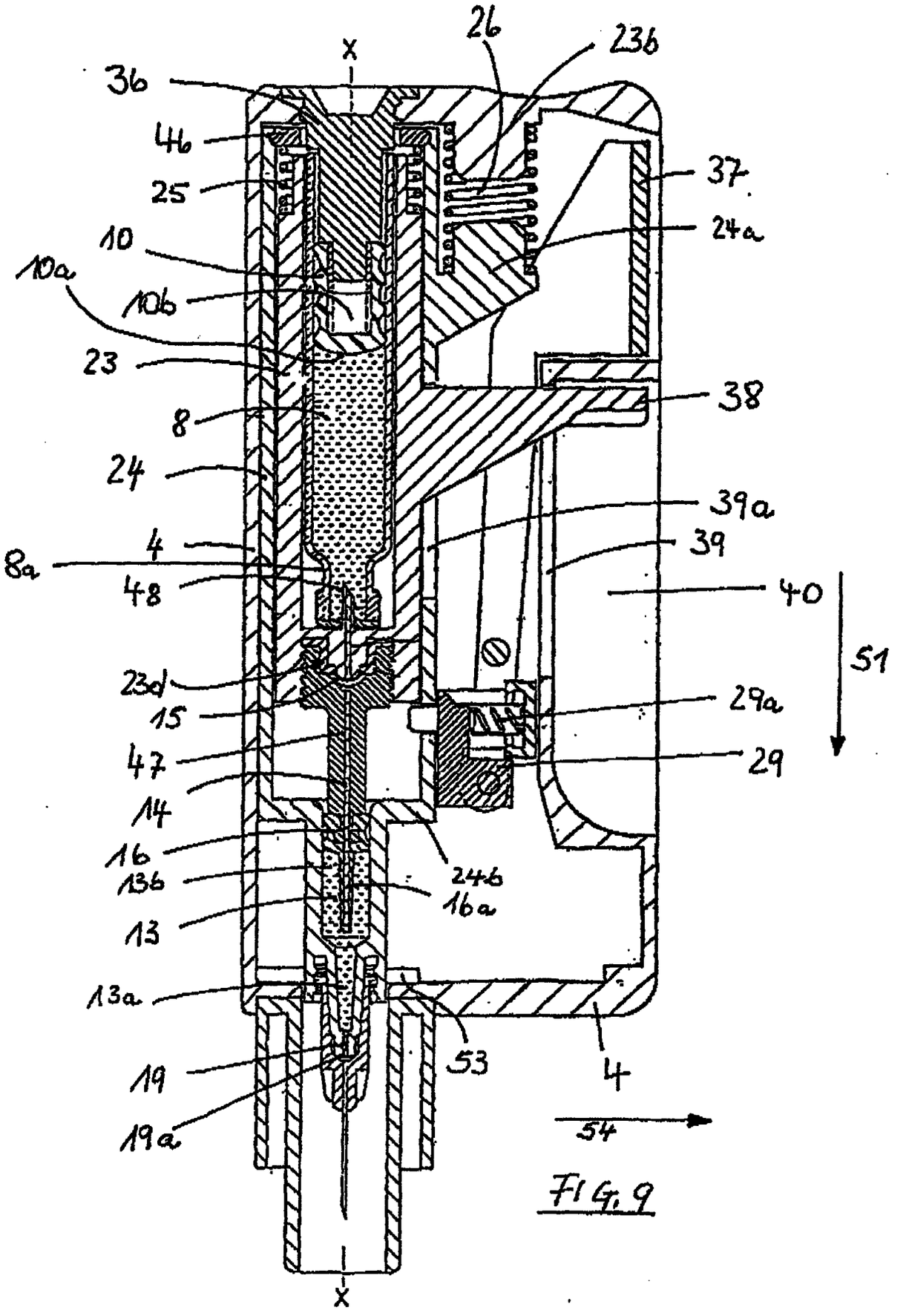


FIG. 9

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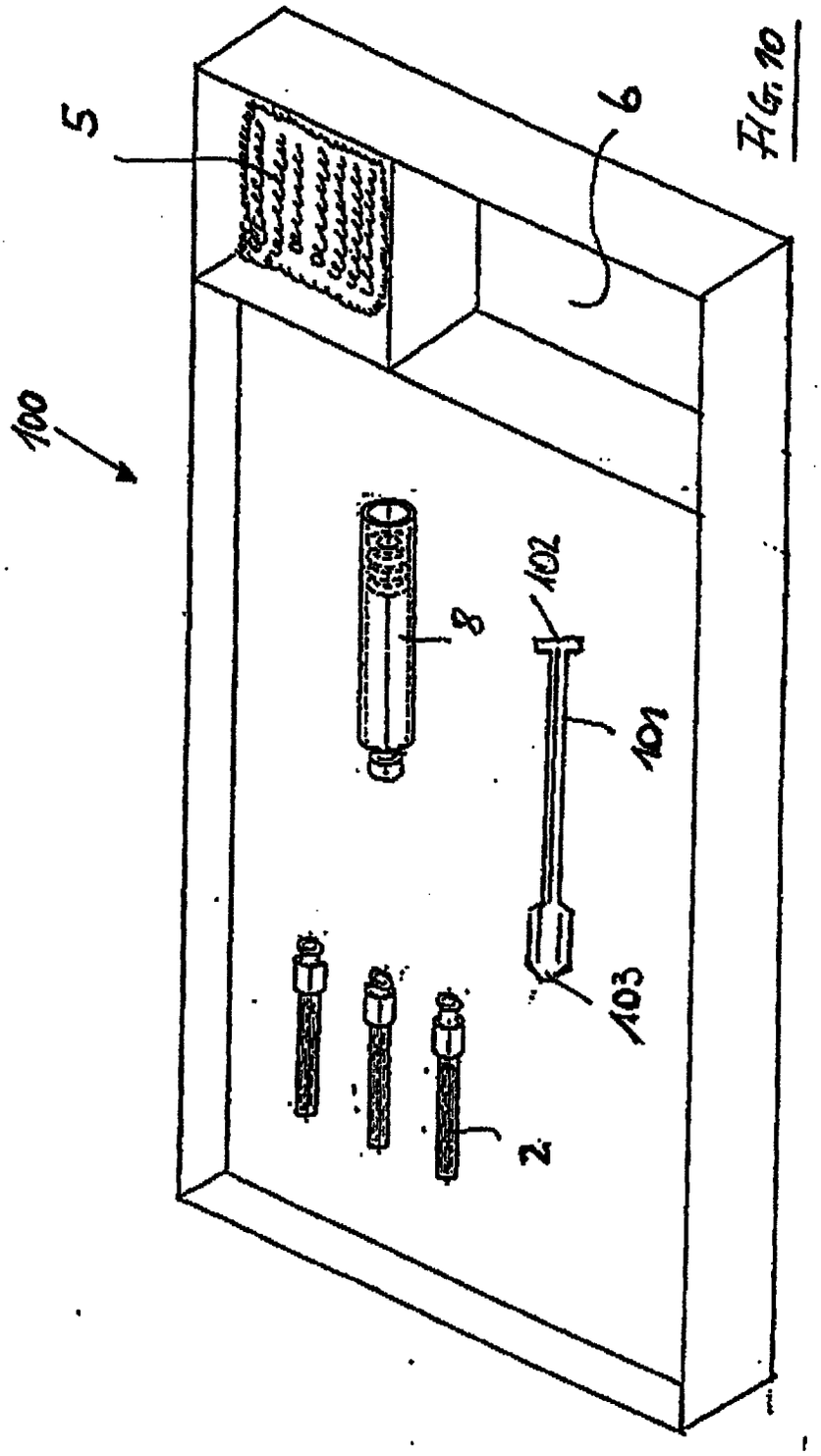


FIG. 10

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REPLACEMENT SHEETS SG
☑ Description : paged 1 to paged 46
☑ Claim(s) : paged 47 to paged 56
☑ Drawing(s) : paged 1 to paged 10
☐ Abstract : paged 57 to paged —
DATE OF RECEIPT 14/5/97

9700299-2

~~A sell unit~~ for the parenteral application, a device for carrying out the parenteral application as well as a refill unit for the above mentioned sell unit

The present invention is directed to a sell unit for the parenteral application of liquid pharmaceutical products, to a device for carrying out this parenteral application and to a refill unit for the afore mentioned sell unit, respectively device.

Parenterally applicable liquid pharmaceutical products, meaning such products that are subcutaneously applied by means of a syringe, nowadays are applied mainly by correspondingly trained professional staff, as for example by doctors or nursing staff. Hereby a usual syringe is used which is filled with the corresponding liquid pharmaceutical product before the parenteral application or which is filled already as a one-way syringe with the liquid pharmaceutical product. However, this means that the respective user has to submit himself to a medical treatment which involves high expenses particularly when, for the therapy of the respective disease, a given amount of a liquid pharmaceutical product has to be injected subcutaneously each day for a given limited time period.

The present invention has the object of elaborating a possibility by which the respective user can parenterally and preferably subcutaneously apply a liquid pharmaceutical product

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particularly easily.

According to the invention, this object is realised by a sell unit with the characteristics of patent claim 1, by a device with the characteristics of patent claim 11, as well as, if necessary, by a refill unit with the characteristics of patent claim 33 completing the sell unit according to patent claim 1, respectively the device according to patent claim 11.

The inventive sell unit for the parenteral application of a liquid pharmaceutical product by the user for the required therapy period is based on the main thought that the user can dispose, during the medically prescribed treatment period, of all necessary parts, so that the user is able to parenterally and preferably subcutaneously apply himself the required liquid pharmaceutical product without the help of medical staff. For that reason, the inventive sell unit comprises at least one cannula, one device for emitting a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel filled with the liquid pharmaceutical product, whereby the vessel can be set in the device and emptied by means of the device and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product. In other words, the user only needs to provide the device for emitting a given liquid amount, the device being arranged within the unit, with a cannula also arranged within the unit and, furthermore, to put the vessel filled with the liquid pharmaceutical product in the emitting device, so that immediately hereafter the user can parenterally and preferably subcutaneously apply himself the

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single dose of the liquid pharmaceutical product prescribed by the doctor.

The inventive sell unit has a range of advantages. Conditioned by the fact that the inventive sell unit comprises all parts that the user needs and that are required for the parenteral application in a single sell unit, it is firstly to be noted that, on one hand, these parts can be commonly stored in the sell unit by the user himself during the treatment and that, on the other hand, it is made particularly easy for the prescribing doctor to prescribe this sell unit as a whole. Since the emitting device of the sell unit forcibly determines, as a result of its construction, the given amount of the liquid pharmaceutical product for each single dose, the liquid pharmaceutical product cannot be underdosed or overdosed in the inventive sell unit, so that hereby the parenteral application of the liquid pharmaceutical product by the user is particularly safe. Moreover, the user can dispose of the parts required for the parenteral application in a well and clearly-arranged way, whereby the acceptance of the inventive sell unit is essentially improved for the user. Furthermore, the inventive sell unit avoids a soiling of its parts, particularly during their use for the user, and makes the expedition and the storing easier since it is formed as a unit, which is particularly advantageous for the use in the trade.

A first embodiment of the inventive sell unit is characterized in that the unit comprises a number of cannulas that corresponds to a number of the single doses of the pharmaceutical product.

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Hereby the user can exchange the used cannula by a corresponding sterile cannula after each parenteral application of the liquid pharmaceutical product, whereby the risk of an infection is avoided. The cannulas provided in the sell unit are preferably constructed in that way that the actual needle of the cannula is protected by a solid plastic jacket, whereby this solid plastic jacket, on one hand, guarantees the sterility of the needle and, on the other hand, keeps the user from unintentionally hurting himself with the needle. Such an embodiment of the sell unit particularly comprises ten of the afore described cannulas, whereby then the vessel being provided in the sell unit and being filled with the liquid pharmaceutical product makes it possible to correspondingly apply ten single doses of the product to be parenterally applied.

In order to make it again easier for the user to operate the inventive sell unit during the parenteral application, a further advantageous development is directed to a sell unit that comprises a number of cannulas that corresponds to a number of sponges, whereby these sponges are moistened with a disinfectant, as for example a low alcohol, ethanol, propanol. In order to avoid on the sponges an undesired evaporation of the disinfectant, the sponges moistened with a disinfectant are wrapped singly in corresponding foils, preferably plastic foils and more preferably compound plastic foils, so that, for the parenteral application, the user removes just one sponge from the wrapping and disinfects herewith the spot chosen for the injection.

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In another embodiment of the inventive sell unit, the unit additionally comprises a section serving to take up the used cannulas and/or used sponges. Hereby this section to take up the used cannulas, respectively the used sponges, is formed in the way that the used cannulas, respectively sponges, cannot fall out of the sell unit while being used, so that the section is formed particularly as a separately closable section. If in the sell unit this section is formed as a section being detachable from the sell unit, as for example as a closable box, the used cannulas and, if necessary, the sponges can be separately wasted, as for example by the special trade, as far as this is required by legal prescriptions.

The inventive sell unit can comprise basically each vessel containing the multitude of single doses of the liquid pharmaceutical product, as far as it is guaranteed that this vessel is formed in that way that it can be set into the device and emptied in single doses by means of the device. However, it is particularly suitable to fill the liquid pharmaceutical product to be parenterally applied by the user in single doses in a cylindrical or cylinder-like glass carpule (glass syringe cylinder), whereby such a glass carpule holds particularly between about 1,5 ml and about 8 ml, preferably between about 2 ml and about 6 ml, of the liquid pharmaceutical product.

A particularly advantageous development of the afore described glass carpule is characterized in that in the inventive sell unit such a glass carpule is arranged which is closed, at its bottom side, by a piercable membrane and, at its top side, by a

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plug being formed in that way that it can be axially shifted within the glass carpule in the direction of the piercable membrane when the liquid level is descending. This special development of the glass carpule has the particular advantage that the bottom section of the plug is located in the immediate proximity of the liquid level or even contacts the liquid level, so that there is no air puffer above the respective liquid level when the liquid level is descending because of the single doses emitted. On one hand, this avoids an undesired oxidative modification of the respective liquid pharmaceutical product and, on the other hand, the special forming of the plug effectively avoids the formation of a vacuum in the glass carpule when the liquid amount is decreasing, whereby such a vacuum would have a negative effect on the exactness of the liquid amount emitted in single doses.

In order to ensure the required tightness between the plug and the inner walling of the glass carpule, according to the afore described embodiment of the glass carpule which disposes of the afore described plug being axially shiftable in the direction of the piercable membrane, a further development of the inventive sell unit is characterized in that the plug comprises on its jacket surface at least one, preferably two to five, disk-like sections directing radially to the outside. Hereby these disk-like sections can be deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid-tightens and air-tightens the inner surface of the carpule. The disk-like sections directing to the outside are preferably dimensioned in that way that an end section of the

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disk-like sections is elastically deformed by the axial shifting of the plug in the glass carpule opposite to the shifting direction with the formation of a correspondingly larger dimensioned sealing surface. In respect to the material that the plug consists of, it is to be noted that herefore preferably an elastic, chemically resistant plastic material or rubber material is chosen, whereby herefore a halogenbutyl-caoutchouc proved to be particularly suitable.

When the afore described plug can be axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N, it is particularly guaranteed that the above described advantages occur in a particularly reproducible way.

By using the inventive sell unit, basically all liquid pharmaceutical products being stable in storage can be parenterally applied by the user himself. Hereby the term liquid pharmaceutical products means all such products which, as actual product, are liquid or from which stable solutions, stable dispersions or stable emulsion can be manufactured in an organic or inorganic, physiologically safe liquid. The afore described vessel or the afore described and particularly used glass carpule preferably comprise an aqueous solution of a heparin, preferably an aqueous solution of a low-molecular heparin, and particularly an aqueous solution of an enoxaparin-sodium. Such a sell unit is then used by such users who, because of their syndrome and from the medical point of view, have to apply the heparin daily in constant single doses for a longer time period,

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in order to prevent, for example, the risk of a thrombosis after having discharged the patient from the hospital. A further preferred employment of the inventive sell unit is the regular parenteral application of a given and constant amount of a growth hormone, whereby, for this case of application, the vessel and particularly the afore described glass carpule is filled with a solution of the growth hormone, preferably an aqueous solution of the growth hormone. Within the scope of the present invention, the term water does not only mean deionized or distilled water, but all aqueous systems, particularly physiological salt solutions or buffer solutions.

The present invention is furthermore directed to a device for emitting a given liquid amount of a pharmaceutical product in single doses, whereby the inventive device comprises a section arranged within a casing, the section taking up the vessel filled with the liquid pharmaceutical product. Moreover, the inventive device contains an outlet section for the single dose of the pharmaceutical product, whereby the outlet section directs into the direction of the user when he parenterally and particularly subcutaneously applies the single dose of the pharmaceutical product. According to the inventive device, the vessel containing the multitude of the single doses, can be connected with the outlet section by an intermediate reservoir in such a way that, when the vessel is set into the inventive device, the given liquid amount of each single dose can be drained firstly from the vessel into the intermediate reservoir and then from the intermediate reservoir into the outlet section. The amount of the liquid pharmaceutical product emitted

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with each single dose can be determined, according to the inventive device, by the volume of the intermediate reservoir. In other words, the amount of the single dose being parenterally applicable is variable in the inventive device by varying the volume of the intermediate reservoir, whereby the volume of the intermediate reservoir is chosen in that way that each single dose of the liquid pharmaceutical product to be applied has a volume of between 0,1 ml and 1 ml, particularly between 0,2 ml and 0,6 ml and preferably between 0,2 ml and 0,4 ml.

The inventive device shows a number of advantages. First of all it is to be noted that it has a relatively simple and unproblematical construction and that it is very easy to handle since for the use of the inventive device by the user, it is only necessary to arrange the vessel containing the multitude of single doses of the liquid pharmaceutical product within the section for taking up the vessel located in the inventive device and to fix it there, if necessary, so that subsequently within the inventive device the vessel is connected with the intermediate reservoir which is then connected with the outlet section. In other words, when the respective user, contrarily to the initially described procedure of parenterally applying a liquid pharmaceutical product by a doctor or the medical staff, uses the inventive device, he does not have to transmit the respective product to be applied from the ampoule into the syringe and to measure the exact amount to be injected since in the inventive device this procedure takes places inevitably because of the construction of the inventive device. This essentially simplifies the use of the inventive device, so that

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by using the inventive device even sick and/or old users are able to inject themselves the required single dose of the product to be parenterally applied without depending on the help of others.

In order to form in the inventive device the afore mentioned connection between the vessel being set into the device and the intermediate reservoir in a particularly simple way, a further development of the inventive device is characterized in that at least one connecting conduct is located between the set in vessel filled with the multitude of the single doses of the liquid pharmaceutical product and the intermediate reservoir. Hereby an end section of this connecting conduct preferably protrudes into the section being arranged within the casing of the inventive device and taking up the vessel filled with the pharmaceutical product, so that, when the vessel has to be put in, this end section simplifies the connecting of the intermediate reservoir and the set in vessel. If hereby the glass carpule, which is described above in connection with the inventive sell unit and which comprises particularly at its top end the afore mentioned piercable membrane, is used as a vessel, it is suitable to form this end section of the connecting conduct as a correspondingly pointed end section or preferably as hollow needle, so that by this pointed end section, respectively by this hollow needle, then the piercable membrane can be pierced and so that thus the afore mentioned connection between the content of the glass carpule and the intermediate reservoir can particularly easily be realised. Such a piercing of the piercable membrane can also be simplified by providing

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the pointed end section, respectively the hollow needle, with a stopping element for the carpule, whereby this stopping element preferably fixes the carpule shaft and thus the whole carpule in its position. If hereby this stopping section is formed as a thread or as a bayonet catch, meaning that the thread, respectively the bayonet catch, can receive the correspondingly formed section of the carpule shaft, the carpule forcibly moves axially in the direction of the connecting conduct when the carpule is screwed in, respectively fixed, so that hereby the end section formed as pointed end section, respectively as hollow needle, penetrates the piercable membrane and so that thus the liquid pharmaceutical product can flow from the glass carpule into the intermediate reservoir.

A further development of the afore described embodiment of the inventive device is characterized in that the connecting conduct comprises a valve avoiding a backflow of the liquid from the intermediate reservoir into the glass carpule. In other words, this embodiment of the inventive device thus comprises a connecting conduct being provided with a reflux valve, so that the liquid to be parenterally applied can superfuse the connecting conduct only in one single direction, meaning from the vessel into the intermediate reservoir.

In respect to the formation of the afore mentioned valve avoids a backflow of the liquid pharmaceutical product from the intermediate reservoir into the vessel, as this is already described above, there are several possibilities. This upper section can be formed, for example, as a usual ball-containing

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reflux valve. However, it is particularly suitable when the reflux valve is formed as a membrane valve, whereby a valve sheet, preferably consisting of a rubber-elastic material, can be moved between a first position in which the valve sheet covers the partial conduct section of the connecting conduct, whereby the partial conduct section is directed to the vessel, and between a second position in which the valve sheet is displaced in the direction of the intermediate reservoir and makes possible the liquid flow from the vessel into the intermediate reservoir. In order to prevent an adhesion of the disk-shaped valve sheet in the first position and to avoid thus a disturbance of the functioning of the reflux valve, it is suitable to provide a ring-shaped distancing element which gets in contact with the valve sheet when the valve sheet is in the first position, so that in all the sealing surface is decreased by the ring-shaped distancing element, as this is subsequently described in detail in a example.

For filling the intermediate reservoir in the inventive device with the single dose of the liquid pharmaceutical product from the vessel, the content of the vessel can flow into the intermediate reservoir and thus fill it for gravitation reasons. It is particularly suitable, however, when a piston being axially shiftable in the direction of the outlet section is arranged within the intermediate reservoir, whereby, with such an axial shifting in the direction of the outlet section, the piston then effectuates the flow of a single dose of the liquid pharmaceutical product, the single dose being located in the intermediate reservoir, in the direction of the outlet section.

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According to an axial shifting in the opposite direction hereof, a vacuum is generated in the intermediate reservoir if the connection between the intermediate reservoir and the outlet section is closed air-tight, so that a connecting conduct extending through the piston, the connecting conduct being located between the vessel and the intermediate reservoir, fills the intermediate reservoir with the liquid from the vessel filled with the liquid pharmaceutical product. Such a filling of the intermediate reservoir has the particularly advantage that hereby a reproducibly and exactly given liquid amount drains from the vessel into the intermediate reservoir, so that correspondingly the single dose of the liquid pharmaceutical product from the intermediate reservoir which is applied by the user can be formed in a particularly exact and reproducible way.

