Description

The invention relates to a disposable hypodermic syringe comprising a berrel having a front open end and a rear open end, said barrel being adapted to receive a piston that is movable in the barrel in sealing relationship therewith, said piston being adapted for connection to a piston rod inserted through the rear open end of the barrel; a needle mount provided at the front open end of the barrel, said needle mount having a narrowed sleeve-like portion at an end remote from the barrel, said sleeve-like portion having an injection needle connected thereto; and a needle guard having a thickened open end that is detachably connected to the sleeve-like portion of the needle mount in a functionally clamping manner, thereby achieving a sterile sealing of the needle.

Such a syringe is disclosed in Netherlands Patent Application 7603511. In the syringe described in said Patent Application the open end of the needle guard is connected in a clamping manner to a part of the needle mount suitable for that purpose. Such a connection of the needle guard is more clearly shown in Netherlands Patent Application 7401607. The part of the needle mount remote from the injection needle is connected to the barrel, for example by means of riveting or shrinking. At its other end the needle mount is narrowed to a sleeve-like part so that an injection needle can be connected in it. The needle guard provided over the injection needle has a thickened open end which is connected to the sleeve-like part of the needle mount in a clamping manner. As a result of this, a sterile sealing for the needle is obtained. Of course, the sterility of the injection needle is an essential condition for using the syringe.

The syringe known from the above-mentioned Netherlands Patent Application 7603511 has the disadvantage that the user cannot satisfactorily control possibility of the sterility of the needle. Specifically the user cannot ascertain whether the needle guard has already been removed previously or, for example, has come loose during transport and has subsequently been replaced in its original position. In other words, the user is not sure of the sterility of the injection needle.

More in particular the invention relates to a disposable hypodermic syringe comprising in addition a sealing member adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe. In this way the above disadvantage can be eliminated. Such a sealing member or safety member has been described in the above-mentioned Netherlands Patent Application 7401607. The safety member described in this Patent Application is a cap having a central bore which is slid around the needle guard up to the thickened end thereof, and which has breakable elements with which it is connected to the syringe in a detachable but irreversible manner. The user of the syringe can establish at a glance by means of said cap whether the needle guard has previously been removed.

The above-mentioned safety member gives excellent satisfaction in a syringe comprising an ampoule holder or cartridge holder; such a syringe is disclosed in the above Netherlands patent Application 7401607. The plastic cap can simply be connected to the plastic cartridge holder in a few points, for example, by spot-welding. However, when such a cartridge holder — which is quite an expensive component for a disposable syringe — is lacking, as in the syringe described in the above mentioned Netherlands Patent Application 7603511, the connection of the safety cap to the needle holder which usually is manufactured from aluminium is substantially impossible, in particular because high requirements have to be imposed upon this connection. In fact, on the one hand the connection elements between safety cap and needle mount must not come loose during storage and transport, but on the other hand it must be possible by a very simple operation, for example a simple rotating movement, to remove the safety member for use of the injection syringe.

In addition to the disadvantage that the above-mentioned safety cap is hardly suitable for use in a syringe not having a cartridge holder, the cap has additional disadvantages. A disposable syringe should be cheap and hence of a simple construction. A safety cap as described above is a comparatively expensive solution to the problem in question.

Another important disadvantage is the extra operation which has to be carried out to remove the cap for use of the syringe.

It is the object of the inventors to develop a sealing member or safety member for a syringe which does not exhibit the above-mentioned disadvantages. For that purpose, they have developed a disposable hypodermic syringe designed to allow a user of the syringe to easily and accurately determine if the sterility of the syringe has been compromised, said syringe comprising: a barrel having a front open end and a rear open end, said barrel being adapted to receive a piston that is movable in the barrel in sealing relationship herewith said piston being adapted for connection to a piston rod inserted through the rear open end of the barrel; a needle mount provided at the front open end of the barrel, said needle mount having a narrowed sleeve-like portion at an end remote from the barrel, said sleeve-like portion having an injection needle connected thereto; a needle guard having a thickened open end that is detachably connected to the sleeve-like portion of the needle mount in a functionally clamping manner, thereby achieving a sterile sealing of the needle; and a sealing member adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe; which syringe is characterized in that said sealing member comprises a sleeve of shrinkable plastic

sheet disposed around the connection between the needle mount and the needle guard, said sleeve having a first end shrunk around a part of the needle guard adjoining the connection to the needle mount and a second end shrunk around the needle mount and optionally also around the barrel or a front part of the barrel.

