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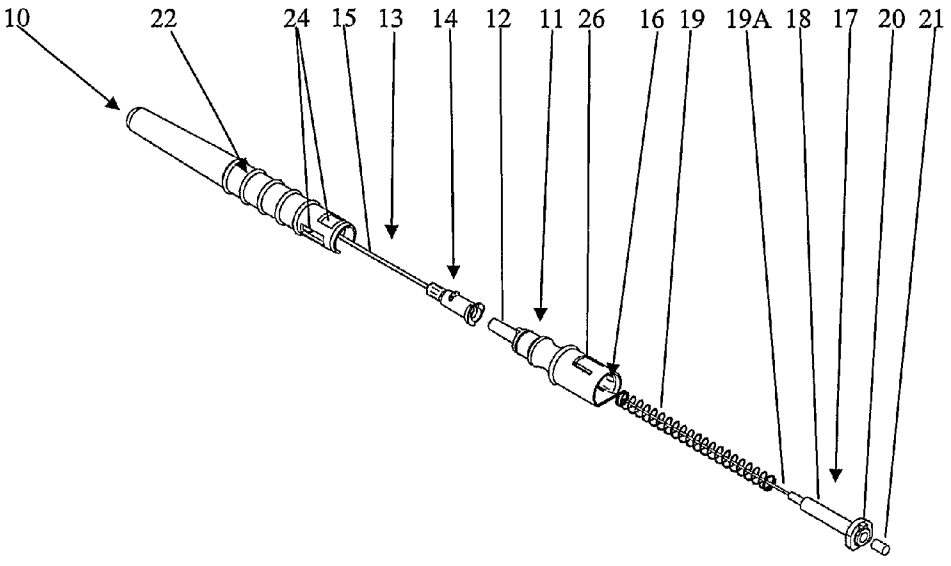
(54) Title: A MEDICAL DEVICE CONTAINING A SHOOT BACK NEEDLE



(57) Abstract: A medical device has a needle that can be used to introduce a cannula or a catheter, where the needle can be retracted into a collection container after use thereby reducing needlestick injury.

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A MEDICAL DEVICE CONTAINING A SHOOT BACK NEEDLE

Field of the Invention.

This invention is directed to a medical device of the type that contains a needle (typically a puncture needle) which can become contaminated, and where the puncture needle can be retracted back into a container in such a manner that there is a reduced incidence of needlestick injury. The invention is particularly directed to a medical device that can fall within the broad class of cannula or catheter.

Background Art.

Needlestick injury is a recognised hazard in the medical profession and is caused by inadvertent contact with a contaminated needle. Therefore, there is a distinct advantage to provide a needle containing a medical device with some sort of mechanism to reduce or to prevent needlestick injury.

A common source of needlestick injury is with medical syringes of the type having a syringe body and a plunger. The applicant has previously invented a shoot back mechanism for a medical syringe and which causes the needle to shoot back after the plunger has been pushed forwardly in the barrel.

Another potential source of needlestick injury comes with insertion of a cannula or a catheter. A cannula typically comprises a small plastic tube which needs to be introduced into a person's vein. This enables blood to be removed from the person and enables drugs and other medicines, drips and the like to be introduced into the person's vein. Catheters similarly comprise a small plastic tube that can be inserted into a body cavity to introduce fluid into the cavity or drain fluid from the cavity. As a cannula is usually introduced into a person's vein, it is necessary to initially have a puncture needle which pierces the person's vein, and then the cannula can be introduced into the vein. Some catheters also use puncture needles, although other catheters comprise a simple plastic tube and can be inserted without the need of a puncture needle.

A typical cannula will comprise the small plastic tube inside which is positioned the puncture needle. Sometimes, a valve is provided on the rear portion of the cannula. The rear of the cannula contains an opening which can be closed with a cap until a blood sample is required and the cap can then be removed and a collection container can be attached to remove blood. Alternatively, fluids/ medicines etc can be introduced through the rear of the cannula.

In use, the cannula containing the puncture needle is positioned on the patient's body, the puncture needle is pushed forwardly (or the cannula is moved rearwardly to expose the puncture needle), and the puncture needle is inserted into the person's vein. The cannula can then be pushed forwardly and the puncture needle can be slowly retracted such that the front end of the cannula is guided by the needle into the person's vein. Once the cannula is in place, the needle is retracted entirely out of the cannula, and the rear end is capped.

The puncture needle becomes contaminated by body fluids/blood etc and needs to be disposed of in a safe manner. Clearly, there is a risk of needlestick injury during the process of introducing the cannula into the person's vein.

If a catheter also contains a puncture needle, there is clearly also a needlestick injury during the process of introducing the catheter into the patient.

There are some disadvantages with existing devices of the type described above. One disadvantage is, as already described, the risk of needlestick injury, and therefore there would be an advantage if it were possible to reduce the risk of needlestick injury. However, another disadvantage with devices that have a needle retraction mechanism is that the needle can be quite long and therefore if the puncture needle is to be retracted into a container to prevent or to reduce needlestick injury, the container will need to be longer than the length of the puncture needle, and this can make the entire device of unacceptable size. Such large devices can be quite unsettling to a patient, and can present handling and storage problems.

Therefore, there would be an advantage if it were possible to provide a device of the

type described above (that is having some form of needle retraction mechanism) and which contains a needle retaining or needle collection chamber (which can be called a sharps container) but where the size, and particularly the length of the device can be reduced.

Another disadvantage with existing devices that have needle retraction mechanisms is that the retraction mechanism can be quite complicated and difficult to manufacture.

It will be clearly understood that, if a prior art publication is referred to herein, this reference does not constitute an admission that the publication forms part of the common general knowledge in the art in Australia or in any other country.

Object of the Invention.

It is an object of the invention to provide a medical device of the type that has a needle that can be used to introduce a cannula or a catheter, and where the needle can be retracted into a collection container after use thereby reducing needlestick injury.

In one form, the invention resides in a medical device containing a puncture needle, the device comprising a main body portion having a forward end and a rear end, a cannula fitted to the forward end, the cannula having a cannula body on the forward end, and a cannula tube extending forwardly from the cannula body, a needle holder positioned within the main body portion, the puncture needle being attached to the needle holder, the puncture needle extending through the cannula body and along the cannula tube, the needle holder being biased to retract through the rear end of the main body portion, retaining means to hold the needle holder against the bias, a used needle collection chamber which communicates with the rear end of the main body portion, and means to release the retaining means when required to cause the puncture needle to be retracted into the collection chamber.

In this manner, the medical device can be provided with the cannula attached to the front of the main body portion and the needle in place. After the cannula has been inserted into position (e.g. a patient's vein), the needle can be retracted from the

cannula, and can be retracted back into the collection chamber thereby making it less susceptible to stick injury. Typically, after the cannula has been introduced, the needle will still be projecting from the front of the main body portion of the medical device, and can then be "triggered" to shoot back or otherwise be retracted back into the needle collection chamber.

In order to overcome the size problem of the introducer (the introducer typically comprising the cannula, the needle, the needle holder etc), an advantage of the present invention is that the needle collection chamber can have two purposes. Initially, the needle collection chamber can form part of the cap of the medical device that protects the needle. During use, the cap can be removed and can then be positioned on the rear of the device to form the collection chamber. This can reduce by up to half the initial size of the device which would otherwise require a needle cap, the needle body etc and then a separate collection chamber.

Thus, the medical device can initially comprise the main body portion as described above, the cannula as described above, and a retraction mechanism as described above, and a cap which is attached to initially protect the needle, the cap being removable and then attachable to the rear of the main body portion to function as the needle collection chamber.

An embodiment of this version of the invention is illustrated in figures 1-5.

