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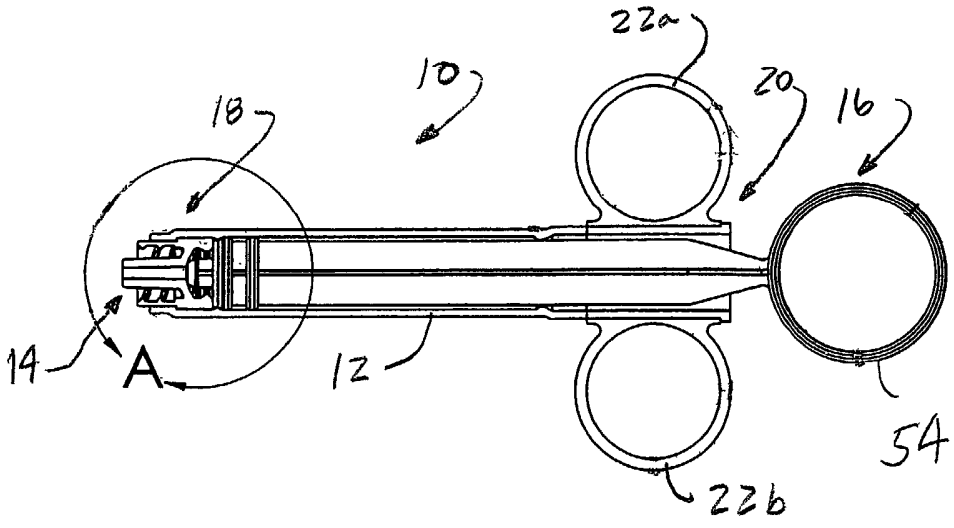
(54) Title: SAFETY SYRINGE



(57) Abstract: A hypodermic syringe provides a simple mechanism for manually retracting its needle into the syringe after injection has been completed. The syringe preferably has an elastomeric barrel to exert a radial bias to seal on a retractable needle carrier and the plunger. Attachment components on the plunger and needle carrier engage such that withdrawal of the plunger releases the needle carrier for withdrawal into the syringe barrel.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

GORDOND03-05 PATENT

SAFETY SYRINGE

Cross-reference to Related Application

This application is a provisional conversion application and claims priority to commonly owned and prior filed provisional application no. 60/401,742 filed on August 6, 2002 and entitled "Safety Syringe" and application ser. no. 10/350,961 filed January 24, 2003 and entitled " "Safety Syringe".

Field of the Invention

The present invention relates to medical devices and more particularly to hypodermic syringes designed to provide cross contamination protection to others by way of a retractable needle assembly that prevents accidental contact with the needle after use.

BACKGROUND OF THE INVENTION

Inadvertent needle stick injuries from used syringes may present a significant health hazard to others if infectious blood products are transmitted. Such accidental needle sticks may spread hepatitis, AIDS and other communicable diseases to health care workers and patients. In certain instances, the resulting disease may be life threatening. Further, the emotional distress from the fear of contracting such diseases can be significant. Still further, in the event of a stick, series of diagnostic blood tests may have to be performed to determine if cross-contamination has occurred in a needle stick injury. In many cases, the victim often is required to receive injections of gamma globulin to prevent further infection and to cure the

patient. This is uncomfortable, inconvenient, and expensive to the victim.

According to the prior art, the usual technique has been to, after use of the needle, to break off the needle and dispose of the needle and syringe in a "sharps" container for secured disposal such as by incineration or stabilization in, for example, plastic of concrete.

Efforts have been made to develop syringes which attempt to prevent inadvertent sticks. In Chen, U. S. Patent 6,432,082 issued August 13, 2002, there is disclosed a safety syringe having a needle holder which is retractable into the barrel of the syringe. The needle holder is secured to the syringe barrel by a frangible component. After use, the uses forces the plunger to couple with the needle holder and withdraws the plunger to rupture the frangible component so that the portion of the holder mounting the needle (cannula) can be withdrawn into the barrel. A drawback of this design is that the frangible portion of membrane must be manufactured to tolerances such that (1) the pressure imposed by the plunger during aspiration of the medicine into or injection of the medicine out of the syringe does not rupture the seal and (2) still provide for rupturing the portion during withdrawal of the plunger without the plunger first separating from the needle holder. It is submitted that such requirements contribute to the expense of such a device. Further, the inability of the health card provider to rupture the portion will cause frustration and abandonment of the operation to withdraw the needle.

In Jenson, U.S. Patent 5,540,660 issued July 30, 1996 there is disclosed another syringe where a needle holder is captured by the plunger for withdrawal into the syringe barrel. In one embodiment of this disclosure,

the plunger makes an interference fit into a tapered sleeve such that withdrawal of the plunger withdraws the sleeve and needle into the barrel. A drawback of this arrangement is that it would be difficult to aspirate medicine into the syringe without creating an interference fit between the plunger and sleeve thus disabling the syringe before injection of the medicine. In another embodiment a snap connection is utilized to couple the plunger to a needle holder. In either embodiment, close tolerances must be adhered to during manufacture to provide the seal between the sleeve and needle holder. Further, for either embodiment, an arcuate cannula is required to prevent re-use of the device.

Mazur, U. S. Patent 5,205,824 issued April 27, 1993 discloses another syringe where the needle holder is retained at the end of the syringe barrel only by the friction between the o-rings and the barrel which, it is believed, would (1) make secure attachment of the needle to the holder difficult since the holder may tend to rotate as the needle is threaded thereon. Further there remains a risk that insertion of he needle into a bottle of medicine for aspiration of medicine into the syringe would dislodge the needle holder and interfere with the seal.