Such a sleeve of shrinkable sheet provides a cheap solution to the problem in question, because it provides an assurance that the needle guard has not been removed. The sleeve can easily be shrunk around said connection between the needle mount and the needle guard, irrespective of the material of which these components of the syringe are constructed. Moreover, no extra operation is necessary to break the seal, because simultaneously with the removal of the needle guard the sleeve detaches from said needle guard or breaks apart. The remaining part of the sleeve, if any, shrunk around the needle guard is then removed simultaneously with the needle guard. Said needle mount is described in the above Netherlands Patent Application 7603511 and may be manufactared from metal or plastic material. Alternatively said needle guard forms an integral part of the barrel and consequently is made from the same material as the barrel, preferably from glass. In the latter case the barrel in the area of the needle connection is narrowed to a sleeve-like part wherein the needle is attached, e.g. by luting.

Shrinkable sheet is now frequently used, in particular in the pharmaceutical and food industries, for example, for the so-called "tamper-proof" sealing of bottles. Examples of shrinkable capsules for bottles are to be found in United States Patent Specification 3,746,201 and German Patent Application 2,057,901. The capsules described in these Patent Publications comprise a pull-off lug and strip by means of which the capsule can be removed from the bottle. Such a pull-off lug would be less suitable for the sealing sleeve for the syringe of the application because again an extra operation would be necessary to remove the sleeve. Moreover, a pull-off lug for a sealing sleeve of a syringe would become too small for ready grasping; as a matter of fact, the size of the sleeve — and hence the dimensions of the pull-off lug — should be adapted to the article to be sealed. United States Patent Specification 3,101,841 relates to a two-part package for an injection needle, namely a holder and a cap. The cap can be connected to the holder by heating the lower edge and then clamping it around the holder by an inwardly directed force. The disadvantage of the sterile packaging while heating of an injection needle is that the whole operation, including the local heating of the package parts to be connected together, would have to take place in a sterile room. In contrast, a needle guard in accordance with the present invention, for example, in the form of a sheath which can simply be slid onto the needle, is an example of a very handy component of a disposable syringe which can be assembled in a sterile room.

The sleeve of shrinkable sheet utilized to seal the needle guard of the syringe according to the invention is made of a known synthetic resin sheet, for example, a monoaxially prestretched sheet of hard PVC.

In U.S. Patent Specification 3,485,239 an injection syringe provided with a gas permeable paper wrap sealably connecting the needle cap and the barrel is disclosed. The purpose of this paper wrap is different from that of the sealing member for the needle guard of the present invention. The paper wrap serves to secure the cap to the barrel in such a manner that the assembled unit can be sterilized. Therefore, the band is of a special material allowing the entry of sterilizing gases during sterilization but maintaining the contents of the syringe after sterilization in a sterilized condition. In addition to the different material, this known sealing band does not provide a good indication of breakage of the seal, such an indication being a prerequisite for the sealing member for the needle guard of the invention.

The sleeve is provided as follows. A sleeve of a suitable shrinkable sheet, having a diameter which is slightly larger than that of the components to be sealed, is slid on the front onto the desired portion of the syringe provided with a needle guard. The sleeve is then shrunk around the components to be sealed by heating, for example by means of hot air or infra-red radiation. The temperature at which the shrinkable sheet can shrink is usually above approximately 80°C. It is not desired to heat the syringe during shrinkage at too high a temperature for too long a period of time, because this may be detrimental to the medicament to be injected and because the stress in the barrel would become too great. It is therefore preferred during shrinking to use a temperature of approximately 90°C and a shrinkage period which is as short as possible. In order to keep the shrinkage time as short as possible, the sealing is preferably carried out automatically.