The medical device can be used to introduce a cannula or catheter into place. No particular limitation should be placed on the invention according to the particular use of the medical device. For instance, the medical device can be used to introduce a cannula into a patient's vein, a catheter into position, but can also be used for ear piercing and other types of body piercing where a small hollow tube is positioned in the formed hole to keep the hole opened to enable jewellery and the like to be inserted through the hole.

The device contains a puncture needle. The puncture needle may be made of any suitable material but will typically be made of steel. The puncture needle can have

any suitable length, but will typically have a length of between 20-100 mm. The puncture needle can have any suitable diameter but will typically have a diameter of between 1-5 mm. The puncture needle will typically contain a sharpened edge to facilitate piercing of a patient's skin. However, for other uses, the puncture needle may have a blunt end and can function to introduce the catheter or other similar member into the desired area.

The device contains a main body portion. The main body portion can comprise a part of the medical device that will typically be held by the practitioner. The main body portion can be made of any suitable material and will typically be made of plastic. The size of the main body portion can vary depending on the size and use of the device, but will typically have a length of between 5-100 mm and a diameter or cross-section size of between 5-30 mm.

The main body portion will have a forward end and a rear end. The forward end can be profiled or otherwise configured to support a cannula. Thus, the forward end will typically comprise a nose portion onto which the cannula can be fitted. The rear end will typically be open and will be in communication ultimately with the needle container such that ultimately the contaminated needle can be retracted into the needle container.

The body portion will typically be substantially hollow to contain a passageway extending from the forward end to the rear end.

In one version of the invention, the medical device will have a cannula fitted. As described above, the cannula will typically be attached to the main body portion and preferably to the nose portion. The cannula can be of conventional design and will typically comprise a larger diameter cannula body which is substantially hollow and which press fits or otherwise can be attached to the main body portion, and a smaller diameter cannula tube which is typically a hollow plastic tube and which is designed for insertion into the patient's vein or other part.

The device contains a needle holder. The needle holder will typically contain a

through passageway and the puncture needle can be fitted to the needle holder in such a manner that the puncture needle communicates with the through passageway. The needle holder can be positioned within the main body portion. The needle holder can be made of any suitable material and will typically be made of plastic. The needle holder in a particular embodiment can support a biasing means (typically a spring) and the needle holder may therefore contain an elongate body portion about which the spring can be fitted, and another portion which can form part of the shoot back, or release, mechanism. This will be described in greater detail below.

The needle holder is biased to retract through the rear end of the main body portion. Thus, if a collection chamber is fitted to, or relative to, the rear end of the main body portion, the needle holder (containing the needle) is biased to retract or "shoot back" into the collection chamber. This can be achieved by a biasing means which may comprise a biasing member such as a spring. The biasing means can be provided on the needle holder.

A retaining means is provided which holds the needle holder, or retains the needle holder, against retraction. Various types of retaining means may be provided. In one form, the retaining means may comprise part of the needle holder and, more particularly, may comprise a first part that can be attached to, or otherwise held by, the main body portion, and a second part that forms part of, or supports, the remainder of the needle holder, and a frangible portion between the first part and the second part that can be broken to release the needle holder and to enable the needle holder to be retracted through the open rear end of the main body portion. Other restraining means are envisaged which may comprise the use of friction to hold the needle holder in place, and where the amount of friction can be reduced such that, at a particular stage, the friction is insufficient to hold the needle holder in place causing the needle holder to be retracted. Mechanical locks may also be provided such that when retraction is required, the lock can be manipulated to release the needle holder.

It is also envisaged that some mechanism is provided to reduce the force required to trigger the shoot back mechanism. The mechanism may comprise a particular design of the retaining means, and the particular design may comprise a projection or "bump"

on the retaining means that can facilitate the shoot back mechanism with reduced force. This will be described in greater detail below.

The device may contain a means to release the retaining means and thereby to trigger or initiate the needle retraction process (also called shoot back). The means may comprise a part that engages with the retaining means, and typically with the second outer part of the retaining means to cause the second part to be disengaged with the remainder of the needle holder thereby enabling the needle holder to shoot back. A mechanism generally like this is described in our earlier patent applications. It is preferred that the part is on the container. Thus, once the container is attached to the main body portion, the container can be slightly pushed forwardly to engage with the retaining means and to trigger the shoot back mechanism. However, it is also envisaged that the part that engages with or to the retaining means, or which otherwise triggers to retraction mechanism may be separate from the container and may comprise a separate part of member that can be pushed or otherwise manipulated to engage with the retaining means, or to otherwise trigger the shoot back mechanism.

In a preferred form of the invention, the container can be attached to the main body portion to accommodate the shoot back needle but still able to be pushed forwardly (or conversely, the main body portion being pulled rearwardly) to trigger the shoot back mechanism. In this form of the invention, it is especially preferred that when the container triggers to shoot back mechanism, it also locks to, or relative to the main body portion in such a manner that it cannot be removed (for instance to access the needle) without destruction.

The device comprises a needle collection chamber. The chamber may comprise an elongate member which may be substantially hollow, or contain a passageway sufficient to hold the needle and needle holder. The length of the collection chamber is preferably sufficient to accommodate most of the needle holder and needle. The collection chamber may be formed from any suitable material such as plastic, glass or metal.

It is preferred that the needle collection chamber is formed separately from the main

body portion and can be attached to the main body portion when required to collect the used needle. Thus, the collection chamber may comprise an elongate member having an open end which is adapted for attachment to the needle body portion and preferably to or adjacent the rear end of the needle body portion to accommodate the used needle. Any means of attachment may be provided including a friction fit, a twist lock, a threaded arrangement, the use of clips, a press lock arrangement, the use of clamps, external fasteners, separate fasteners, adhesive and the like.

It is especially preferred that the needle collection chamber also functions initially as a needle cap which can then be removed from the front of the main body portion and reattached to the rear of the main body portion to function as the collection chamber.

hi another form, the invention resides in a medical device generally as described above and containing a needle container, but this time having the cannula/needle/needle body and retraction mechanism initially positioned in a rear end of the needle container (thereby reducing the overall length) but able to be moved to a forward part of the container prior to use. After the cannula has been introduced, and the needle retracted from the cannula, the needle can then be triggered to retract back into the container and therefore out of harm's way.

In this version of the invention, the needle can be attached to a needle holder. In one variation of the retraction mechanism, the needle holder can be biased by a compressed needle positioned on the needle holder or operatively with the needle holder such that upon release of the needle holder, the compressed spring shoots the needle and the needle holder back into the container and out of harm's way.

In another variation of the retraction mechanism, the needle holder can be biased by an extension spring or other stretchable member such that as the needle holder is moved from the initial rear portion of the container to the front portion of the container, the spring or other member is tensioned, and therefore upon release of the needle holder, this causes the needle holder and the needle to be pulled back into the container body and out of harm's way.

Brief Description of the Drawings.

Embodiments of the invention will be described with reference to the following drawings in which:

FIRST EMBODIMENT OF THE INVENTION.

Figure 1. Is an exploded view of a medical device according to a first embodiment of the invention.

Figure 2. Illustrates the medical device of the first embodiment in the "packed" configuration (that is, prior to use).

Figure 3. Illustrates the medical device in the "use" configuration (that is, able to introduce a cannula etc).

Figure 4. Illustrates the medical device similar to that illustrated in figure 3, but this time with the cannula removed from the needle (that is, in the "contaminated" condition).

Figure 5. Illustrates the medical device of the first embodiment in the retracted (shoot back) condition where the contaminated needle has been retracted.

SECOND EMBODIMENT OF THE INVENTION

Figure 6. Illustrates a section view of a medical device according to a second embodiment of the invention and in the "packed" condition (that is, prior to use).

Figure 7. Illustrates the view of figure 6, but at 90° to the view of figure 6.

Figure 8. Illustrates the medical device of the second embodiment in the use condition (that is, ready to introduce a cannula etc).