There is a need for a safety syringe which is easy and inexpensive to manufacture, which provides for withdrawal of the needle into the barrel of the syringe, which can be re-used if desired, which has a positive coupling to provide for attachment of the needle and retention of the needle during aspiration and injection, which provides for a positive stop during withdrawal

of the needle to indicate full withdrawal of the needle and which overcomes the drawbacks noted above.

SUMMARY OF THE INVENTION

There is, therefore, set forth according to the present invention, a safety hypodermic syringe designed to provide cross contamination protection to others by way of a retractable needle assembly obviating accidental contact with the needle to another person and which is of simple and inexpensive construction.

Toward this end the safety syringe is disclosed which includes a hollow barrel having a forward and rear end. Proximate the forward end a first retention structure is provided which may be in the form of a circumferential groove or ridge or other suitable structure. A first coupling structure is also provided at the first end. Proximate said rear end is a second retention structure which may also be in the form of a circumferential groove or ridge.

A needle carrier is disposed at said forward end and has a third retention structure configured to engage with the first retention structure to releaseably retain the needle carrier at the forward end and to engage the second retention structure to retain said needle carrier in a position withdrawn into the barrel. To prevent the needle carrier from rotating in the barrel at the first end, the barrel and needle carrier have cooperative coupling structures which may be embodied as engaging tabs or teeth. Also provided is a mounting for mounting a needle such as a threaded or luer lock connection as is known in the art.

A plunger is disposed in the barrel and has a head to slideably seal within the barrel for aspiration of fluid into and out of the barrel. At the head and at the needle carrier are cooperative attachment components which, when engaged, attach the needle carrier to the plunger for withdrawal thereof. Withdrawal of the plunger disengages the third retention structure from the first retention structure to release the needle carrier to be withdrawn to a position in the barrel where the third retention structure engages the second retention structure to retain the needle carrier with its needle in the withdrawn position safely retained within the barrel of the syringe.

The barrel may be rigid but is preferably fashioned from an elastomeric material such as plastic or the like to be radially biased at least in the regions of the first and second retention structures for engagement with the third retention structure of the needle carrier. The barrel may also be rigid with an elastomeric liner.

Accordingly, the health care provider positions the plunger adjacent the needle carrier and secures the needle to the needle carrier. The needle is inserted into a vial of fluid and the plunger is withdrawn to aspirate the fluid into the barrel. The needle is withdrawn from the vial and, for example, inserted into a patient. The plunger is pushed through the barrel to aspirate the fluid from the barrel, through the needle, into the patient. At the forward end the plunger is positioned such that the cooperative retention structures on the head and needle carrier engage to capture the needle carrier to the plunger. Thereafter the plunger is withdrawn disengaging the needle carrier from the forward end of the syringe barrel and continued withdrawal of the

plunger withdraws the needle carrier and needle to a position nested within the barrel whereat the needle carrier engages the second retention structure. In this position the needle is safely withdrawn into the barrel to prevent inadvertent sticks. The syringe may then be disposed of in a sharps disposal container. If desired, the syringe may be sterilized and re-used.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages will become better understood with reference to the description, claims and drawings wherein:

FIG 1 is a side section view of the syringe without a needle;

FIG.2 is a an enlarged section view of section A of FIG. 1;

FIG 3 is an end view of the needle carrier for the syringe of FIG. 1;

FIG. 4 is a side section view of the needle carrier of FIG. 3 taken along line A - A of FIG. 3;

FIG. 5 is a side view of the needle carrier;

FIG. 6 is an enlarged section view of a portion of the needle carrier;

FIG. 7 is a side view of the plunger for the syringe of FIG. 1;

FIG. 8 is an end view of the plunger of FIG. 4;

FIG. 9 is an enlarged side view Z of portion of the plunger of FIG. 7;

FIG. 10 is a side section view of an embodiment the barrel;

FIG. 11 is an end view of the barrel of FIG. 10

FIG. 12 is an enlarged view at X of FIG. 10;

FIG. 13 is an enlarged view at Y of FIG. 10; and

FIG. 14 is an enlarged view at Z of FIG. 10.

DESCRIPTION

Turning to the drawings, FIG. 1 shows the safety syringe 10 according to the present invention. The syringe 10 includes a barrel 12 which may be cylindrical and rigid, such as by being manufactured from a hard plastic. Alternatively and preferably, the barrel may be constructed from an elastomeric or elastically deformable material such as such as vinyl, soft polyurethane or other elastically, radially biased, deformable plastic. The deformable plastic should be somewhat elastic but still able to retain its overall cylindrical shape and should be selected to withstand sterilization processes. Still alternatively, the barrel 12 may be rigid with an interior, elastic, lining. Thus, the elastic characteristic permits the barrel 12 to impose a radial bias against expansion and are contractile, to a degree.

To provide for aspiration of the desired amount of fluid, e.g. medicine, into the barrel 12, the barrel 12 should transparent or semi-transparent and include graduation markings to indicate volume of liquid within the barrel 12.

The syringe 10 also includes a needle carrier 14 , the details of which will hereafter be described.

To provide for aspiration of fluid into an out of the syringe barrel 12, the syringe 10 includes a plunger 16, the details of which will hereafter be described.

The barrel 12 is hollow and preferably cylindrical having a forward end 18 and rear end 20. At the rear end 20 a pair of finger loops 22a, b may be mounted to the barrel 12 to receive the fingers of the health care provider using the syringe 10.