In order to obtain in the inventive device the air-tight blocking which is required before for the filling and which blocks the conduct located between the intermediate reservoir and the outlet section, there a several possibilities. For example, a valve , particularly a reflux valve, can be arranged also in this conduct, whereby this valve does not allow an air flow or a liquid flow from the outlet section into the intermediate reservoir, but only a liquid flow from the intermediate reservoir into the outlet section. It is particularly suitable, however, when the conduct comprises a closing element being operable from the outside, as for example a corresponding valve.

An embodiment of the inventive device which is particularly easy

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to handle by the respective user for a long time period is characterized in that the already afore mentioned closing element by which the conduct connecting the outlet section with the intermediate reservoir can be closed air-tight is formed as detachable closing element being located at the conduct. Hereby a sealing section of the closing element air-tightens the outer conduct outlet located at the outlet section. This closing element is preferably formed as a closing element which can be screwed onto the device in the outlet section or which can be fixed by a bayonet catch in such a way that it is detachably connectable with outlet section and/or the casing of the device. If in this embodiment of the inventive device it is desired to fill the intermediate reservoir with the single dose of the liquid pharmaceutical product in the afore described manner, which means that an air flow from the conduct outlet of the outlet section into the intermediate reservoir is avoided and that thus the vacuum required for the filling of the intermediate reservoir is generated, this closing element is screwed onto the outlet section, respectively onto the corresponding zone of the casing, so that the sealing section located at the closing element gears in with the conduct outlet. After filling the intermediate reservoir, the closing element is detached from the outlet section, respectively from the zone of the device casing, so that the single dose of the liquid pharmaceutical product, the single dose being located in the intermediate reservoir, can be drained out of the inventive device by axially shifting the piston in the direction of the outlet section and the consequently opened conduct.

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A particularly high reproducibility in respect to the liquid pharmaceutical product amount emitted with each single dose can be obtained in such an embodiment of the inventive device, when it is guaranteed that the intermediate reservoir can be completely emptied by axially shifting the piston being arranged in the intermediate reservoir in the direction of the outlet section.

Such a complete emptying furtherly avoids an undesired crystallisation or the deposition of residues of the pharmaceutical product on the intermediate reservoir wallings and/or the piston wallings, whereby, on one hand, the exactness of dosing each single dose and, on the other hand, the function of the inventive device would be endangered.

A particularly embodiment of the inventive device which makes it possible to emit single dose from the intermediate reservoir in an reproducible and untroubled way, is characterized in that the intermediate reservoir is formed in a cylindrical way and comprises a subsequent end section being conically shaped and directing to the outlet section, whereby the end section is connected with the outlet section by the afore described conduct. In this development the form of the piston moreover corresponds to the form of the afore described intermediate reservoir, so that correspondingly the piston comprises a cylindrical piston section and an end section being conically formed and being connected with the cylindrical piston section. If in this embodiment of the inventive device additionally the connecting conduct being located between the vessel and the

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intermediate reservoir extends through the piston section up to the conical piston point, not only the complete emptying is guaranteed to a high degree in such a development of the inventive device, but also the reproducible filling of the intermediate reservoir.

In respect to the formation of the conical end section, there are several possibilities. This conical piston end section can, for example, consist of the same material as the rest of the piston, whereby, however, in a particularly advantageous embodiment the conical piston end section can be formed by a conically extending jacket tube being closed at its end which is located opposite to the piston section. The connecting conduct then extends almost over the whole axial length of the jacket tube, whereby the connecting conduct is located between the vessel and the intermediate reservoir, and whereby the conically shaped jacket tube comprises outlets for the liquid advanced from the vessel on its jacket surface. Hereby it is guaranteed that the intermediate reservoir is impeccably filled with the single dose of the liquid pharmaceutical product coming from out of the vessel.

The inventive device basically makes it possible to parenterally apply the single dose of the liquid pharmaceutical product being located in the intermediate reservoir directly over the outlet section connected with the intermediate reservoir by means of the conduct by submitting the single dose of the liquid pharmaceutical product to a high pressure. It is particularly suitable, however, when the outlet section comprises a mounting

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section for the detachable fixing of a cannula in such a way that the conduct can be connected with the cannula in a liquid-tight manner. In this embodiment of the inventive device, the mounting section thus holds a cannula which can be detachably fixed and which, during the application of the liquid pharmaceutical product, penetrates the body zone chosen by the user and then effectuates the parenteral application of the product.

A further embodiment of the inventive device is characterized in that additionally the afore described closing element which effectuates a closing of the conduct being located between the intermediate reservoir and the outlet section during the filling of the intermediate reservoir can be detachably fixed at the mounting section. Depending on the formation of the mounting section and the closing element, the closing element and the cannula can either be fixed at the same time at the mounting section or the closing element and the cannula can be fixed optionally at the mounting section, whereby the latter mentioned possibility is preferred since hereby the risk of getting hurt by removing the closing element is avoided by cannula still being fixed at the mounting section.

Another embodiment of the inventive device is characterized in that moreover the mounting section comprises a protecting element, whereby this protecting element then covers a cannula fixed at the mounting section at least partially or completely. This protecting element protecting the respective user from an undesired hurting by the cannula can hold the closing element or

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additionally support the fixing of the closing element at the mounting section, so that hereby a handle section is formed which the user touches while preparing the inventive device for the application.

A further particularly suitable embodiment of the inventive device comprises first cylinder being located in the casing and a second cylinder surrounding the first cylinder, whereby the first cylinder and the second cylinder are axially shiftable relative to the casing. The section for taking up the vessel, particularly the afore described carpule, is arranged within the first cylinder, whereas the intermediate reservoir being connected with the vessel is arranged within the second cylinder. In this embodiment of the inventive device, the first cylinder and the second cylinder can be axially shifted from a first position in which the cannula being fixable to the mounting section protrudes over the afore described protecting element, respectively the device casing, and in which the intermediate reservoir is emptied over the conduct and the cannula following hereafter, and a second position in which a cannula being fixable to the mounting section is covered by the protecting element and in which the intermediate reservoir is filled with the single dose, and vice-versa.

The afore described embodiment of the inventive device permits a parenteral application of the corresponding single dose of the liquid pharmaceutical product in a particularly simple way. Herefore it is only necessary to transmit the first cylinder and the second cylinder from a first position in which the

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intermediate reservoir is empty into a second position by axially shifting the cylinders relatively to the casing. This axial shifting leads to the fact that the intermediate reservoir is filled with the liquid being drained out of the vessel. After attaching a corresponding cannula at the mounting section, the penetration of the cannula into the body zone of the user and the emptying of the intermediate reservoir is carried out by axially shifting both cylinders in the direction of the mounting section, whereby as a consequence the single dose is parenterally applied. Both cylinders are preferably formed in that way that they additionally can be axially shifted relatively to each other, so that there is a time difference between the actual penetration procedure of the cannula into the body zone of the user and the emptying of the intermediate reservoir, whereby it is made possible to apply the liquid pharmaceutical product in a corresponding time retardation.

In order to cause the afore described axial shifting of both cylinders from the first position into the second position and from the second position into the first position, these axial shiftings can be realised manually in both directions. This means, however, that, when the respective user transmits both cylinders from the second position into the first position in the afore mentioned way, the penetration of the cannula into the body zone has to be carried out manually by the user himself, which the user considers to be extremely unpleasant and invincible. For that reason a particularly advantageous development of the afore described embodiment of the inventive device is characterized in that the first cylinder and the

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second cylinder comprise each a spring in such a way that in the second position of the cylinders both springs are tensioned and that in the first position of the cylinders the springs are released.

In order to fix both cylinders in their second position being tensioned by the corresponding springs, each cylinder in the inventive device can comprise a corresponding locking element. By releasing the locking of the second cylinder, the second cylinder is then transmitted from the second position into the first position caused by the spring power of the spring located at the second cylinder, which causes an inevitable penetration of a cannula being fixed at the mounting section into the chosen body zone of the user, whereby the user has no influence on this. Subsequently the locking being provided for the first cylinder is released, whereby the first cylinder is axially moved in the direction of the outlet section by the spring being provided for the first cylinder, whereby the intermediate reservoir is emptied, so that the corresponding single dose of the liquid pharmaceutical product is parenterally applied.

According to a particularly suitable and easy to handle development of the embodiment of the inventive device, both cylinders are fixable in the second position by a single locking element. This means that the user has to release only one locking element in order to commonly transmit both spring-tensioned pistons being fixed in the second position into the first position, whereby the penetration procedure of the cannula into the body zone and the injection of the single dose takes

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place.

In order to obtain in the afore described embodiment of the inventive device that firstly the penetration of the cannula into the body zone takes place and hereafter the injection of the single dose, a particularly suitable development of this embodiment is characterized in that it comprises springs corresponding to each other in respect to their characteristic spring line. Hereby the spring provided for the second cylinder has a steeper characteristic spring line than the spring being located at the first cylinder, so that the already afore mentioned time retardation between the penetration of the cannula and the subsequent injection can be regulated by accommodating the characteristic spring lines to each other in a high range.

A further advantageous embodiment of the inventive device is directed to a first cylinder and a second cylinder surrounding the first cylinder being arranged within the casing, whereby the first cylinder and the second cylinder are axially shiftable relatively to the casing. The section for taking up the vessel, preferably the afore mentioned glass carpule, is arranged within the first cylinder, whereas the intermediate reservoir connected with the vessel is arranged within the second cylinder in such a way that the first and the second cylinder can be commonly and axially shifted from a first position in which the cannula being fixable to the mounting section protrudes over the protecting element, respectively the casing, and in which the intermediate reservoir is emptied, into a second position in which a cannula

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being fixable to the mounting section is covered by the protecting element, and vice-versa. For filling the intermediate reservoir the first cylinder can be axially shifted into a third position in the direction of the vessel relatively to the second position of the second cylinder.

In other words, this afore described and particularly advantageous development of the inventive device is characterized in that it provides also a third position, contrarily to the afore described embodiments of the inventive device in which the cylinders can only be arranged in a first and a second position.

In order to use the inventive device, firstly both cylinders are transmitted from the first position into the second position, which causes that a cannula being fixed at the mounting section is covered by a protecting element. At this time the intermediate reservoir is not yet filled with the single dose of the liquid pharmaceutical product. Subsequently the first cylinder is axially shifted into a third position relatively to the second cylinder which remains in the second position, whereby the intermediate reservoir is completely filled with the liquid pharmaceutical product being drained out of the vessel by the connecting conduct. As the first cylinder is moved from the second position into the third position, the conduct connecting the cannula with the intermediate reservoir is blocked in an air-tight way by one of the afore described valves or by the also afore mentioned closing element. A vacuum causing the liquid flow from the vessel into the intermediate reservoir is

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thus generated in the intermediate reservoir.

Hereafter the ready-to-operate device is brought into contact with the chosen body zone, so that then the user moves the second cylinder from the second position into the first position, whereby the penetration procedure of the cannula into the body zone is manually effectuated. Hereafter the user moves the first cylinder from the third position into the first position, whereby the corresponding injection of the single dose of the liquid pharmaceutical product from the intermediate reservoir into the body is caused.

As it is, however, mentioned above, some user have the problem with this application that they have to carry out themselves the corresponding injection of the single dose of the liquid pharmaceutical product from the intermediate reservoir into the body. In order to avoid this, a further development of the afore described embodiment of the inventive device is characterized in that each cylinder (first cylinder, second cylinder) comprises a spring, whereby a first spring pre-tensions the arrangement of the cylinder in the third position and a second spring pre-tensions the arrangement of the second cylinder in the second position. Moreover, the first cylinder is fixable in the third position by first locking and the second cylinder is fixable in the second position by a second locking in such a way that this fixing is caused by corresponding lockings can preferably be released by a single release button.

In order to apply such a device, the respective user transmits

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the second cylinder into the second position against the power of the corresponding second spring, whereby such an axial shifting of the second cylinder is realised preferably by a shifting element arranged at the outside of the casing. Concurrently to operating this shifting element, the first cylinder is shifted into its second position against the power of the first spring, whereby then the second locking fixes the second cylinder in the second position. When the shifting element is furtherly operated, the first cylinder is axially shifted relatively to the second cylinder from the second position into the third position against the power of the corresponding first spring and is then fixed in the third position by the first locking.

By operating the common release button both cylinders are axially shifted from the third position (first cylinder), respectively from the second position (second cylinder), into the first position as a result of the spring power of the first and the second spring, whereby the penetration of the cannula into the body zone and the injection of the single dose from the intermediate reservoir is forcibly effectuated without being influenced by the user.

A further development of the afore described embodiment is preferably characterized in that, by operating the release button, firstly the second locking fixing the second cylinder in the second position is released and then the first locking fixing the first cylinder in the third position is released in a corresponding time retardation.

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the afore described inventive device are particularly used in the initially discussed inventive sell unit, whereby, however, the inventive device can be traded on the market independently from the sell unit.

Furthermore, the present invention is directed to a refill unit to be employed in the initially described inventive sell unit or in the afore discussed inventive device.

Hereby this inventive refill unit comprises at least one cannula as well as at least on vessel filled with the liquid pharmaceutical product, whereby the vessel can be arranged within the afore described inventive device and emptied in single doses by means of this device.

The inventive refill unit has the essential advantage of being perfectly adjusted to the afore described sell unit as well as to the inventive device in respect to its constructive features, so that the user of the afore described inventive sell unit or of the afore discussed inventive device can apply the inventive refill unit when a longer parenteral application of the liquid pharmaceutical product is required from the medical point of view and when the vessel being filled with the liquid pharmaceutical product and being provided in the afore described inventive sell unit is emptied.

A first development of the inventive refill unit is characterized in that a detaching element to remove the emptied

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vessel from the inventive device for emitting a given liquid amount in single doses is arranged in the refill unit. The detaching element is formed correspondingly to the respective form of the section for taking up the vessel filled with the liquid pharmaceutical product, this section being located within the casing of the inventive device, whereby this detaching element preferably comprises a grip section so that the user can grip the detaching element and a fixing section for the form-fit and/or non-positive fixing of the emptied vessel.

As already described above in the inventive sell unit, a first embodiment of the inventive refill unit is characterized in that the unit comprises a number of cannulas that corresponds to a number of the single doses of the pharmaceutical product. Hereby the user can exchange the used cannula by a corresponding sterile cannula after each parenteral application of the liquid pharmaceutical product, whereby the risk of an infection is avoided. The cannulas provided in the refill unit are preferably constructed in that way that the actual needle of the cannula is protected by a solid plastic jacket, whereby this solid plastic jacket, on one hand, guarantees the sterility of the needle and, on the other hand, keeps the user from unintentionally hurting himself with the needle. Such an embodiment of the refill unit particularly comprises ten of the afore described cannulas, whereby then the vessel being provided in the refill unit and being filled with the liquid pharmaceutical product makes it possible to correspondingly apply ten single doses of the product to be parenterally applied.

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In order to make it again easier for the user to operate the inventive refill unit during the parenteral application, a further advantageous development is directed to a refill unit that comprises a number of cannulas that corresponds to a number of sponges, whereby these sponges are moistened with a disinfectant, as for example a low alcohol (ethanol, propanol). In order to avoid on the sponges an undesired evaporation of the disinfectant, the sponges moistened with a disinfectant are wrapped singly in corresponding foils, preferably plastic foils and more particular compound plastic foils, so that, for the parenteral application, the user removes just one sponge from the wrapping and disinfects herewith the spot chosen for the injection.

In another embodiment of the inventive refill unit, the unit additionally comprises a section serving to take up the used cannulas and/or used sponges. Hereby this section to take up the used cannulas, respectively the used sponges, is formed in the way that the used cannulas, respectively sponges, cannot fall out of the refill unit while being used, so that the section is formed particularly as a separately closable section. If in the refill unit this section is formed as a section being detachable from the refill unit, as for example as a closable box, the used cannulas and, if necessary, the sponges can be separately wasted, as for example by the special trade, as far as this is required by legal prescriptions.

The inventive refill unit can comprise basically each vessel containing the multitude of single doses of the liquid

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pharmaceutical product, as far as it is guaranteed that this vessel is formed in that way that it can be set into the device and emptied in single doses by means of the device. However, it is particularly suitable to fill the liquid pharmaceutical product to be parenterally applied by the user in single doses in a cylindrical or cylinder-like glass carpule, whereby such a glass carpule holds particularly between about 1,5 ml and about 8 ml, preferably between about 2 ml and about 6 ml, of the liquid pharmaceutical product.

A particularly advantageous development of the afore described glass carpule is characterized in that in the inventive refill unit such a glass carpule is arranged which is closed, at its bottom side, by a piercable membrane and, at its top side, by a plug being formed in that way that it can be axially shifted within the glass carpule in the direction of the piercable membrane when the liquid level is descending. This special development of the glass carpule has the particular advantage that the bottom section of the plug is located in the immediate proximity of the liquid level or even contacts the liquid level, so that there is no air puffer above the respective liquid level when the liquid level is descending because of the single doses emitted. On one hand, this avoids an undesired oxidative modification of the respective liquid pharmaceutical product and, on the other hand, the special forming of the plug effectively avoids the formation of a vacuum in the glass carpule when the liquid amount is decreasing, whereby such a vacuum would have a negative effect on the exactness of the liquid amount emitted in single doses.

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In order to ensure the required tightness between the plug and the inner walling of the glass carpule, according to the afore described embodiment of the glass carpule which disposes of the afore described plug being axially shiftable in the direction of the piercable membrane, a further development of the inventive refill unit is characterized in that the plug comprises on its jacket surface at least one, preferably two to five, disk-like sections directing radially to the outside. Hereby these disk-like sections can be deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid-tightens and air-tightens the inner surface of the carpule. The disk-like sections directing to the outside are preferably dimensioned in that way that an end section of the disk-like sections is elastically deformed by the axial shifting of the plug in the glass carpule opposite to the shifting direction with the formation of a correspondingly larger dimensioned sealing surface. In respect to the material that the plug consists of, it is to be noted that herefore preferably an elastic, chemically resistant plastic material or rubber material is chosen, whereby herefore a halogenbutyl-caoutchouc proved to be particularly suitable.

When the afore described plug can be axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N, it is particularly guaranteed that the above described advantages occur in a particularly reproducible way.

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By using the inventive refill unit in connection with the inventive device of the inventive sell unit, basically all liquid pharmaceutical products being stable in storage can be parenterally applied by the user himself. Hereby the term liquid pharmaceutical products means all such products which, as actual product, are liquid or from which stable solutions, stable dispersions or stable emulsion can be manufactured in an organic or inorganic, physiologically safe liquid. The afore described vessel or the afore described and particularly used glass carpule preferably comprise an aqueous solution of a heparin, preferably an aqueous solution of a low-molecular heparin, and particularly an aqueous solution of an enoxaparin-sodium. Such a refill unit is then used by such users who, because of their syndrome and from the medical point of view, have to apply the heparin daily in constant single doses for a longer time period, in order to prevent, for example, the risk of a thrombosis after having discharged the user from the hospital. A further preferred employment of the inventive refill unit is the regular parenteral application of a given and constant amount of a growth hormone, whereby, for this case of application, the vessel and particularly the afore described glass carpule is filled with a solution of the growth hormone, preferably an aqueous solution of the growth hormone.

The inventive sell unit, the inventive device as well as the inventive refill unit will be described in detail by embodiments in connection with drawings as follows. The figures show:

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Figure 1 a perspective view of an embodiment of the sell unit;

Figure 2 a perspective, schematical view of the device for emitting a given liquid amount in single doses;

Figure 3 an explosion drawing of figure 2;

Figure 4 an enlarged schematical sectional view of a closing element;

Figure 5 an sectional explosion view of the axially shiftable cylinder;

Figure 6 a sectional view of a first embodiment with emptied intermediate reservoir;

Figure 7 as figure 6, but with filled intermediate reservoir;

Figure 8 an enlarged schematical sectional view of a reflux valve;

Figure 9 a sectional view of a second embodiment of the device with filled intermediate reservoir; and

Figure 10 a perspective view of an embodiment of the refill unit.

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In the figures 1 to 10 the same parts are designated with the same reference numbers.

A sell unit collectively designated with 1 and shown in figure 1 comprises a device 3 for emitting a given liquid amount of the pharmaceutical product, a multitude of cannulas 2 being provided with a corresponding cannula protector 45 (figure 3) for the sterile storing, a glass carpule designated with 8 serving as vessel being filled with the liquid pharmaceutical product. Moreover, the sell unit 1 comprises a number of sponges 5 moistened with an disinfectant, whereby the number of sponges 5 corresponds to the number of the cannulas 2. The sell unit 1 furthermore contains a section 6 taking up used cannulas, whereby, according to the embodiment shown in figure 1, this section can be closed by a cover which is not shown. This section 6 is collectively arranged at the sell unit 1 in a detachable way, so that, after taking up the used cannulas, this section 6 can be separately wasted, as far as this is legally prescribed or desired. The sell unit 1 usually comprises 10 cannulas 2, so that correspondingly the glass carpule 8 contains the liquid amount for 10 cannulas. Usually the liquid amount emitted each in single doses varies between 0,1 ml and 1 ml, so that correspondingly the glass carpule contains between 1 ml and 10 ml of the liquid pharmaceutical product. In order to avoid an evaporation of the disinfectant of the sponges 5, each sponge 5 is separately wrapped by a corresponding plastic foil in an air-tight way. The sell unit 1 taking up the afore described parts is collectively closed by a cover (not shown) or is arranged in the usual plastic wrapping, if necessary even in a sterile way.

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The device 3 for emitting a given liquid amount of the liquid pharmaceutical product, the device 3 being shown in detail in figure 2, comprises a protecting element 22, whereby this protecting element 22 consists of a outer cylinder 22 a and inner cylinder 22 b being concentrically arranged relative to the outer cylinder 22 a which are manufactured from a transparent plastic material and which can cover a cannula 2 fixed at the device 3, as this is shown, for example, in figure 3. Furthermore, the device 3 comprises a casing 4, whereby an upper grip section 33, a window 34, a counting device 35, a second grip section 33 a, a cover 36 being detachable from the casing, a release button 37, a shifting element 38 being fixed by a corresponding slot 39, as well as a deepening 40 are arranged at the casing 4.

In the device 3 shown in figure 2 furthermore a closing element 18 is fixed at the casing 4, whereby the closing element 18 is subsequently described in detail in connection with figure 4. The user can thus easily hold the device 3 at the grip sections 33 and 33 a as well as at the closing element 18. The afore mentioned counting device 35 serves to count the single doses of the liquid pharmaceutical product emitted by means of the device 3, whereas the window 34 arranged in the casing makes it possible to control the liquid level in the glass carpule 8, as far as the glass carpule 8 is taken up by the device 3, whereby the cover 36 is removed in order to arrange the glass carpule 8, as this is shown in figure 3.