Figure 9. Illustrates the view of figure 8, but at 90° to the view of figure 8.

Figure 10. Illustrates the medical device generally as indicated in figure 8, but now with the cannula removed to expose the potentially contaminated needle.

Figure 11. Illustrates the medical device of figure 10, but at 90° to the view of figure 10.

Figure 12. Illustrates the medical device of the second embodiment in the retracted (shoot back) position where the needle has been retracted into the body.

Figure 13. Illustrates the medical device of figure 12, but at 90° to the view of figure 12.

THIRD EMBODIMENT OF THE INVENTION.

Figure 14. Illustrates a medical device according to a third embodiment of the invention in the "packed" condition (that is prior to use).

Figure 15. Illustrates the medical device of figure 14, but at 90° to the view of figure 14.

Figure 16. Illustrates the medical device in the extended "use" condition.

Figure 17. Illustrates the medical device in the retracted (shoot back) condition where the potentially contaminated needle is now safely within the confines of the medical device.

Figure 18. Illustrates the medical device of figure 17, but at 90° to the view of figure 17.

Figure 19. Illustrates an exploded view of the medical device.

Figure 20. Illustrates a view of the outer body of the medical device.

Figure 21. Illustrates a view of the needle holder.

Best Mode.

Three embodiments of the invention will be described. The first embodiment is illustrated with reference to figures 1-5. The second embodiment is illustrated with reference to figure 6-13. The third embodiment is illustrated with reference to figures 14-21. Each embodiment is directed to a device having a retractable needle which acts as an introducer for a cannula. The second and third embodiments are related in that in both of these embodiments, the needle assembly is pushed forwardly along the main body.

Initially, reference will be made to the first embodiment as described with reference to figures 1-5. Referring initially to figure 1, there is illustrated the main parts of the medical device. Briefly, the medical device comprises a container 10 which, in the embodiment, has two purposes being to initially act as a covering cap for the needle/cannula, but then functioning as a container to hold the retracted contaminated needle (for instance, also functioning as a medical sharps container). This will be described in greater detail below. The device contains a main body portion 11 having a forward end containing a nose portion 12 onto which a cannula 13 can be fitted,

cannula 13 able to be of conventional design and containing a cannula head portion 14 and a cannula tube (typically a hollow plastic tube) 15. Main body portion 11 has an open rear end 16. Inside the main body portion (but in figure 1 shown as exploded from the main body portion) is a needle holder 17. Needle holder 17 contains an elongate body portion 18. A spring 19 is positioned about elongate body portion 18. A needle 19A can be fitted to the front of elongate body portion 18. The elongate body portion is substantially hollow and therefore has a through passageway. A retaining means 20 is formed on the rear of needle holder 17. A small plug 21 is inserted into the otherwise open rear passageway of needle holder 17.

Referring now to figure 2, there is illustrated the medical device in the "package" position that is prior to use. hi this position, the cap 10, is attached to the front of needle holder 17 and functions to cover and protect the needle 19A and the attached cannula 13. Cap 10 is made of plastic, and contains outer grip profiles 22. Cap 10 contains an open end illustrated generally as 23. This open end area has a particular profile and contains openings 24 which are used later on to connect and to lock the cap to the rear portion of main body portion as will be described in greater detail below.

Needle holder 17 as mentioned before is substantially hollow and contains a forward flash chamber 24A. The concept of a flash chamber is known, but an advantage of the design of the medical device according to the present invention is that the flash chamber will be forwardly of the area where practitioner will grip the medical device and therefore is quite easily viewable. Many existing devices that contain a flash chamber have the flash chamber partially hidden or fully hidden when the device is gripped.

Spring 19 is compressed about needle holder 17 and is supported by the elongate body portion 18 of the needle holder 17. Spring 19 is held in a compressed state between the retaining means 20, and a forward shoulder inside needle holder 17. Consequently, the spring functions to bias needle holder 17 out of the open rear end 16. However, the needle holder 17 is held, or clamped, in position against the bias of spring 19 by retaining means 20. Retaining means 20 is substantially disk shaped and

is connected about the lower end of needle holder 17. The retaining means 20 contains a frangible or breakable portion to enable the retaining means to be released from, or broken away from, the needle holder. Thus, as long as retaining means 20 is attached to the needle holder 17, the needle holder is held in position in the main body portion 11. However, when the retaining means 20 is removed (for instance snapped off the needle holder via the frangible or breakable portion), the needle holder will be shot out of the main body portion under the bias of the spring.

The outer edge of retaining means 20 abuts against the end of a finger 26 which is on main body portion 11. Finger 26 comprises a small tab member which is formed in the wall of main body portion 11 but which has a gap around the tab member. The edge of the tab member provides an abutment surface for a portion of the outer wall of retaining means 20, this being illustrated in figure 2.

Retaining means 20 is not entirely circular and has a flattened portion (see figure 1) and it can be seen that the main body portion 11 (and especially the open rear end 16 of main body portion 11) is also flattened. Thus, the needle holder can slide within main body portion 11, but cannot appreciably rotate.

Retaining means 20, as mentioned above, is attached to the remainder of needle holder 17 by a frangible portion. The frangible portion can comprise an annular groove which weakens the wall thickness. Alternatively, the frangible portion may comprise one or more smaller connecting members etc.

To release (snap away) retaining means 20 from the remainder of needle holder 17, it is necessary to push the retaining means 20 forwardly by a small distance, but this being enough to snap the retaining means away from the remainder of needle holder 17. To facilitate this action, and especially to reduce the force required to cause this breaking action to occur, the rear face of retaining means 20 (that is the face pointing out of open rear end 16) contains a small projection or "bump" 27. The reason for this projection is that if a member (this will be described in greater detail below) is pushed against the rear face of retaining means 20, the member will first contact and push against bump 27 and this will cause preferential breaking of the retaining means

initially in this area, and with less force. Once the retaining means is partially broken, a relatively small amount of force is required to completely remove the retaining means from the remainder of the needle holder 17 thereby enabling the shoot back mechanism to trigger.

Referring now to figure 3, in this configuration, the medical device is ready to function as an introducer for the cannula. In this configuration, cannula tube 15 is exposed and is supported by the needle 19A which sits inside the cannula tube and which slightly projects from the outer end of the cannula tube, this being quite conventional. The main difference is that cap 10 has been removed from the front of the device (see figure 2) and has been attached to the rear of the device, and specifically to the open rear end 16 of main body portion 11. Thus, cap 10 can now be seen as a container (which will also be given reference 10). The attachment is in a particular manner. Specifically, the open end of cap/container 10 contains a small lip 28 this being best illustrated in figure 2. When the cap/container 10 is in the capping position illustrated in figure 2, lip 28 has no function. However, when cap/container 10 has been moved to the position illustrated in figure 3, lip 28 engages in opening 29 (see figure 2) on the rear portion of main body portion 11. Thus, in this position, the cap/container 10 is attached to main body portion 11, but does not push against the retaining means 20 needle holder 17.

The medical device in the configuration illustrated in figure 3 can then be used to introduce the cannula into a person's vein (for instance). This can be done according to conventional techniques which are basically to initially prick the sharp end of needle 11 into the person's vein, and then, while the needle is in position, to slowly push the cannula forwardly along the needle such that the cannula tube 15 enters into the person's vein. The needle can then be slowly retracted such that ultimately only the cannula remains. The medical device is then in the position illustrated in figure 4 which is where the potentially contaminated needle 19A is now exposed as the cannula has been slid off the needle. This is the riskiest period as needlestick injury can easily occur, especially with traditional methods where a cap is placed over the contaminated needle. With the present invention, the needle is retracted back into the cap 10 which now functions as a container, and will therefore hereinafter be called

container 10.