With reference to FIGS. 10 - 14, the barrel 12 includes proximate the forward end 18 a rearward facing, circumferential shoulder 24 which defines a first coupling structure the purposes of which will hereinafter become evident. The shoulder 24 may have teeth 26, tabs, notches or other cooperative structure to engage with structure on the needle carrier 14 to prevent coaxial rotation thereof relative to the barrel 12.

Disposed rearward of the shoulder 24 inside the barrel 12 is a first retention structure 28 illustrated as one or more circumferentially arranged, radial projections fashioned within the barrel 12. As shown in the drawings, the first retention structure 28 may be a continuous, circumferential ridge or projection. The forward and trailing edges of the first retention structure may be chamfered at 30 degrees. Alternatively the first retention structure 28 may be discontinuous.

Disposed proximate the rear end 20 of the barrel 12 and inside thereof is a second retention structure 30. The second retention structure 30 has a construction similar to the first retention structure 28; however the forward and trailing edges may be chamfered at 20 degrees and 45 degrees, respectively, as shown in FIG. 13. . The second retention structure 30 is disposed such that, as hereinafter described, the needle carrier 14 and attached needle can be fully withdrawn into the barrel 12.

In an alternative embodiment, the first and second retention structures 28, 30 may be embodied as continuous or discontinuous circumferential grooves in the inside wall of the barrel 12.

Unlike the embodiment illustrated in FIG. 1, the embodiment of the

barrel 12 of FIGS 10 - 14 includes sets of finger flanges 31a, b in lieu of the loops 22a, b of FIG. 1. Further in this embodiment, the barrel 12 includes proximate the rear end 20 a stop surface 33 shown in FIGS. 10 and 14 as a circumferential ridge which may have forward and trailing edges chamfered at 45 degrees and 20 degrees, respectively, as shown in FIG. 14.

Turning to FIGS. 2 and 3 - 6, an embodiment of the needle carrier 14 is shown. The needle carrier 14 is generally cylindrical to be received at the forward end 18 of the barrel 12. A cylindrical first portion 32 defines a third retention structure 34 shown as the portion between a forward directed, circumferential, rim 36 and the rear edge 35 for the needle carrier 14. The rim 36 includes teeth 37 dimensioned to engage and interlock with the teeth 26 of the barrel 12 to prevent relative rotation between the needle carrier 14 and the barrel 12. Further, as shown in FIG.2, the first portion 32 is dimensioned to be closely received within the barrel 12 and to nest between the barrel 12 shoulder 24 and first retention structure 28. Forward movement of the needle carrier 14 is prevented by the engagement between the rim 26 and shoulder 24 and rearward movement is restrained by the engagement of the rear edge 35 with the first retention structure 28. Where the first and second retention structures 28, 30 are grooves or depressions, the third retention structure 34 would include a radial projection on the first portion 32 to engage with the first and second retention structures 28, 30.

The first portion 32 transitions by the rim 36 to a smaller diameter second portion 38 which defines a second coupling structure. The rim36, as described above, is cooperatively configured to engage with the first coupling

structure defined by the shoulder 24 and its teeth 26 to couple the needle carrier 14 to the barrel 12 against axial rotation. It should be noted that the first and second coupling structures could have any suitable configuration for coupling thereof such as one or more interlocking tabs, pins, or the like.

At the forward end of the needle carrier 14 there is defined a mounting structure suitable for mounting of a standard needle or cannula. Accordingly the forward end of the needle carrier 14 includes an axially projecting, hollow, nipple 44. The nipple 44 is supported by a radial substrate 46 which extends to the first portion 32. The inside surface of the second portion 38 includes threads 50. As in known with standard leur lock needles, the needle has an exteriorly threaded cap which is received over the nipple 44 and is threaded into the space defined between the nipple 44 and second portion 38, the needle's threads engaging with the threads 50 to secure the needle to the needle carrier 14. When the needle is mounted to the needle carrier 14, a fluid passageway is defined through the nipple 44 and needle for fluid to be aspirated into and from the syringe barrel 12 though the needle.

Opposite the nipple 44 the needle carrier 14 has a first attachment component 70 adapted for coupling the needle carrier 14 to the plunger 16. With reference to FIG. 6, the first attachment component 70 is defined as an ellipsoidal recess 72 defined in the needle carrier 14 and which intersects with the hollow of the nipple 44. The recess 72 opens to the inside of the barrel 12 through a reducing neck 74. The neck 74 projects into the recess 72 and may be continuous or discontinuous. The space of the recess 72 forward of the neck 74 defines a socket 76, the purposes of which will hereinafter become

evident.

To provide for aspiration of fluid and for engaging and withdrawing the needle carrier 14 and needle into the barrel 12, the syringe 10 also includes the plunger 16 as shown in FIGS. 1, 2 and 7 - 9. The plunger 16 includes at one end a thumb loop 54 to receive the thumb of the health care provider for manipulation of the plunger 16. A shaft 56 extends between the thumb loop 54 and a plunger head 58. The shaft 56 may be orthogonally fluted or of any other suitable shape.

At the head 58 there are disposed axially spaced and radially extending first and second seals 60a, b which are, when the barrel 12 is rigid, elastically deformable to engage and seal against the inside surface of the barrel 12. Where the barrel 12 is elastomeric or includes an elastomeric lining, the seals 60a, b may be rigid.

