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"SYRINGE OR LIKE PARENTERAL DEVICE"

THIS INVENTION relates to a syringe or like parenteral device.

Throughout this specification the term "syringe or like device" shall be taken to include any device which can be used for the conveyance of parenteral fluids which are to be introduced into or drawn from the body through the skin and shall include within its scope a syringe, a cannula, a hypodermic needle, an intravenous infusion line, and like devices.

A primary characteristic of parenteral devices is the provision of a sharp hollow needle to facilitate the transfer of fluids to or from the body. The difficulty created by the presence of such a needle arises from the possibility of injury which may be caused to a user or to medical staff when using the device, or indeed to any person who may be required to handle the device before or after use.

Of course, the injury itself does not represent the major concern. The major concern arising from the dangers of infection from such injuries is due to the pathogens which may be present on the needle as a result of its use. Indeed, it has been proven that a number of viral infections, notably the HIV virus and hepatitis B, can be transmitted by the reuse of needles previously used to inject an infected individual.

These dangers have resulted in the development of very careful and sometimes detailed disposal procedures being adopted in institutions where such parenteral devices are used. It has also resulted in attempts being made at developing single use parenteral devices that are not capable of being reused.

However, the disposal procedures adopted by such institutions are not able to be enforced in out-of-clinic situations, such as those situations where individuals inject recreational drugs. Further, the users of recreational drugs are often capable of quite easily manipulating a so called "one use" syringe to be able to continue using that same syringe.

It is an object of the present invention to provide an improved parenteral device wherein operation of the device in performing an injection alters the configuration of the device such that the device becomes extremely difficult to refill and also to reuse. A further object is to provide a parenteral device having a needle that retracts so as not to be exposed after use.

The present invention provides a syringe or like device comprising a tubular body having a forward end and a rearward end, the forward end being capable of receiving a hollow needle therein so as to be able to project therefrom, the retractable needle being slidable relative to the body, the body also including a chamber capable of receiving parenteral fluid and capable of being reduced in volume to expel fluid contained therein, wherein; the needle is capable of being manually retracted within the body by a retracting means such that the chamber reduces in volume to expel fluid contained therein and such that the needle is retracted to be wholly contained within the body; the needle is supported at one end from the body by a plug, the plug being configured to be sealingly engaged with the internal walls of the body and to be slidable within the body; the chamber is located rearwardly of the plug and the plug is adapted to enable the needle to communicate with the chamber through the plug; a stop is provided in the

body rearward of the plug to define the rear end of the chamber, the stop means being slidable relative to the body and being in sealing engagement with the internal walls of the body, whereby a greater degree of force is required to move the stop than to move the plug; the rearward end of the body slidably supporting a slider for axial slidable movement, a protrusion on said slider for manipulation thereof to effect said axial movement, wherein said retracting means comprises a flexible member, secured at one end to the plug secured at its other end to the slider and slidably and sealingly received through the stop.

By holding the forward end of the body of the syringe closely adjacent the skin of the user, the needle may continue to be retracted into the body of the device during injection such that the sharp end of the needle is not caused to be exposed whatsoever between insertion of the needle into the body and completion of the injection.

When using the parenteral device of this invention it thus becomes important to use the device accurately to ensure that the dose is delivered subcutaneously. Thus, the initial retracting of the needle causes the volume of the chamber to reduce so as to expel the fluid therefrom, to a point where the plug abuts the stop means. Further retraction of the needle then causes the rearward movement of both the plug and the stop means to allow the needle to be fully withdrawn into the body. A greater degree of force is required to move the stop means than to expel the fluid.

The present invention provides an improved parenteral device that allows for the complete retraction of its needle during use within the body thereof. The lack of any externally operable rigid elements which are rigidly

connected to the needle and that may allow the re-extension of the needle assists in causing the device to be primarily a one use device. The construction of the device is simple and cheap and allows for relatively easily filling with minimal complexity. Further, it is expected that as the injection of parenteral fluid and withdrawal of the needle occurs simultaneously, there may be the additional beneficial effect of depositing the parenteral fluid throughout the deeper part of the needle track. This is expected to provide an advantage in reducing the pain which may be caused in conventional syringes by the distension of tissues at the single point of injection and more rapid absorption of the fluid.

It will also be appreciated that the dimensions and extent of travel of the needle and plug may be optimised for expelling a parenteral fluid into any body cavity. In particular, the needle may be inserted into a vein and retracted along the lumen of the vein as the parenteral fluid is expelled, the chamber being completely emptied before the needle is retracted out of the vein.

According to a preferred feature of the invention, the stop when defining the rearward end of the chamber is sealingly and slidably received in the body and on completion of the movement of the plug to the minimum volume position of the chamber, the stop is movable with the plug whereby the stop will be accommodated in a non sealing manner in the rearward end. The sealing engagement can be effected by forming the rearward end of the body with a greater internal diameter than the remainder of the body. Alternatively the cross-sectional configuration of the rearward end may be formed with a portion having a greater transverse dimension than the diameter of the remainder of the body. This can be achieved by formation of a

longitudinal groove in the internal wall of rearward end of the body. In addition, if desired the plug when at its rearmost position is non sealingly engaged in the rearward end of the body. As a further alternative the rearward end of the body can have a different cross-sectional configuration to that of the body. For example, the body may be of circular cross-section and the rearward end may be of square or eliptical cross-section.