To retract contaminated needle 19A into container 10, it is necessary to trigger the retraction mechanism. Specifically, it is necessary to cause the needle holder 17 (containing the contaminated needle 19A) to shoot back under the influence of spring 19 into container 10. To do so, it is necessary to break away retaining means 20. In the particular embodiment, this is achieved by pushing container 10 forwardly by a few millimetres. When this happens, the front edge (e.g. lip 28) on container 10 is pushed forwardly and pushes against the small bump 27 on the rear face of retaining means 20. This is the position illustrated in figure 4. Continued forward pressure will cause the front edge of container 10 to push this part of the retaining means backwards and will cause the frangible portion (that connects the retaining means to the remainder of needle holder 17) to break. Initially, the breaking will be preferentially about the bump area and therefore the amount of force required will be reduced as it is not, at this initial stage, necessary to break the entire frangible portion, just the portion around the bump. Once this happens, slight further forward movement of the container will cause retaining means 20 to be entirely removed from needle holder 17, or sufficiently removed such that the force of spring 19 can shoot the needle holder containing the contaminated needle into the main body of container 10. This is the position illustrated in figure 5.

Referring to figure 5, the contaminated needle 19A (attached to needle holder 17) has been shot back into container 10 by (now expanded) spring 19. The retaining means 20 remains substantially in its original position in main body portion 17, but because it has been released from needle holder 17, the needle holder has shot back into container 10.

Importantly, this slight further forward movement of container 10 to break retaining means 20 away from needle holder 17, has also caused the lip 28 on the front of container 10 to "snap" into the small gap around finger/tab 26 on main body portion 11. Consequently, container 10 is now locked to main body portion 11 and cannot be removed.

Referring now to the second embodiment of the invention, this embodiment is illustrated with reference to figures 6-13.

The second embodiment of the invention is also to a medical device that can introduce a cannula into a person's vein (for example) and also contains a retractable needle, and also has a relatively compact shape, but the mechanism is somewhat different.

Referring initially to figures 6-7, this illustrates the medical device according to the second embodiment of the invention in the "packaged" position that is the nonuse position.

The main components comprise an elongate substantially hollow outer body 31 which can also be seen as a housing, and sometimes as a "trigger chamber". The outer body contains an open front end 32 and a closed rear end 33 and is typically substantially cylindrical. The outer body 31 contains a pair of diametrically opposed longitudinal slots (one slot being illustrated in figures 8 and 21). The slots terminate inwardly from the open front end and a closed rear end to prevent the outer body from simply falling apart. The outside of the outer body may contain grip enhancing profiles 34.

Inside the outer body 31 is a retraction housing 45, a needle holder 35 and a needle 36. The retraction housing 45 contains a pair of "wings" 38 that extend through slots 37. Wings 38 can be gripped by a medical practitioner. The retraction housing 45 also contains the forward nose portion onto which a cannula 39 can be fitted in the manner generally described with reference to the first embodiment.

The needle holder 35 can have a design generally similar to that described in the first embodiment and therefore can contain a generally elongate body portion 46 to which the needle 36 is fitted. The rear end of the needle holder 35 contains a retaining means 42 which is like the retaining means of the first embodiment in that it comprises a ring that extends about the remainder of the needle holder, and which can be broken away to cause retraction of the needle holder. The retaining means 42 can be attached to the remainder of the needle holder by any suitable method, These methods include providing a weakened portion, or a frangible portion, but also friction

fit, a mechanical lock of some sort and the like. Thus, as long as retaining means 42 is in place, the needle and the remaining portion of the needle holder cannot be retracted. The retaining means 42 in the particular embodiment is somewhat dish shaped to contain a peripheral side wall 47, and side wall 47 which can be stepped 43 to provide a good location point for the free end of finger members 41.

Therefore, initially, the medical device has the retraction housing 45 containing attached wings 38 and a cannula attached to the front of the retraction housing 45, and the needle holder 35 inside the retraction housing 45 and attached thereto via the retaining means 42.

When the medical device is in the extended "use" position, and needle holder 35 is attached to the front of the outer body 31, the finger members 41 are positioned behind retaining means 42. To facilitate this, retaining means 42 contains the stepped portion 43 to seat the ends of finger members 41. Therefore, the needle holder is held in the extended position by being supported by the ends of finger members 41.

A cannula 39 is attached to the front of needle holder 35, and cannula 39 can be of conventional design.

A spring (or other type of biasing member/stretching member) 40 is attached to needle holder 35 and also to a rear portion of outer body 31. Spring 40 has one and attached to the closed rear wall of outer body 31 (see figure 6). The other end is attached to the rear of needle holder 35. Importantly, spring 40 is not directly attached to retaining means 42.

The front of outer body 31 contains a pair of diametrically opposed finger members/tabs 41 which extends slightly inwardly into the outer body this being illustrated in figure 6.

The medical device can be converted from the "packaging" position illustrated in figure 6-7 to the "use" position illustrated in figures 8-9 as follows. The medical device is gripped by the medical practitioner, and the medical practitioner holds

opposed wings 38 and pushes the retraction housing 45 from the rear position illustrated in figure 6-7 to the extended position illustrated in figures 8-9. In the extended position, the retractable housing 45 [containing the needle holder] is in a front part of the outer body. The cannula and needle project from the front of outer body 31. The cannula can then be introduced into a person's vein in a conventional manner.

When the retractable housing 45 has been slid forwardly to be in the front portion of outer body, the retraction housing 45 is locked against the outer body. To achieve this, the retaining means 42 which is at this stage attached to needle housing 35 engages against the finger members 41 in the front of outer body.

After the cannula has been removed from the needle and the needle holder, the device is in the position illustrated in figures 10-11 and where the possibly contaminated needle 36 is now fully exposed.

To cause the needle to be retracted back into outer body (see figures 12-13), it is necessary to break retaining means 42. This is done by pushing the retraction housing 45 against finger members 41 (alternatively, holding the retraction housing by wings 38, and pushing outer body against the retaining means 42). Either way, the force of the fingers against the back of the retaining means 42, causes the retaining means to become dislodged from attachment to the remainder of needle holder 35. Again, and to reduce the amount of force required, a projection or button 44 can be provided on retaining means 42 which causes preferential dislodgement of the retaining means around this area (this being similar to that described with reference to the first embodiment).

Once retaining means 42 has been dislodged, spring 40 will pull back the remainder of the needle holder containing needle 36 back into the confines of outer body this being illustrated in figures 12-13. The retraction housing 45 containing the retaining means 42 stays in the front of outer body 31 as it is "locked" behind finger members 41.

A third embodiment of the invention will now be described with reference to figures

14-21. This embodiment is similar to the second embodiment in that a retraction housing 60 containing a needle holder 54 containing the attached needle 57 and cannula 56 is slid forwardly along an outer body 50 to the forward end and is then held in place. However, one variation in the third embodiment is that the extension spring of the second embodiment is not provided. Instead, the third embodiment contains a mechanism similar to that described in the first embodiment in that the needle holder itself is provided with a small compressed shoot back spring 58 (or similar member) which can be triggered to shoot the needle back into the outer body.

Describing the third embodiment in greater detail, figures 14-15 illustrate a medical device according to the third embodiment in the packaged (non-use) condition. The medical device contains an outer body 50 having a closed rear end 51 and an open front end 52, and diametrically opposed slots 37 one of which being illustrated in figure 20. Open front end 52 contains locking fingers 53 similar to that described with reference to the second embodiment. The locking fingers 53 extend into the outer body. Inside the outer body is a retraction housing 60 containing a needle holder 54. The retraction housing 60 contains opposed wings 55 that extend through slots 37 to enable a medical practitioner to grip wings 55 and push the retraction housing/ needle holder from the retracted position illustrated in figures 14-15 to the extended use position illustrated in figure 16. In the use position, retraction housing 60 has been pushed to the front end of the outer body and fingers 53 are initially pushed away as the retraction housing moves to the front of the outer body 50, and then snap back into the original position illustrated in figure 14, where the fingers are behind the retraction housing and prevent the retraction housing from being retracted. Thus, the retraction housing/needle holder is now locked in the forward position illustrated in figure 16. The front of the retraction housing 60 can contain a cannula 56 which can then be introduced into a person's vein (for example), and when this has occurred, the needle is retracted such that the needle 57 is exposed.