Forward of the seals 60a, b, the head 58 includes a radially extending stop 62. Forward of the stop 62 is a radially extending, deformable disk 64 of a size to (1) deform to pass through the neck 74 and to expand to engage into the socket 76 for coupling the needle carrier 14 to the plunger 16. The disk 64 defines a second attachment component for the syringe 10. Forward of the disk 64 is an end piece 66 which is adapted to be received into the recess 72 and socket 76. The disk 64 may be circular or, as suggested in FIG. 8, discontinuous.

With the foregoing in mind the operation of the syringe 10 will now be described. The syringe 10 is assembled with the needle carrier 14 disposed in the forward end 18 of the barrel 12 but disengaged with the needle carrier

14. In this position the needle carrier 14 is disposed such that its cylindrical first portion 32 is nested between the barrel shoulder 24 and the first retention structure 28 of the barrel. The teeth 26 and 37 are engaged to prevent rotation of the needle carrier 14 such as, for example, attachment of the needle. The elastomeric character of the barrel 12 constricts to retain the components. Thus, to displace the needle carrier 14, i.e. disengage the first and third retention structures, a first axial displacement force is required. This force may act to locally expand the barrel 12 or, if the barrel 12 is rigid, compress the first portion 32 of the needle carrier 14 or compress an elastically deformable first retention structure 28, or both. In a preferred embodiment the interference retention of the needle carrier 14 in the barrel 12 is with a force F_1 greater than that required for insertion of the needle into a medicine vial, patient or other intended use. That is, during aspiration, the needle carrier 14 remains retained by the engagement of the first and third retention structures.

As manufactured, the plunger 16 is retained in the barrel 12 in readiness for aspiration of medicine into the syringe 10.

The needle is threaded and secured onto the needle carrier 14. As stated above, the needle carrier 14 is retained against rotation during the mounting of the needle 42 by the coupling between the shoulder teeth 26 and the teeth of the surface 40. Once the needle 42 is secured to the needle carrier 14, the needle is inserted into a medicine vial, for example, and the plunger 16 is withdrawn in the barrel 12 to aspirate medicine into the barrel 12. The seals 60a, b seal the plunger head 58 within the barrel 12. Any air

remaining in the barrel 12 is aspirated from the barrel 12 by forward movement of the plunger 16.

The needle is then inserted into the patient and the medicine is aspirated from the barrel 12 by forward motion of the plunger 16 and injected into the patient. The elastomeric character of the barrel 12 helps seal against the plunger 16. At the end of the injection, the plunger 16 is displaced to cause the head 58 to approach the needle carrier 14. The disk 64 deforms to pass through the neck 47 and ultimately snap outward to engage into the socket 76 to thereby couple the needle carrier 14 to the plunger 16 as shown in FIG. 2. The stop 62 engages the needle carrier 14 to limit and guide the insertion of the head 58 components into the recess 72. The snap action of the disk 64 may provide a feel and sound to the user that the plunger 16 and needle carrier 14 are coupled. Further, the disk 64 is configured so as to retain the plunger 16 and needle carrier 14 together when the plunger exerts forces greater than F_1 on the needle carrier 14. The plunger 16 may then be withdrawn with a force greater than F_1 to overcome the retention force offered by the engagement by first and third retention structures 28, 34 to dislodge the needle carrier 14 from the forward end 18 for withdrawal of the needle carrier 14 and attached needle into the barrel 12. Continued withdrawal of the plunger 16 pulls the needle carrier 14 into the barrel 12. When the second retention structure 30 is engaged by the third retention structure 34 of the needle carrier 14, continued withdrawal of the plunger 16 permits the third retention structure, i.e. needle carrier first portion 32, to pass over the second retention structure 30 to nest within the space defined between the second

retention structure and the stop surface 33. With the needle carrier 14 in the withdrawn position, the needle is nested within the barrel 12 from the open forward end 18 preventing inadvertent sticks by the needle 42.

As can be appreciated, the force F_2 necessary to separate the plunger from the needle carrier 14 must be greater than F_1 in order for the plunger to withdraw the needle carrier 14.

To re-use the syringe, it would be sterilized by suitable means such as an autoclave (steam or suitable gas) and the plunger would be re-positioned to locate the needle carrier 14 such that the first and third retention structures engage as do the teeth 26 and 43. The needle is removed. The needle holder nipple 44 is held while the plunger 16 is withdrawn with a force sufficient to overcome force F2 thereby releasing the plunger 16 from the needle carrier 14 for re-use thereof.

In the alternative, when withdrawing the needle carrier 14 from the forward end 18 of the barrel 12, withdrawal may stop when the rim 35 first engages the second retention structure 30. The second retention structure 30 provides resistence to further withdrawal of the plunger 16 indicating full withdrawal. In such an embodiment, the stop surface 33 may be eliminated from the barrel 12 as shown in FIG. 1.

Still further, the angles of the chamfers of the second retention structure 30 and stop surface 33 may be configured. as shown, such that for the second retention structure 30 the needle carrier 14 encounters a 20 degree chamfer enabling the third retention structure 34 to be gradually guided over the second retention structure 30 whereas encountering a 45

degree chamfer for the stop surface 33 resists further withdrawal of the needle carrier 14 while still permitting ultimate removal of the plunger 16 from the barrel 12 for sterilization and re-use.

Still further, withdrawal of the needle carrier 14 may be complete when the seal 60b passes over the second retention surface 30 to trap the second retention surface 30 between the seals 60a, b.