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Figure 3 schematically shows the insertion of the glass carpule 8 into the device 3 and the arrangement of the closing element 18 as well as the arrangement of a cannula 2. During the insertion of the glass carpule the cover 36 is firstly removed in order to open the section 41 taking up the vessel filled with the liquid pharmaceutical product, whereby this section 41 is located within the casing 4. When the glass carpule 8 has been inserted into the section 41, the corresponding opening is closed with the cover 36. At its bottom side the cover 36 comprises an axially extending lengthening pin 42 ending in an end section 42 a, whereby the lengthening pin 42 and the end section 42 a can be axially shifted together with the cover 36.

In a further, not shown and preferably used embodiment the lengthening pin 42 and the section 42 a are axially shiftable in the direction of the arrow 51 relative to the cover 36 so that after fixing the cover 36 on the casing 4 an axial shifting of the lengthening pin 42 and the section 42 a can be reached by a manuel operation done by the user independent of the kind in which the cover 36 is fixed on the casing 4. This axially shifting is done by the user by forcing a section of the lengthening pin 42 protruding over the cover 36 when the cover is fixed.

This end section 42 a can gear into a deepening being correspondingly carved into a plug 10, whereby the glass carpule 8 can be submitted to a power being axially directed downward can be, as soon as the glass carpule 8 is arranged in the section 41 and the cover 36 is screwed onto the corresponding

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opening or fixed by means of a bayonet closing. At its bottom side the glass carpule 8 filled with the liquid pharmaceutical product is closed by a piercable membrane 9 being fixed by a bead in connection with a metal strap 44 in a usual way. A cannula 2 or the closing element 18 can be optionally fixed at a mounting section 21 (for example a shown in figure 7) by a corresponding weight, as these options are shown in figure 3. Hereby the cannula 2 is surrounded by a cannula protector 45 which makes it possible for the user not to hurt himself when he operates the cannula 2. The cannula protector 45 can be clamped onto the base section 2 a of the cannula 2 and, if necessary, fixed at the base section 2 a by a thread.

The cylindrical closing element 18 (figure 4) comprises a sealing element 18 a which can contact a conduct outlet 19 (figure 5 and 6) and which can close the conduct outlet in an air-tight and liquid-tight way, as soon as the closing element 18 is fixed at the mounting section 21 by a corresponding thread 18 b. Moreover, the closing element 18 comprises a slot section 18 c to take up the walling of the inner cylinder 22 b of the protecting element 22.

The schematical explosion view of figure 5 shows the essential interior parts of the device 3. These are a first, inner cylinder 23, a second, outer cylinder 24, whereby the second cylinder 24 end with its bottom side in the mounting section 21 to which a cannula 2 or the closing element 18 can be optionally fixed. In this section the protecting element 22 is detachably mounted at the casing 4 which is only partially shown in figure

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5. The first cylinder 23 is provided with a first spring 25 and the second cylinder 24 is provided with a second spring 26, whereby the first spring 25 extends between an upper section 23 a of the first cylinder 23 and a ring element 46 being fixed at the second cylinder 24, whereas the second spring 26 is supported by an lower bearing 24 a being located at the second cylinder 24 and an upper bearing 23 b being located at the casing 4. The shifting element 38 is formed as on piece with the first cylinder 23.

Furthermore, the first cylinder 23 comprises a bottom plate 23 c being provided with a projection 23 d at its bottom side. The shaft 47 of a piston 16 can be connected with this projection 23 d, so that the piston 16 is fixed at the first cylinder 23 and moved together with the first cylinder 23. A connecting conduct 14 extends within the shaft 47 and within the piston 16, whereby this connecting conduct 14 is guided also by the bottom plate 23 c and the projection 23 d and ends in a hollow needle 48.

If then the glass carpule 8 filled with the liquid pharmaceutical product is set into the inner space of the first cylinder 23, the inner space forming the section 41 taking up the vessel, and if hereby the glass carpule 8 is submitted to a pressure in the direction of the mounting section 21 by means of the plug and the lengthening pin 42, respectively the end section 42 a, the hollow needle 5 pierces the piercable membrane 9 of the glass carpule 8, so that the connecting conduct 14 is connected to the content of the glass carpule 8. Hereby the connecting conduct 14 is provided with a reflux valve 15 in the

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section connecting the shaft 47 with the projection 23 d, whereby this reflux valve 15 is shown enlarged in figure 8.

This reflux valve 15 comprises, according to figure 8, a disk-like, round sealing membrane 49 being held by a ring bearing 50. A section which is superfused by the liquid and which enlarges the conduct inlet 14 a of the connecting conduct 14 is arranged underneath the sealing membrane 49. If the liquid flows in the direction of the arrow 51, as this is required in the conduct 14 for the filling of the intermediate reservoir, the sealing membrane 49 is lifted from the ring bearing 50 and does thus not block the flow of the liquid. Hereby this movement of the sealing membrane 49 is limited by four radially arranged linking elements 52, so that it is avoided that the sealing membrane 49 closes the enlarged conduct inlet 14 a. If the liquid flows in the opposite direction of the arrow 51, the sealing membrane 49 is brought into a position in which it seals the ring bearing 50, so that hereby a flow in the opposite direction of the arrow 51 is avoided without risking an adhesion of the sealing membrane 49.

I the figures 6 and 7 the same embodiments are shown, however, in different operating situations. Hereby figure 6 shows the device in a situation in which the intermediate reservoir 13 is empty, whereby in this situation the single dose of the liquid pharmaceutical product has thus been parenterally applied, and in which the respective user finds the device in order to then prepare it for the next single dose. In figure 7 the intermediate reservoir 13 is filled with a single dose of the

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liquid pharmaceutical product being supplied from the glass carpule 8 over the conduct 14. In the operating situation shown in figure 7 a cannula 2 is furthermore fixed at the mounting section 19, so that figure 7 as a whole shows the device in an operating situation occurring immediately before the parenteral application of the single dose of the liquid pharmaceutical product by the user.

The parts shown in figure 5 and described above are provided as well in the figures 6 and 7 and designated with the same reference numbers.

In the first cylinder 23 the glass carpule 8 is arranged in the adequate section 41, whereas the second cylinder 24 forms the intermediate reservoir 13 in its bottom section 24 c (also figure 5).

Starting from the operating situation shown in figure 6 in which the closing element 18 is fixed at the mounting section 21 and in which the closing element 18 a closes the conduct outlet 19 a of the conduct 19 which connects the intermediate reservoir with the conduct outlet, the first cylinder 23 and the second cylinder 24 were commonly transmitted from a first position not shown, in which the spring 25 is released and in which the second cylinder 24 contacts a casing section 53 by means of the recessing section 24 b (figure 5), into a second position as this is shown in figure 6, whereby this transmitting was realised by axially shifting both cylinders in the opposite direction of the arrow 51 and relatively to the casing 4. In

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this second position the spring 25 being released in the first position of both cylinders is thus tensioned, whereby a fixing of this second position is realised by a second locking 27 gearing in at the recessing section 24 b.

This common axial shifting of both cylinders 23 and 24 is caused by manually operating the shifting element 38 arranged at the outside of the casing, whereby this axial shifting of the shifting element 38 is guided through a slot 39 (figure 3) located in the casing 4.

In order to fill the intermediate reservoir 13 in this second position with a single dose of the liquid pharmaceutical product supplied by the glass carpule 8 arranged within the first cylinder 23, the first cylinder 23 is shifted into the third position in the opposite direction of the arrow 51 and relatively to the casing 4 and to the second cylinder 24 remaining in the second position, whereby this shifting is realised by means of the shifting element 38 against the power of the second spring 26, and whereby this third position is axially shifted in the opposite direction of the arrow 51, which is shown in figure 7.

In this third position of the first cylinder, the first cylinder 23 is fixed by a first locking 28 (figure 7).

Conditioned by the fact that the closing element 18 avoids a ventilation of the intermediate reservoir 13 by means of the conduct 19 as a result of the fluid-tight contacting of the

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sealing element 18 a with the conduct outlet 19 a, a vacuum is generated in the intermediate reservoir 13 when the first cylinder 23 is axially shifted from the second position into the third position. This depends on the fact that concurrently with the shifting of the first cylinder 23 the piston 16 which is fixed to the first cylinder 23 by piston shaft 47 is axially shifted in the opposite direction of the arrow 51. This vacuum generated in the intermediate reservoir 13 then causes a complete filling of the intermediate reservoir with exactly one single dose of the liquid pharmaceutical product being supplied from the glass carpule 8 by means of the connecting conduct 14 and the opened reflux valve 15 which is arranged in the projection 23 d of the first cylinder 23 and which is shown in figure 8.

This axial shifting of the first cylinder from the second position into the third position relatively to the casing and to the second cylinder is made possible by providing the walling of the second cylinder with a slot-like guidance 39 a through which a section of the shifting element 38 extends, whereby the shifting element 38 is formed in one piece with the first cylinder 23.

The closing element 18 is then replaced by a cannula 2, whereby the cannula 2 is gripped by user at the cannula protector 45 and the cannula 2 is screwed onto the mounting section 21. Hereafter the user removes the cannula protector 45, whereby the device is prepared to apply the single dose of the liquid pharmaceutical product.

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With this object the respective user chooses a body zone and brings the bottom zone of the inner cylinder 22 b of the protecting element 22 in contact with this body zone. By operating the release button 37 the second locking 27 is shifted in the direction of the arrow 54 against the spring power 27 a, so that the first cylinder 23 and the second cylinder 24 are commonly and axially shifted relatively to the casing 4 in the direction of the arrow 51 by means of the spring 26. This leads to the fact that the point of the cannula 2 penetrates the chosen body zone of the user. During the common axial shifting of both cylinders 23 and 24, a projection 27 b being located at the second locking 27 gets in contact with a projection 28 a being located at the first locking 28, whereby this causes a shifting of the first locking 28 also in the direction of the arrow 54 against the spring power of the spring 28 b located at the first locking 28. Hereby the first cylinder 23 is released from its third position, so that it is also axially shifted in the direction of the arrow 51 by means of the spring 25. This again leads to the fact that the piston 16 being connected with the first cylinder 23 by the shaft 47 is axially shifted in the direction of the arrow 51 and that thus the single dose of the liquid pharmaceutical product located in the intermediate reservoir 13 is injected into the body zone by the cannula 2. The axial shifting of the first cylinder 23 is terminated by the recessing section 24 b of the second cylinder 24 and by the axial movement of the second cylinder 24 through the casing section 53.

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After the parenteral application the user pulls the cannula 2 out of the body zone by means of the device, attaches the cannula protector 45 on the cannula 2, unscrews the cannula 2 from the mounting section 21 and screw the closing element 18 onto the mounting section 21. Independently of the power performed hereby by the user, the first cylinder and the second cylinder remain either in the first position or both cylinders are transmitted into a position as it is shown in figure 6.

The second embodiment of the device, the embodiment being shown in figure 9, presents the device in such an operating situation in which the intermediate reservoir 13 is filled with the single dose of the liquid pharmaceutical product. The embodiment shown in figure 9 is thus ready to operate meaning that is ready to inject. Contrarily to the embodiment described above in figures 6 and 7, the embodiment shown in figure 9 is characterized in that both cylinders 23 and 24 can be axially shifted in the direction of the arrow 51 and vice-versa only between a first position (not shown) in which the first cylinder 23 contacts the recessing section 24 b and the recessing section 24 b contacts the casing section 53 and in which the intermediate reservoir 13 is emptied, and a second position as this is shown in figure 9 and in which the intermediate reservoir 13 is filled with the single dose. Moreover, the embodiment shown in figure 9 provides only a single locking 29 which fixes the first cylinder 23 and the second cylinder 24 in the second position and which can be released by means of the release button 37.

In order to make it possible in the embodiment shown in figure 9

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to cause the time retardation between the penetration procedure of the cannula into the body zone of the user and hereafter the emptying of the intermediate reservoir 13 and thus the actual parenteral application of the single dose of the liquid pharmaceutical product, the characteristic spring lines of the springs 25 and 26 are adjusted to each other in such a way that the characteristic spring line of the spring 26 is steeper than the characteristic spring line of the spring 25. By operating the release button 37 the locking 29 is shifted in the direction of the arrow 54 against the spring power of the spring 29 a, so that the locking 29 is released and that thus the first cylinder 23 and the second cylinder 24 can be commonly and axially shifted in the direction of the arrow 51 relatively to the casing. Caused by the steeper characteristic spring line of the spring 26, the second cylinder 24 projects, during the axial shifting, relatively to the first cylinder 23 the spring 25 of which has a more levelled characteristic spring line, over the first cylinder 23, so that the cannula 2 firstly penetrates the body zone and that then the first cylinder 23 and thus also the piston 16 connected with the first cylinder 23 by the shaft 47 transmits the single dose of the liquid pharmaceutical product from the intermediate reservoir 13 into the body zone of the user.

In order to guarantee in the afore described embodiment of the inventive device a complete emptying of the intermediate reservoir, the intermediate reservoir 13 comprises a cylindrical section 13 b and a subsequent conical section 13 a (figure 9), whereby the outlet of the conical section 13 a opens into the

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conduct 19, as this can be seen perfectly in figure 9. The piston 16 being axially shiftable within the intermediate reservoir 13 correspondingly comprises a cylindrical piston section and conical piston section 16 a directed to the conduct 19, whereby this conical piston section is formed by a corresponding conically-shaped jacket tube surrounding the outlet of the connecting conduct 14. This jacket tube is closed at its bottom side and it comprises outlets on its conical surface, so that by these outlets the liquid supplied by the conduct 14 is transported into the intermediate reservoir. When the piston is axially lowered in the direction of the arrow 51, the conical piston section 16 a displaces the liquid located in the intermediate reservoir 13 in that way that the conical piston section 16 a enters the conical cylinder section 13 a and thus fills it completely.

It is even possible to provide an intermediate reservoir 13 which dos not comprises the afore described and especially in figure 9 shown conical section 13 a or which comprises a conical section 13 a having restricted length. In other words in this embodiment the cylindrical section 13 b of the intermediate reservoir empties directly into the conduct 19, or the cylindrical section 13 b is connected with the conduct via a correspondingly restricted conical section 13 a. Appropriate to that the plug 16 located inside of the intermediate reservoir 13 is adapted to such a formed intermediate reservoir 13 whereby preferably a sealing provided to the piston skirt and more preferably an O-formed flexible piston ring makes a safe use sure.

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In all afore described embodiments the plug 10 arranged within the glass carpule 8 is also axially shifted in the direction of the arrow 51 as a result of the descending liquid level in the glass carpule 8. Hereby it is avoided that a vacuum is generated in the glass carpule or that a gas puffer is formed above the liquid level. In order to furthermore guarantee a complete emptying of the glass carpule 8, the front surface 10 a (figure 9) of the plug 10 tapers, so that it contacts the shaft section of the glass carpule 8 a (figure 9) when the liquid is completely descended.

In this state, the completely emptied glass carpule 8 can be removed from the device together with the detaching element 101 shown in figure 10. For this purpose, the detaching element comprises a grip section 102 for handling the detaching element 101 as well as a fixing section which can gear non-positively into a deepening 10 b (figure 9) being provided in the plug 10 when the plug 10 is removed.

Moreover the refill unit shown in figure 10 comprises a multitude of cannulas 2 being provided with a corresponding cannula protector 45 (figure 3) for the sterile storing, a glass carpule designated with 8 serving as vessel being filled with the liquid pharmaceutical product. Moreover, the refill unit 100 comprises a number of sponges 5 moistened with an disinfectant, whereby the number of sponges 5 corresponds to the number of the cannulas 2. The refill unit 100 furthermore contains a section 6 taking up used cannulas, whereby, according to the embodiment

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shown in figure 10, this section can be closed by a cover which is not shown. This section 6 is collectively arranged at the refill unit 100 in a detachable way, so that, after taking up the used cannulas, this section 6 can be separately wasted, as far as this is legally prescribed or desired. The sell unit 1 usually comprises 10 cannulas 2, so that correspondingly the glass carpule 8 contains the liquid amount for 10 cannulas. Usually the liquid amount emitted each in single doses varies between 0,1 ml and 1 ml, so that correspondingly the glass carpule contains between 1 ml and 10 ml of the liquid pharmaceutical product. In order to avoid an evaporation of the disinfectant of the sponges 5, each sponge 5 is separately wrapped by a corresponding plastic foil in an air-tight way. The refill unit 100 taking up the afore described parts is collectively closed by a cover (not shown) or is arranged in the usual plastic wrapping, if necessary even in a sterile way. The afore described detaching element 101 is arranged in the refill unit 100.

The used term piercable membrane several times repeated means a flexible sealing disc being fixed at the carpule 8 by a flared flange, preferably by a metallic flared flange, as it is clearly shown in the drawings.

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Patent claims

1. A sell unit for the parenteral application of liquid pharmaceutical products by the user, characterized in that the unit (1) comprises at least one cannula (2), a device (3) to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel (8) filled with the pharmaceutical product, the vessel (8) being arranged within the device (3) and emptied in single doses by means of the device (3), whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

2. The sell unit according to claim 1, characterized in that the unit (1) contains a number of cannulas (2) corresponding to the number of single doses.

3. The sell unit according to claim 1 or 2, characterized in that the unit (1) comprises a number of sponges (5) being moistened with a disinfectant, whereby the number of sponges (5) corresponds to the number of cannulas (2).

4. The sell unit according to one of the preceding claims, characterized in that the unit (1) comprises a section (6) for taking up the used cannulas (2).

5. The sell unit according to one of the preceding claims, characterized in that the vessel (8) filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule (8).

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6. The sell unit according to claim 5, characterized in that the glass carpule (8) is closed, at its bottom side, by a piercable membrane (9) and, at its top side, by a plug (10) being formed in that way that it can be axially shifted within the glass carpule (8) in the direction of the piercable membrane (9) when the liquid level is descending.

7. The sell unit according to claim 5 or 6, characterized in that the plug (10) has, on its jacket surface, at least one, preferably two to five, disk-like sections radially directing to the outside, whereby these sections are deformed when the plug (10) is inserted into the glass carpule (8) with the formation of a sealing surface which liquid- or air-tightens the inner surface of the carpule (8).

8. The sell unit according to one of the claims 6 to 8, characterized in that the plug (10) is axially shifted within the glass carpule (8) by a power of less than 10 N, preferably by a power of between 4 N and 8 N.

9. The sell unit according to one of the preceding claims, characterized in that the vessel (8) is filled with an aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

10. The sell unit according to one of the preceding claims, characterized in that the vessel (8) is filled with a solution

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of a growth hormone, preferably an aqueous solution of a growth hormone.

11. A device for emitting a given liquid amount of a pharmaceutical product, characterized in that the device (3) for emitting a given liquid amount in single doses comprises a section (41) for taking up the vessel (8) being located within a casing (4) and being filled with the liquid pharmaceutical product, as well as an outlet section for the single dose of the pharmaceutical product, and in that the vessel (8) can be connected with the outlet section by an intermediate reservoir (13) in that way that, when the vessel (8) is set in, the given liquid amount of each single dose can firstly be drained from the vessel (8) into the intermediate reservoir (13) and then from the intermediate reservoir (13) into the outlet section, whereby the amount of the drained liquid can be determined for each single dose by the volume of the intermediate reservoir (13).

12. The device according to claim 11, characterized in that a connecting conduct (14) is arranged between the inserted vessel (8) and the intermediate reservoir (13).

13. The device according to claim 12, characterized in that the connecting conduct (14) comprises a valve (15) which avoids a liquid backflow from the intermediate reservoir (13) into the vessel (8).

14. The device according to one of the claims 11 to 13,

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characterized in that the intermediate reservoir (13) comprises a piston (16) for the transporting of each single dose of the liquid pharmaceutical product in the direction of the outlet section, whereby the piston (16) is located within the intermediate reservoir (13) and axially shiftable in the direction of the outlet section.

15. The device according to one of the claims 11 to 14, characterized in that the intermediate reservoir (13) is to fill with a single dose of the pharmaceutical product by an axial shifting of the piston (16) in the direction of the vessel (8).

16. The device according to claim 15, characterized in that, by axially shifting the piston (16), a vacuum is produced in the intermediate reservoir (13) for the transport of a single dose of the liquid pharmaceutical product from the vessel (8) into the intermediate reservoir (13).

17. The device according to claim 16, characterized in that the intermediate reservoir (13) is connected with the outlet section by a conduct (19) and that this conduct (19) can be air-tightened by a closing element (18).

18. The device according to claim 16 or 17, characterized in that the closing element (18) is formed as a detachable closing element located at the conduct (19) in that way that a sealing section (18 a) of the closing element (18) air-tightens the conduct outlet (19 a).

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19. The device according to one of the claims 14 to 17, characterized in that, by axially shifting the piston (16) within the intermediate reservoir (13) in the direction of the outlet section, the intermediate reservoir (13) is completely emptied.

20. The device according to one of the claims 11 to 19, characterized in that the intermediate reservoir (13) is formed in a cylindrical way and comprises a conically-shaped end section (13 a) following hereafter and directing to the outlet section, whereby the end section (13 a) is connected with the outlet section by the conduct (19), and that the piston (16) has a corresponding shape.

21. The device according to one of the claims 11 to 20, characterized in that the outlet section comprises a mounting section (21) for the detachable fixing of a cannula (2) in that way that the conduct (19) is connected with the cannula (2) in a fluid-tight way.

22. The device according to claim 17, 18 or 21, characterized in that a closing element (18) is fixed at the mounting section (21) in such a way that the conduct section (19 a) directing to the outside can be fluid-tightened by the closing element (18).

23. The device according to one of the claims 11 to 22, characterized in that the mounting section (21) comprises a protecting element (22) which covers at least a part of a cannula (2) being fixed at the mounting section (21).

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24. The device according to one of the claims 11 to 23, characterized in that a first cylinder (23) and a second cylinder (24) surrounding the first cylinder (23) are arranged within the casing (4), that the first cylinder (23) and the second cylinder (24) are shiftable axially relative to the casing (4), that the section (41) to take up the vessel (8) is situated within the first cylinder (23) and the intermediate reservoir (13) connected with the vessel (8) is located within the second cylinder (24), in such a way, that the first and the second cylinder (23; 24) are axially shiftable from a first position in which the cannula (2) being fixable to the mounting section (21) protrudes over the protecting element (22) and in which the intermediate reservoir (13) is emptied over the conduct (19) and the subsequent cannula (8), and a second position in which a cannula (2) being fixable to the mounting section (21) is covered by the protecting element (22) and in which the intermediate reservoir (13) is filled with the single dose, and vice-versa.