The needle holder supports a small compressed spring 58 which is positioned about the needle holder in a manner similar to that described in the first embodiment. The exploded view of the third embodiment is illustrated in figure 19 and illustrates spring 58 which is ordinarily about needle holder 54.

The needle holder contains a retaining means 59, which is similar to that described with reference to the second embodiment and comprises a generally dish shaped or part tubular shaped member having a peripheral side wall 62 which is stepped to provide an engagement portion to enable fingers 53 to properly engage against the back of retaining means 59 when the retraction housing 60 has been pushed to the forward position. The retaining means 59 is attached to the rear portion of needle holder 55 in a manner that can allow the retaining means 59 to be decoupled from the remainder of needle holder 55. Thus, the retaining means 59 can be attached via a frangible or weakened portion, by friction, using an adhesive, using a mechanical lock or by any other suitable manner.

To retract the needle, it is necessary to push fingers 53 with a degree of force against the back of retaining means 59. Once this occurs, the retaining means 59 is dislodged, and spring 58 can then shoot back needle holder 54 containing the contaminated needle 57 into outer body 50. Again, it may be beneficial to reduce the force required to dislodge retaining means 59, and this may be achieved by providing a small projection/button/bump on the rear wall of the retaining means that can preferentially contact the fingers to allow this area to be initially dislodged.

Li a variation of further modification, there may be provided a medical device substantially according to the second embodiment and the third embodiment in that the medical device contains both a small compressed spring about the needle holder to shoot the needle holder back into the outer body (third embodiment) and also a small stretchable member or extension spring to facilitate retraction as well (second embodiment).

Throughout the specification and the claims (if present), unless the context requires otherwise, the term "comprise", or variations such as "comprises" or "comprising", will be understood to apply the inclusion of the stated integer or group of integers but not the exclusion of any other integer or group of integers.

Throughout the specification and claims (if present), unless the context requires

otherwise, the term "substantially" or "about" will be understood to not be limited to the value for the range qualified by the terms.

CLAIMS.

1. A medical device containing a puncture needle, and comprising a main body portion having a forward end and a rear end,

a cannula fitted to the forward end, and which has a cannula body and a cannula tube extending forwardly from the cannula body,

a needle holder positioned within the main body portion,

the puncture needle being attached to the needle holder, the puncture needle extending through the cannula body and along the cannula tube,

biasing means to bias the needle holder to retract through the rear end of the main body portion,

retaining means to hold the needle holder against the bias,

a used needle collection chamber adapted to communicate with the rear end of the main body portion, and,

means to release the retaining means when required to cause the puncture needle to be retracted into the collection chamber.

2. The device of claim 1, wherein the collection chamber also functions initially as a cap for the puncture needle and which can be removed and fitted to the rear end of the main body portion to function as the collection chamber.

3. The device of claim 2, wherein the main body portion has a nose portion on the forward end to support the cannula and an open rear end to which the collection chamber is adapted to fit.

4. The device of claim 3, wherein the needle holder comprises an elongate body portion containing a through passageway communicating with the needle.

5. The device of claim 4, wherein the biasing means to bias the needle holder to retract through the rear end of the main body portion comprises a spring which extends about the elongate body portion of the needle holder.

6. The device of claim 5, wherein the retaining means comprises a first

part that attached to the main body portion, a second part that forms part of the needle holder, and a frangible portion between the first part and the second part that can be broken to release the needle holder and to enable the needle holder to be retracted through the open rear end of the main body portion.

7. The device of claim 6, wherein the first part comprises a bump on the to trigger the shoot back mechanism with reduced force.

8. The device of claim 1, wherein the means to release the retaining means when required to cause the puncture needle to be retracted into the collection chamber, comprises the used needle collection chamber which is attached to the rear end main body portion and is slightly pushed forwardly to engage with the retaining means and to trigger the shoot back mechanism.

9. The device of claim 9, wherein movement of the used needle collection chamber to engage with the retaining means and to trigger the shoot back mechanism also causes the chamber to lock to the main body portion in such a manner that it cannot be removed (for instance to access the needle) without destruction.

10. A medical device comprising a body portion in the form of a retraction housing [45] having a forward end and a rear end,

a cannula [39] fitted to the forward end and which has a cannula body and a cannula tube extending forwardly from the cannula body,

a needle holder [35] positioned within the main body portion,

a puncture needle [36] attached to the needle holder and extending through the cannula body and along the cannula tube,

biasing means [40] to bias the needle holder to retract through the rear end of the main body portion,

retaining means [42] to hold the needle holder against the bias,

a needle collection chamber in the form of a hollow outer body [31] having an open front end [32], the retraction housing moveable in the hollow outer body from a retracted position where the needle [36] is in the body [31] to an extended position where the needle projects from the open front end [32] of the body,

and,

means to release the retaining means when required to cause the puncture needle to be retracted into the collection chamber, the means comprising at least one deflectable finger member [41] adjacent the end [32].

11. The device of claim 10, wherein the body [31] contains a pair of diametrically opposed longitudinal slots [37] which terminate inwardly from the open front end and a closed rear end to prevent the outer body from falling apart.

12. The device of claim 11, wherein the retraction housing [45] contains a pair of wings [38] that extend through slots [37], the wings adapted to be gripped by a medical practitioner.

13. The device of claim 12, wherein the needle holder [35] has an elongate body portion to which the needle 36 is fitted, the needle holder having a rear containing the retaining means [42].

14. The device of claim 13, wherein the retaining means comprises a ring that extends about the remainder of the needle holder and which is adapted to be broken to cause retraction of the needle holder.

15. The device of claim 14, wherein the retaining means is dish shaped to have a peripheral side wall [47] which is stepped [43] to provide a location point for the free end of finger members [41].

16. The device of claim 10, wherein the biasing means [40] to bias the needle holder to retract through the rear end of the main body portion comprises a spring [40] which is attached to needle holder 35 and also to a rear portion of outer body 31.

17. The device of claim 10, wherein the retraction housing [45] is pressed against the deflectable finger member [41] to release the retaining means.

18 A medical device comprising a body portion in the form of a retraction housing [60] having a forward end and a rear end,

a cannula [56] fitted to the forward end, and which has a cannula body and a cannula tube extending forwardly from the cannula body,

a needle holder [54] positioned within the main body portion,

a puncture needle [57] being attached to the needle holder, the puncture needle extending through the cannula body and along the cannula tube,

biasing means [58] to bias the needle holder to retract through the rear end of the main body portion,

retaining means [53] to hold the needle holder against the bias,

a used needle collection chamber comprising an outer body [50] with an open front end [52] , the main body portion [60] able to move along the outer body and to the open front end [52] adapted to communicate with the rear end of the main body portion, and,

means to release the retaining means when required to cause the puncture needle to be retracted into the collection chamber.

19. The device of claim 18, wherein the outer body [50] contains a pair of diametrically opposed longitudinal slots [37] which terminate inwardly from the open front end and a closed rear end to prevent the outer body from falling apart.

20. The device of claim 19, wherein the retraction housing [60] contains a pair of wings [55] that extend through slots [37], the wings adapted to be gripped by a medical practitioner.

21. The device of claim 20, wherein the needle holder [54] has an elongate body portion to which the needle is fitted, the needle holder having a rear portion containing the retaining means [59].

22. The device of claim 21, wherein the retaining means comprises a ring that extends about the remainder of the needle holder and which is adapted to be broken to cause retraction of the needle holder.