It should be noted that the present invention is subject to many modifications without departing from scope of the invention as expressed in the claims. For example, the barrel 12 need not be cylindrical. Further, only a portion of the barrel 12 may be elastomeric or coated with an elastomeric liner.

CLAIMS

I Claim:

1. A safety syringe comprising:

a hollow barrel having a forward and rear end, said barrel including proximate the forward end a first retention structure and a first coupling structure and proximate said rear end a second retention structure ;

a needle carrier disposed at said forward end and including (i) a third retention structure engaging the first retention structure to releaseably retain the needle carrier at said forward end and to engage the second coupling structure to retain said needle carrier in the barrel, (ii) a second coupling structure to engage the first coupling structure to prevent rotation of the needle carrier at said forward end, (iii) a mounting for mounting a needle and (iv) a first attachment component disposed opposite said mounting; and

a plunger having a head to slideably seal within the barrel for aspiration of fluid into an out of the barrel and a second attachment component to engage the first attachment component of the needle carrier to attach the needle carrier to said head, withdrawal of the plunger disengaging the third retention structure from the first retention structure to release the needle carrier and needle to be withdrawn a position in the barrel where the third retention structure engages the second retention structure retaining the needle carrier and needle in the withdrawn position.

2. The safety syringe of claim 1 comprising said first and second retention structures include radial projections in said barrel and said third retention

structure includes a cooperative radial depression in said needle carrier to receive said projections.

3. The safety syringe of claim 2 comprising said first and second retention structures include radially projecting ridges and said third retention structure includes a radial groove in said needle carrier.

4. The safety syringe of claim 1 comprising said first and second retention structures include grooves in said barrel and said third retention structure includes a radial protuberance to engage into said grooves.

5. The safety syringe of claim 1 comprising said barrel is constructed from an elastomeric material radially constricting against said carrier and plunger head.

6. The safety syringe of claim 1 comprising said first and second attachment components includes a deformable tab snap-engaging a cooperative recess.

7. The safety syringe of claim 1 comprising said mounting is a luer lock mounting.

8. The syringe of claim 1 comprising said first and third retention structures cooperating to release the needle carrier at a first withdrawal force and said second and third retention structures cooperating to release the needle carrier at a greater, second withdrawal force.

9. A safety syringe comprising:

a hollow cylindrical barrel having a forward and rear end, said barrel including proximate the forward end a first radial projection and a first coupling structure and proximate said rear end a second radial projection;

a needle carrier disposed at said forward end and including (i) a

depression to receive the first projection to releaseably retain the needle carrier at said forward end and to receive the second projection to retain said needle carrier in the barrel, (ii) a second coupling structure to engage the first coupling structure to prevent rotation of the needle carrier at said forward end, (iii) a mounting for mounting a needle and (iv) a first attachment component disposed opposite said mounting; and

a plunger having a head to slideably seal within the barrel for aspiration of fluid into an out of the barrel and a second attachment component to engage the first attachment component of the needle carrier to attach the needle carrier to said head, withdrawal of the plunger disengaging the third retention structure from the first retention structure to release the needle carrier and needle to be withdrawn a position in the barrel where the third retention structure engages the second retention structure to retain the needle carrier and needle in the withdrawn position.

10. A safety syringe comprising:

a hollow barrel having a forward and rear end, said barrel including proximate the forward end a first groove and a first coupling structure and proximate said rear end a second groove ;

a needle carrier disposed at said forward end and including (i) a protuberance to engage into the first groove to releaseably retain the needle carrier at said forward end and to engage into the second groove to retain said needle carrier in the barrel, (ii) a second coupling structure to engage the first coupling structure to prevent rotation of the needle carrier at said forward end, (iii) a mounting for mounting a needle and (iv) a first attachment

component disposed opposite said mounting; and

a plunger having a head to slideably seal within the barrel for aspiration of fluid into an out of the barrel and a second attachment component to engage the first attachment component of the needle carrier to attach the needle carrier to said head, withdrawal of the plunger disengaging the third retention structure from the first retention structure to release the needle carrier and needle to be withdrawn a position in the barrel where the third retention structure engages the second retention structure to retain the needle carrier and needle in the withdrawn position.