According to a further alternative preferred feature of the invention the protrusion comprises an axially directed shaft which can take the same form as the handle of a plunger of a conventional syringe. Alternatively the external protrusion may comprise a radially directed protrusion extending laterally from the side wall of the rearward end.

According to a further preferred feature of the invention, a protrusion is provided on the interior of the body which is engaged by the sealing surface of the stop and/or the plug on joint rearward movement of the stop and plug to cause damage to the sealing surface. As an alternative feature, the protrusion may pierce the stop and/or plug on joint rearward movement of the stop and plug to destroy the sealing integrity of the stop and/or plug.

According to a further preferred feature of the invention, free end of the needle is received in a nipple-like element which is provided at the forward most end of the body and whereby manual withdrawal of the nipple-like element away for the body will cause extension of the needle within said body, whereby the nipple-like element is capable of being removed from the needle. A further feature of the feature, the nipple-like element is provided with a port which is engagable with a receptacle of a parenteral agent such as an ampoule and the opening in the free end of the needle opens into the port.

According to a further preferred feature of the invention, a resilient means is provided between the body and the plug and is associated with a trigger means whereby when the needle is in the extended position the resilient means is maintained in a stressed state and on release of the trigger mechanism the resilient means is able to move to an unstressed state and cause movement of the needle, plug and stop to the fully retracted position.

The present invention will now be described in relation to the accompanying drawings. However, it is to be appreciated that the following description is not to limit the generality of the above description.

In the drawings:

Figure 1 is a sectional view of a parenteral device according to a first embodiment of the present invention with the chamber filled;

Figure 2 is a sectional view of the embodiment of Figure 1 during injection;

Figure 3 is a sectional view of the embodiment of Figure 1 after the chamber has been emptied;

Figure 4 is a sectional elevation of the embodiment of Figure 1 ready for disposal;

Figure 5 is a sectional view of the embodiment of Figure 1 prior to filling; and

Figure 6 is a sectional view of the embodiment of Figure 1 at the conclusion of filling.

Figure 1 illustrates a parenteral device 10 having a body 12 in the form of a substantially tubular barrel 11 which provides a sealed chamber 14 between a plug 16 and a stop 18. A sharpened tubular needle 20 is firmly fixed to the plug 16 and passes through it so as to provide fluid communication within the hollow interior of the needle 20 between the chamber 14 and the open end 22 of the needle 20. The needle 20 passes through an opening 24 in the forward end 26 of the body 12.

The body 12 further comprises an axial extension 34 which is of tubular configuration and is coaxial with the tubular barrel 12 but is of greater diameter to provide a step 36 at the junction between the tubular barrel and the axial extension. The stop 18 when in its normal position bridges the step 36 and is configured to be sealingly engaged with the bore of both the tubular barrel 12 and the axial extension 34.

The axial extension 34 slidably supports a slider 38 through a pair of diametrically opposed slots formed in the side wall of the axial extension. The slider comprises a main portion accommodated within the axial extension and a protruberance 40 to each side of the main body which extends through the slots. The protruberances provide a handle to enable movement of the slider 38 in the axial extension.

A retracting means in the form of a flexible member 28 is secured at one end to the rear 30 of the plug 16 and at the other end to the slider 38. The flexible member 28 passes through the stop 18 in sealing engagement therewith.

The chamber 14 is capable of receiving and containing a parenteral fluid such that by moving the slider 40 outwardly within the tubular extension, the plug 16 through its connection to the flexible member is moved to the rear of the body 12. Thus serves to retract the needle 20 into the main body and also in reducing the volume of the chamber 14 to expel the parenteral fluid from the open end 22 of the needle 20.

The device 10 is shown in use in Figure 2 with the needle 20 having been inserted below the surface of the skin of a person. With the parenteral device 10 in this position, where its forward end 26 lies closely adjacent the skin, the slider 38 may be pulled in the direction of arrow A to reduce the volume of chamber 14 by urging the plug 16 towards the stop 18 to expel the parenteral fluid from the needle 20. As this occurs, the needle 20 is being withdrawn into the body 12 of the device 10. In this form, the device 10 is preferably configured such that all of the parenteral fluid is expelled from the chamber 14 by the time that the open end 22 of the needle 20 reaches point B which is about 5 mm below the surface of the skin.

Figure 3 illustrates the device 10 after all of the parenteral fluid has been expelled from the chamber 14. At this position, the flexible member 28 has been pulled through the stop 18 to a point where the chamber 14 has been fully reduced in volume and the plug 16 is in contact with the stop 18. On the application of a further force to the flexible member 28 the slidable stopping means 18 is urged towards the rear 34 of the body 12 such that the entire length of the needle 20 is retracted within the body 12. Figure 4 illustrates the device after the needle 20 has been retracted completely within the body 12. The axial

extension 34 provides a region of increased diameter within which the stop 18 is able to be received and the plug 16 is caused to enter and in which the plug is loosely received when the free end 22 of the needle lies inward of the opening 24. Since there is no rigid interconnection between the plug 16 and the slider 38 it is extremely difficult for a user to realign the plug 16 in the main body and cause the needle 20 to be extended to be able to reuse the syringe. The step 36 provides a sharp reduction in diameter of the bore of the body, so as to provide a well defined shoulder which creates a difficulty in re- engaging the plug 16 in the tubular barrel 12.