23. The device of claim 22, wherein the retaining means is dish shaped to have a peripheral side wall [62] which is stepped to provide a location point for the means to release the retaining means which comprise at least one finger member [53].

24. The device of claim 18, wherein the biasing means [58] to bias the needle holder to retract through the rear end of the main body portion comprises a spring [40] which is attached to needle holder 35.

25. The device of claim 18, wherein the retraction housing [60] is pressed against the deflectable finger member [53] to release the retaining means.

AMENDED CLAIMS

[received by the International Bureau on 05 January 2007 (05.01.07);
original claim 1 amended; remaining claims unchanged]

+ STATEMENT

1. A medical device containing a puncture needle, and comprising a main body portion having a forward end and a rear end,

a cannula fitted to the forward end, and which has a cannula body and a cannula tube extending forwardly from the cannula body,

a needle holder positioned within the main body portion,

the puncture needle being attached to the needle holder, the puncture needle extending through the cannula body and along the cannula tube,

biasing means to bias the needle holder to retract through the rear end of the main body portion,

retaining means to hold the needle holder against the bias, and which is attached to the needle holder by a frangible portion,

a used needle collection chamber adapted to communicate with the rear end of the main body portion, and,

means to release the retaining means when required to cause the puncture needle to be retracted into the collection chamber.

2. The device of claim 1, wherein the collection chamber also functions initially as a cap for the puncture needle and which can be removed and fitted to the rear end of the main body portion to function as the collection chamber.

3. The device of claim 2, wherein the main body portion has a nose portion on the forward end to support the cannula and an open rear end to which the collection chamber is adapted to fit.

4. The device of claim 3, wherein the needle holder comprises an elongate body portion containing a through passageway communicating with the needle.

5. The device of claim 4, wherein the biasing means to bias the needle holder to retract through the rear end of the main body portion comprises a spring which extends about the elongate body portion of the needle holder.

6. The device of claim 5, wherein the retaining means comprises a first

Statement under Article "19 (1)

We wish to amend claim 1 to better distinguish from the citations. The amendment clarifies that the retaining means is of a particular type and is attached to the needle holder by a frangible portion.

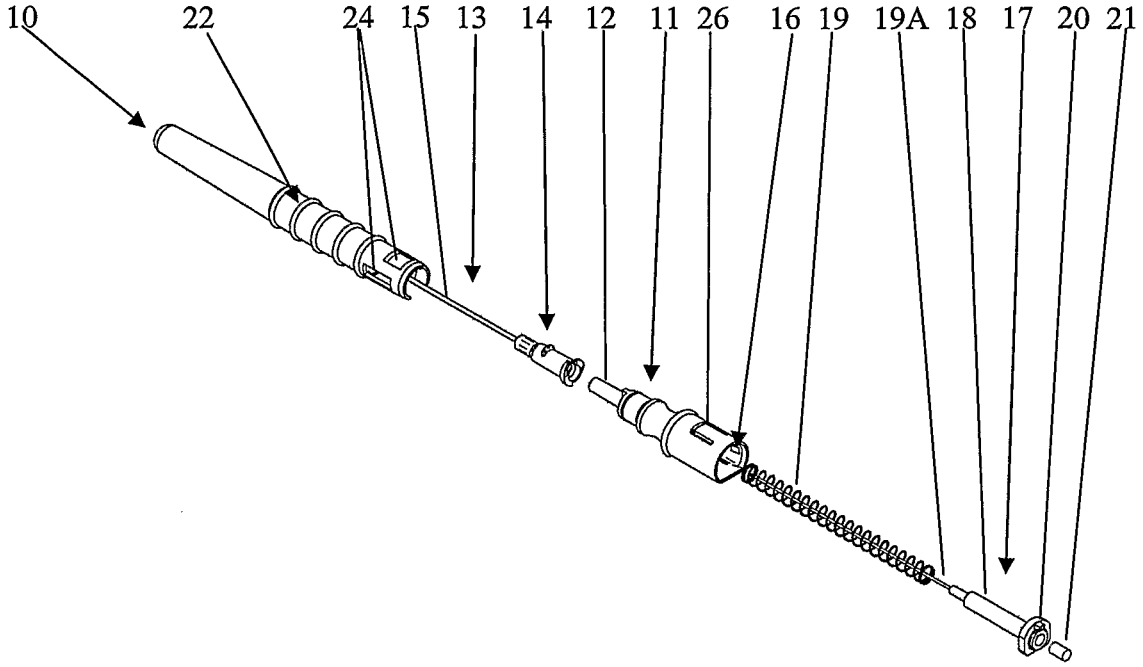
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FIG 1

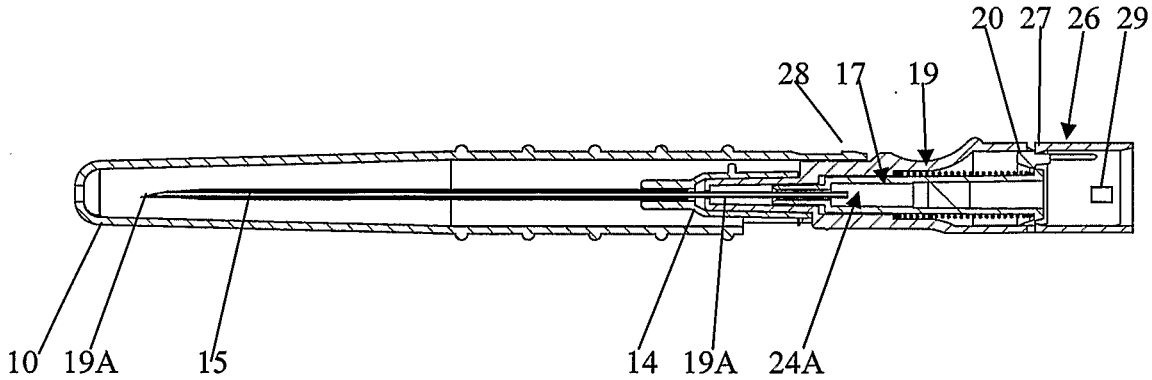
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FIG 2