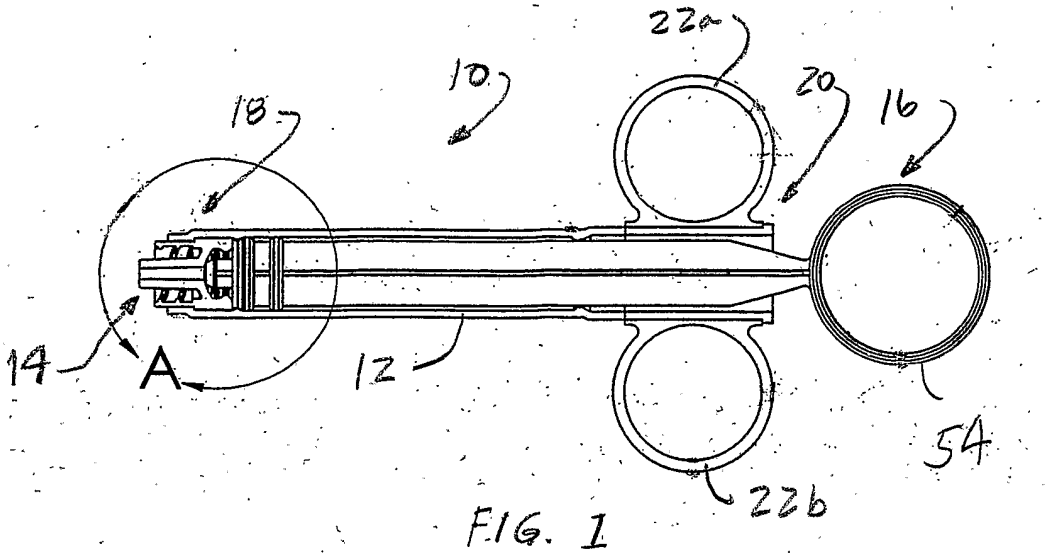


FIG. 1

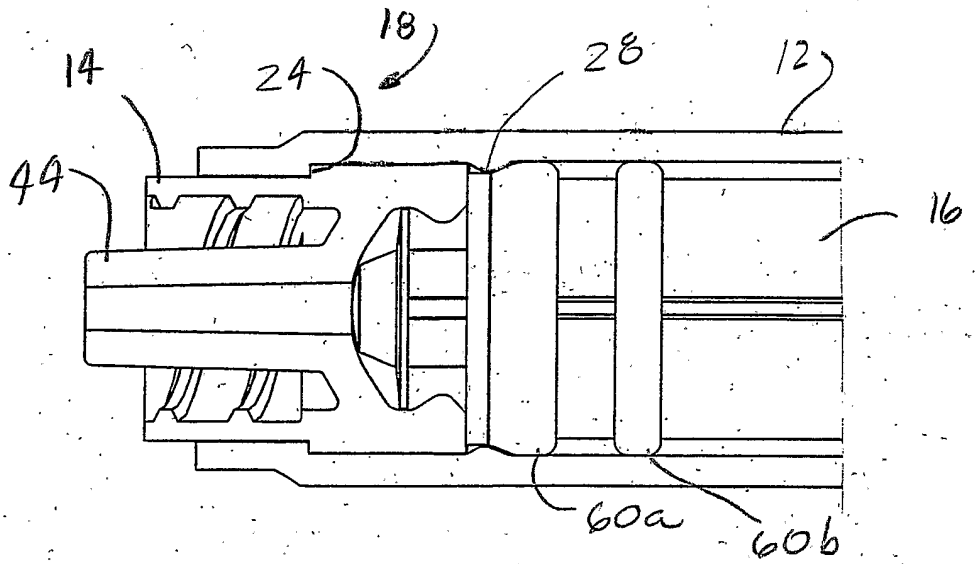


FIG. 2

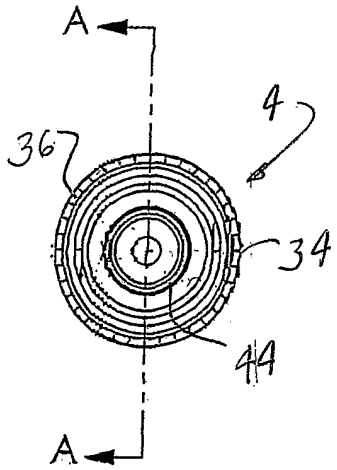


FIG. 3

FIG. 4

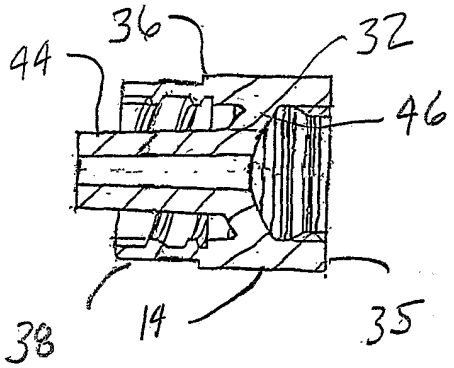
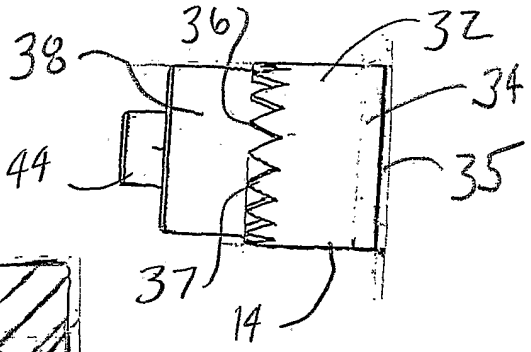