In a further embodiment projections are formed in the inner wall of the body 12, which are intended to damage the sealing surfaces of the stop 18 and/or the plug on movement to a fully retracted position.

According to another preferred embodiment, a spike or the like may be fitted to the plug 16 or stopping means 18 which will pierce the stop 18, or plug 16 respectively on their coming into an abutting relationship to destroy the sealed nature of the chamber 14.

As shown in Figure 5 and 6 a fresh unused syringe according to the embodiment can be provided with a rigid shaped nipple-like element 42 which is engaged in the opening 24 and with the free end of the nipple is engaged with the cover seal 48 of the ampoule. The needle is only partly retracted into the body such that its free end 22 extends from the opening 24. The engagement between the needle is such that the element 42 can be grasped by the user and pulled to cause the needle to be pulled to the fully extended position. The nipple-like element is is shaped to receive a "Luer" or similar fitting. In addition, the

outer end of the needle is configured such that it is able to pierced the seal of an ampoule. In each instance the frictional engagement affected with an ampoule may be sufficient to facilitate withdrawal of the needle.

The tight fit of the needle 20 within the seal 44 of the nipple and is preferably sufficient to enable the needle 20 with the attached plug 16 to be moved to the extended position to causes the chamber 14 to be increased in volume. This results in the transfer of fluid into the chamber 14 to allow the filling of the chamber. On the full extension of the needle and with a greater force on the element 42, the needle 20 withdrawn from within the nipple 42 to allow use of the needle when the needle has reached its outermost position.

In an alternative embodiment, a spring, or a like resilient device is provided within the space forward of the plug 16 between the plug and the forward end of the body 12. For example, a spring that is resiliently compressed to fill the chamber with parenteral fluid and is able to expand under its normal bias to reduce the volume of the chamber 14, may be suitable. A suitable trigger is provided to hold the spring in its compressed state and to allow the release and subsequent expansion of the spring for injection. The trigger mechanism may be located externally of the body and may be operatively connected with the spring through the forward wall of the body of the device.

In a further embodiment the resilient device referred to above is located within a space located rearward of the plug. In this alternative form, the resilient device can be a spring configured so as to be able to expand to fill the chamber with parenteral fluid and then resiliently to contract under its normal bias to reduce the volume of the

chamber and expel the fluid. In such an arrangement, the flexible member referred to above may be secured to one end of the spring such that contraction of the spring moves the one end of the spring rearwardly to pull the plug rearwardly. Further, the spring is preferably configured so as to be able also to displace the stopping means in the same manner as described above. An appropriate trigger mechanism may again be utilised to control the actions of this rearwardly located spring.

Finally, the parenteral device of this invention may be marked with external graduations, according to normal practice, to assist in ensuring the administration of correct doses of parenteral fluid. This normal practice results in graduations from zero to a suitable number being included from the forward end of the device to the rearward end.

It will be appreciated that there may be other modifications and variations that may be made to the configurations described herein that are also within the scope of the present invention.

THE CLAIMS defining the invention are as follows:-

1. A syringe or like device comprising a tubular body having a forward end and a rearward end, the forward end being capable of receiving a hollow needle therein so as to be able to project therefrom, the needle being slidable relative to the body, the body also including a chamber capable of receiving a parenteral fluid and capable of being produced in volume to expel the fluid contained therein, wherein; the needle is capable of being manually retracted into the body by a retracting means such that the chamber reduces in volume to expel the fluid contained therein and such that the needle is retracted to be wholly contained within the body; the needle being able to be supported at one end from the body by a plug which is slidably and sealingly received in the body, the chamber is located rearward of the plug and the plug is adapted to enable the needle to communicate with the chamber through the plug, a stop provided in the body rearward of the plug to define the rearward end of the chamber, the stop being slidably and sealingly received in the body, whereby a greater degree of force is required to move the stop than to move the plug, the rearward end of the body slidably supporting a slider for axial slidable movement, an external protrusion on said slider for manipulation thereof to effect axial movement, said retracting means comprising a flexible member secured at one end to the plug and secured at the other end to the slider and slidably and sealingly received through the stop.

2. A syringe as claimed at claim 1 wherein the stop when defining the rearend of the chamber is sealingly and slidably received in the body and on completion of the movement of the plug to the minimum volume position of the chamber, the stop is movable with the plug where the stop will be accommodated in a non sealing manner in the rearward end of the body.

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3. A syringe or like device as claimed at claim 2 wherein the rearward end has a greater internal diameter than the remainder of the body.

4. A syringe or like device wherein the cross-sectional configuration of the rearward end of the body is formed with a portion of greater transverse dimension that the diameter of the remainder of the body.