A good indication of seal breakage is extraordinarily important. In fact, it is the object of the seal to provide an indication for the user whether the needle guard has previously been removed. The location where the sleeve is shrunk around the components to be sealed is of great importance for a good indication of seal breakage. The sleeve may be unperforated or perforated. When an unperforated sleeve is used said first end thereof, which is shrunk around a part of the needle guard adjoining the connection to the needle mount, forms a cylinder having a diameter which remains the same throughout the area were the needle guard is connected to the needle mount, whereas said second end thereof, which is shrunk around the needle mount and optionally also around the barrel or a front part of the barrel, forms a radially inwardly directed collar behind a thickened portion of the needle mount. When the needle guard is removed, the end of the sleeve which is shrunk around the open end of the needle guard will come loose from the needle guard, after which it will become substantially impossible to put the

needle guard back again in its original location, since the now open end of the sleeve remaining on the needle mount will in fact prevent the reconnection of the needle guard to the needle mount.

Although an unperforated sleeve can contribute to the maintenance of the sterility of the syringe, a sleeve of shrinkable sheet comprising a circumferential perforation is nevertheless to be preferred. When the needle guard is removed, the sleeve will break apart on said perforation. In contrast to an unperforated sleeve, the force which has to be applied to break the seal can be adjusted at will by adjusting the degree of perforation of the circumferential perforation in the sleeve.

Furthermore, in an unperforated sleeve it is more difficult to combine a sufficiently rigid seal of the needle guard with a good indication of seal breakage. In a sleeve of shrinkable sheet having a circumferential perforation, the location of the perforation can be determined at will without this influencing the firmness of the seal of the needle guard. Finally, after breaking the seal, the sleeve does not form an obstruction for the use of the syringe, that is to say, when administering an injection. This use without obstruction is achieved with greater difficulty in an unperforated sleeve because the sleeve after removal of the needle guard is still intact.

Of course, in a sleeve having a circumferential perforation, the indication of seal breakage is also of the utmost importance. Therefore, said perforation of the sleeve shrunk around the syringe is located around a portion of the needle guard adjoining the needle mount at a point a short distance from the thickened open end of the needle guard. This distance between the perforation and the end of the needle guard is not critical and, dependent on the length of the sleeve of shrinkable sheet, usually is between 1 and 10 mm. If this distance is any greater the fragment of the sleeve remaining on the needle mount may form an obstruction when administering an injection. When using a needle mount as described in the above-mentioned Netherlands Patent Application 7401607 and 7603511, a sleeve of shrinkable sheet having a length of approximately 2 cm is preferably used and is shrunk around the syringe in such manner that the perforation is present at a point approximately 2 mm from the end of the needle guard. When the needle guard has been removed, it has now become substantially impossible to return it to its original location because the broken portion of the sleeve, which has remained on the needle mount, prevents the reconnection of the needle guard to the needle mount.

When the syringe according to the invention is used, the needle guard should be removed by rotating it relative to the barrel and then exerting a force directed away from the barrel on the needle guard. In the first movement, the rotating movement, the seal must also be broken. It will be obvious that the force which is necessary to detach the needle guard from the needle connection or the front end of the barrel is increased by the seal. When the user of the syringe has to apply too large a force to remove the needle guard, the possibility exists that the needle will be bent or broken. It is therefore important for the breaking of the perforation to take place without much effort. It has been found that the seal, when the sealing member used is a sleeve having a circumferential perforation, can be easily broken when the degree of perforation of the sleeve of shrinkable sheet is at least 50%, preferably 60—75%.

Of course the invention also relates to a prefilled syringe, i.e. a syringe in which the barrel is filled with an injection liquid, which is locked in a sealing manner by the piston at the rear side of the barrel.

The invention also relates to a multi-chamber syringe, wherein more than one injection liquid are or can be stored separately from each other, e.g. by stoppers.

The invention will now be described in greater detail with reference to the drawing. In the drawing,

Figure 1 is longitudinal sectional view of an embodiment of a syringe according to the invention prior to use of the syringe;

Figure 2 shows the essential part of the longitudinal sectional view of the syringe shown in Figure 1;

Figure 3 is a longitudinal sectional view of the same part of the syringe as shown in Figure 2, but while the needle guard is removed; and

Figure 4 is a longitudinal sectional view of another embodiment of a syringe according to the invention.