25. The device according to claim 24, characterized in that, by axially moving the first and the second cylinder (23; 24) relatively to the casing (4) from the first position into the second position, the intermediate reservoir (13) is filled with a single dose of the liquid pharmaceutical product.

26. The device according to claim 25, characterized in that the first and the second cylinder (23; 24) comprise each a spring (25; 26) in such a way that, in the second position of the

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cylinders (23; 24), the springs (25; 26) are tensioned and that, in the first position of the cylinders (23; 24), the springs (25; 26) are released.

27. The device according to one of the claims 24 to 26, characterized in that both cylinders (23; 24) are fixed in the second position by a locking element (29).

28. The device according to one of the claims 26 or 27, characterized in that the spring (26) of the second cylinder (24) has a steeper characteristic spring line than the spring (25) of the first cylinder (23).

29. The device according to one of the claims 11 to 23, characterized in that a first cylinder (23) and second cylinder (24) surrounding the first cylinder (23) are arranged within the casing (4), that the first cylinder (23) and the second cylinder (24) are shiftable axially relative to the casing (4), that the section (41) to take up the vessel (8) is situated within the first cylinder (23) and the intermediate reservoir (13) connected with the vessel (8) is located within the second cylinder (24), in such a way, that the first and the second cylinder (23; 24) are axially shiftable from a first position in which the cannula (2) being fixable to the mounting section (21) protrudes over the protecting element (22) and in which the intermediate reservoir (13) is emptied, into a second position in which the cannula (2) being fixable to the mounting section (21) is covered by the protecting element (22), and vice-versa, that for filling the intermediate reservoir (13), the first

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cylinder (23) is axially shiftable into a third position in the direction of the vessel (8) relatively to the second position of the second cylinder (24).

30. The device according to claim 29, characterized in that each cylinder (23; 24) contains a spring (25; 26), whereby a first spring (25) pre-tensions the position of the first cylinder (23) in the third position and a second spring (26) pre-tensions the position of the second cylinder (24) in the second position, and that the first cylinder (23) is fixable in the third position by a first locking (28) and the second cylinder (24) is fixable in the second position by a second locking (27).

31. The device according to claim 29 or 30, characterized in that, by operating a common release button (37), firstly the second locking (27) is released and then the first locking (28) is released in a corresponding time retardation.

32. The device according to one of the claims 11 to 31 for the use in a sell unit (1) according to one of the claims 1 to 10.

33. A refill unit for the use in the sell unit or the device according to one of the preceding claims, characterized in that the refill unit (100) comprises at least one cannula (2) as well as at least vessel (8) filled with the liquid pharmaceutical product, whereby the vessel (8) is insertable in the device (3) and emptied in single doses by means of the device (3).

34. The refill unit according to claim 33, characterized in that

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a detaching element (101) for the removal of an emptied vessel (8) out of the device (3) for emitting a given liquid amount in single doses is arranged within the refill unit (100).

35. The refill unit according to claim 33 or 34, characterized in that the refill unit (100) comprises the number of single doses corresponding to a number of cannulas (2) and/or sponges (5) moistened with disinfectant.

36. The refill unit according to one of the claims 33 to 35, characterized in that the refill unit (100) comprises a section (6) that takes up the used cannulas (2).

37. The refill unit according to one of the claims 33 to 36, characterized in that the vessel (8) filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule (8).

38. The refill unit according to claim 37, characterized in that the glass carpule (8) is closed, at its bottom side, by a piercable membrane (9) and, at its top side, by a plug (10) being formed in that way that it is axially shiftable within the glass carpule (8) in the direction of the piercable membrane (9) when the liquid level is descending.

39. The refill unit according to claim 37 or 38, characterized in that the plug (10) has, on its jacket surface, at least one, preferably two to five, disk-like, lip-tight sections radially directing to the outside, whereby these sections are deformable

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when the plug (10) is inserted into the glass carpule (8) with the formation of a sealing surface liquid-tightening the inner surface of the carpule (8).

40. The refill unit according to one of the claims 37 to 39, characterized in that the plug (10) is axially shiftable within the glass carpule (8) by a power being lower than 10 N, preferably by a power of between 4 N and 8 N.

41. The refill unit according to one of the claims 33 to 40, characterized in that the vessel (8) is filled with am aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

42. The refill unit according to one of the claims 33 to 40, characterized in that the vessel (8) is filled with a solution of a growth hormone, preferably an aqueous solution of a growth hormone.

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A SELL UNIT FOR THE PARENTERAL APPLICATION, A DEVICE FOR CARRYING OUT THE PARENTERAL APPLICATION AS WELL AS A REFILL UNIT FOR THE ABOVE MENTIONED SELL UNIT

Abstract

A sell unit for the parenteral application of liquid pharmaceutical products by the user is describes, whereby the unit (1) comprises at least one cannula (2), a device (3) to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel (8) filled with the pharmaceutical product, the vessel (8) being arranged within the device (3) and emptied in single doses by means of the device (3), and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

FIG. 1

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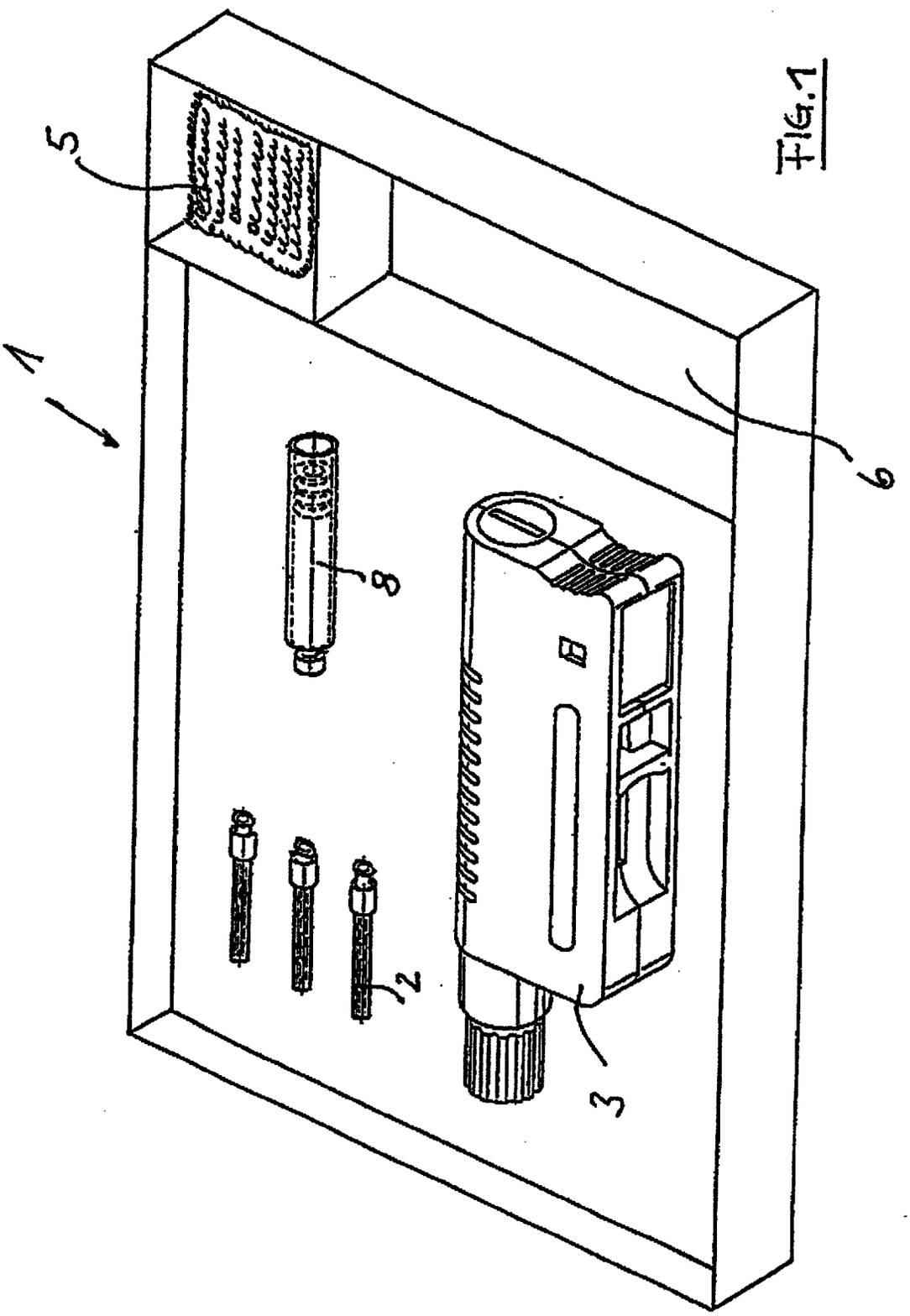


Fig.1

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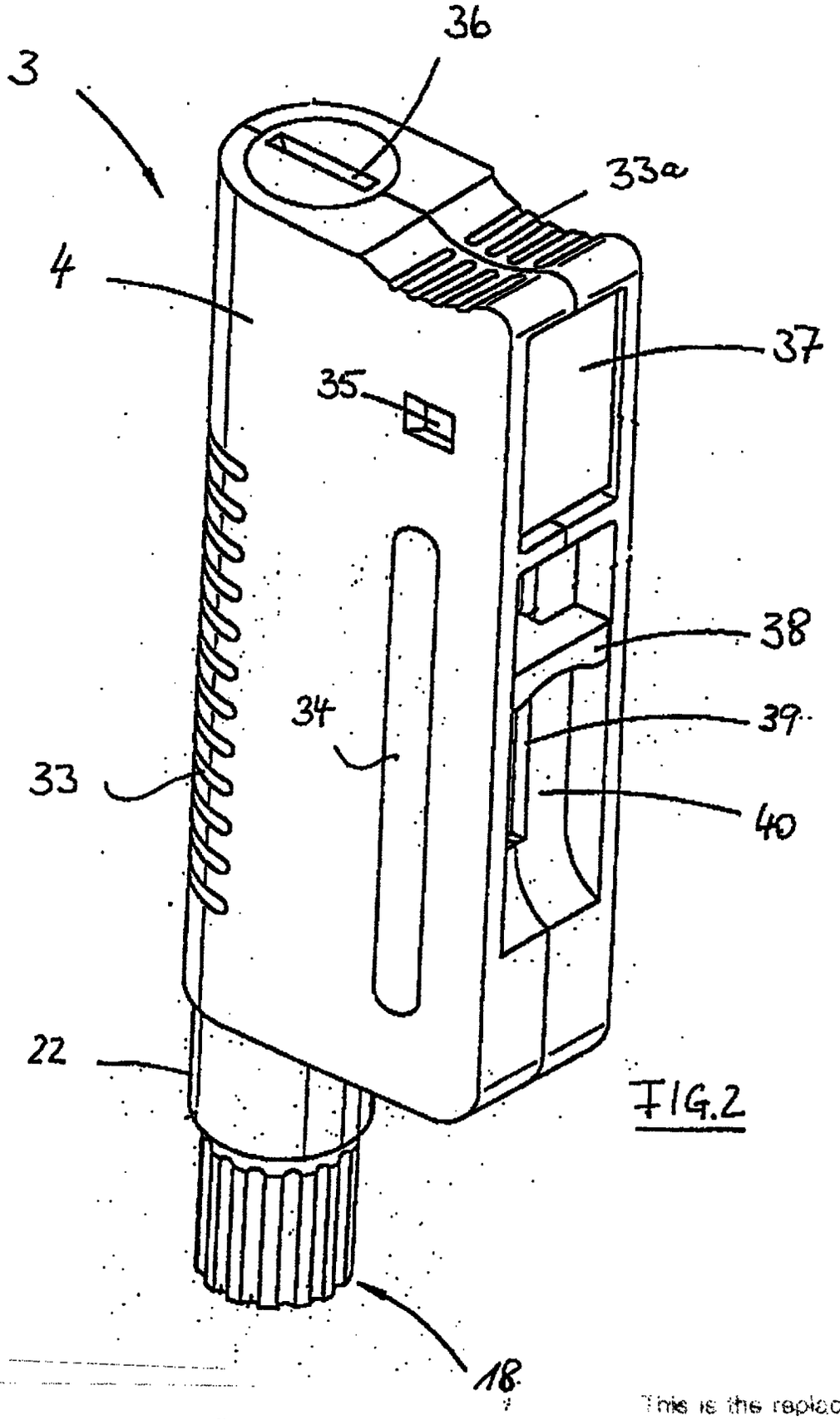


FIG.2

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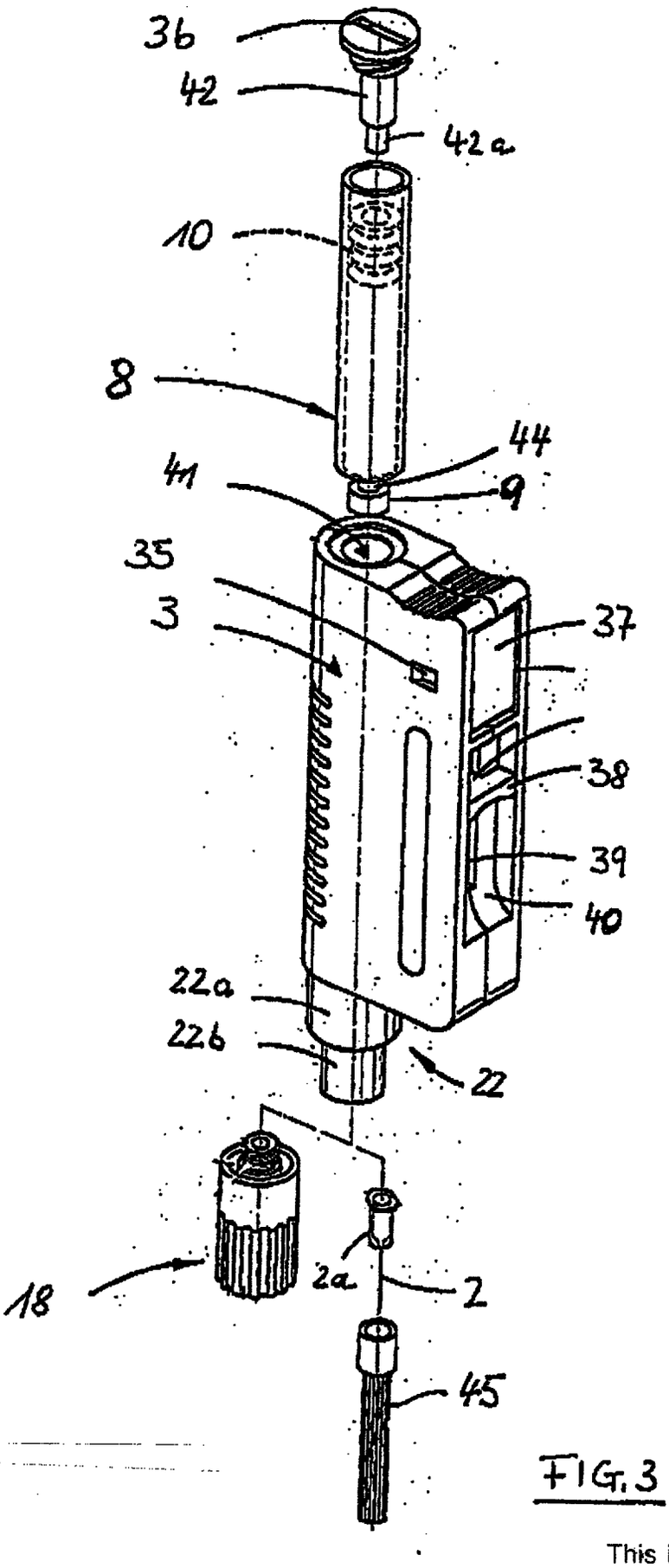


FIG. 3

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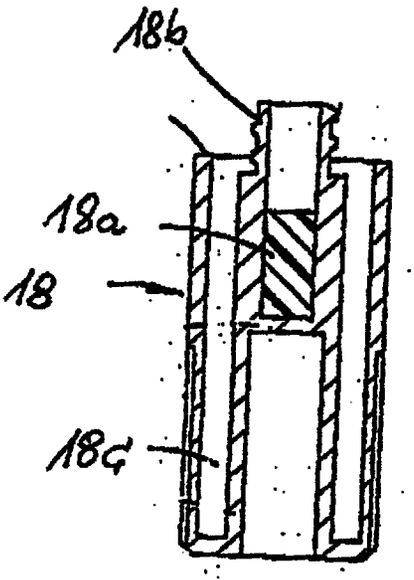


FIG.4

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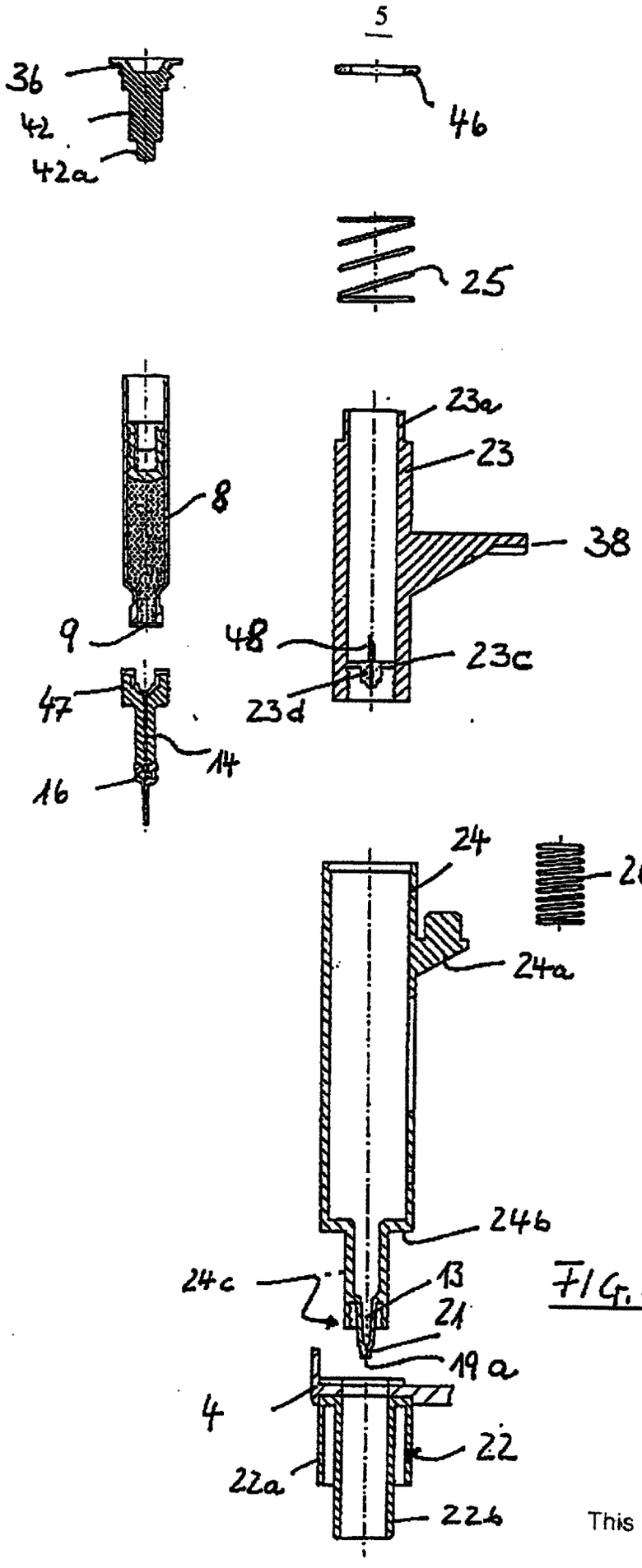


FIG. 5

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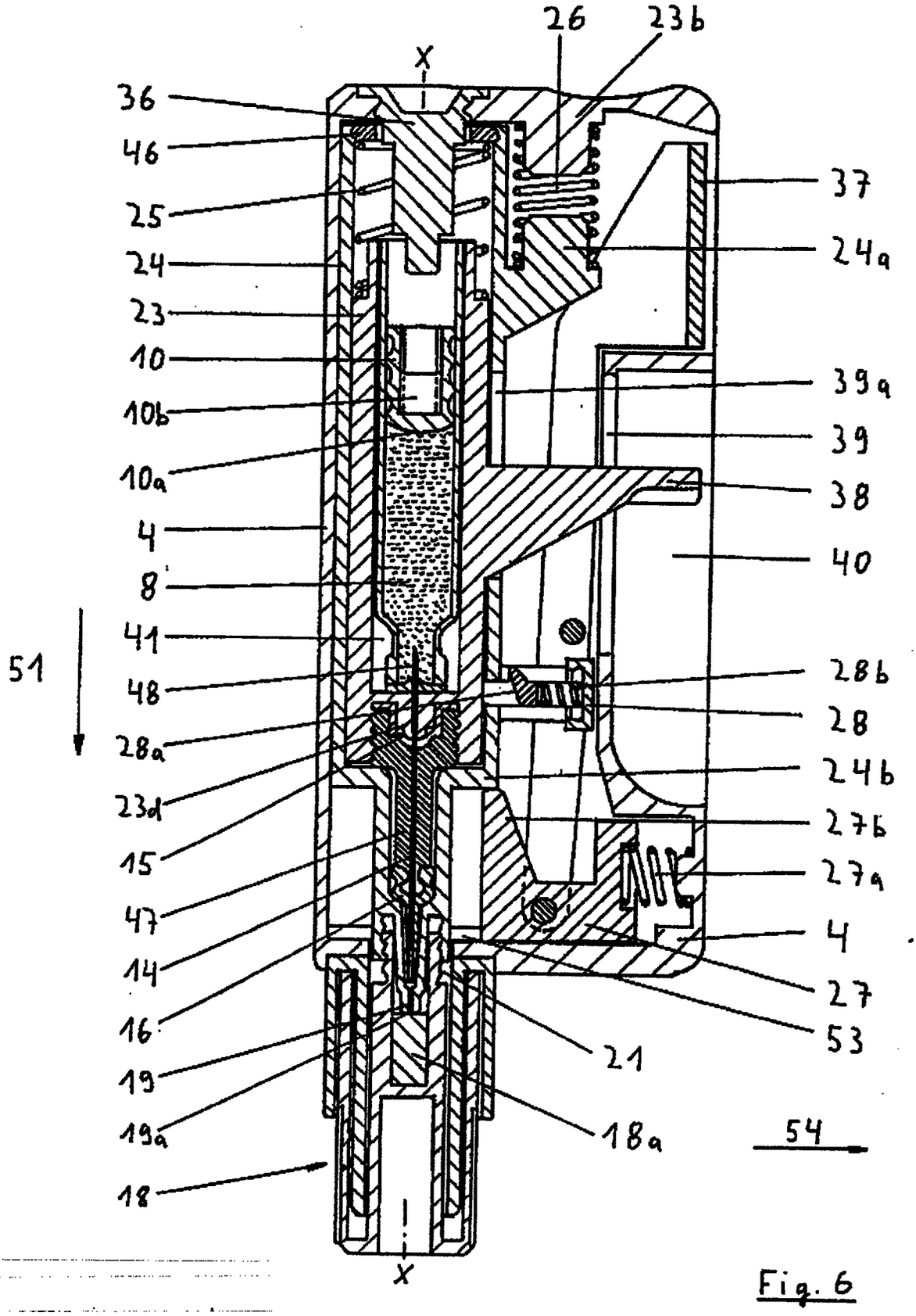