5. A syringe or like device as claimed at any one of claims 2, 3 or 4 wherein the plug when at its rearmost position is non sealingly received in the rearward end.

6. A syringe or like device as claimed at anyone of the preceding claims wherein the external protrusion comprises an axial directed protrusion.

7. A syringe or like device as claimed at any one of claims 1 to 5 wherein the external protrusion comprises a radially directed protrusion.

8. A syringe or like device as claimed at claim 3 wherein the stop when at its forward most position is located at the junction between the rear most end of the body and the remainder of the body.

9. A syringe or like device as claimed at claim 8 wherein the junction is formed as a step in the internal wall body.

10. A syringe or like device as claimed at any one of claims 2 to 9 wherein a protrusion is provided on the interior of the body which is engaged by the sealing surface of the stop and/or plug on the joint rearward movement of the stop and plug to cause damage to the sealing surface.

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11. A syringe or like device as claimed at any one of claims 2 to 9 wherein a protrusion is provided within the body to pierce the stop and/or plug on joint rearward movement of the stop and plug.

12. A syringe or like device as claimed at any one of the preceding claims wherein the free end of the needle is received in a nipple-like element at the forward most end of the body whereby manual withdrawal of the nipple-like element away from the body will cause extension of the needle, said nipple-like element being removable from the needle.

13. A syringe or like device as claimed at claim 12 wherein the nipple-like device is provided with a port which is engagable with a receptacle of a parenteral agent and the opening in the free end of the needle opens into said port.

14. A syringe or like device as claimed at any one of the preceding claims wherein a resilient means is provided between the body and the plug and is associated with a trigger means, said resilient means being in a stressed state when the needle is extended and whereby release of said trigger enables movement of the resilient means to an unstressed state, movement of the needle, plug and stop of the fully retracted position.

15. A syringe or like device substantially as herein described.

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"SYRINGE OR LIKE PARENTERAL DEVICE"

ABSTRACT

A syringe or like device which can be used for the conveyance of parenteral fluids which are to be introduced into or drawn from the body to the skin comprising a tubular body (11) having a forward end (26) and a rearward end (34) where the forward end is capable of receiving a hollow needle (20) to enable the needle to be able to project from the body, the needle (20) slidable relative to the body (11), the body (11) also including a chamber (14) capable of receiving a parenteral fluid and capable of being produced in volume to expel the fluid contained therein, the needle (20) is capable of being manually retracted into the body (11) by a retracting means (28) such that the chamber reduces in volume to expels in volume to expel the fluid contained therein and such that the needle (20) is retracted to be wholly contained within the body (11). The needle is able to be supported at one end from the body by a plug (16) which is slidably and sealing received in the body (11). The chamber (14) is located rearward of the plug (16) and the plug is adapted to enable the needle to communicate with the chamber (14) through the plug, a stop (18) provided in the body rearward of the plug (16) to define the rearward end of the chamber (14). The stop (18) being slidably and sealingly received in the body (11) whereby a greater degree of forces required to move the stop (18) than to move the plug (16). The rearward end (34) of the body slidably supporting a slider (38) for axial movement, an external protrusion (40) on the slider (38) for manipulation of the slider to effect axial movement. The retracting means (28) comprising a flexible member secured at one end to the plug (16) and secured at the other end to the slider (38) slidably and sealingly received through the stop (18).

FIGURE 1 IS SUGGESTED FOR PUBLICATION

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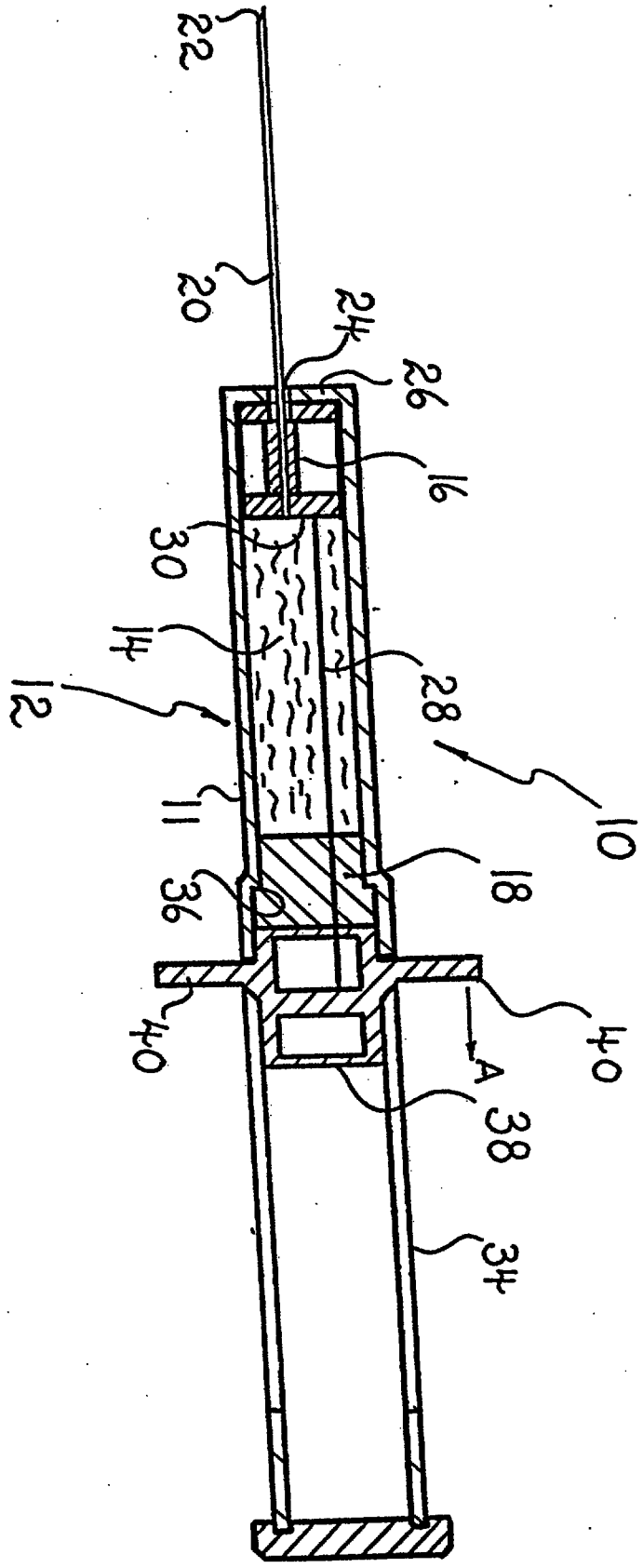