FIG. 5



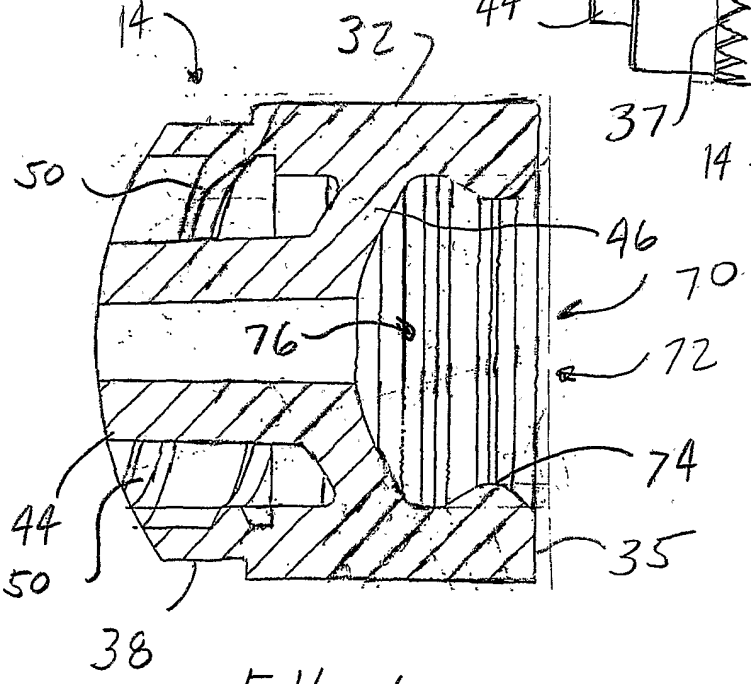


FIG. 6

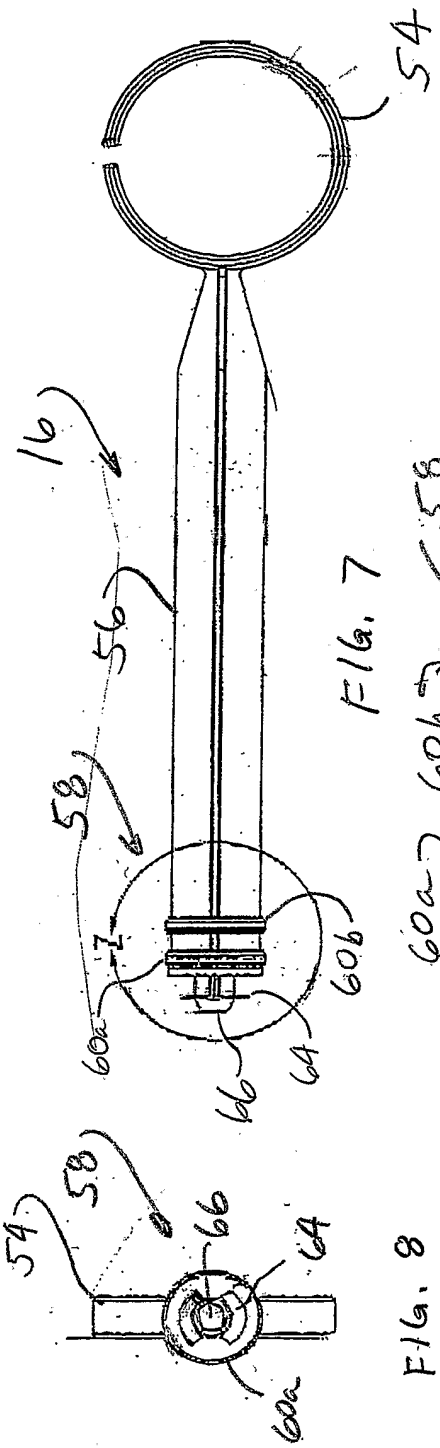


FIG. 7

FIG. 8

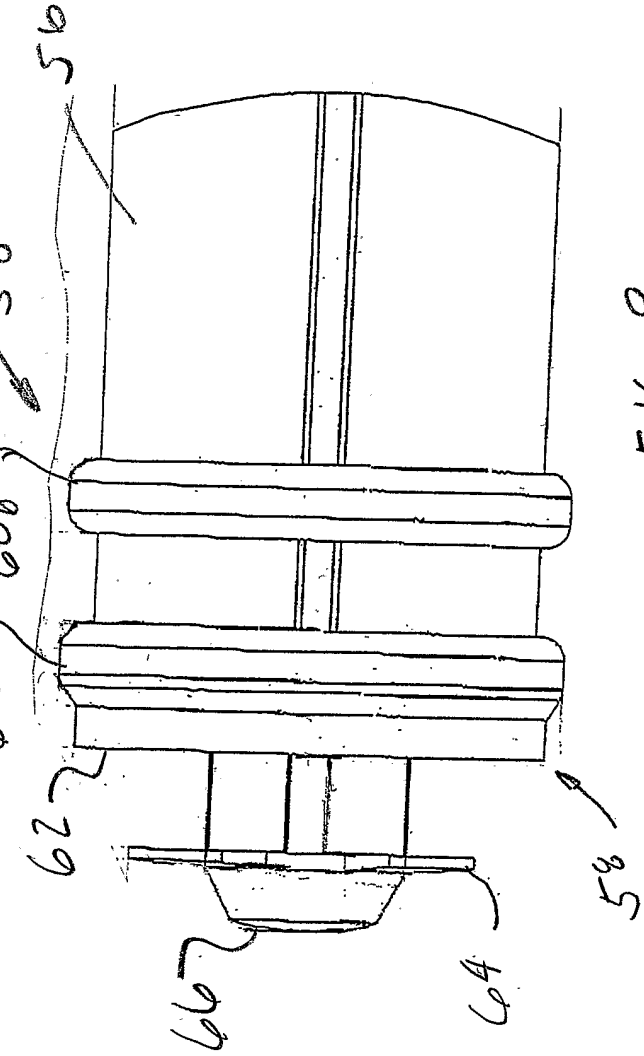


FIG. 9

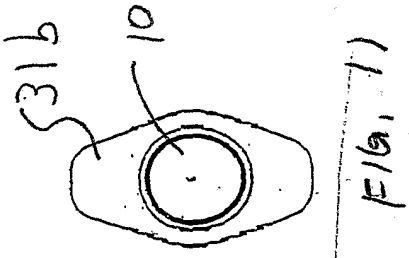