Reference sign 11 in Figure 1 denotes a glass barrel which communicates with an injection needle 12. A breakable seal, not visible in the drawing, in the form of a diaphragm or a stopper is present between the barrel and the needle cannula. The injection needle is connected to the barrel by means of the needle mount 14. The needle is surrounded by a needle guard 13 which is connected to the neck of the needle mount by means of the thickened open end 23. The injection liquid present in the barrel is bounded on the lower side by a piston 15 which can be moved by a piston rod 16. The barrel furthermore comprises on its outside a finger grip 17. As is also shown in Figure 2, a sleeve 18 of PVC shrinkable sheet having a perforation 19 is shrunk around the needle mount and around the thickened open end of the needle guard. Said perforation is present at the area of the thickened part of the needle guard, at a point approximately 2 mm in distance from the open end 21 of the needle guard.

Figure 3 shows the syringe during the instant at which the needle guard is removed to enable use of the syringe. At that instant during which the rotating movement of the needle guard relative to the barrel has already taken place and the perforation has then also been broken, the needle guard is removed from the injection needle. It will be

obvious from Figure 3 that it has now become substantially impossible to place the needle guard back to its original position because the broken portion 20 of the sleeve prevents this return.

In the embodiment shown in Figure 4, the sleeve 22 of PVC shrinkable sheet has an elongated portion remote from the injection needle, that is shrunk around the main part of the barrel. Thus the barrel is almost completely — apart from the fingertip connection — tightly enwrapped by the sleeve, so that the sleeve also serves as a protection against breakage of the glass barrel.

Claims

1. A disposable hypodermic syringe designed to allow a user of the syringe to easily and accurately determine if the sterility of the syringe has been compromised, said syringe comprising:

a barrel (11) having a front open end and a rear open end, said barrel being adapted to receive a piston (15) that is movable in the barrel in sealing relationship therewith, said piston being adapted for connection to a piston rod (16) inserted through the rear open end of the barrel;

a needle mount (14) provided at the front open end of the barrel, said needle mount having a narrowed sleeve-like portion at an end remote from the barrel, said sleeve-like portion having an injection needle (18) connected thereto;

a needle guard (13) having a thickened open end (21) that is detachably connected to the sleeve-like portion of the needle mount in a functionally clamping manner, thereby achieving a sterile sealing of the needle; and a sealing member (18, 22) adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe, characterized in that said sealing member (18, 22) adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe, characterized in that said sealing member (18, 22) comprises a sleeve of shrinkable plastics sheet disposed around the connection between the needle mount (14) and the needle guard (13), said sleeve being unperforated and having a first end shrunk around a part (23) of the needle guard adjoining the connection to the needle mount, said first end forming a cylinder having a diameter which remains the same throughout the area where the needle guard is connected to the needle mount, and a second end shrunk around the needle mount and optionally also around the barrel (11) or a front part of the barrel, said second end forming a radially inwardly directed collar behind a thickened portion of the needle mount, the arrangement being such that, when the needle guard is removed, the end of the sleeve, which is shrunk around the open end of the needle guard, comes loose therefrom, whereby the open end of the sleeve remaining on the needle mount will prevent the reconnection of the needle guard to the needle mount.

2. A disposable hypodermic syringe designed to allow a user of the syringe to easily and accurately determine if the sterility of the syringe has been compromised, said syringe comprising:

a barrel (11) having a front open end and a rear open end, said barrel being adapted to receive a piston (15) that is movable in the barrel in sealing relationship therewith, said piston being adapted for connection to a piston rod (16) inserted through the rear open end of the barrel;

a needle mount (14) provided at the front open end of the barrel, said needle mount having a narrowed sleeve-like portion at an end remote from the barrel, said sleeve-like portion having an injection needle (12) connected thereto;

a needle guard (13) having a thickened open end (21) that is detachably connected to the sleeve-like portion of the needle mount in a functionally clamping manner, thereby achieving a sterile sealing of the needle; and a sealing member (18, 22) adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe, characterized in that said sealing member (18, 22) comprises a sleeve of shrinkable plastics sheet disposed around the connection between the needle mount (14) and the needle guard (13), said sleeve having a first end shrunk around a part (23) of the needle guard adjoining the connection to the needle mount and a second end shrunk around the needle mount and optionally also around the barrel (11) or a front part of the barrel, said second end forming a radically inwardly directed collar behind a thickened portion of the needle mount, the arrangement being such that, when the needle guard is removed, the end of the sleeve, which is shrunk around the open end of the needle guard, comes loose therefrom, whereby the open end of the sleeve remaining on the needle mount will prevent the reconnection of the needle guard to the needle mount and said sleeve further including a circumferential perforation (19), said perforation being located around a portion of the needle guard adjoining the needle mount at a point a short distance from the thickened open end of the needle guard.