Fig 1

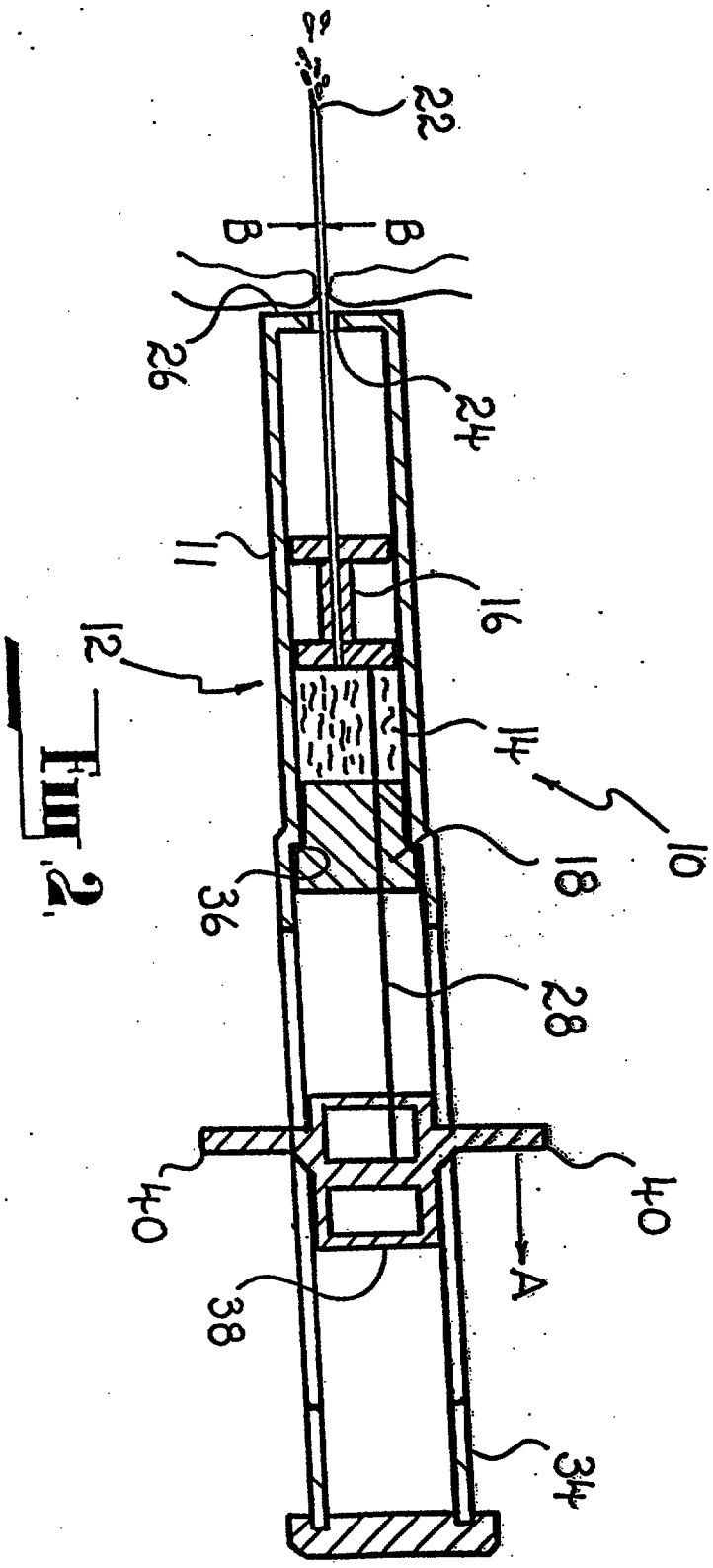


Fig. 2