FIG. 11

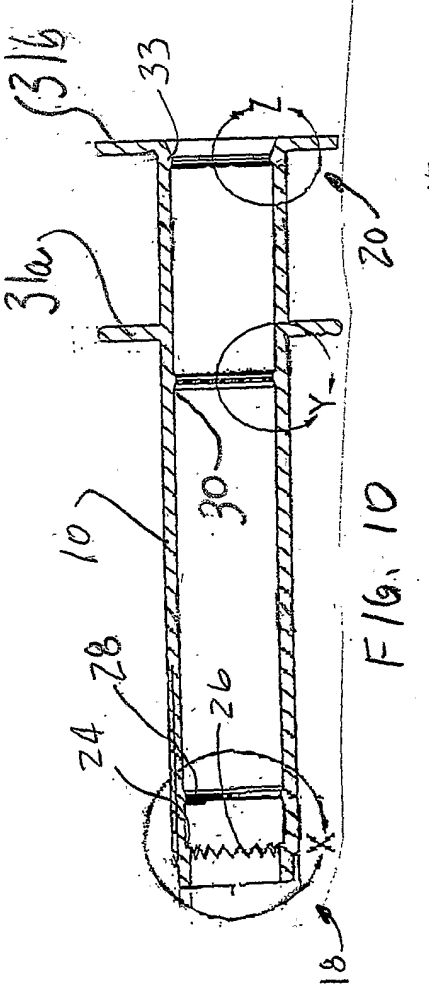


FIG. 10

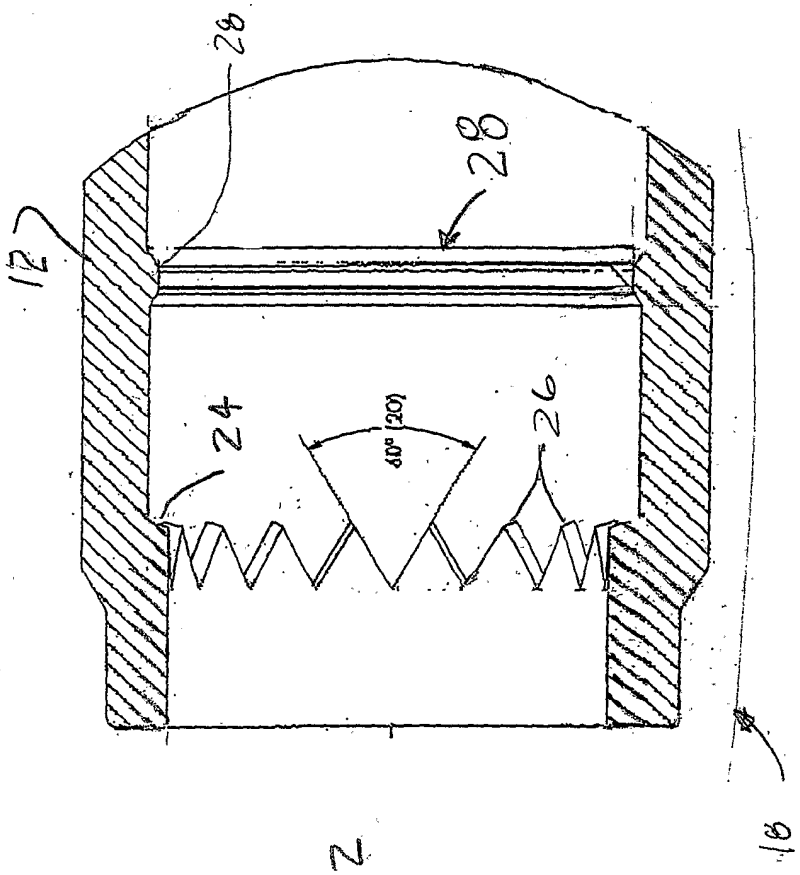


FIG. 12

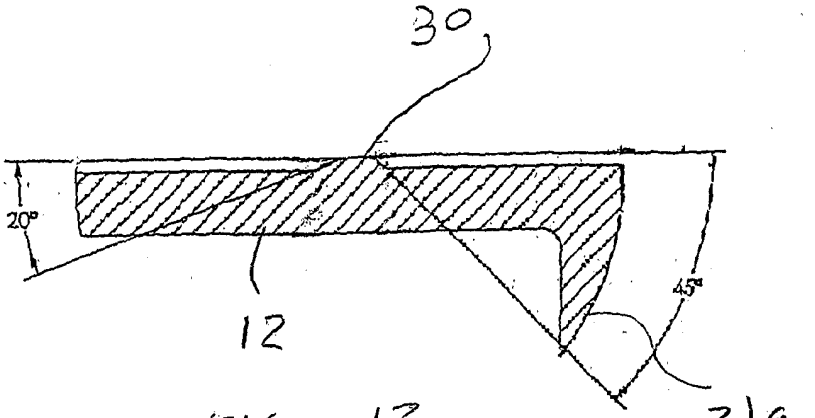


FIG. 13

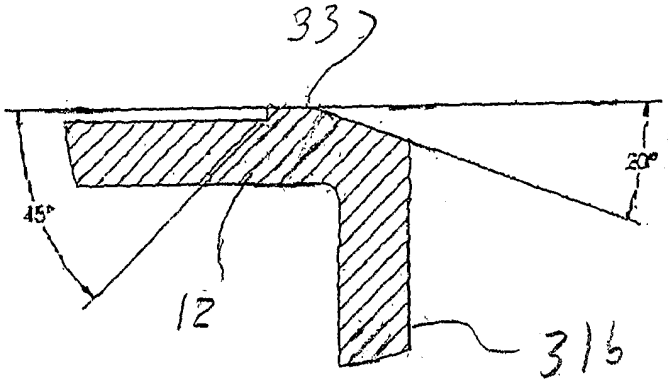


FIG. 14