Fig. 6

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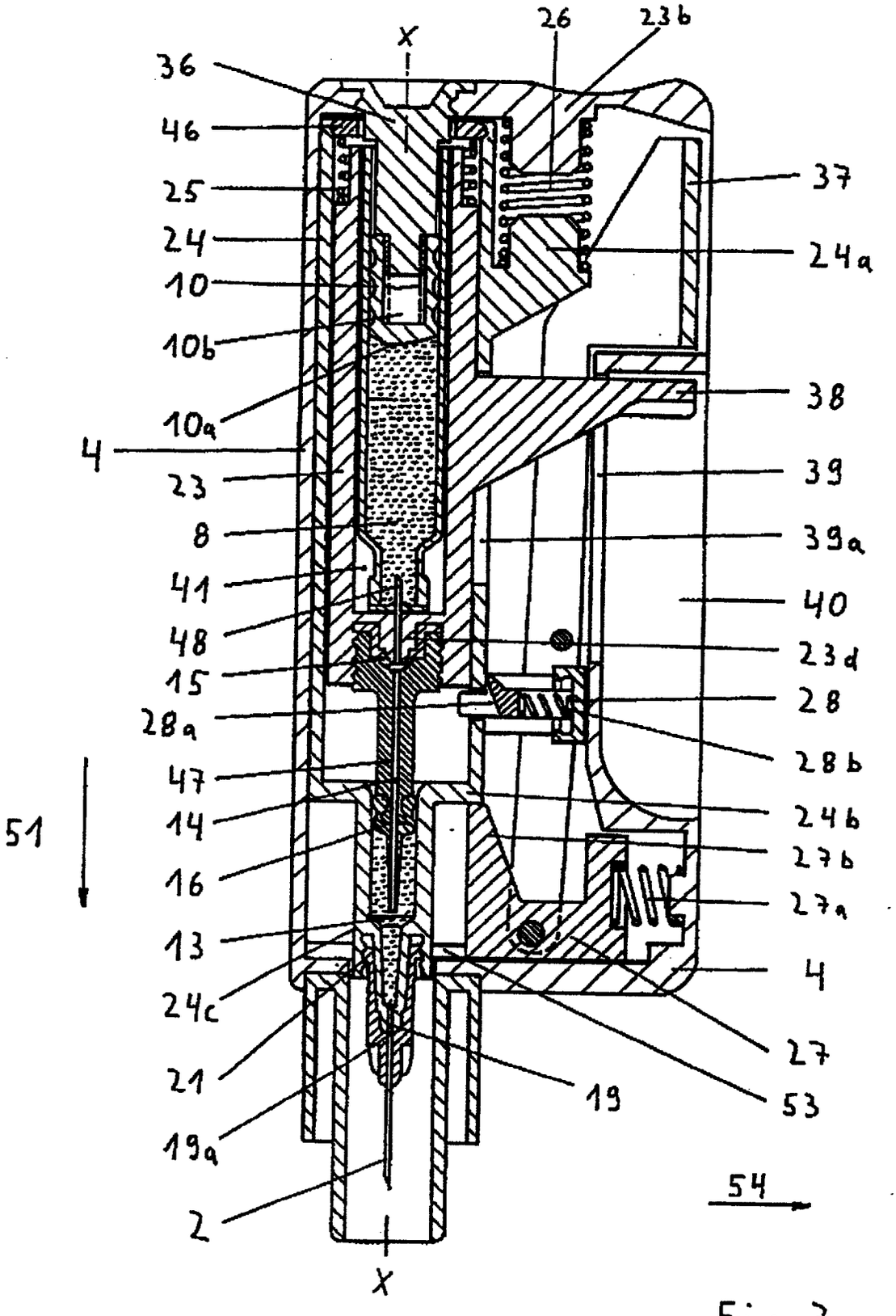


Fig. 7

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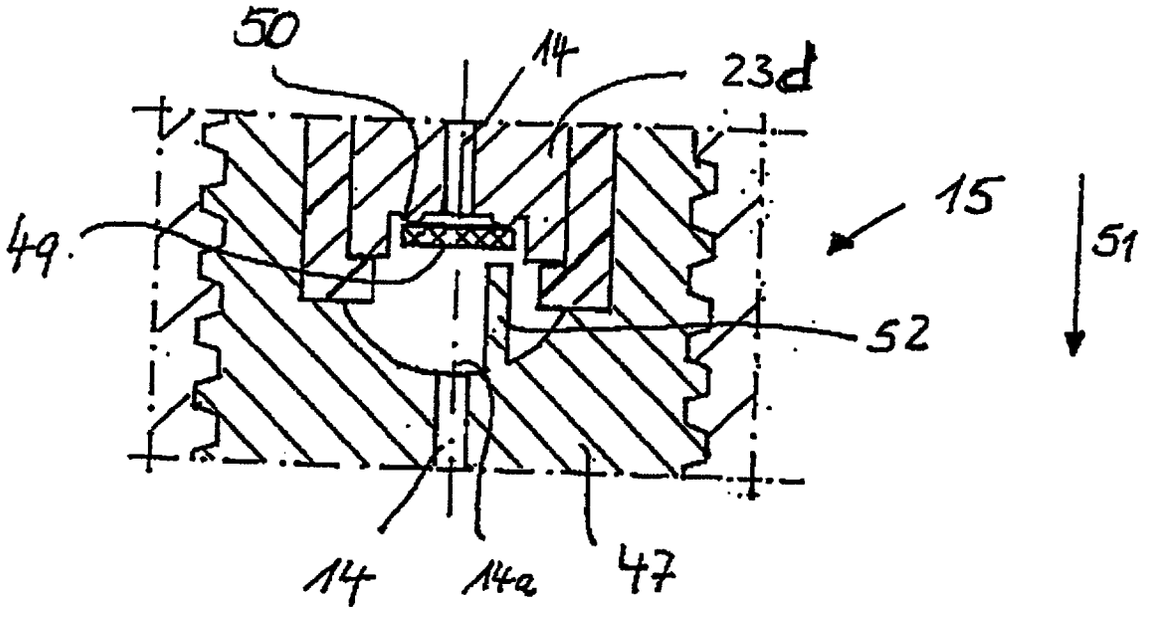


FIG.8

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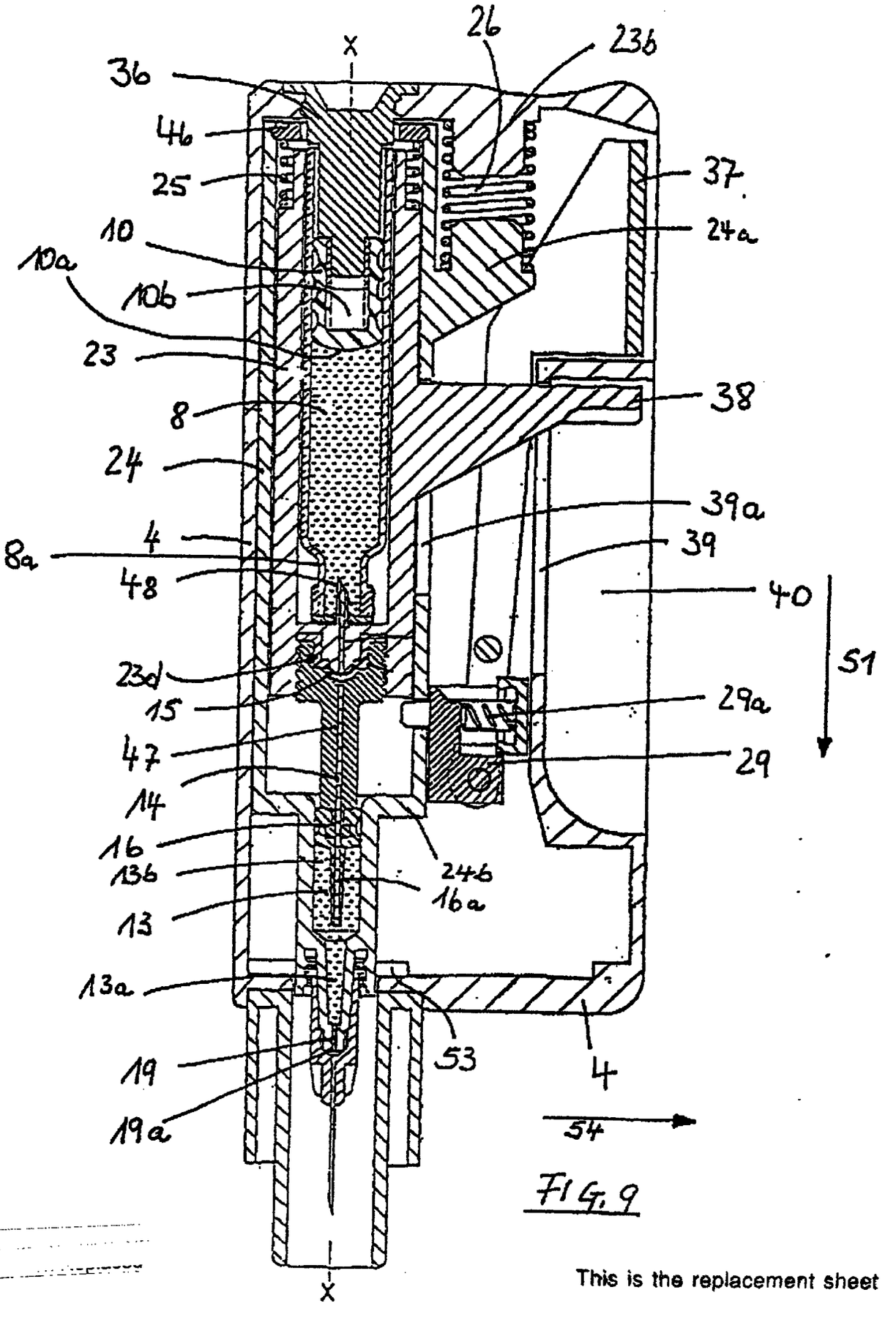


FIG. 9

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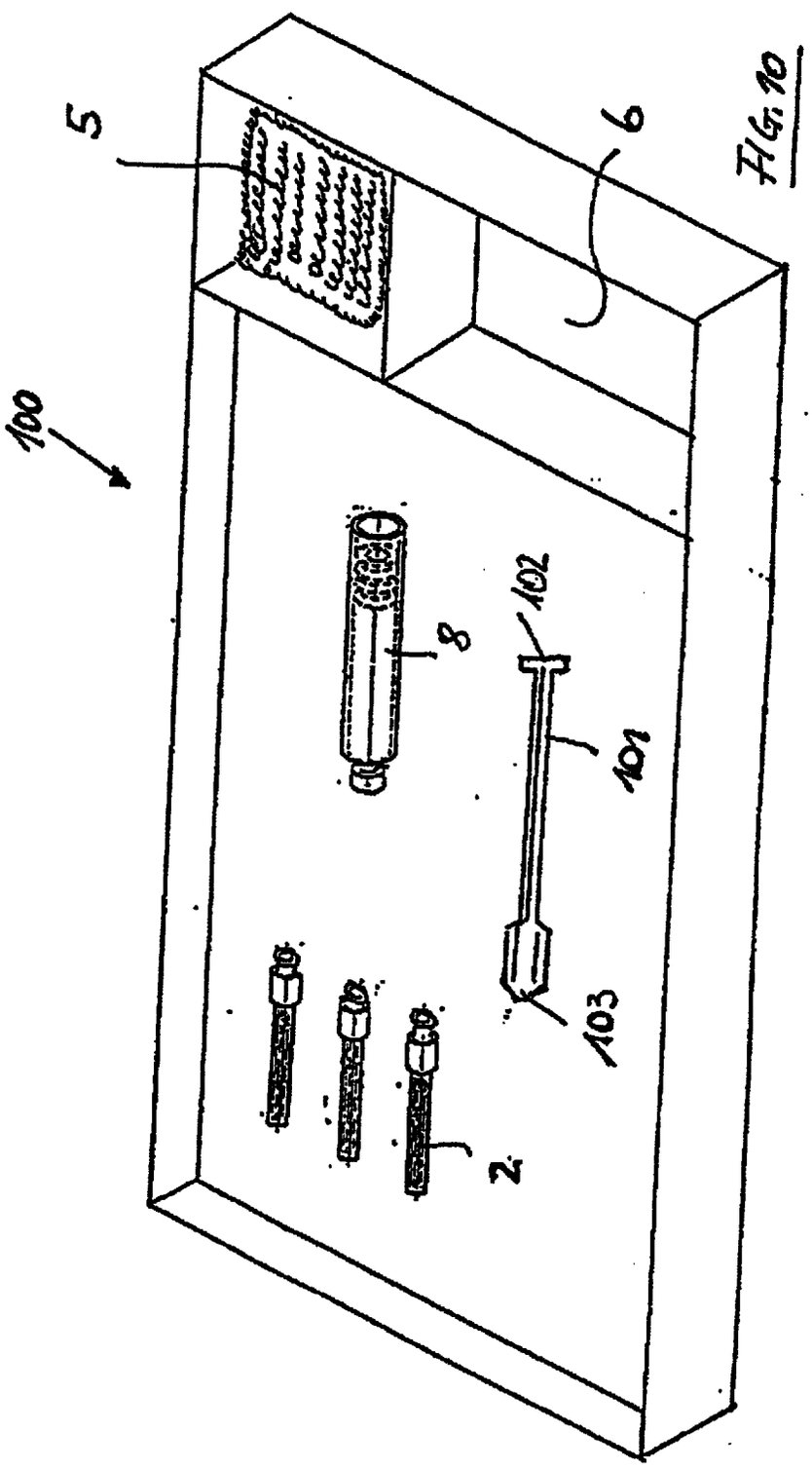


Fig. 10

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A sale unit for the parenteral application, a device for carrying out the parenteral application as well as a refill unit for the above mentioned sell unit

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The present invention is directed to a sale unit for the parenteral application of liquid pharmaceutical products, to a device for carrying out this parenteral application and to a refill unit for the afore mentioned sale unit, respectively device.

Parenterally applicable liquid pharmaceutical products, meaning such products that are subcutaneously applied by means of a syringe, nowadays are applied mainly by correspondingly trained professional staff, as for example by doctors or nursing staff. Hereby a usual syringe is used which is filled with the corresponding liquid pharmaceutical product before the parenteral application or which is filled already as a one-way syringe with the liquid pharmaceutical product. However, this means that the respective user has to submit himself to a medical treatment which involves high expenses particularly when, for the therapy of the respective disease, a given amount of a liquid pharmaceutical product has to be injected subcutaneously each day for a given limited time period.

The present invention has the object of elaborating a possibility by which the respective user can parenterally and preferably subcutaneously apply a liquid pharmaceutical product

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☐ Description : paged 1 ..... to paged —
☑ Claim(s) : paged 47 to paged 55
☐ Drawing(s) : paged ..... to paged —
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particularly easily.

According to the invention, this object is realised by a sale unit with the characteristics of patent claim 1, by a device with the characteristics of patent claim 11, as well as, if necessary, by a refill unit with the characteristics of patent claim 33 completing the sale unit according to patent claim 1, respectively the device according to patent claim 11.

The inventive sale unit for the parenteral application of a liquid pharmaceutical product by the user for the required therapy period is based on the main thought that the user can dispose, during the medically prescribed treatment period, of all necessary parts, so that the user is able to parenterally and preferably subcutaneously apply himself the required liquid pharmaceutical product without the help of medical staff. For that reason, the inventive sale unit comprises at least one cannula, one device for emitting a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel filled with the liquid pharmaceutical product, whereby the vessel can be set in the device and emptied by means of the device and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product. In other words, the user only needs to provide the device for emitting a given liquid amount, the device being arranged within the unit, with a cannula also arranged within the unit and, furthermore, to put the vessel filled with the liquid pharmaceutical product in the emitting device, so that immediately hereafter the user can parenterally and preferably subcutaneously apply himself the single dose of the liquid pharmaceutical product prescribed

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by the doctor.

The inventive sale unit has a range of advantages. Conditioned by the fact that the inventive sale unit comprises all parts that the user needs and that are required for the parenteral application in a single sale unit, it is firstly to be noted that, on one hand, these parts can be commonly stored in the sale unit by the user himself during the treatment and that, on the other hand, it is made particularly easy for the prescribing doctor to prescribe this sale unit as a whole. Since the emitting device of the sale unit forcibly determines, as a result of its construction, the given amount of the liquid pharmaceutical product for each single dose, the liquid pharmaceutical product cannot be underdosed or overdosed in the inventive sale unit, so that hereby the parenteral application of the liquid pharmaceutical product by the user is particularly safe. Moreover, the user can dispose of the parts required for the parenteral application in a well and clearly-arranged way, whereby the acceptance of the inventive sale unit is essentially improved for the user. Furthermore, the inventive sale unit avoids a soiling of its parts, particularly during their use for the user, and makes the expedition and the storing easier since it is formed as a unit, which is particularly advantageous for the use in the trade.

A first embodiment of the inventive sale unit is characterized in that the unit comprises a number of cannulas that corresponds to a number of the single doses of the pharmaceutical product. Hereby the user can exchange the used cannula by a corresponding sterile cannula after each

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parenteral application of the liquid pharmaceutical product, whereby the risk of an infection is avoided. The cannulas provided in the sale unit are preferably constructed in that way that the actual needle of the cannula is protected by a solid plastic jacket, whereby this solid plastic jacket, on one hand, guarantees the sterility of the needle and, on the other hand, keeps the user from unintentionally hurting himself with the needle. Such an embodiment of the sale unit particularly comprises ten of the afore described cannulas, whereby then the vessel being provided in the sale unit and being filled with the liquid pharmaceutical product makes it possible to correspondingly apply ten single doses of the product to be parenterally applied.

In order to make it again easier for the user to operate the inventive sale unit during the parenteral application, a further advantageous development is directed to a sale unit that comprises a number of cannulas that corresponds to a number of sponges, whereby these sponges are moistened with a disinfectant, as for example a low alcohol, ethanol, propanol. In order to avoid on the sponges an undesired evaporation of the disinfectant, the sponges moistened with a disinfectant are wrapped singly in corresponding foils, preferably plastic foils and more preferably compound plastic foils, so that, for the parenteral application, the user removes just one sponge from the wrapping and disinfects herewith the spot chosen for the injection.

In another embodiment of the inventive sale unit, the unit

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additionally comprises a section serving to take up the used cannulas and/or used sponges. Hereby this section to take up the used cannulas, respectively the used sponges, is formed in the way that the used cannulas, respectively sponges, cannot fall out of the sale unit while being used, so that the section is formed particularly as a separately closable section. If in the sale unit this section is formed as a section being detachable from the sale unit, as for example as a closable box, the used cannulas and, if necessary, the sponges can be separately wasted, as for example by the special trade, as far as this is required by legal prescriptions.

The inventive sale unit can comprise basically each vessel containing the multitude of single doses of the liquid pharmaceutical product, as far as it is guaranteed that this vessel is formed in that way that it can be set into the device and emptied in single doses by means of the device. However, it is particularly suitable to fill the liquid pharmaceutical product to be parenterally applied by the user in single doses in a cylindrical or cylinder-like glass carpule (glass syringe cylinder), whereby such a glass carpule holds particularly between about 1,5 ml and about 8 ml, preferably between about 2 ml and about 6 ml, of the liquid pharmaceutical product.

A particularly advantageous development of the afore described glass carpule is characterized in that in the inventive sale unit such a glass carpule is arranged which is closed, at its bottom side, by a piercable membrane and, at its top side, by a plug being formed in that way that it can be axially shifted

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within the glass carpule in the direction of the piercable membrane when the liquid level is descending. This special development of the glass carpule has the particular advantage that the bottom section of the plug is located in the immediate proximity of the liquid level or even contacts the liquid level, so that there is no air puffer above the respective liquid level when the liquid level is descending because of the single doses emitted. On one hand, this avoids an undesired oxidative modification of the respective liquid pharmaceutical product and, on the other hand, the special forming of the plug effectively avoids the formation of a vacuum in the glass carpule when the liquid amount is decreasing, whereby such a vacuum would have a negative effect on the exactness of the liquid amount emitted in single doses.

In order to ensure the required tightness between the plug and the inner walling of the glass carpule, according to the afore described embodiment of the glass carpule which disposes of the afore described plug being axially shiftable in the direction of the piercable membrane, a further development of the inventive sale unit is characterized in that the plug comprises on its jacket surface at least one, preferably two to five, disk-like sections directing radially to the outside. Hereby these disk-like sections can be deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid-tightens and air-tightens the inner surface of the carpule. The disk-like sections directing to the outside are preferably dimensioned in that way that an end section of the disk-like sections is elastically deformed by the axial shifting of the plug in the glass carpule opposite

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to the shifting direction with the formation of a correspondingly larger dimensioned sealing surface. In respect to the material that the plug consists of, it is to be noted that herefore preferably an elastic, chemically resistant plastic material or rubber material is chosen, whereby herefore a halogenbutyl-caoutchouc proved to be particularly suitable.

When the afore described plug can be axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N, it is particularly guaranteed that the above described advantages occur in a particularly reproducible way.

By using the inventive sale unit, basically all liquid pharmaceutical products being stable in storage can be parenterally applied by the user himself. Hereby the term liquid pharmaceutical products means all such products which, as actual product, are liquid or from which stable solutions, stable dispersions or stable emulsion can be manufactured in an organic or inorganic, physiologically safe liquid. The afore described vessel or the afore described and particularly used glass carpule preferably comprise an aqueous solution of a heparin, preferably an aqueous solution of a low-molecular heparin, and particularly an aqueous solution of an enoxaparin-sodium. Such a sale unit is then used by such users who, because of their syndrome and from the medical point of view, have to apply the heparin daily in constant single doses for a longer time period, in order to prevent, for example, the risk of a thrombosis after having discharged the patient from the hospital. A further preferred employment of the inventive

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sale unit is the regular parenteral application of a given and constant amount of a growth hormone, whereby, for this case of application, the vessel and particularly the afore described glass carpule is filled with a solution of the growth hormone, preferably an aqueous solution of the growth hormone. Within the scope of the present invention, the term water does not only mean deionized or distilled water, but all aqueous systems, particularly physiological salt solutions or buffer solutions.