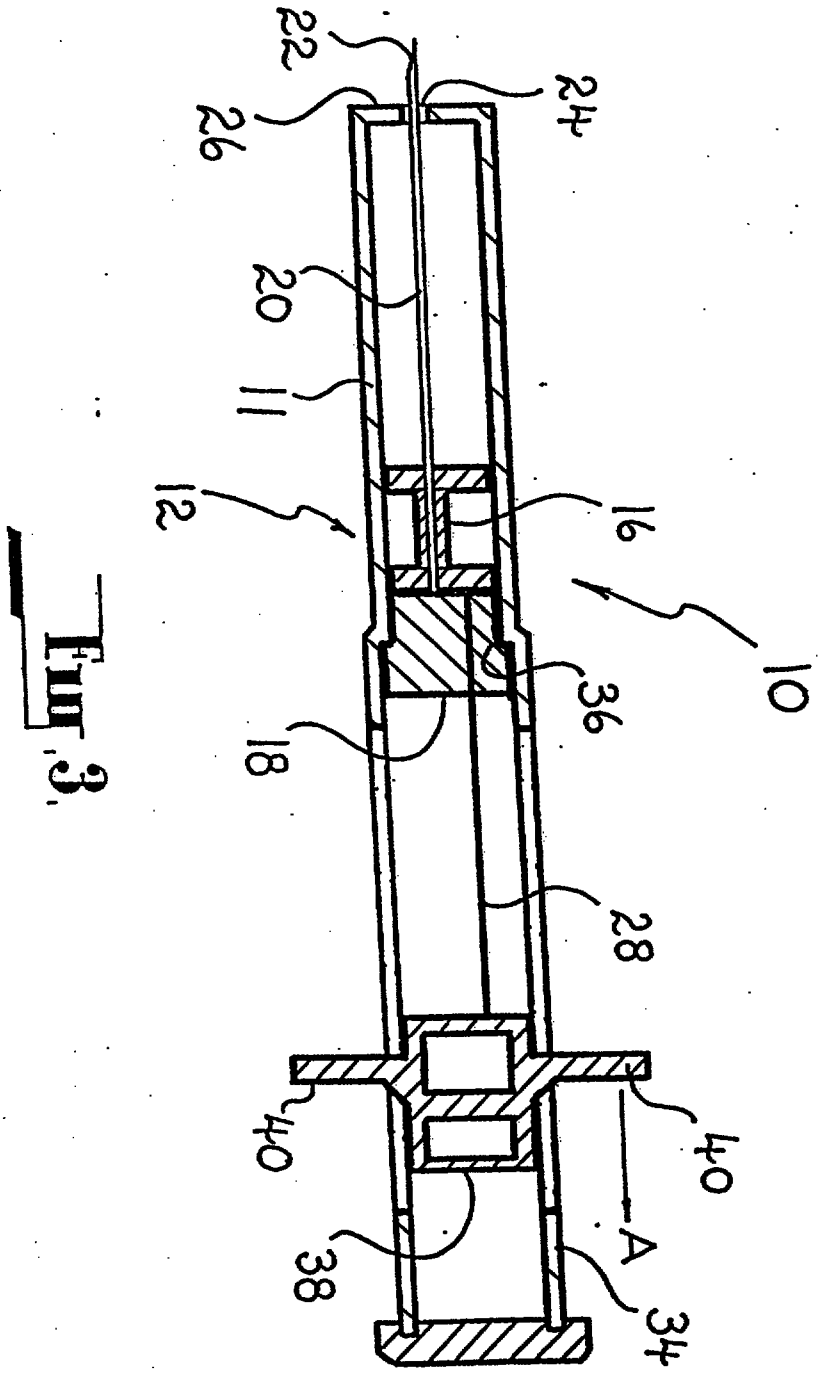


Fig. 3

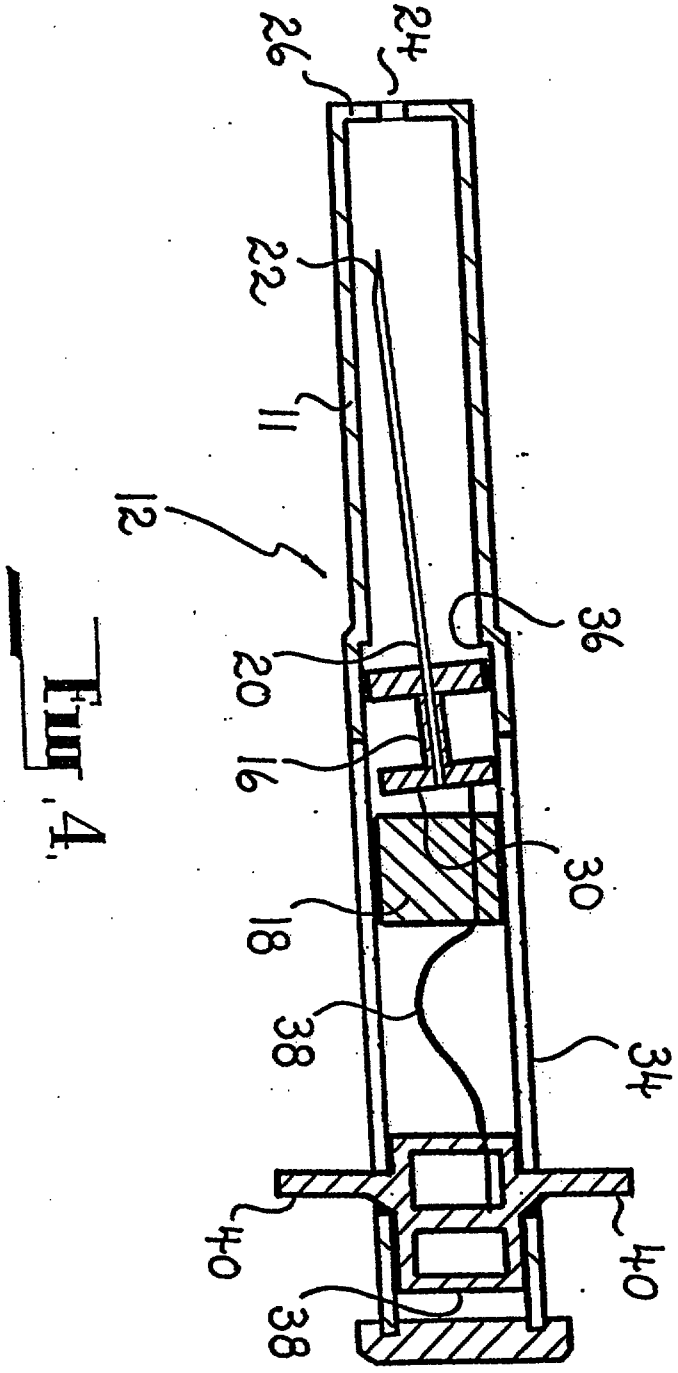