3. A syringe as claimed in Claim 2, characterized in that the degree of perforation in the circumferential perforation (19) of the sleeve is at least 50 percent, preferably from 60 to 75 percent.

Patentansprüche

1. Wegwerfbare Injektionsspritze, die ausgebildet ist, um einem Benutzer der Spritze zu ermöglichen, leicht und fehlerfrei festzustellen, ob die Sterilität der Spritze gefährdet worden ist, welche Spritze

ein Rohr (11) mit einem offenen vorderen Ende und einem offenen hinteren Ende, welches Rohr geeignet ist, einen Kolben (15) aufzunehmen, der

obvious from Figure 3 that it has now become substantially impossible to place the needle guard back to its original position because the broken portion 20 of the sleeve prevents this return.

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a barrel (11) having a front open end and a rear open end, said barrel being adapted to receive a piston (15) that is movable in the barrel in sealing relationship therewith, said piston being adapted for connection to a piston rod (16) inserted through the rear open end of the barrel;

a needle mount (14) provided at the front open end of the barrel, said needle mount having a narrowed sleeve-like portion at an end remote from the barrel, said sleeve-like portion having an injection needle (18) connected thereto;

a needle guard (13) having a thickened open end (21) that is detachably connected to the sleeve-like portion of the needle mount in a functionally clamping manner, thereby achieving a sterile sealing of the needle; and a sealing member (18, 22) adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe, characterized in that said sealing member (18, 22) adapted to seal the connection between the needle mount and the needle guard in a manner such that breakage of the seal is easily and accurately detectable by a user of the syringe, characterized in that said sealing member (18, 22) comprises a sleeve of shrinkable plastics sheet disposed around the connection between the needle mount (14) and the needle guard (13), said sleeve being unperforated and having a first end shrunk around a part (23) of the needle guard adjoining the connection to the needle mount, said first end forming a cylinder having a diameter which remains the same throughout the area where the needle guard is connected to the needle mount, and a second end shrunk around the needle mount and optionally also around the barrel (11) or a front part of the barrel, said second end forming a radially inwardly directed collar behind a thickened portion of the needle mount, the arrangement being such that, when the needle guard is removed, the end of the sleeve, which is shrunk around the open end of the needle guard, comes loose therefrom, whereby the open end of the sleeve remaining on the needle mount will prevent the reconnection of the needle guard to the needle mount.

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3. A syringe as claimed in Claim 2, characterized in that the degree of perforation in the circumferential perforation (19) of the sleeve is at least 50 percent, preferably from 60 to 75 percent.

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ein Rohr (11) mit einem offenen vorderen Ende und einem offenen hinteren Ende, welches Rohr geeignet ist, einen Kolben (15) aufzunehmen, der

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im Rohr abgedichtet bewegbar ist, wobei der Kolben zur Verbindung mit einer Kolbenstange (16) geeignet ist, die durch das offene hintere Ende des Rohres eingesetzt wird;

eine Nadelhalterung (14), die am offenen vorderen Ende des Rohres vorgesehen ist, welche Nadelhalterung einen verengten hülsenartigen Teil am vom Rohr abgelegenen Ende aufweist, mit welchem, hülsenartigen Teil eine Injektionsnadel (12) verbunden ist;