The present invention is furthermore directed to a device for emitting a given liquid amount of a pharmaceutical product in single doses, whereby the inventive device comprises a section arranged within a casing, the section taking up the vessel filled with the liquid pharmaceutical product. Moreover, the inventive device contains an outlet section for the single dose of the pharmaceutical product, whereby the outlet section directs into the direction of the user when he parenterally and particularly subcutaneously applies the single dose of the pharmaceutical product. According to the inventive device, the vessel containing the multitude of the single doses, can be connected with the outlet section by an intermediate reservoir in such a way that, when the vessel is set into the inventive device, the given liquid amount of each single dose can be drained firstly from the vessel into the intermediate reservoir and then from the intermediate reservoir into the outlet section. The amount of the liquid pharmaceutical product emitted with each single dose can be determined, according to the inventive device, by the volume of the intermediate reservoir. In other words, the amount of the single dose being

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parenterally applicable is variable in the inventive device by varying the volume of the intermediate reservoir, whereby the volume of the intermediate reservoir is chosen in that way that each single dose of the liquid pharmaceutical product to be applied has a volume of between 0,1 ml and 1 ml, particularly between 0,2 ml and 0,6 ml and preferably between 0,2 ml and 0,4 ml.

The inventive device shows a number of advantages. First of all it is to be noted that it has a relatively simple and unproblematical construction and that it is very easy to handle since for the use of the inventive device by the user, it is only necessary to arrange the vessel containing the multitude of single doses of the liquid pharmaceutical product within the section for taking up the vessel located in the inventive device and to fix it there, if necessary, so that subsequently within the inventive device the vessel is connected with the intermediate reservoir which is then connected with the outlet section. In other words, when the respective user, contrarily to the initially described procedure of parenterally applying a liquid pharmaceutical product by a doctor or the medical staff, uses the inventive device, he does not have to transmit the respective product to be applied from the ampoule into the syringe and to measure the exact amount to be injected since in the inventive device this procedure takes places inevitably because of the construction of the inventive device. This essentially simplifies the use of the inventive device, so that by using the inventive device even sick and/or old users are able to inject themselves the required single dose of the product to be parenterally applied without depending on the

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help of others.

In order to form in the inventive device the afore mentioned connection between the vessel being set into the device and the intermediate reservoir in a particularly simple way, a further development of the inventive device is characterized in that at least one connecting conduct is located between the set in vessel filled with the multitude of the single doses of the liquid pharmaceutical product and the intermediate reservoir. Hereby an end section of this connecting conduct preferably protrudes into the section being arranged within the casing of the inventive device and taking up the vessel filled with the pharmaceutical product, so that, when the vessel has to be put in, this end section simplifies the connecting of the intermediate reservoir and the set in vessel. If hereby the glass carpule, which is described above in connection with the inventive sale unit and which comprises particularly at its top end the afore mentioned piercable membrane, is used as a vessel, it is suitable to form this end section of the connecting conduct as a correspondingly pointed end section or preferably as hollow needle, so that by this pointed end section, respectively by this hollow needle, then the piercable membrane can be pierced and so that thus the afore mentioned connection between the content of the glass carpule and the intermediate reservoir can particularly easily be realised. Such a piercing of the piercable membrane can also be simplified by providing the pointed end section, respectively the hollow needle, with a stopping element for the carpule, whereby this stopping element preferably fixes the carpule shaft and thus the whole carpule in its position. If hereby

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this stopping section is formed as a thread or as a bayonet catch, meaning that the thread, respectively the bayonet catch, can receive the correspondingly formed section of the carpule shaft, the carpule forcibly moves axially in the direction of the connecting conduct when the carpule is screwed in, respectively fixed, so that hereby the end section formed as pointed end section, respectively as hollow needle, penetrates the piercable membrane and so that thus the liquid pharmaceutical product can flow from the glass carpule into the intermediate reservoir.

A further development of the afore described embodiment of the inventive device is characterized in that the connecting conduct comprises a valve avoiding a backflow of the liquid from the intermediate reservoir into the glass carpule. In other words, this embodiment of the inventive device thus comprises a connecting conduct being provided with a reflux valve, so that the liquid to be parenterally applied can superfuse the connecting conduct only in one single direction, meaning from the vessel into the intermediate reservoir.

In respect to the formation of the afore mentioned valve avoids a backflow of the liquid pharmaceutical product from the intermediate reservoir into the vessel, as this is already described above, there are several possibilities. This upper section can be formed, for example, as a usual ball-containing reflux valve. However, it is particularly suitable when the reflux valve is formed as a membrane valve, whereby a valve sheet, preferably consisting of a rubber-elastic material, can be moved between a first position in which the valve sheet

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covers the partial conduct section of the connecting conduct, whereby the partial conduct section is directed to the vessel, and between a second position in which the valve sheet is displaced in the direction of the intermediate reservoir and makes possible the liquid flow from the vessel into the intermediate reservoir. In order to prevent an adhesion of the disk-shaped valve sheet in the first position and to avoid thus a disturbance of the functioning of the reflux valve, it is suitable to provide a ring-shaped distancing element which gets in contact with the valve sheet when the valve sheet is in the first position, so that in all the sealing surface is decreased by the ring-shaped distancing element, as this is subsequently described in detail in a example.

For filling the intermediate reservoir in the inventive device with the single dose of the liquid pharmaceutical product from the vessel, the content of the vessel can flow into the intermediate reservoir and thus fill it for gravitation reasons. It is particularly suitable, however, when a piston being axially shiftable in the direction of the outlet section is arranged within the intermediate reservoir, whereby, with such an axial shifting in the direction of the outlet section, the piston then effectuates the flow of a single dose of the liquid pharmaceutical product, the single dose being located in the intermediate reservoir, in the direction of the outlet section.

According to an axial shifting in the opposite direction hereof, a vacuum is generated in the intermediate reservoir if the connection between the intermediate reservoir and the

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outlet section is closed air-tight, so that a connecting conduct extending through the piston, the connecting conduct being located between the vessel and the intermediate reservoir, fills the intermediate reservoir with the liquid from the vessel filled with the liquid pharmaceutical product. Such a filling of the intermediate reservoir has the particularly advantage that hereby a reproducibly and exactly given liquid amount drains from the vessel into the intermediate reservoir, so that correspondingly the single dose of the liquid pharmaceutical product from the intermediate reservoir which is applied by the user can be formed in a particularly exact and reproducible way.

In order to obtain in the inventive device the air-tight blocking which is required before for the filling and which blocks the conduct located between the intermediate reservoir and the outlet section, there a several possibilities. For example, a valve , particularly a reflux valve, can be arranged also in this conduct, whereby this valve does not allow an air flow or a liquid flow from the outlet section into the intermediate reservoir, but only a liquid flow from the intermediate reservoir into the outlet section. It is particularly suitable, however, when the conduct comprises a closing element being operable from the outside, as for example a corresponding valve.

An embodiment of the inventive device which is particularly easy to handle by the respective user for a long time period is characterized in that the already afore mentioned closing element by which the conduct connecting the outlet section with

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the intermediate reservoir can be closed air-tight is formed as detachable closing element being located at the conduct.Hereby a sealing section of the closing element air-tightens the outer conduct outlet located at the outlet section. This closing element is preferably formed as a closing element which can be screwed onto the device in the outlet section or which can be fixed by a bayonet catch in such a way that it is detachably connectable with outlet section and/or the casing of the device. If in this embodiment of the inventive device it is desired to fill the intermediate reservoir with the single dose of the liquid pharmaceutical product in the afore described manner, which means that an air flow from the conduct outlet of the outlet section into the intermediate reservoir is avoided and that thus the vacuum required for the filling of the intermediate reservoir is generated, this closing element is screwed onto the outlet section, respectively onto the corresponding zone of the casing, so that the sealing section located at the closing element gears in with the conduct outlet. After filling the intermediate reservoir, the closing element is detached from the outlet section, respectively from the zone of the device casing, so that the single dose of the liquid pharmaceutical product, the single dose being located in the intermediate reservoir, can be drained out of the inventive device by axially shifting the piston in the direction of the outlet section and the consequently opened conduct.

A particularly high reproducibility in respect to the liquid pharmaceutical product amount emitted with each single dose can be obtained in such an embodiment of the inventive device, when

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it is guaranteed that the intermediate reservoir can be completely emptied by axially shifting the piston being arranged in the intermediate reservoir in the direction of the outlet section.

Such a complete emptying furtherly avoids an undesired crystallisation or the deposition of residues of the pharmaceutical product on the intermediate reservoir wallings and/or the piston wallings, whereby, on one hand, the exactness of dosing each single dose and, on the other hand, the function of the inventive device would be endangered.

A particularly embodiment of the inventive device which makes it possible to emit single dose from the intermediate reservoir in an reproducible and untroubled way, is characterized in that the intermediate reservoir is formed in a cylindrical way and comprises a subsequent end section being conically shaped and directing to the outlet section, whereby the end section is connected with the outlet section by the afore described conduct. In this development the form of the piston moreover corresponds to the form of the afore described intermediate reservoir, so that correspondingly the piston comprises a cylindrical piston section and an end section being conically formed and being connected with the cylindrical piston section. If in this embodiment of the inventive device additionally the connecting conduct being located between the vessel and the intermediate reservoir extends through the piston section up to the conical piston point, not only the complete emptying is guaranteed to a high degree in such a development of the inventive device, but also the reproducible filling of the

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intermediate reservoir.

In respect to the formation of the conical end section, there are several possibilities. This conical piston end section can, for example, consist of the same material as the rest of the piston, whereby, however, in a particularly advantageous embodiment the conical piston end section can be formed by a conically extending jacket tube being closed at its end which is located opposite to the piston section. The connecting conduct then extends almost over the whole axial length of the jacket tube, whereby the connecting conduct is located between the vessel and the intermediate reservoir, and whereby the conically shaped jacket tube comprises outlets for the liquid advanced from the vessel on its jacket surface. Hereby it is guaranteed that the intermediate reservoir is impeccably filled with the single dose of the liquid pharmaceutical product coming from out of the vessel.

The inventive device basically makes it possible to parenterally apply the single dose of the liquid pharmaceutical product being located in the intermediate reservoir directly over the outlet section connected with the intermediate reservoir by means of the conduct by submitting the single dose of the liquid pharmaceutical product to a high pressure. It is particularly suitable, however, when the outlet section comprises a mounting section for the detachable fixing of a cannula in such a way that the conduct can be connected with the cannula in a liquid-tight manner. In this embodiment of the inventive device, the mounting section thus holds a cannula which can be detachably fixed and which, during the application

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of the liquid pharmaceutical product, penetrates the body zone chosen by the user and then effectuates the parenteral application of the product.

A further embodiment of the inventive device is characterized in that additionally the afore described closing element which effectuates a closing of the conduct being located between the intermediate reservoir and the outlet section during the filling of the intermediate reservoir can be detachably fixed at the mounting section. Depending on the formation of the mounting section and the closing element, the closing element and the cannula can either be fixed at the same time at the mounting section or the closing element and the cannula can be fixed optionally at the mounting section, whereby the latter mentioned possibility is preferred since hereby the risk of getting hurt by removing the closing element is avoided by cannula still being fixed at the mounting section.

Another embodiment of the inventive device is characterized in that moreover the mounting section comprises a protecting element, whereby this protecting element then covers a cannula fixed at the mounting section at least partially or completely. This protecting element protecting the respective user from an undesired hurting by the cannula can hold the closing element or additionally support the fixing of the closing element at the mounting section, so that hereby a handle section is formed which the user touches while preparing the inventive device for the application.

A further particularly suitable embodiment of the inventive

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device comprises first cylinder being located in the casing and a second cylinder surrounding the first cylinder, whereby the first cylinder and the second cylinder are axially shiftable relative to the casing. The section for taking up the vessel, particularly the afore described carpule, is arranged within the first cylinder, whereas the intermediate reservoir being connected with the vessel is arranged within the second cylinder. In this embodiment of the inventive device, the first cylinder and the second cylinder can be axially shifted from a first position in which the cannula being fixable to the mounting section protrudes over the afore described protecting element, respectively the device casing, and in which the intermediate reservoir is emptied over the conduct and the cannula following hereafter, and a second position in which a cannula being fixable to the mounting section is covered by the protecting element and in which the intermediate reservoir is filled with the single dose, and vice-versa.

The afore described embodiment of the inventive device permits a parenteral application of the corresponding single dose of the liquid pharmaceutical product in a particularly simple way. Herefore it is only necessary to transmit the first cylinder and the second cylinder from a first position in which the intermediate reservoir is empty into a second position by axially shifting the cylinders relatively to the casing. This axial shifting leads to the fact that the intermediate reservoir is filled with the liquid being drained out of the vessel. After attaching a corresponding cannula at the mounting section, the penetration of the cannula into the body zone of the user and the emptying of the intermediate reservoir is

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carried out by axially shifting both cylinders in the direction of the mounting section, whereby as a consequence the single dose is parenterally applied. Both cylinders are preferably formed in that way that they additionally can be axially shifted relatively to each other, so that there is a time difference between the actual penetration procedure of the cannula into the body zone of the user and the emptying of the intermediate reservoir, whereby it is made possible to apply the liquid pharmaceutical product in a corresponding time retardation.

In order to cause the afore described axial shifting of both cylinders from the first position into the second position and from the second position into the first position, these axial shiftings can be realised manually in both directions. This means, however, that, when the respective user transmits both cylinders from the second position into the first position in the afore mentioned way, the penetration of the cannula into the body zone has to be carried out manually by the user himself, which the user considers to be extremely unpleasant and invincible. For that reason a particularly advantageous development of the afore described embodiment of the inventive device is characterized in that the first cylinder and the second cylinder comprise each a spring in such a way that in the second position of the cylinders both springs are tensioned and that in the first position of the cylinders the springs are released.

In order to fix both cylinders in their second position being tensioned by the corresponding springs, each cylinder in the

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inventive device can comprise a corresponding locking element. By releasing the locking of the second cylinder, the second cylinder is then transmitted from the second position into the first position caused by the spring power of the spring located at the second cylinder, which causes an inevitable penetration of a cannula being fixed at the mounting section into the chosen body zone of the user, whereby the user has no influence on this. Subsequently the locking being provided for the first cylinder is released, whereby the first cylinder is axially moved in the direction of the outlet section by the spring being provided for the first cylinder, whereby the intermediate reservoir is emptied, so that the corresponding single dose of the liquid pharmaceutical product is parenterally applied.

According to a particularly suitable and easy to handle development of the embodiment of the inventive device, both cylinders are fixable in the second position by a single locking element. This means that the user has to release only one locking element in order to commonly transmit both spring-tensioned pistons being fixed in the second position into the first position, whereby the penetration procedure of the cannula into the body zone and the injection of the single dose takes place.

In order to obtain in the afore described embodiment of the inventive device that firstly the penetration of the cannula into the body zone takes place and hereafter the injection of the single dose, a particularly suitable development of this embodiment is characterized in that it comprises springs corresponding to each other in respect to their characteristic

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spring line. Hereby the spring provided for the second cylinder has a steeper characteristic spring line than the spring being located at the first cylinder, so that the already afore mentioned time retardation between the penetration of the cannula and the subsequent injection can be regulated by accommodating the characteristic spring lines to each other in a high range.

A further advantageous embodiment of the inventive device is directed to a first cylinder and a second cylinder surrounding the first cylinder being arranged within the casing, whereby the first cylinder and the second cylinder are axially shiftable relatively to the casing. The section for taking up the vessel, preferably the afore mentioned glass carpule, is arranged within the first cylinder, whereas the intermediate reservoir connected with the vessel is arranged within the second cylinder in such a way that the first and the second cylinder can be commonly and axially shifted from a first position in which the cannula being fixable to the mounting section protrudes over the protecting element, respectively the casing, and in which the intermediate reservoir is emptied, into a second position in which a cannula being fixable to the mounting section is covered by the protecting element, and vice-versa. For filling the intermediate reservoir the first cylinder can be axially shifted into a third position in the direction of the vessel relatively to the second position of the second cylinder.

In other words, this afore described and particularly advantageous development of the inventive device is

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characterized in that it provides also a third position, contrarily to the afore described embodiments of the inventive device in which the cylinders can only be arranged in a first and a second position.

In order to use the inventive device, firstly both cylinders are transmitted from the first position into the second position, which causes that a cannula being fixed at the mounting section is covered by a protecting element. At this time the intermediate reservoir is not yet filled with the single dose of the liquid pharmaceutical product. Subsequently the first cylinder is axially shifted into a third position relatively to the second cylinder which remains in the second position, whereby the intermediate reservoir is completely filled with the liquid pharmaceutical product being drained out of the vessel by the connecting conduct. As the first cylinder is moved from the second position into the third position, the conduct connecting the cannula with the intermediate reservoir is blocked in an air-tight way by one of the afore described valves or by the also afore mentioned closing element. A vacuum causing the liquid flow from the vessel into the intermediate reservoir is thus generated in the intermediate reservoir.

Hereafter the ready-to-operate device is brought into contact with the chosen body zone, so that then the user moves the second cylinder from the second position into the first position, whereby the penetration procedure of the cannula into the body zone is manually effectuated. Hereafter the user moves the first cylinder from the third position into the first position, whereby the corresponding injection of the single

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dose of the liquid pharmaceutical product from the intermediate reservoir into the body is caused.

As it is, however, mentioned above, some user have the problem with this application that they have to carry out themselves the corresponding injection of the single dose of the liquid pharmaceutical product from the intermediate reservoir into the body. In order to avoid this, a further development of the afore described embodiment of the inventive device is characterized in that each cylinder (first cylinder, second cylinder) comprises a spring, whereby a first spring pre-tensions the arrangement of the cylinder in the third position and a second spring pre-tensions the arrangement of the second cylinder in the second position. Moreover, the first cylinder is fixable in the third position by first locking and the second cylinder is fixable in the second position by a second locking in such a way that this fixing is caused by corresponding lockings can preferably be released by a single release button.

In order to apply such a device, the respective user transmits the second cylinder into the second position against the power of the corresponding second spring, whereby such an axial shifting of the second cylinder is realised preferably by a shifting element arranged at the outside of the casing. Concurrently to operating this shifting element, the first cylinder is shifted into its second position against the power of the first spring, whereby then the second locking fixes the second cylinder in the second position. When the shifting element is furtherly operated, the first cylinder is axially

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shifted relatively to the second cylinder from the second position into the third position against the power of the corresponding first spring and is then fixed in the third position by the first locking.

By operating the common release button both cylinders are axially shifted from the third position (first cylinder), respectively from the second position (second cylinder), into the first position as a result of the spring power of the first and the second spring, whereby the penetration of the cannula into the body zone and the injection of the single dose from the intermediate reservoir is forcibly effectuated without being influenced by the user.

A further development of the afore described embodiment is preferably characterized in that, by operating the release button, firstly the second locking fixing the second cylinder in the second position is released and then the first locking fixing the first cylinder in the third position is released in a corresponding time retardation.

the afore described inventive device are particularly used in the initially discussed inventive sale unit, whereby, however, the inventive device can be traded on the market independently from the sale unit.

Furthermore, the present invention is directed to a refill unit to be employed in the initially described inventive sale unit or in the afore discussed inventive device.
Hereby this inventive refill unit comprises at least one

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cannula as well as at least on vessel filled with the liquid pharmaceutical product, whereby the vessel can be arranged within the afore described inventive device and emptied in single doses by means of this device.

The inventive refill unit has the essential advantage of being perfectly adjusted to the afore described sale unit as well as to the inventive device in respect to its constructive features, so that the user of the afore described inventive sale unit or of the afore discussed inventive device can apply the inventive refill unit when a longer parenteral application of the liquid pharmaceutical product is required from the medical point of view and when the vessel being filled with the liquid pharmaceutical product and being provided in the afore described inventive sale unit is emptied.

A first development of the inventive refill unit is characterized in that a detaching element to remove the emptied vessel from the inventive device for emitting a given liquid amount in single doses is arranged in the refill unit. The detaching element is formed correspondingly to the respective form of the section for taking up the vessel filled with the liquid pharmaceutical product, this section being located within the casing of the inventive device, whereby this detaching element preferably comprises a grip section so that the user can grip the detaching element and a fixing section for the form-fit and/or non-positive fixing of the emptied vessel.

As already described above in the inventive sale unit, a first

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embodiment of the inventive refill unit is characterized in that the unit comprises a number of cannulas that corresponds to a number of the single doses of the pharmaceutical product. Hereby the user can exchange the used cannula by a corresponding sterile cannula after each parenteral application of the liquid pharmaceutical product, whereby the risk of an infection is avoided. The cannulas provided in the refill unit are preferably constructed in that way that the actual needle of the cannula is protected by a solid plastic jacket, whereby this solid plastic jacket, on one hand, guarantees the sterility of the needle and, on the other hand, keeps the user from unintentionally hurting himself with the needle. Such an embodiment of the refill unit particularly comprises ten of the afore described cannulas, whereby then the vessel being provided in the refill unit and being filled with the liquid pharmaceutical product makes it possible to correspondingly apply ten single doses of the product to be parenterally applied.

In order to make it again easier for the user to operate the inventive refill unit during the parenteral application, a further advantageous development is directed to a refill unit that comprises a number of cannulas that corresponds to a number of sponges, whereby these sponges are moistened with a disinfectant, as for example a low alcohol (ethanol, propanol). In order to avoid on the sponges an undesired evaporation of the disinfectant, the sponges moistened with a disinfectant are wrapped singly in corresponding foils, preferably plastic foils and more particular compound plastic foils, so that, for the parenteral application, the user removes just one sponge from

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the wrapping and disinfects herewith the spot chosen for the injection.

In another embodiment of the inventive refill unit, the unit additionally comprises a section serving to take up the used cannulas and/or used sponges. Hereby this section to take up the used cannulas, respectively the used sponges, is formed in the way that the used cannulas, respectively sponges, cannot fall out of the refill unit while being used, so that the section is formed particularly as a separately closable section. If in the refill unit this section is formed as a section being detachable from the refill unit, as for example as a closable box, the used cannulas and, if necessary, the sponges can be separately wasted, as for example by the special trade, as far as this is required by legal prescriptions.

The inventive refill unit can comprise basically each vessel containing the multitude of single doses of the liquid pharmaceutical product, as far as it is guaranteed that this vessel is formed in that way that it can be set into the device and emptied in single doses by means of the device. However, it is particularly suitable to fill the liquid pharmaceutical product to be parenterally applied by the user in single doses in a cylindrical or cylinder-like glass carpule, whereby such a glass carpule holds particularly between about 1,5 ml and about 8 ml, preferably between about 2 ml and about 6 ml, of the liquid pharmaceutical product.

A particularly advantageous development of the afore described glass carpule is characterized in that in the inventive refill

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unit such a glass carpule is arranged which is closed, at its bottom side, by a piercable membrane and, at its top side, by a plug being formed in that way that it can be axially shifted within the glass carpule in the direction of the piercable membrane when the liquid level is descending. This special development of the glass carpule has the particular advantage that the bottom section of the plug is located in the immediate proximity of the liquid level or even contacts the liquid level, so that there is no air puffer above the respective liquid level when the liquid level is descending because of the single doses emitted. On one hand, this avoids an undesired oxidative modification of the respective liquid pharmaceutical product and, on the other hand, the special forming of the plug effectively avoids the formation of a vacuum in the glass carpule when the liquid amount is decreasing, whereby such a vacuum would have a negative effect on the exactness of the liquid amount emitted in single doses.

In order to ensure the required tightness between the plug and the inner walling of the glass carpule, according to the afore described embodiment of the glass carpule which disposes of the afore described plug being axially shiftable in the direction of the piercable membrane, a further development of the inventive refill unit is characterized in that the plug comprises on its jacket surface at least one, preferably two to five, disk-like sections directing radially to the outside. Hereby these disk-like sections can be deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid-tightens and air-tightens the inner surface of the carpule. The disk-like sections directing

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to the outside are preferably dimensioned in that way that an end section of the disk-like sections is elastically deformed by the axial shifting of the plug in the glass carpule opposite to the shifting direction with the formation of a correspondingly larger dimensioned sealing surface. In respect to the material that the plug consists of, it is to be noted that herefore preferably an elastic, chemically resistant plastic material or rubber material is chosen, whereby herefore a halogenbutyl-caoutchouc proved to be particularly suitable.

When the afore described plug can be axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N, it is particularly guaranteed that the above described advantages occur in a particularly reproducible way.

By using the inventive refill unit in connection with the inventive device of the inventive sale unit, basically all liquid pharmaceutical products being stable in storage can be parenterally applied by the user himself. Hereby the term liquid pharmaceutical products means all such products which, as actual product, are liquid or from which stable solutions, stable dispersions or stable emulsion can be manufactured in an organic or inorganic, physiologically safe liquid. The afore described vessel or the afore described and particularly used glass carpule preferably comprise an aqueous solution of a heparin, preferably an aqueous solution of a low-molecular heparin, and particularly an aqueous solution of an enoxaparin-sodium. Such a refill unit is then used by such users who, because of their syndrome and from the medical point of view,

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have to apply the heparin daily in constant single doses for a longer time period, in order to prevent, for example, the risk of a thrombosis after having discharged the user from the hospital. A further preferred employment of the inventive refill unit is the regular parenteral application of a given and constant amount of a growth hormone, whereby, for this case of application, the vessel and particularly the afore described glass carpule is filled with a solution of the growth hormone, preferably an aqueous solution of the growth hormone.

The inventive sale unit, the inventive device as well as the inventive refill unit will be described in detail by embodiments in connection with drawings as follows. The figures show:

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Figure 1 a perspective view of an embodiment of the sell unit;

Figure 2 a perspective, schematical view of the device for emitting a given liquid amount in single doses;

Figure 3 an explosion drawing of figure 2;

Figure 4 an enlarged schematical sectional view of a closing element;

Figure 5 an sectional explosion view of the axially shiftable cylinder;

Figure 6 a sectional view of a first embodiment with emptied intermediate reservoir;

Figure 7 as figure 6, but with filled intermediate reservoir;

Figure 8 an enlarged schematical sectional view of a reflux valve;

Figure 9 a sectional view of a second embodiment of the device with filled intermediate reservoir; and

Figure 10 a perspective view of an embodiment of there refill unit.

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In the figures 1 to 10 the same parts are designated with the same reference numbers.

A sale unit collectively designated with 1 and shown in figure 1 comprises a device 3 for emitting a given liquid amount of the pharmaceutical product, a multitude of cannulas 2 being provided with a corresponding cannula protector 45 (figure 3) for the sterile storing, a glass carpule designated with 8 serving as vessel being filled with the liquid pharmaceutical product. Moreover, the sale unit 1 comprises a number of sponges 5 moistened with an disinfectant, whereby the number of sponges 5 corresponds to the number of the cannulas 2. The sale unit 1 furthermore contains a section 6 taking up used cannulas, whereby, according to the embodiment shown in figure 1, this section can be closed by a cover which is not shown. This section 6 is collectively arranged at the sale unit 1 in a detachable way, so that, after taking up the used cannulas, this section 6 can be separately wasted, as far as this is legally prescribed or desired. The sale unit 1 usually comprises 10 cannulas 2, so that correspondingly the glass carpule 8 contains the liquid amount for 10 cannulas. Usually the liquid amount emitted each in single doses varies between 0,1 ml and 1 ml, so that correspondingly the glass carpule contains between 1 ml and 10 ml of the liquid pharmaceutical product. In order to avoid an evaporation of the disinfectant of the sponges 5, each sponge 5 is separately wrapped by a corresponding plastic foil in an air-tight way. The sale unit 1 taking up the afore described parts is collectively closed by a cover (not shown) or is arranged in the usual plastic wrapping, if necessary even in a sterile way.

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The device 3 for emitting a given liquid amount of the liquid pharmaceutical product, the device 3 being shown in detail in figure 2, comprises a protecting element 22, whereby this protecting element 22 consists of a outer cylinder 22 a and inner cylinder 22 b being concentrically arranged relative to the outer cylinder 22 a which are manufactured from a transparent plastic material and which can cover a cannula 2 fixed at the device 3, as this is shown, for example, in figure 3. Furthermore, the device 3 comprises a casing 4, whereby an upper grip section 33, a window 34, a counting device 35, a second grip section 33 a, a cover 36 being detachable from the casing, a release button 37, a shifting element 38 being fixed by a corresponding slot 39, as well as a deepening 40 are arranged at the casing 4.

In the device 3 shown in figure 2 furthermore a closing element 18 is fixed at the casing 4, whereby the closing element 18 is subsequently described in detail in connection with figure 4. The user can thus easily hold the device 3 at the grip sections 33 and 33 a as well as at the closing element 18. The afore mentioned counting device 35 serves to count the single doses of the liquid pharmaceutical product emitted by means of the device 3, whereas the window 34 arranged in the casing makes it possible to control the liquid level in the glass carpule 8, as far as the glass carpule 8 is taken up by the device 3, whereby the cover 36 is removed in order to arrange the glass carpule 8, as this is shown in figure 3.

Figure 3 schematically shows the insertion of the glass carpule 8 into the device 3 and the arrangement of the closing element

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18 as well as the arrangement of a cannula 2. During the insertion of the glass carpule the cover 36 is firstly removed in order to open the section 41 taking up the vessel filled with the liquid pharmaceutical product, whereby this section 41 is located within the casing 4. When the glass carpule 8 has been inserted into the section 41, the corresponding opening is closed with the cover 36. At its bottom side the cover 36 comprises an axially extending lengthening pin 42 ending in an end section 42 a, whereby the lengthening pin 42 and the end section 42 a can be axially shifted together with the cover 36.

In a further, not shown and preferably used embodiment the lengthening pin 42 and the section 42 a are axially shiftable in the direction of the arrow 51 relative to the cover 36 so that after fixing the cover 36 on the casing 4 an axial shifting of the lengthening pin 42 and the section 42 a can be reached by a manuel operation done by the user independent of the kind in which the cover 36 is fixed on the casing 4. This axially shifting is done by the user by forcing a section of the lengthening pin 42 protruding over the cover 36 when the cover is fixed.

This end section 42 a can gear into a deepening being correspondingly carved into a plug 10, whereby the glass carpule 8 can be submitted to a power being axially directed downward can be, as soon as the glass carpule 8 is arranged in the section 41 and the cover 36 is screwed onto the corresponding opening or fixed by means of a bayonet closing. At its bottom side the glass carpule 8 filled with the liquid

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pharmaceutical product is closed by a piercable membrane 9 being fixed by a bead in connection with a metal strap 44 in a usual way. A cannula 2 or the closing element 18 can be optionally fixed at a mounting section 21 (for example a shown in figure 7) by a corresponding weight, as these options are shown in figure 3. Hereby the cannula 2 is surrounded by a cannula protector 45 which makes it possible for the user not to hurt himself when he operates the cannula 2. The cannula protector 45 can be clamped onto the base section 2 a of the cannula 2 and, if necessary, fixed at the base section 2 a by a thread.

The cylindrical closing element 18 (figure 4) comprises a sealing element 18 a which can contact a conduct outlet 19 (figure 5 and 6) and which can close the conduct outlet in an air-tight and liquid-tight way, as soon as the closing element 18 is fixed at the mounting section 21 by a corresponding thread 18 b. Moreover, the closing element 18 comprises a slot section 18 c to take up the walling of the inner cylinder 22 b of the protecting element 22.

The schematical explosion view of figure 5 shows the essential interior parts of the device 3. These are a first, inner cylinder 23, a second, outer cylinder 24, whereby the second cylinder 24 end with its bottom side in the mounting section 21 to which a cannula 2 or the closing element 18 can be optionally fixed. In this section the protecting element 22 is detachably mounted at the casing 4 which is only partially shown in figure 5. The first cylinder 23 is provided with a first spring 25 and the second cylinder 24 is provided with a

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second spring 26, whereby the first spring 25 extends between an upper section 23 a of the first cylinder 23 and a ring element 46 being fixed at the second cylinder 24, whereas the second spring 26 is supported by an lower bearing 24 a being located at the second cylinder 24 and an upper bearing 23 b being located at the casing 4. The shifting element 38 is formed as on piece with the first cylinder 23.

Furthermore, the first cylinder 23 comprises a bottom plate 23 c being provided with a projection 23 d at its bottom side. The shaft 47 of a piston 16 can be connected with this projection 23 d, so that the piston 16 is fixed at the first cylinder 23 and moved together with the first cylinder 23. A connecting conduct 14 extends within the shaft 47 and within the piston 16, whereby this connecting conduct 14 is guided also by the bottom plate 23 c and the projection 23 d and ends in a hollow needle 48.

If then the glass carpule 8 filled with the liquid pharmaceutical product is set into the inner space of the first cylinder 23, the inner space forming the section 41 taking up the vessel, and if hereby the glass carpule 8 is submitted to a pressure in the direction of the mounting section 21 by means of the plug and the lengthening pin 42, respectively the end section 42 a, the hollow needle 5 pierces the piercable membrane 9 of the glass carpule 8, so that the connecting conduct 14 is connected to the content of the glass carpule 8. Hereby the connecting conduct 14 is provided with a reflux valve 15 in the section connecting the shaft 47 with the projection 23 d, whereby this reflux valve 15 is shown enlarged

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in figure 8.

This reflux valve 15 comprises, according to figure 8, a disk-like, round sealing membrane 49 being held by a ring bearing 50. A section which is superfused by the liquid and which enlarges the conduct inlet 14 a of the connecting conduct 14 is arranged underneath the sealing membrane 49. If the liquid flows in the direction of the arrow 51, as this is required in the conduct 14 for the filling of the intermediate reservoir, the sealing membrane 49 is lifted from the ring bearing 50 and does thus not block the flow of the liquid. Hereby this movement of the sealing membrane 49 is limited by four radially arranged linking elements 52, so that it is avoided that the sealing membrane 49 closes the enlarged conduct inlet 14 a. If the liquid flows in the opposite direction of the arrow 51, the sealing membrane 49 is brought into a position in which it seals the ring bearing 50, so that hereby a flow in the opposite direction of the arrow 51 is avoided without risking an adhesion of the sealing membrane 49.

I the figures 6 and 7 the same embodiments are shown, however, in different operating situations. Hereby figure 6 shows the device in a situation in which the intermediate reservoir 13 is empty, whereby in this situation the single dose of the liquid pharmaceutical product has thus been parenterally applied, and in which the respective user finds the device in order to then prepare it for the next single dose. In figure 7 the intermediate reservoir 13 is filled with a single dose of the liquid pharmaceutical product being supplied from the glass carpule 8 over the conduct 14. In the operating situation

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shown in figure 7 a cannula 2 is furthermore fixed at the mounting section 19, so that figure 7 as a whole shows the device in an operating situation occurring immediately before the parenteral application of the single dose of the liquid pharmaceutical product by the user.

The parts shown in figure 5 and described above are provided as well in the figures 6 and 7 and designated with the same reference numbers.

In the first cylinder 23 the glass carpule 8 is arranged in the adequate section 41, whereas the second cylinder 24 forms the intermediate reservoir 13 in its bottom section 24 c (also figure 5).

Starting from the operating situation shown in figure 6 in which the closing element 18 is fixed at the mounting section 21 and in which the closing element 18 a closes the conduct outlet 19 a of the conduct 19 which connects the intermediate reservoir with the conduct outlet, the first cylinder 23 and the second cylinder 24 were commonly transmitted from a first position not shown, in which the spring 25 is released and in which the second cylinder 24 contacts a casing section 53 by means of the recessing section 24 b (figure 5), into a second position as this is shown in figure 6, whereby this transmitting was realised by axially shifting both cylinders in the opposite direction of the arrow 51 and relatively to the casing 4. In this second position the spring 25 being released in the first position of both cylinders is thus tensioned, whereby a fixing of this second position is realised by a

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second locking 27 gearing in at the recessing section 24 b.

This common axial shifting of both cylinders 23 and 24 is caused by manually operating the shifting element 38 arranged at the outside of the casing, whereby this axial shifting of the shifting element 38 is guided through a slot 39 (figure 3) located in the casing 4.

In order to fill the intermediate reservoir 13 in this second position with a single dose of the liquid pharmaceutical product supplied by the glass carpule 8 arranged within the first cylinder 23, the first cylinder 23 is shifted into the third position in the opposite direction of the arrow 51 and relatively to the casing 4 and to the second cylinder 24 remaining in the second position, whereby this shifting is realised by means of the shifting element 38 against the power of the second spring 26, and whereby this third position is axially shifted in the opposite direction of the arrow 51, which is shown in figure 7.

In this third position of the first cylinder, the first cylinder 23 is fixed by a first locking 28 (figure 7).

Conditioned by the fact that the closing element 18 avoids a ventilation of the intermediate reservoir 13 by means of the conduct 19 as a result of the fluid-tight contacting of the sealing element 18 a with the conduct outlet 19 a, a vacuum is generated in the intermediate reservoir 13 when the first cylinder 23 is axially shifted from the second position into the third position. This depends on the fact that concurrently

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with the shifting of the first cylinder 23 the piston 16 which is fixed to the first cylinder 23 by piston shaft 47 is axially shifted in the opposite direction of the arrow 51. This vacuum generated in the intermediate reservoir 13 then causes a complete filling of the intermediate reservoir with exactly one single dose of the liquid pharmaceutical product being supplied from the glass carpule 8 by means of the connecting conduct 14 and the opened reflux valve 15 which is arranged in the projection 23 d of the first cylinder 23 and which is shown in figure 8.

This axial shifting of the first cylinder from the second position into the third position relatively to the casing and to the second cylinder is made possible by providing the walling of the second cylinder with a slot-like guidance 39 a through which a section of the shifting element 38 extends, whereby the shifting element 38 is formed in one piece with the first cylinder 23.

The closing element 18 is then replaced by a cannula 2, whereby the cannula 2 is gripped by user at the cannula protector 45 and the cannula 2 is screwed onto the mounting section 21. Hereafter the user removes the cannula protector 45, whereby the device is prepared to apply the single dose of the liquid pharmaceutical product.

With this object the respective user chooses a body zone and brings the bottom zone of the inner cylinder 22 b of the protecting element 22 in contact with this body zone. By operating the release button 37 the second locking 27 is

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shifted in the direction of the arrow 54 against the spring power 27 a, so that the first cylinder 23 and the second cylinder 24 are commonly and axially shifted relatively to the casing 4 in the direction of the arrow 51 by means of the spring 26. This leads to the fact that the point of the cannula 2 penetrates the chosen body zone of the user. During the common axial shifting of both cylinders 23 and 24, a projection 27 b being located at the second locking 27 gets in contact with a projection 28 a being located at the first locking 28, whereby this causes a shifting of the first locking 28 also in the direction of the arrow 54 against the spring power of the spring 28 b located at the first locking 28. Hereby the first cylinder 23 is released from its third position, so that it is also axially shifted in the direction of the arrow 51 by means of the spring 25. This again leads to the fact that the piston 16 being connected with the first cylinder 23 by the shaft 47 is axially shifted in the direction of the arrow 51 and that thus the single dose of the liquid pharmaceutical product located in the intermediate reservoir 13 is injected into the body zone by the cannula 2. The axial shifting of the first cylinder 23 is terminated by the recessing section 24 b of the second cylinder 24 and by the axial movement of the second cylinder 24 through the casing section 53.

After the parenteral application the user pulls the cannula 2 out of the body zone by means of the device, attaches the cannula protector 45 on the cannula 2, unscrews the cannula 2 from the mounting section 21 and screw the closing element 18 onto the mounting section 21. Independently of the power performed hereby by the user, the first cylinder and the second

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cylinder remain either in the first position or both cylinders are transmitted into a position as it is shown in figure 6.

The second embodiment of the device, the embodiment being shown in figure 9, presents the device in such an operating situation in which the intermediate reservoir 13 is filled with the single dose of the liquid pharmaceutical product. The embodiment shown in figure 9 is thus ready to operate meaning that is ready to inject. Contrarily to the embodiment described above in figures 6 and 7, the embodiment shown in figure 9 is characterized in that both cylinders 23 and 24 can be axially shifted in the direction of the arrow 51 and vice-versa only between a first position (not shown) in which the first cylinder 23 contacts the recessing section 24 b and the recessing section 24 b contacts the casing section 53 and in which the intermediate reservoir 13 is emptied, and a second position as this is shown in figure 9 and in which the intermediate reservoir 13 is filled with the single dose. Moreover, the embodiment shown in figure 9 provides only a single locking 29 which fixes the first cylinder 23 and the second cylinder 24 in the second position and which can be released by means of the release button 37.

In order to make it possible in the embodiment shown in figure 9 to cause the time retardation between the penetration procedure of the cannula into the body zone of the user and hereafter the emptying of the intermediate reservoir 13 and thus the actual parenteral application of the single dose of the liquid pharmaceutical product, the characteristic spring lines of the springs 25 and 26 are adjusted to each other in

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such a way that the characteristic spring line of the spring 26 is steeper than the characteristic spring line of the spring 25. By operating the release button 37 the locking 29 is shifted in the direction of the arrow 54 against the spring power of the spring 29 a, so that the locking 29 is released and that thus the first cylinder 23 and the second cylinder 24 can be commonly and axially shifted in the direction of the arrow 51 relatively to the casing. Caused by the steeper characteristic spring line of the spring 26, the second cylinder 24 projects, during the axial shifting, relatively to the first cylinder 23 the spring 25 of which has a more levelled characteristic spring line, over the first cylinder 23, so that the cannula 2 firstly penetrates the body zone and that then the first cylinder 23 and thus also the piston 16 connected with the first cylinder 23 by the shaft 47 transmits the single dose of the liquid pharmaceutical product from the intermediate reservoir 13 into the body zone of the user.

In order to guarantee in the afore described embodiment of the inventive device a complete emptying of the intermediate reservoir, the intermediate reservoir 13 comprises a cylindrical section 13 b and a subsequent conical section 13 a (figure 9), whereby the outlet of the conical section 13 a opens into the conduct 19, as this can be seen perfectly in figure 9. The piston 16 being axially shiftable within the intermediate reservoir 13 correspondingly comprises a cylindrical piston section and conical piston section 16 a directed to the conduct 19, whereby this conical piston section is formed by a corresponding conically-shaped jacket tube surrounding the outlet of the connecting conduct 14. This

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jacket tube is closed at its bottom side and it comprises outlets on its conical surface, so that by these outlets the liquid supplied by the conduct 14 is transported into the intermediate reservoir. When the piston is axially lowered in the direction of the arrow 51, the conical piston section 16 a displaces the liquid located in the intermediate reservoir 13 in that way that the conical piston section 16 a enters the conical cylinder section 13 a and thus fills it completely.

It is even possible to provide an intermediate reservoir 13 which dos not comprises the afore described and especially in figure 9 shown conical section 13 a or which comprises a conical section 13 a having restricted length. In other words in this embodiment the cylindrical section 13 b of the intermediate reservoir empties directly into the conduct 19, or the cylindrical section 13 b is connected with the conduct via a correspondingly restricted conical section 13 a. Appropriate to that the plug 16 located inside of the intermediate reservoir 13 is adapted to such a formed intermediate reservoir 13 whereby preferably a sealing provided to the piston skirt and more preferably an O-formed flexible piston ring makes a safe use sure.

In all afore described embodiments the plug 10 arranged within the glass carpule 8 is also axially shifted in the direction of the arrow 51 as a result of the descending liquid level in the glass carpule 8. Hereby it is avoided that a vacuum is generated in the glass carpule or that a gas puffer is formed above the liquid level. In order to furthermore guarantee a complete emptying of the glass carpule 8, the front surface 10

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a (figure 9) of the plug 10 tapers, so that it contacts the shaft section of the glass carpule 8 a (figure 9) when the liquid is completely descended.

In this state, the completely emptied glass carpule 8 can be removed from the device together with the detaching element 101 shown in figure 10. For this purpose, the detaching element comprises a grip section 102 for handling the detaching element 101 as well as a fixing section which can gear non-positively into a deepening 10 b (figure 9) being provided in the plug 10 when the plug 10 is removed.

Moreover the refill unit shown in figure 10 comprises a multitude of cannulas 2 being provided with a corresponding cannula protector 45 (figure 3) for the sterile storing, a glass carpule designated with 8 serving as vessel being filled with the liquid pharmaceutical product. Moreover, the refill unit 100 comprises a number of sponges 5 moistened with an disinfectant, whereby the number of sponges 5 corresponds to the number of the cannulas 2. The refill unit 100 furthermore contains a section 6 taking up used cannulas, whereby, according to the embodiment shown in figure 10, this section can be closed by a cover which is not shown. This section 6 is collectively arranged at the refill unit 100 in a detachable way, so that, after taking up the used cannulas, this section 6 can be separately wasted, as far as this is legally prescribed or desired. The sale unit 1 usually comprises 10 cannulas 2, so that correspondingly the glass carpule 8 contains the liquid amount for 10 cannulas. Usually the liquid amount emitted each in single doses varies between 0,1 ml and

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1 ml, so that correspondingly the glass carpule contains between 1 ml and 10 ml of the liquid pharmaceutical product. In order to avoid an evaporation of the disinfectant of the sponges 5, each sponge 5 is separately wrapped by a corresponding plastic foil in an air-tight way. The refill unit 100 taking up the afore described parts is collectively closed by a cover (not shown) or is arranged in the usual plastic wrapping, if necessary even in a sterile way.
The afore described detaching element 101 is arranged in the refill unit 100.

The used term piercable membrane several times repeated means a flexible sealing disc being fixed at the carpule 8 by a flared flange, preferably by a metallic flared flange, as it is clearly shown in the drawings.

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Patent claims

1. A sale unit for the parenteral application of liquid pharmaceutical products by the user, characterized in that the unit comprises at least one cannula, a device to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel filled with the pharmaceutical product, the vessel being arranged within the device and emptied in single doses by means of the device, whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

2. The sale unit according to claim 1, characterized in that the unit contains a number of cannulas corresponding to the number of single doses.

3. The sale unit according to claim 1 or 2, characterized in that the unit comprises a number of sponges being moistened with a disinfectant, whereby the number of sponges corresponds to the number of cannulas.

4. The sale unit according to one of the preceding claims, characterized in that the unit comprises a section for taking up the used cannulas.

5. The sale unit according to one of the preceding claims, characterized in that the vessel filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule.

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6. The sale unit according to claim 5, characterized in that the glass carpule is closed, at its bottom side, by a piercable membrane and, at its top side, by a plug being formed in that way that it can be axially shifted within the glass carpule in the direction of the piercable membrane when the liquid level is descending.

7. The sale unit according to claim 5 or 6, characterized in that the plug has, on its jacket surface, at least one, preferably two to five, disk-like sections radially directing to the outside, whereby these sections are deformed when the plug is inserted into the glass carpule with the formation of a sealing surface which liquid- or air-tightens the inner surface of the carpule.

8. The sale unit according to one of the claims 6 to 8, characterized in that the plug is axially shifted within the glass carpule by a power of less than 10 N, preferably by a power of between 4 N and 8 N.

9. The sale unit according to one of the preceding claims, characterized in that the vessel is filled with an aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

10. The sale unit according to one of the preceding claims, characterized in that the vessel is filled with a solution of

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a growth hormone, preferably an aqueous solution of a growth hormone.

11. A device for emitting a given liquid amount of a pharmaceutical product, characterized in that the device for emitting a given liquid amount in single doses comprises a section for taking up the vessel being located within a casing and being filled with the liquid pharmaceutical product, as well as an outlet section for the single dose of the pharmaceutical product, and in that the vessel can be connected with the outlet section by an intermediate reservoir in that way that, when the vessel is set in, the given liquid amount of each single dose can firstly be drained from the vessel into the intermediate reservoir and then from the intermediate reservoir into the outlet section, whereby the amount of the drained liquid can be determined for each single dose by the volume of the intermediate reservoir.

12. The device according to claim 11, characterized in that a connecting conduct is arranged between the inserted vessel and the intermediate reservoir.

13. The device according to claim 12, characterized in that the connecting conduct comprises a valve which avoids a liquid backflow from the intermediate reservoir into the vessel.

14. The device according to one of the claims 11 to 13,

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characterized in that the intermediate reservoir comprises a piston for the transporting of each single dose of the liquid pharmaceutical product in the direction of the outlet section, whereby the piston is located within the intermediate reservoir and axially shiftable in the direction of the outlet section.

15. The device according to one of the claims 11 to 14, characterized in that the intermediate reservoir is to fill with a single dose of the pharmaceutical product by an axial shifting of the piston in the direction of the vessel.

16. The device according to claim 15, characterized in that, by axially shifting the piston, a vacuum is produced in the intermediate reservoir for the transport of a single dose of the liquid pharmaceutical product from the vessel into the intermediate reservoir.

17. The device according to claim 16, characterized in that the intermediate reservoir is connected with the outlet section by a conduct and that this conduct can be air-tightened by a closing element.

18. The device according to claim 16 or 17, characterized in that the closing element is formed as a detachable closing element located at the conduct in that way that a sealing section of the closing element air-tightens the conduct outlet (19 a).

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19. The device according to one of the claims 14 to 17, characterized in that, by axially shifting the piston within the intermediate reservoir in the direction of the outlet section, the intermediate reservoir is completely emptied.

20. The device according to one of the claims 11 to 19, characterized in that the intermediate reservoir is formed in a cylindrical way and comprises a conically-shaped end section following hereafter and directing to the outlet section, whereby the end section is connected with the outlet section by the conduct, and that the piston has a corresponding shape.

21. The device according to one of the claims 11 to 20, characterized in that the outlet section comprises a mounting section for the detachable fixing of a cannula in that way that the conduct is connected with the cannula in a fluid-tight way.

22. The device according to claim 17, 18 or 21, characterized in that a closing element is fixed at the mounting section in such a way that the conduct section directing to the outside can be fluid-tightened by the closing element.

23. The device according to one of the claims 11 to 22, characterized in that the mounting section comprises a protecting element which covers at least a part of a cannula being fixed at the mounting section.

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24. The device according to one of the claims 11 to 23, characterized in that a first cylinder and a second cylinder surrounding the first cylinder are arranged within the casing, that the first cylinder and the second cylinder are shiftable axially relative to the casing, that the section to take up the vessel is situated within the first cylinder and the intermediate reservoir connected with the vessel is located within the second cylinder, in such a way, that the first and the second cylinder are axially shiftable from a first position in which the cannula being fixable to the mounting section protrudes over the protecting element and in which the intermediate reservoir is emptied over the conduct and the subsequent cannula, and a second position in which a cannula being fixable to the mounting section is covered by the protecting element and in which the intermediate reservoir is filled with the single dose, and vice-versa.

25. The device according to claim 24, characterized in that, by axially moving the first and the second cylinder relatively to the casing from the first position into the second position, the intermediate reservoir is filled with a single dose of the liquid pharmaceutical product.

26. The device according to claim 25, characterized in that the first and the second cylinder comprise each a spring in such a way that, in the second position of the cylinders, the springs are tensioned and that, in the first position of the

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cylinders, the springs are released.

27. The device according to one of the claims 24 to 26, characterized in that both cylinders are fixed in the second position by a locking element.

28. The device according to one of the claims 26 or 27, characterized in that the spring of the second cylinder has a steeper characteristic spring line than the spring of the first cylinder.

29. The device according to one of the claims 11 to 23, characterized in that a first cylinder and second cylinder surrounding the first cylinder are arranged within the casing, that the first cylinder and the second cylinder are shiftable axially relative to the casing, that the section to take up the vessel is situated within the first cylinder and the intermediate reservoir connected with the vessel is located within the second cylinder, in such a way, that the first and the second cylinder are axially shiftable from a first position in which the cannula being fixable to the mounting section protrudes over the protecting element and in which the intermediate reservoir is emptied, into a second position in which the cannula being fixable to the mounting section is covered by the protecting element, and vice-versa, that for filling the intermediate reservoir, the first cylinder is

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axially shiftable into a third position in the direction of the vessel relatively to the second position of the second cylinder.

30. The device according to claim 29, characterized in that each cylinder contains a spring, whereby a first spring pre-tensions the position of the first cylinder in the third position and a second spring pre-tensions the position of the second cylinder in the second position, and that the first cylinder is fixable in the third position by a first locking and the second cylinder is fixable in the second position by a second locking.

31. The device according to claim 29 or 30, characterized in that, by operating a common release button, firstly the second locking is released and then the first locking is released in a corresponding time retardation.

32. The device according to one of the claims 11 to 31 for the use in a sale unit according to one of the claims 1 to 10.

33. A refill unit for the use in the sale unit or the device according to one of the preceding claims, characterized in that the refill unit comprises at least one cannula as well as at least vessel filled with the liquid pharmaceutical product, whereby the vessel is insertable in the device and emptied in single doses by means of the device.

34. The refill unit according to claim 33, characterized in

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that a detaching element for the removal of an emptied vessel out of the device for emitting a given liquid amount in single doses is arranged within the refill unit.

35. The refill unit according to claim 33 or 34, characterized in that the refill unit comprises the number of single doses corresponding to a number of cannulas and/or sponges moistened with disinfectant.

36. The refill unit according to one of the claims 33 to 35, characterized in that the refill unit comprises a section that takes up the used cannulas.

37. The refill unit according to one of the claims 33 to 36, characterized in that the vessel filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule.

38. The refill unit according to claim 37, characterized in that the glass carpule is closed, at its bottom side, by a piercable membrane and, at its top side, by a plug being formed in that way that it is axially shiftable within the glass carpule in the direction of the piercable membrane when the liquid level is descending.

39. The refill unit according to claim 37 or 38, characterized in that the plug has, on its jacket surface, at least one, preferably two to five, disk-like, lip-tight sections radially directing to the outside, whereby these sections are deformable

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when the plug is inserted into the glass carpule with the formation of a sealing surface liquid-tightening the inner surface of the carpule.

40. The refill unit according to one of the claims 37 to 39, characterized in that the plug is axially shiftable within the glass carpule by a power being lower than 10 N, preferably by a power of between 4 N and 8 N.

41. The refill unit according to one of the claims 33 to 40, characterized in that the vessel is filled with am aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

42. The refill unit according to one of the claims 33 to 40, characterized in that the vessel is filled with a solution of a growth hormone, preferably an aqueous solution of a growth hormone.

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A SALE UNIT FOR THE PARENTERAL APPLICATION, A DECIVE FOR CARRYING OUT THE PARENTERAL APPLICATION AS WELL AS A REFILL UNIT FOR THE ABOVE MENTIONED SELL UNIT

Abstract

A sale unit for the parenteral application of liquid pharmaceutical products by the user is describes, whereby the unit comprises at least one cannula, a device to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel filled with the pharmaceutical product, the vessel being arranged within the device and emptied in single doses by means of the device, and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

FIG. 1

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A Sale Unit For The Parenteral Application, A Device For Carrying Out The Parenteral Application As Well As A Refill Unit For The Above Mentioned Sale Unit

The present invention is directed to a sale unit for the parenteral application of liquid pharmaceutical products, to a device for carrying out this parenteral application and to a refill unit for the afore mentioned sale unit, respectively device.

Parenterally applicable liquid pharmaceutical products, meaning such products that are subcutaneously applied by means of a syringe, nowadays are applied mainly by correspondingly trained professional staff, as for example by doctors or nursing staff. Hereby a usual syringe is used which is filled with the corresponding liquid pharmaceutical product before the parenteral application or which is filled already as a one-way syringe with the liquid pharmaceutical product. However, this means that the respective user has to submit himself to a medical treatment which involves high expenses particularly when, for the therapy of the respective disease, a given amount of a liquid pharmaceutical product has to be injected subcutaneously each day for a given limited time period.

The present invention has the object of elaborating a possibility by which the respective user can parenterally and preferably subcutaneously apply a liquid pharmaceutical product particularly easily.

According to the invention, this object is realised by a sale unit with the characteristics of patent claim 1, by a device with the characteristics of patent claim 11, as well as, if necessary, by a refill unit with the characteristics of patent claim 33 completing the sale unit according to patent claim 1, respectively the device according to patent claim 11.

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A SALE UNIT FOR THE PARENTERAL APPLICATION, A DEVICE FOR CARRYING OUT THE PARENTERAL APPLICATION AS WELL AS A REFILL UNIT FOR THE ABOVEMENTIONED SALE UNIT

Abstract

A sale unit for the parenteral application of liquid pharmaceutical products by the user is describes, whereby the unit comprises at least one cannula, a device to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel filled with the pharmaceutical product, the vessel being arranged within the device and emptied in single doses by means of the device, and whereby each single dose corresponds to the given liquid amount of the pharmaceutical product.

FIG. 1

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Patent claims

1. A sale unit for the parenteral application of liquid pharmaceutical products by the user, whereby the unit (1) comprises at least one cannula (2), a device (3) to emit a given liquid amount of the pharmaceutical product in single doses, as well as at least one vessel (8) filled with the pharmaceutical product, the vessel (8) being arranged within the device (3) and emptied in single doses by means of the device (3), whereby each single dose corresponds to the given liquid amount of the pharmaceutical product, and whereby said unit (1) contains a number of cannulas (2) corresponding to the number of single doses.

2. The sale unit according to claim 1, characterized in that the unit (1) comprises a number of sponges (5) being moistened with a disinfectant, whereby the number of sponges (5) corresponds to the number of cannulas (2).

3. The sale unit according to claim 1 or 2, characterized in that the unit (1) comprises a section (6) for taking up the used cannulas (2).

4. The sale unit according to one of the preceding claims, characterized in that the vessel (8) filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule (8).

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5. The sale unit according to claim 4, characterized in that the glass carpule (8) is closed, at its bottom side, by a piercable membrane (9) and, at its top side, by a plug (10) being formed in that way that it can be axially shifted within the glass carpule (8) in the direction of the piercable membrane (9) when the liquid level is descending.

6. The sale unit according to claim 4 or 5, characterized in that the plug (10) has, on its jacket surface, at least one, preferably two to five, disk-like sections radially directing to the outside, whereby these sections are deformed when the plug (10) is inserted into the glass carpule (8) with the formation of a sealing surface which liquid- or air-tightens the inner surface of the carpule (8).

7. The sale unit according to one of the claims 5 to 7, characterized in that the plug (10) is axially shifted within the glass carpule (8) by a power of less than 10 N, preferably by a power of between 4 N and 8 N.

8. The sale unit according to one of the preceding claims, characterized in that the vessel (8) is filled with an aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

9. The sale unit according to one of the preceding claims, characterized in that the vessel (8) is filled with a solution of a growth hormone, preferably an aqueous solution of a growth

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hormone.

10. A device for emitting a given liquid amount of a pharmaceutical product, whereby the device (3) for emitting a given liquid amount in single doses comprises a section (41) for taking up the vessel (8) being located within a casing (4) and being filled with the liquid pharmaceutical product, as well as an outlet section for the single dose of the pharmaceutical product, whereby the vessel (8) can be connected with the outlet section by an intermediate reservoir (13) in that way that, when the vessel (8) is set in, the given liquid amount of each single dose can firstly be drained from the vessel (8) into the intermediate reservoir (13) and then from the intermediate reservoir (13) into the outlet section, whereby the amount of the drained liquid is determined for each single dose by the volume of the intermediate reservoir (13) and whereby a vacuum is produced in the intermediate reservoir (13) for the transport of each single dose of the liquid pharmaceutical product from the vessel (8) into the intermediate reservoir (13).

11. The device according to claim 10, characterized in that a connecting conduct (14) is arranged between the inserted vessel (8) and the intermediate reservoir (13).

12. The device according to claim 11, characterized in that the connecting conduct (14) comprises a valve (15) which avoids a liquid backflow from the intermediate reservoir (13) into the vessel (8).

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13. The device according to one of the claims 10 to 12, characterized in that the intermediate reservoir (13) comprises a piston (16) for the transporting of each single dose of the liquid pharmaceutical product in the direction of the outlet section, whereby the piston (16) is located within the intermediate reservoir (13) and axially shiftable in the direction of the outlet section.

14. The device according to one of the claims 10 to 13, characterized in that the intermediate reservoir (13) is to fill with a single dose of the pharmaceutical product by an axial shifting of the piston (16) in the direction of the vessel (8).

15. The device according to claim 14, characterized in that, by axially shifting the piston (16), said vacuum is produced in the intermediate reservoir (13) for said transport of each single dose of the liquid pharmaceutical product from the vessel (8) into the intermediate reservoir (13).

16. The device according to claim 15, characterized in that the intermediate reservoir (13) is connected with the outlet section by a conduct (19) and that this conduct (19) can be air-tightened by a closing element (18).

17. The device according to claim 15 or 16, characterized in that the closing element (18) is formed as a detachable closing element located at the conduct (19) in that way that a sealing section (18 a) of the closing element (18) air-tightens the conduct outlet (19 a).

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18. The device according to one of the claims 13 to 16, characterized in that, by axially shifting the piston (16) within the intermediate reservoir (13) in the direction of the outlet section, the intermediate reservoir (13) is completely emptied.

19. The device according to one of the claims 10 to 18, characterized in that the intermediate reservoir (13) is formed in a cylindrical way and comprises a conically-shaped end section (13 a) following hereafter and directing to the outlet section, whereby the end section (13 a) is connected with the outlet section by the conduct (19), and that the piston (16) has a corresponding shape.

20. The device according to one of the claims 10 to 19, characterized in that the outlet section comprises a mounting section (21) for the detachable fixing of a cannula (2) in that way that the conduct (19) is connected with the cannula (2) in a fluid-tight way.

21. The device according to claim 16, 17 or 20, characterized in that a closing element (18) is fixed at the mounting section (21) in such a way that the conduct section (19 a) directing to the outside can be fluid-tightened by the closing element (18).

22. The device according to one of the claims 10 to 21, characterized in that the mounting section (21) comprises a protecting element (22) which covers at least a part of a cannula (2) being fixed at the mounting section (21).

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23. The device according to one of the claims 10 to 22, characterized in that a first cylinder (23) and a second cylinder (24) surrounding the first cylinder (23) are arranged within the casing (4), that the first cylinder (23) and the second cylinder (24) are shiftable axially relative to the casing (4), that the section (41) to take up the vessel (8) is situated within the first cylinder (23) and the intermediate reservoir (13) connected with the vessel (8) is located within the second cylinder (24), in such a way, that the first and the second cylinder (23; 24) are axially shiftable from a first position in which the cannula (2) being fixable to the mounting section (21) protrudes over the protecting element (22) and in which the intermediate reservoir (13) is emptied over the conduct (19) and the subsequent cannula (8), and a second position in which a cannula (2) being fixable to the mounting section (21) is covered by the protecting element (22) and in which the intermediate reservoir (13) is filled with the single dose, and vice-versa.

24. The device according to claim 23, characterized in that, by axially moving the first and the second cylinder (23; 24) relatively to the casing (4) from the first position into the second position, the intermediate reservoir (13) is filled with a single dose of the liquid pharmaceutical product.

25. The device according to claim 24, characterized in that the first and the second cylinder (23; 24) comprise each a spring (25; 26) in such a way that, in the second position of the cylinders (23; 24), the springs (25; 26) are tensioned and that, in the

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first position of the cylinders (23; 24), the springs (25; 26) are released.

26. The device according to one of the claims 23 to 25, characterized in that both cylinders (23; 24) are fixed in the second position by a locking element (29).

27. The device according to one of the claims 25 or 26, characterized in that the spring (26) of the second cylinder (24) has a steeper characteristic spring line than the spring (25) of the first cylinder (23).

28. The device according to one of the claims 10 to 22, characterized in that a first cylinder (23) and second cylinder (24) surrounding the first cylinder (23) are arranged within the casing (4), that the first cylinder (23) and the second cylinder (24) are shiftable axially relative to the casing (4), that the section (41) to take up the vessel (8) is situated within the first cylinder (23) and the intermediate reservoir (13) connected with the vessel (8) is located within the second cylinder (24), in such a way, that the first and the second cylinder (23; 24) are axially shiftable from a first position in which the cannula (2) being fixable to the mounting section (21) protrudes over the protecting element (22) and in which the intermediate reservoir (13) is emptied, into a second position in which the cannula (2) being fixable to the mounting section (21) is covered by the protecting element (22), and vice-versa, that for filling the intermediate reservoir (13), the first cylinder (23) is axially shiftable into a third position in the direction of the vessel (8)

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relatively to the second position of the second cylinder (24).

29. The device according to claim 28, characterized in that each cylinder (23; 24) contains a spring (25; 26), whereby a first spring (25) pre-tensions the position of the first cylinder (23) in the third position and a second spring (26) pre-tensions the position of the second cylinder (24) in the second position, and that the first cylinder (23) is fixable in the third position by a first locking (28) and the second cylinder (24) is fixable in the second position by a second locking (27).

30. The device according to claim 28 or 29, characterized in that, by operating a common release button (37), firstly the second locking (27) is released and then the first locking (28) is released in a corresponding time retardation.

31. The device according to one of the claims 10 to 30 for the use in a sale unit (1) according to one of the claims 1 to 9.

32. A refill unit for the use in the sale unit or the device according to one of the preceding claims, characterized in that the refill unit (100) comprises at least one cannula (2) as well as at least vessel (8) filled with the liquid pharmaceutical product, whereby the vessel (8) is insertable in the device (3) and emptied in single doses by means of the device (3).

33. The refill unit according to claim 32, characterized in that a detaching element (101) for the removal of an emptied vessel (8) out of the device (3) for emitting a given liquid amount in single

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doses is arranged within the refill unit (100).

34. The refill unit according to claim 32 or 33, characterized in that the refill unit (100) comprises the number of single doses corresponding to a number of cannulas (2) and/or sponges (5) moistened with disinfectant.

35. The refill unit according to one of the claims 32 to 34, characterized in that the refill unit (100) comprises a section (6) that takes up the used cannulas (2).

36. The refill unit according to one of the claims 32 to 35, characterized in that the vessel (8) filled with the liquid pharmaceutical product is a cylindrical or cylinder-like glass carpule (8).

37. The refill unit according to claim 36, characterized in that the glass carpule (8) is closed, at its bottom side, by a piercable membrane (9) and, at its top side, by a plug (10) being formed in that way that it is axially shiftable within the glass carpule (8) in the direction of the piercable membrane (9) when the liquid level is descending.

38. The refill unit according to claim 36 or 37, characterized in that the plug (10) has, on its jacket surface, at least one, preferably two to five, disk-like, lip-tight sections radially directing to the outside, whereby these sections are deformable when the plug (10) is inserted into the glass carpule (8) with the formation of a sealing surface liquid-tightening the inner surface

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of the carpule (8).

39. The refill unit according to one of the claims 36 to 38, characterized in that the plug (10) is axially shiftable within the glass carpule (8) by a power being lower than 10 N, preferably by a power of between 4 N and 8 N.

40. The refill unit according to one of the claims 32 to 39, characterized in that the vessel (8) is filled with an aqueous solution of a heparin, preferably with an aqueous solution of low-molecular heparin, and particularly with an aqueous solution of a enoxaparin-sodium.

41. The refill unit according to one of the claims 32 to 39, characterized in that the vessel (8) is filled with a solution of a growth hormone, preferably an aqueous solution of a growth hormone.

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