Fig. 4.

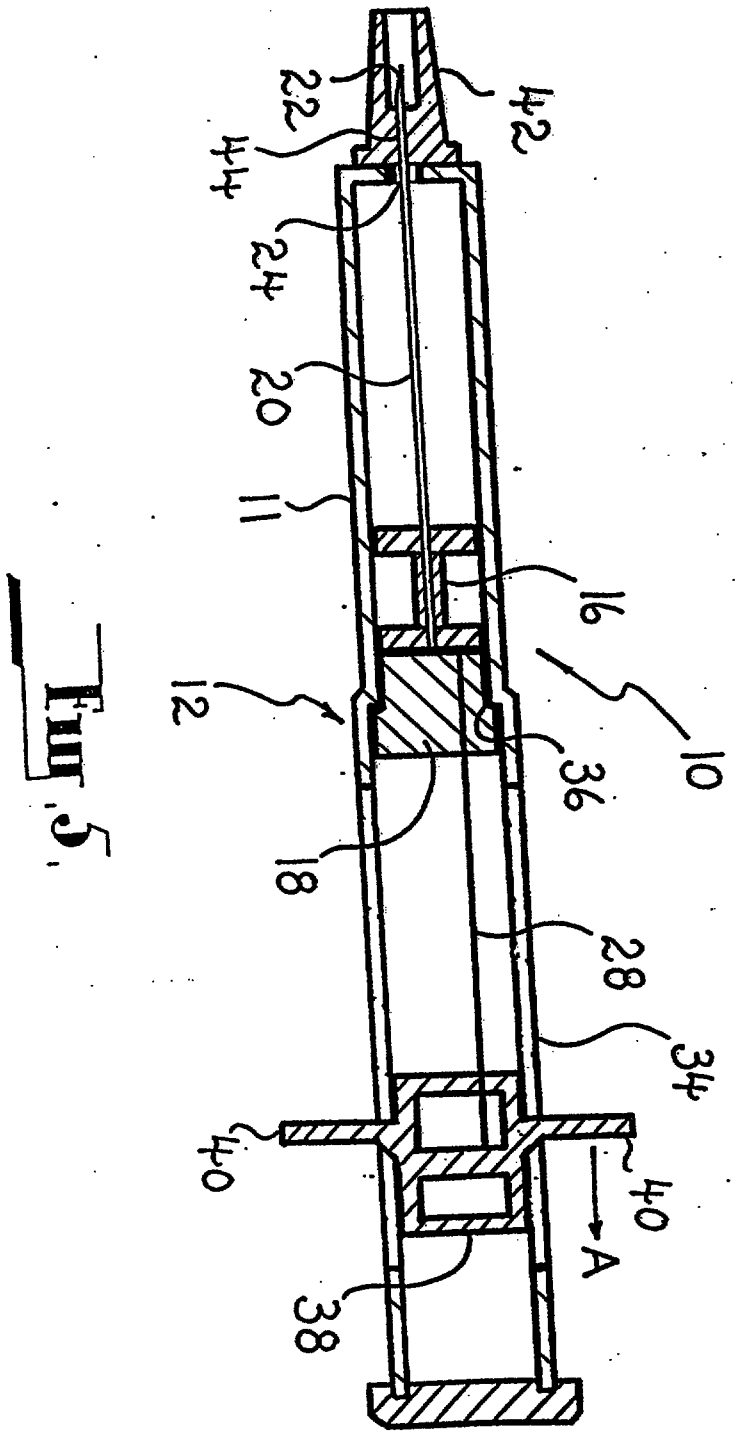


Fig. 5.

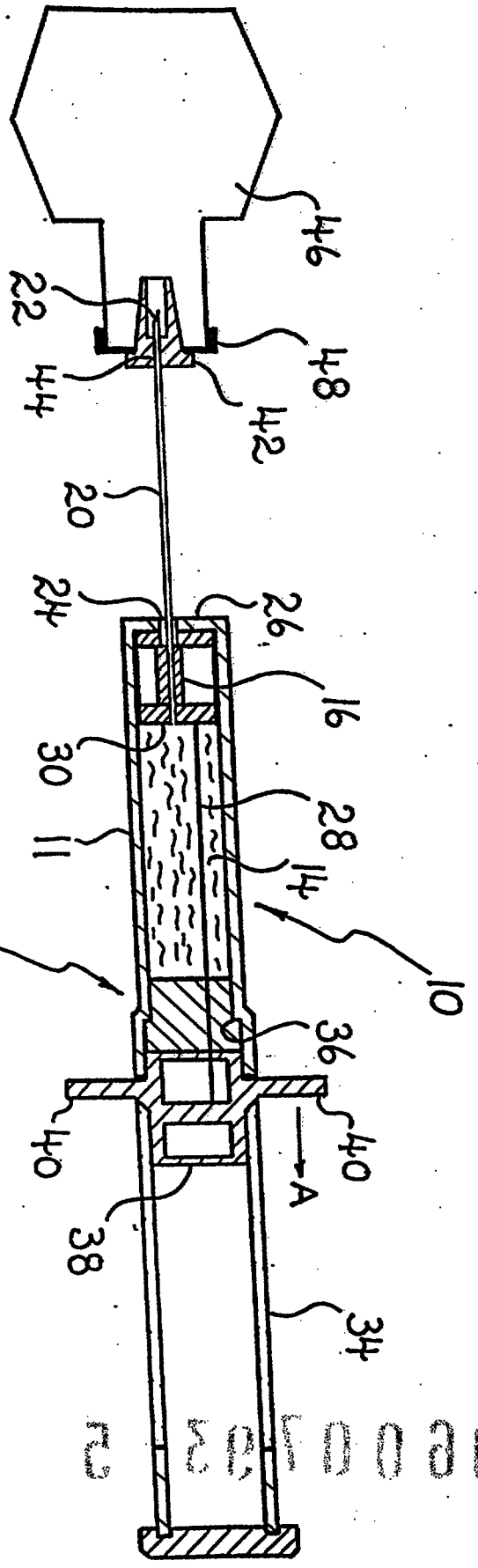


Fig. 6.

THE CLAIMS defining the invention are as follows:-

1. A syringe or like device comprising a tubular body having a forward end and a rearward end, the forward end being capable of receiving a hollow needle therein so as to be able to project therefrom, the needle being slidable relative to the body, the body also including a chamber capable of receiving a parenteral fluid and capable of being reduced in volume to expel the fluid contained therein, wherein; the needle is capable of being manually retracted into the body by a retracting means such that the chamber reduces in volume to expel the fluid contained therein and such that the needle is retracted to be wholly contained within the body; the needle being able to be supported at one end from the body by a plug which is slidably and sealingly received in the body, the chamber is located rearward of the plug and the plug is adapted to enable the needle to communicate with the chamber through the plug, a stop provided in the body rearward of the plug to define the rearward end of the chamber, the stop being slidably and sealingly received in the body, whereby a greater degree of force is required to move the stop than to move the plug, the rearward end of the body slidably supporting a slider for axial slidable movement, an external protrusion on said slider for manipulation thereof to effect axial movement, said retracting means comprising a flexible member secured at one end to the plug and secured at the other end to the slider and slidably and sealingly received through the stop.

2. A syringe as claimed at claim 1 wherein the stop when defining the rearend of the chamber is sealingly and slidably received in the body and on completion of the movement of the plug to the minimum volume position of the chamber, the stop is movable with the plug where the stop will be accommodated in a non sealing manner in the rearward end of the body.

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Date: - 4 SEP 1996

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REPLACEMENT SHEET
4 JUL 1996

SYRINGE OF LIKE PARENTERAL DEVICE

ABSTRACT

A syringe or like device comprising a needle (20) capable of being manually retracted by a retracting means (28) such that the chamber reduces in volume to expel the fluid contained therein and such that the needle (20) is retracted to be wholly contained within the body (11). The needle is supported at one end by a plug (16) which is slidably and sealingly received in the body (11). The chamber (14) is located rearward of the plug (16) and the plug is adapted to enable the needle to communicate with the chamber (14) through the plug. A stop (18) is slidably and sealingly received in the body rearward of the plug. The retracting means (28) comprises a flexible member secured at one end of the plug (16) and secured at the other end to the slider (38) slidably and sealing received through the stop.

(FIG. 1 IS SUGGESTED FOR PUBLICATION)