einen Nadelschutz (13) mit einem verdickten offenen Ende (21), das lösbar mit dem hülsenartigen Teil der Nadelhalterung in einer funktionellen Klemmart verbunden ist, wodurch eine sterile Abdichtung der Injektionsnadel erreicht wird; und ein zum derartigen Abdichten er Verbindung zwischen der Nadelhalterung und dem Nadelschutz geeignetes Dichtglied (18, 22) aufweist, daß ein Bruch der Dichtung leicht und fehlerfrei von einem Benutzer der Spritze feststellbar ist, dadurch gekennzeichnet, daß das Dichtglied (18, 22) eine Manschette aus einer schrumpffähigen Kunststoffoilie aufweist, die rund um die Verbindung zwischen der Nadelhalterung (14) und dem Nadelschutz (13) angeordnet ist, welche Manschette unperforiert ist und mit einem ersten Ende rund um einen Teil (23) des Nadelschutzes benachbart der Verbindung mit der Nadelhalterung aufgeschrumpft ist, wobei das erste Ende einen Zylinder mit einem Durchmesser bildet, der über den gesamten Bereich, wo der Nadelschutz mit der Nadelhalterung verbunden ist, gleichbleibt, und mit einem zweiten Ende rund um die Nadelhalterung und Vorzugsweise auch rund um das Rohr (11) oder einem vorderen Teil des Rohres aufgeschrumpft ist, wobei das zweite Ende einem radial einwärts gerichteten Kragen hinter einem verdickten Teil der Nadelhalterung bildet, wobei die Anordnung derart ist, daß sich bei Entfernen des Nadelschutzes das rund um das offene Ende des Nadelschutzes aufgeschrumpfte Ende der Manschette davon löst, wodurch das offene Ende der Manschette, die an der Nadelhalterung bleibt, die Wiederverbindung des Nadelschutzes mit der Nadelhalterung verhindert.

2. Wegwerfbare Injektionsspritze, die ausgebildet ist, um einem Benutzer der Spritze zu ermöglichen, leicht und fehlerfrei festzustellen, ob die Sterilität der Spritze gefärdet worden ist, welche Spritze

ein Rohr (11) mit einem offenen vorderen Ende und einem offenen hinteren Ende, welches Rohr geeignet ist, einen Kolben (15) aufzunehmen, der im Rohr abgedichtet bewegbar ist, wobei der Kolben zur Verbindung mit einer Kolbenstange (16) geeignet ist, die durch das offene hintere Ende des Rohres eingesetzt wird;

eine Nadelhalterung (14), die am offenen vorderen Ende des Rohres vorgesehen ist, welche Nadelhalterung einen verengten hülsenartigen Teil am vom Rohr abgelegenen Ende aufweist, mit welchem, hülsenartigen Teil eine Injektionsnadel (12) verbunden ist;

einen Nadelschutz (13) mit einem verdickten offenen Ende (21), das lösbar mit dem hülsenartigen Teil der Nadelhalterung in einer funktionellen Klemmart verbunden ist, wodurch eine sterile Abdichtung der Injektionsnadel erreicht wird; und ein zum derartigen Abdichten er Verbindung zwischen der Nadelhalterung und dem Nadelschutz geeignetes Dichtglied (18, 22) aufweist, daß ein Bruch der Dichtung leicht und fehlerfrei von einem Benutzer der Spritze feststellbar ist, dadurch gekennzeichnet, daß das Dichtglied (18, 22) eine Manschette aus einer schrumpffähigen Kunststoffolie aufweist, die rund um die Verbindung zwischen der Nadelhalterung (14) und dem Nadelschutz (13) angeordnet ist, welche Manschette mit einem ersten Ende rund um einen Teil (23) des Nadelschutzes benachbart der Verbindung mit der Nadelhalterung und mit einem zweiten Ende rund um die Nadelhalterung und vorzugsweise auch um das Rohr (11) oder einen vorderen Teil des Rohres aufgeschrumpft ist, wobei das zweite Ende einen radial einwärts gerichteten Kragen hinter einem verdickten Teil der Nadelhalterung bildet, wobei die Anordnung derart ist, daß sich bei Entfernen des Nadelschutzes das rund um das offene Ende des Nadelschutzes aufgeschrumpfte Ende der Manschette davon löst, wodurch das offene Ende der Manschette, die an der Nadelhalterung bleibt, die Wiederverbindung des Nadelschutzes mit der Nadelhalterung verhindert, und die Manschette ferner eine Umfangsperforation (19) enthält, die rund um einen Teil des Nadelschutzes benachbart der Nadelhalterung an einer Stelle in kurzem Abstand vom verdickten offenen Ende des Nadelschtzes angeordnet ist.

3. Spritze nach Anspruch 2, dadurch gekennzeichnet, daß das Ausmaß der Perforation in der Umfangsperforation (19) der Manschette zumindest 50%, vorzugsweise 60 bis 75%, beträgt.

Revendications

1. Seringue hypodermique à usage conçue pour permettre à l'utilisateur de la seringue de déterminer facilement et avec précision si la sterilité de la seringue a été compromise, ladite seringue comprenant:

un corps (11) présentant une extrémité ouverte avant et une extrémité ouverte arrière, ledit corps étant adapté pour recevoir un piston (15) mobile dans le corps en relation d'étanchéité avec celuici, ledit piston étant adapté pour être relié à une tige de piston (16) introduite par l'extrémité ouverte arrière du corps;

une embase (14) prévue à l'extrémité ouverte avant du corps, ladite embase comportant une partie rétrécie formant manchon à une extrémité distante du corps, ce tronçon formant cône à laquelle une aiguille d'injection (12) est fixée;

un manchon (13) présentant une extrémité ouverte renforcée (21) reliée de façon amovible à la partie en forme de cône de l'embase de manière à provoquer un serrage fonctionnel en assurant par là le scellement stérile de l'aiguille; et

un organe d'étanchéité (18, 22) propre à sceller

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le raccordement entre l'embase et la manchon de telle manière que la rupture du joint soit détectable aisément et avec précision par l'utilisateur de la seringue;

caractérisée en ce que ledit organe d'étanchéité (18, 22) comprend une bague en feuille de plastique rétractable disposée autour du raccordement entre l'embase (14) et le manchon (13), ladite bague étant non perforée et présentant une première extrémité rétreinte autour d'une partie (23) du manchon contiguë au raccordement de l'embase, cette première extrémité formant un cylindre dont de diamètre reste le même sur toute la zone où le manchon est raccordé à l'embase, et une seconde extrémité rétreinte autour de l'embase et facultativement aussi autour du corps (11) ou d'une partie avant du corps, ladite seconde extrémité constituant un collet dirigé vers l'intérieur derrière une partie renforcée de l'embase, l'agencement étant tel que, quand on retire l'embase, l'extrémité de la bague, qui est rétreinte autour de l'extrémité ouverte du manchon, se détache de celui-ci, de sorte que l'extrémité ouverte de la bague subsistant sur le manchon empêche de raccorder à nouveau le manchon à l'embase.

2. Seringue hypodermique à usage unique conçue de manière à permettre à l'utilisateur de la seringue de déterminer aisément et avec précision si la sterilité de la seringue n'a pas été compromise, ladite seringue comprenant:

un corps (11) présentant une extrémité ouverte avant et une extrémité ouverte arrière, ce corps étant adapté pour recevoir un piston (15) mobile dans le corps en relation d'étanchéité avec celui-ci, ledit piston étant adapté pour être relié à une tige de piston (16) introduite par l'extrémité ouverte arrière du corps;

une embase (14) prévue à l'extrémité ouverte avant du corps, cette embase comportant une partie rétrécie formant bague à une extrémité distante du corps, cette partie formant bague portant une aiguille d'injection (12) reliée à cell-ci.

un manchon (13) présentant une extrémité ouverte renforcée (21) reliée de manière amovible à la partie formant bague de l'embase de manière à créer un serrage fonctionnel, assurant par là le scellement stérile de l'aiguille; et

un organe d'étanchéité (18, 22) propre à sceller le raccordement entre l'embase et le manchon de telle manière que la rupture du joint soit décelable aisément et avec précision par l'utilisateur de la seringue;

caractérisée en ce que ledit organe d'étanchéité (18, 22) comprend une bague en feuille de plastique rétractable disposé autour de la jonction entre l'embase (14) et le manchon (13), ladire bague comportant une première extrémité rétreinte autour d'une partie (23) du manchon contiguë au raccordement avec l'embase et une seconde extrémité rétreinte autour de l'embase et facultativement aussi autour du corps (11) ou d'une partie avant du corps, cette seconde extrémité constituant un collet dirigé radialement vers l'intérieur derrière une partie renforcée de l'embase, l'agencement étant tel que, lorsqu'on retire le manchon, l'extrémité de la bague, rétreinte autour de l'extrémité ouverte du manchon, se détache de celle-ci, de sorte que l'extrémité ouverte de la bague restant sur l'embase empêche de relier à nouveau le manchon à l'embase et ladite bague présentant encore une perforation périphérique (19), cette perforation étant située autour d'une partie du manchon contiguë à l'embase en un point peu éloigné de l'extrémité ouverte renforcée du manchon.

3. Seringue selon la revendication 2, caractérisée en ce que l'importance de la perforation périphérique (19) de la bague est d'au moins 50%, de préférence de 60 à 75%.

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