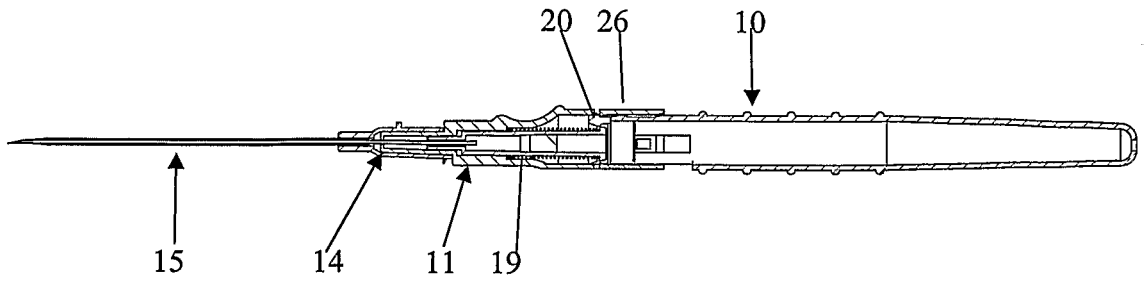

FIG 3

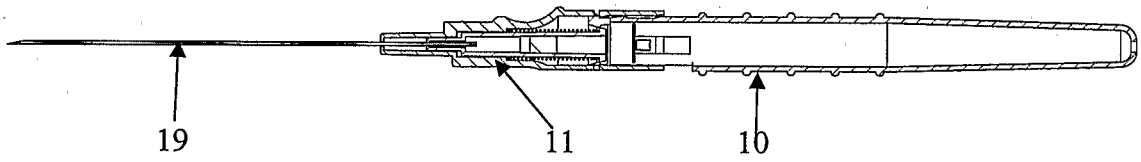

FIG 4

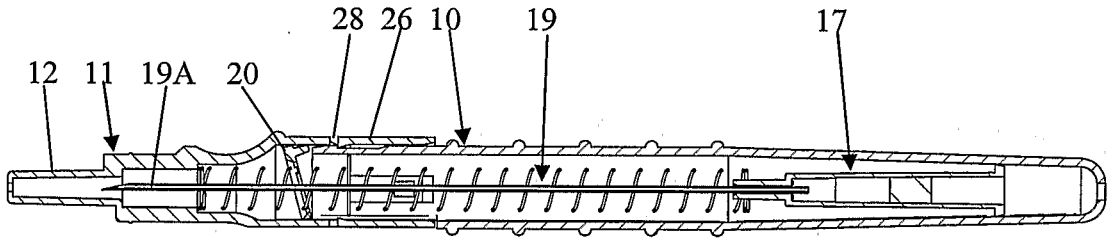

FIG 5

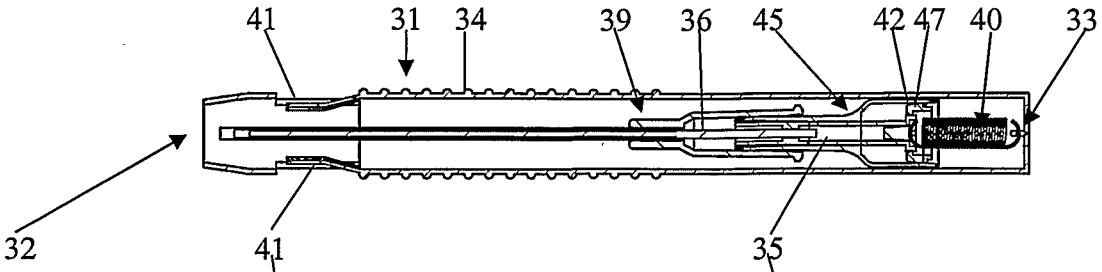

FIG 6

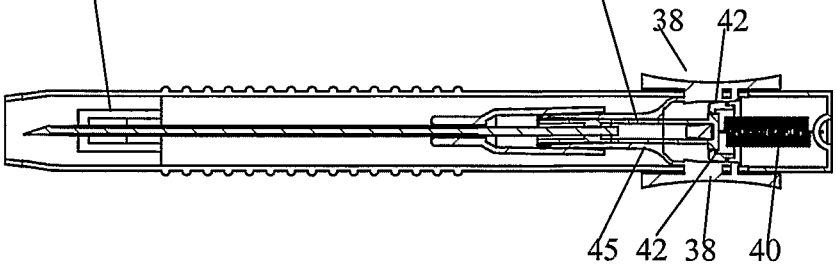

FIG 7

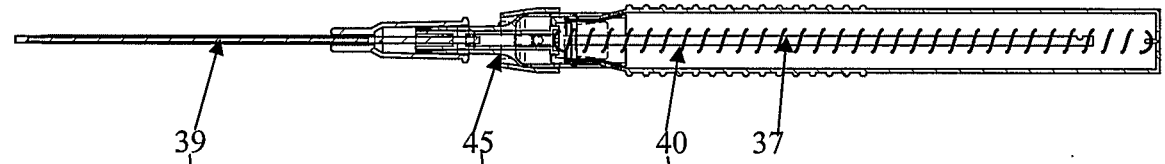

FIG 8

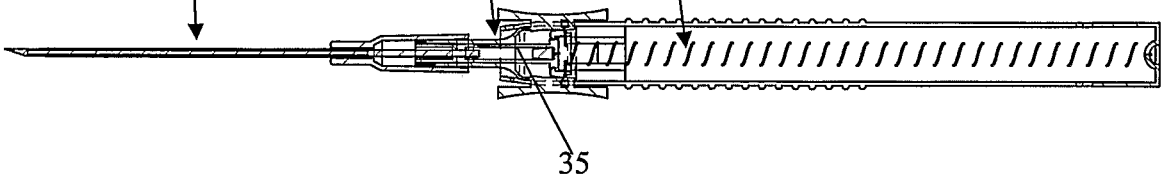

FIG 9

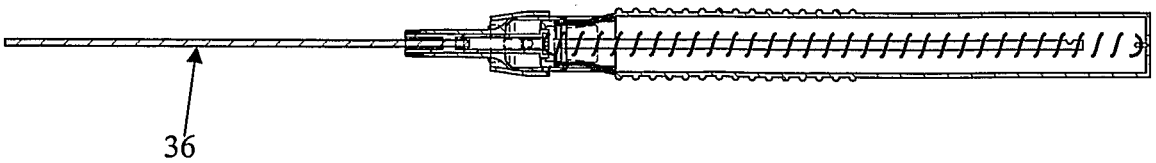

FIG 10

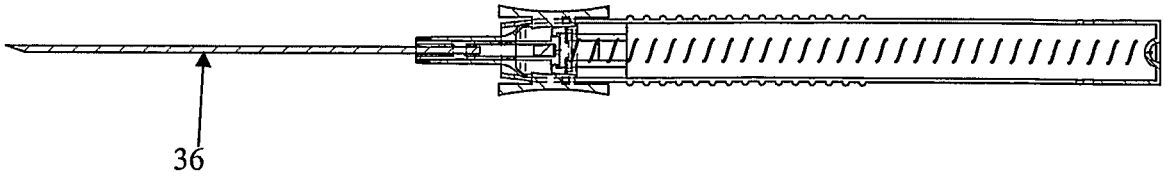

FIG 11

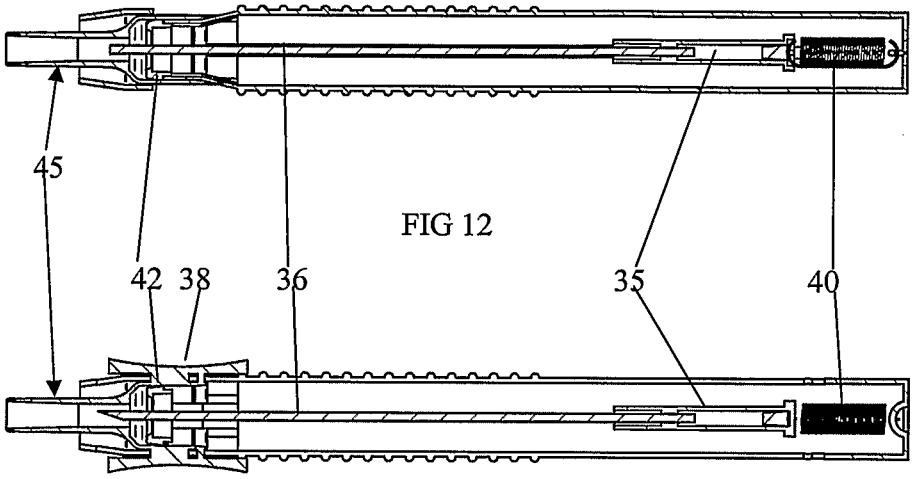

FIG 12

FIG 13

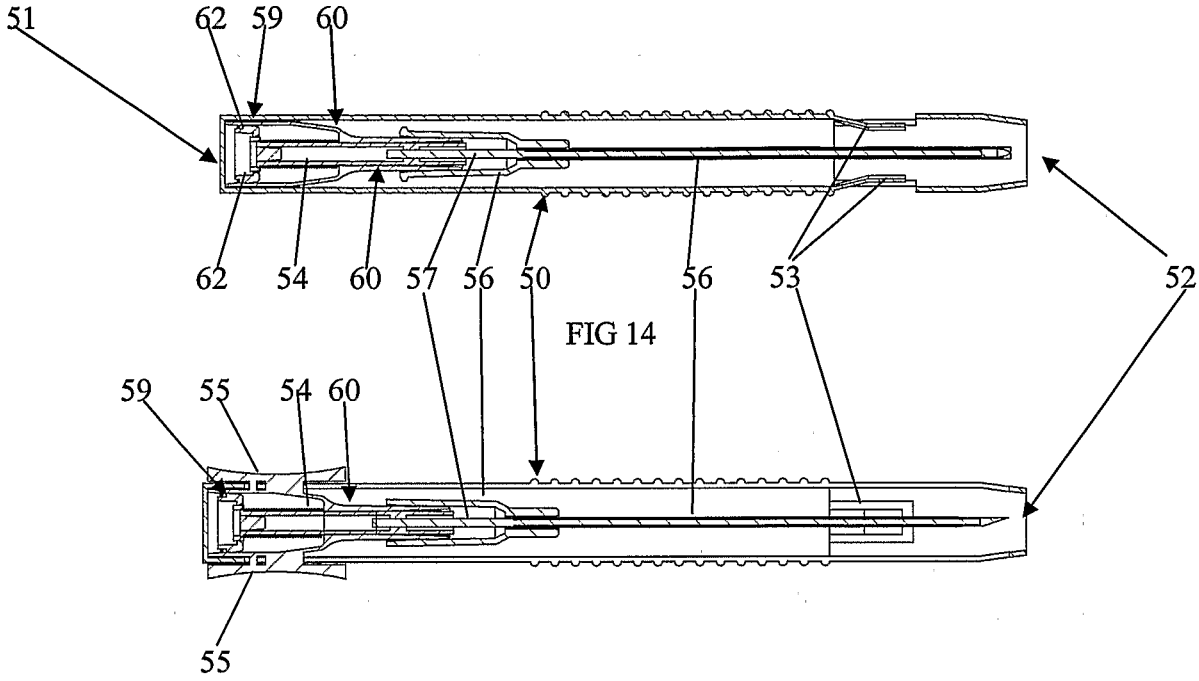

FIG 14

FIG 15

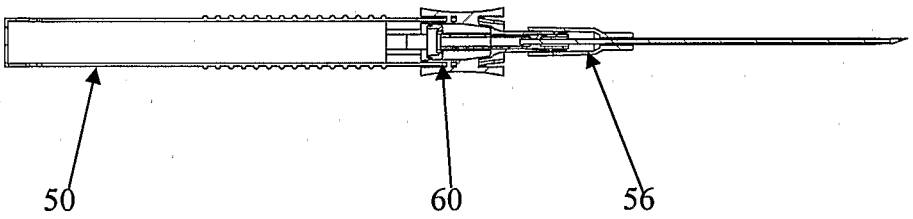

FIG 16

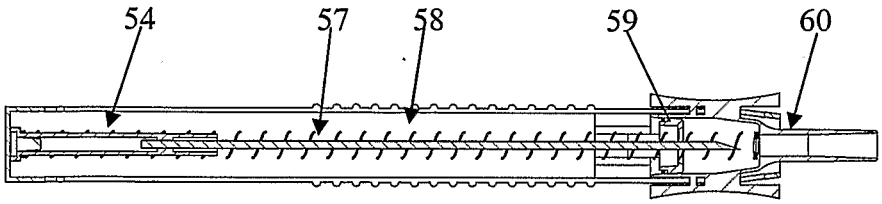

FIG 17

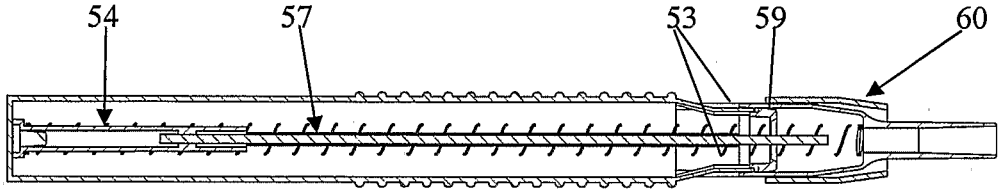

FIG 18

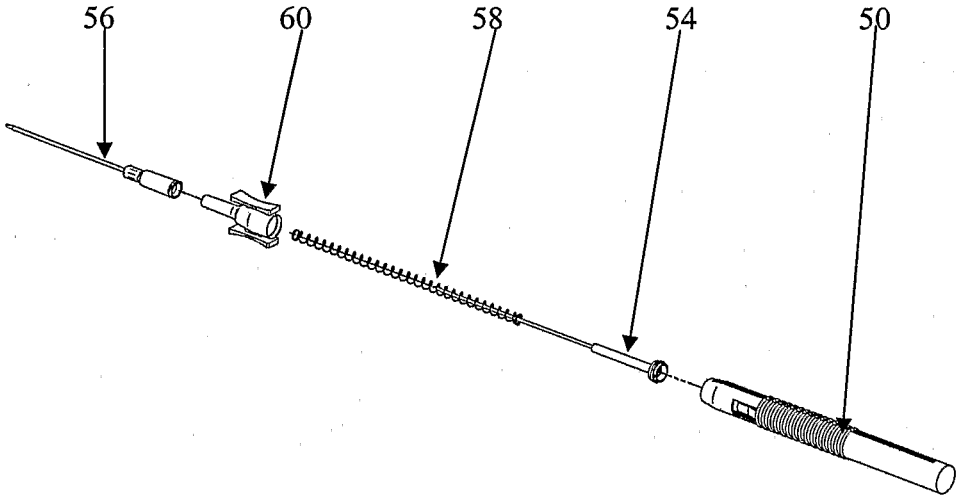

FIG 19

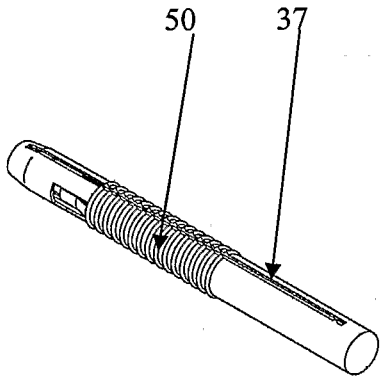

FIG 20

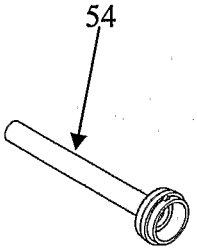

FIG 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001292

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 5/50 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI EPC A61M 5/IC, A61M 25/IC + keywords (catheter, cannula, introduce, insert, retract withdraw, shoot, needle, bias, spring and similar terms)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1998/028028 A1 (SHAW) 2 July 1998 See figures	1, 8, 9, 18, 24
X	US 2003/0083621 A1 (SHAW et al) 1 May 2003 Pages 1-4	1, 8, 9, 18, 24
A	US 6436070 B1 (BOTICH et al) 20 August 2002 Whole document	
A	US 5989220 A (SHAW et al) 23 November 1999 Whole document	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 November 2006	13 NOV 2006
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Sue Thomas** Telephone No : (02) 6283 2454

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001292

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 7

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

The scope **of** claim 7 cannot **be** determined because **it** defines "a **bump** *ori the to trigger* the shoot back mechanism".

3. ☐ Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. Ill Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001292

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	6096005 A (BOTICH et al) 1 August 2000 Columns 3-13	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2006/001292

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6096005	CA	2096026	EP	0568525	US	4994034
		US	5188599	US	5407431	WO	9208505
US	5989220	AU	41957/99	CA	2332918	EP	1079879
		EP	1486225	US	5989220	WO	9961087
us	6436070	AU	14570/99	AU	55946/98	EP	0942760
		EP	1030597	US	5800395	US	6004278
		WO	9824493	WO	9824494	WO	9923947
us	2003083621	AU	2002367958	CA	2495571	EP	1569708
		US	2005131350	WO	2004050138		
WO	9828028	**us**	5817058				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX