Needle Assembly for a Prefilled Syringe System

The invention relates to a needle assembly for a prefilled injection syringe, especially but not exclusively of the type that is coated on the inside by means of baked siliconizing and sterilized in a heating tunnel at a temperature of up to 350°C, comprising: a needle holder with a needle secured thereto, the needle being securable to a syringe barrel of the injection syringe, a needle shielding sheath, the distal end of which fixedly sterile seals the needle holder, but releasably connected thereto and shieldingly surrounding the needle, a needle seal for mounting the needle tip arranged at least in part in the proximal end of the needle shielding sheath closed off by a closure element.

Systems of this kind are known and described inter alia in patents. Many of these known systems are, however, at a disadvantage or complicated in production and/or application.

Thus, a system is described in WO 94/22511 wherein a preassembled needle assembly with a bonded needle, needle seal as well as needle shield can be assembled e.g. in an aseptic environment to a siliconized and sterilized syringe barrel. A snap-action connector between end cap and cannula shield constitutes no microbiological shield for the needle in conjunction with the end contact face. Rendering the needle surface sterile is achieved by snap-action connection of cap and cannula shield, compressing the cannula shield of cap and cannula shield in sealing the resulting cavity surrounding the needle surface. Such a snap-action connector can be engineered releasable and thus represents a certain risk as regards rendering the needle surface sterile, as may be the case, e.g. when having become loose unnoticed during shipment or handling.

EP 0 240 787 describes a system for shielding parenteral needles involving a bonded needle, a needle seal and needle shield. There is no mention of how rendering the needle sterile is assured. Connecting the housing and needle hub is said to be achieved by axially staggered ribs which although achieving a certain secure location of the housing, fail to assure the necessary microbiological or sterile seal.

The invention is thus based on the object of improving a generic needle holder so that a sterile seal of the needle holder is assured in cost-saving production thereof so that maintaining the complete needle sterile in the time between sterilizing the needle assembly and the moment it is put to use is now reliably assured.

To achieve this object the invention is characterized by the closure connection between the closure element and the needle shielding sheath being configured as a non-releasable and sterile barrier produced by means of a bonding or welding technique.

Advantageous further embodiments of the invention read from the sub-claims.

Thus, the sterile barrier is preferably a closure connection produced by ultrasonic or laser welding.

Where a bonded connection finds application it is recommended to use non-toxic, acrylic-based adhesives for curing by means of UV light or at room temperature, such as e.g. adhesive type LOCTITE® 3011, Henkel Loctite Deutschland GmbH, 81925 Munich, epoxy resin by Barton Solvents Inc., Desmoines, USA.

Tests have shown that producing the closure element and the needle shielding sheath preferably of an amorphous thermoplastic, such as polycarbonate or polystyrene or a partly crystalline thermoplastic, such as polypropylene or polythene produces good results.

Particularly preferred is an embodiment in which the closure element is a cap with a cylindrical sleeve, and the needle shielding sheath is a tubular member, the proximal end of which is provided with a ring flange, the distal rim of the cap shell connecting the ring flange of the needle shielding sheath in forming a sterile barrier.

In this embodiment the ring flange of the needle shielding sheath may be provided at the outer edge of its proximal side to advantage with an annular face for securing the bottom rim of the cap shell.

It is furthermore advantageous when the distal rim of the cap shell comprises an interlocking profile, and the annular securing face of the ring flange of the needle shielding sheath comprises a receiving profile shaped to comply with the interlocking profile of the cap shell and in which the interlocking profile is inserted for positive and/or non-positive interlocking. The interlocking profile at the distal rim of the cap shell may also be shaped as an energy director where an ultrasonic weld with the needle shielding sheath is feasible.

Another aspect of the invention is characterized by a supporting collar jutting forwards from the proximal side of the ring flange of the needle shielding sheath radially within the outer annular securing face for the closure element.

To supplement this configuration the needle seal is provided at its proximal end preferably with a flange-type extension which is supported by the supporting collar of the needle shielding sheath. The distal side of the cover contacts the proximal end of the needle seal. In a further embodiment of the invention the proximal side of the flange-type extension of the needle seal is provided with a ring collar contacting the distal side of the head side of the closure element.

In this arrangement, preferably the supporting flange of the needle shielding sheath and the supporting collar may each comprise at the supporting flange of the needle shielding sheath a cylindrical centre hole whose bore corresponds to the bore of the cylindrical inner surface area of the needle shielding sheath.

This aspect can be modified in a second embodiment such that the inner surface area of the supporting collar of the needle shielding sheath is flared conically proximally and that the flange-type extension of the needle seal has a circumferential surface area which at least over a portion of its distal end matches the shape of the conical inner surface area of the supporting collar and is supported by this conical portion at the inner surface area of the supporting collar.

In addition, it is recommended that the distal end of the needle seal receiving the needle tip contains a central opening for the needle.

It is furthermore provided for that a longitudinal portion of the needle seal arranged distally of the flange-type extension extends by the supporting collar into the proximal

end of the needle shielding sheath. In this arrangement the diameter of this distal longitudinal portion may be smaller or equal to the diameter of the inner space of the needle shielding sheath.

In addition it is particularly preferred that the needle shielding sheath is integrally connected at its distal end by a designed frangible connection to a proximal portion of the needle holder in thus making it possible to totally expose the needle ready for use after having destroyed just a single designed frangible connection.

It is recommended to produce the needle seal of a pharmaceutical rubber or a thermoplastic elastomer.

In conclusion, the needle should be preferably made of a stainless steel and either fixedly bonded in the needle holder coaxially to the barrel of the syringe or fixedly connected to the needle holder by a plastics potting. The needle holder itself may be made preferably of a thermoplastic, such as polycarbonate, polypropylene or polyamide.

From the above comments it will be appreciated that the needle assembly in accordance with the invention is excellently tamperproof on opening the prefilled injection syringe due to the sterile barrier between closure element and needle shielding sheath whilst assuring simple production and component assembly in producing the needle assembly as well as simple assembly of the needle assembly to a siliconized syringe barrel.

The preferred method of manufacturing the needle assembly includes securing a needle to a needle holder that is adapted

to be secured to a syringe barrel of the injection syringe, releasably connecting the distal end of a needle sheath to the needle holder to form a sterile seal, and to surround and shield the needle, locating a needle seal on the needle tip and at least in part in the proximal end of the needle sheath, and closing off the proximal end of the needle seal with a closure element by forming a closure connection between the closure element and the needle sheath, configured as a non-releasable and sterile barrier, by means of bonding or welding.

In one particular manufacturing method, a first subassembly of the needle seal, closure element and needle sheath is formed, in which the needle seal is arranged at least in part in the proximal end of the needle sheath and the closure element closes off the proximal end of the needle seal, a second subassembly is formed by securing the needle to the needle holder, and the first and second subassemblies are offered up to one another so that the needle sheath releasably connects at its distal end to the needle holder to form a sterile seal, and surrounds and shields the needle, and the needle seal locates on the needle tip.

In an alternative manufacturing method, a first subassembly is formed by securing the needle to the needle holder, a second subassembly is formed by inserting the first subassembly into the needle sheath, a third subassembly is formed by mounting the needle seal onto needle tip and needle sheath of the second subassembly, and the needle assembly is completed by forming the closure connection between the closure element and the needle sheath of the third subassembly.

The invention will now be detailed by way of example embodiments with reference to the diagrammatic drawing in which:

FIG. 1 is a longitudinal centreline section through a first embodiment of a needle assembly in accordance with the invention as it leaves production;

FIG. 2 is a longitudinal centreline section through a second embodiment of the invention as it leaves production;

FIG. 3 is a longitudinal centreline section, on a magnified scale, through a cover with an energy director prior to assembly, for a needle shielding sheath of the needle assembly as shown in FIGS. 1 or 2;

FIG. 4 is a longitudinal centreline section, on a magnified scale, through a second modified embodiment of a cover for needle assembly;

FIG. 5 is a longitudinal centreline section, on a magnified scale, through a needle seal of the needle assembly as shown in FIG. 1; and

FIG. 6 is a longitudinal centreline section, on a magnified scale, through a needle seal of the needle assembly as shown in FIG. 2.

Referring now to FIG. 1 there is illustrated a needle assembly for a prefilled injection syringe made of glass or plastics, known as such and thus not shown, coated on the inside by means of baked siliconizing and sterilized in a heating tunnel at a temperature of up to 350°C. The needle assembly 10 is composed of a needle holder 12 and secured thereto a needle 14, a needle shielding sheath 16, a needle seal 18 and a closure element 20.

In detail, the needle holder 12 is tapered, featuring at its distal end a conical opening 22 provided with an annular

groove 24 so that the needle holder 12 can be fitted to a moulded barrel with an annular bead of a prefilled injection syringe known as such and thus not shown, and secured thereto by snap-action connection. The conical opening 22 translates at its proximal end into a cylindrical bore 26 in which the needle 14 is coaxially secured by its distal end with the aid of an adhesive 28. Useful adhesives are non-toxic, acrylic-based adhesives for curing by means of UV light or at room temperature, such as e.g. adhesive type LOCTITE® 3011, Henkel Loctite Deutschland GmbH, 81925 Munich, epoxy resin by Barton Solvents Inc., Desmoines, USA.

Where necessary the needle 14 may also be secured by sleeve moulding it in the needle holder, whereby the same plastics material can be used for sleeve moulding the needle holder in an injection moulding technique as serving for production of the needle holder.

The needle 14 can be configured differing in length and is preferably made of a stainless steel of the type AISI 314 and is a cannula, the coaxially bore of which is exposed at the distal end. A proximal end of the needle holder 12 is an annular face 30 surrounding the bonded needle 14. The needle holder 12 is preferably made of a thermoplastic such as e.g. polycarbonate, polypropylene or polyamide.

The needle shielding sheath 16 mainly comprises a tubular longitudinal portion 32, the distal end of which is a secure and sterile seal connecting the outer edge of the annular face 30 of the needle shielding sheath 16 by a circumferential designed frangible connection 52, but which can be released manually by exerting a fracturing force.

The needle shielding sheath 16 extends coaxially to the needle holder 12 in surrounding the needle 14 with a full length consistent radial spacing. The outer diameter of the needle shielding sheath 16 is dimensioned only slightly larger than the diameter of the annular face 30 of the needle holder 12.

The needle shielding sheath 16 extends by its tubular longitudinal portion 32 beyond the tip (not shown in FIG. I) of the needle, the proximal end of the tubular longitudinal portion 32 featuring a ring flange 34 surrounding an opening, the diameter of which roughly corresponds to the inner diameter of the needle shielding sheath 16.

The ring flange 34 extends outwards beyond the cylindrical outer side of the needle shielding sheath 16. The proximal end of the ring flange 34 features at its outer edge an annular securing face 36, an annular supporting collar 38 being arranged within this annular securing face 36. The inner diameter of this supporting collar 38 roughly corresponds to that of the needle shielding sheath 16 and ring flange 34 respectively. The needle shielding sheath 16 is preferably made of a partly crystalline thermoplastic, such as e.g. polypropylene or polythene.

In both embodiments of the needle assembly as shown in FIGS. 1 and 2 the needle seal 18 is made of an elastomeric material, such as pharmaceutical rubber or a thermoplastic elastomer, and serves to shieldingly receive a proximal end of the needle 14 comprising a bevelled needle tip, and which is arranged at least in part in the proximal end of the needle shielding sheath 16.

Referring now to the first embodiment as shown in FIG. 1 it is evident how the needle seal 18 comprises a moulding featuring a conical distal end 40 containing a centring opening 42 for the needle tip in extending over roughly half the length of the needle seal 18. The conical distal end 40 then translates into a short cylindrical longitudinal portion 44 contacting a cylindrical inner surface area 46 of the supporting collar 38 of the needle shielding sheath 16. Before this short cylindrical longitudinal portion 44 the needle seal 18 is provided with a flange-type extension 48 supporting the needle seal 18 at the supporting collar 38 of the needle shielding sheath 16. A proximal end of the needle seal 18 is formed by an annular collar 50 protruding from an outer edge of the proximal end of the flange-type extension 48 of the needle seal 18.

Referring now to FIG. 5 there is illustrated a modified embodiment of the needle seal 18 in which merely a conical longitudinal portion 40 and a cylindrical longitudinal portion 44 located therebefore are dimensioned roughly the same in length. The annular collar 50 has a triangular cross-section, the apex of which is proximal.

The proximal end of the needle assembly 10 comprises the closure element 20 closing off the needle shielding sheath 16, this closure connection between the closure element 20 and needle shielding sheath 16 being configured as a sterile barrier 54.

Referring now to FIG. 1 again, there is illustrated how the closure element 20 is a cap 56 with a header plate 58, from the outer rim of which a cylindrical shell 60 extends distally. A distal rim 62 of the cylindrical shell 60 is connected to the securing face 36 of the ring flange 34 of

the needle shielding sheath 16 in forming the sterile barrier 54. In this arrangement the closure element 20 clasps the portion of the needle seal 18 located before the supporting collar 38 as well as the supporting collar 38.

The sterile barrier 54 between the closure element 20 and the needle shielding sheath 16 comprises particularly to advantage a bonded or welded connection.

Where a bonded connection finds application it is recommended as mentioned above to use non-toxic acrylic-based adhesives for curing by means of UV light or at room temperature, such as e.g. adhesive type LOCTITE® 3011, Henkel Loctite Deutschland GmbH, 81925 Munich, epoxy resin by Barton Solvents Inc., Desmoines, USA.

In application of a welding technique preference is given to ultrasonic or laser welding techniques.

Where an ultrasonic weld is involved, the closure element 20, as shown in FIG. 3. is equipped at the distal rim 62 of its cap shell 60 preferably with an energy director 64 tapered distally into a triangular cross-section for faster, more effective welding of the distal rim 62 of the cap shell 60 to the securing face 36 at the outer edge of the ring flange 34 of the needle shielding sheath 16.

Referring now to FIG. 4 there is illustrated a cap 66 as a closure element 20, the cylindrical shell of which comprises a distal free end having a smooth annular surface area 68 extending perpendicular to the longitudinal centreline of the closure element 20. This embodiment is provided to close off the needle shielding sheath 16 by a bonded connection forming the sterile barrier 54.

It is recommended to produce the closure element 20 of an amorphous thermoplastic, such as polycarbonate or polystyrene or a partly crystalline thermoplastic, such as polypropylene or polythene.

Referring now to FIG. 1 again there is illustrated how the header plate 58 of the cap-type closure element 20 contacts a proximal end of the needle seal 18 by its distal side 70 (FIG. 3). In this arrangement of a first embodiment, the closure element 20 merely contacts the elastomeric annular collar 50 of the needle seal 18 in compressing it in part, so that the needle seal 18 with its flange-type extension 48 is pressed against the supporting collar 38 of the needle shielding sheath 16 when the needle shielding sheath 16 is closed off sterile by the closure element 20.

Referring now to FIG. 2 there is illustrated the needle assembly 210 in a second embodiment in accordance with the invention in which like or similar elements of the second embodiment are identified by like reference numerals of the first embodiment but prefixed by 2.

This needle assembly 210 differs from that of the first embodiment substantially in that the inner surface area of a supporting collar 238 of the needle shielding sheath 216 is flared conically proximally. As is evident from FIG. 2 and FIG. 6 a proximal flange-type extension 248 of the needle seal 218 comprises a circumferential surface area adapted at least in a partial portion of its distal end to the shape of the conical inner surface area 246 of the supporting collar 238 in being supported by this conical partial portion 246 on the conical inner surface area 246 of the supporting collar 238.

A portion 240 of the needle seal 218 extending distally of the flange-type extension 248 is formed cylindrical in interlocking the supporting collar 238 as well as the proximal end of the needle shielding sheath 216 in creating a free, annular space 251. The needle seal 218 in this case too is made of a pharmaceutical rubber or thermoplastic elastomer.

Missing furthermore from this second embodiment at the needle seal 218 is an annular collar protruding from the flange-type extension distally in the direction of the distal side of the header plate 258 of the closure element 220, resulting in the proximal side of the flange-type extension of the needle seal 218 directly contacting the distal side 270 of the header plate 258 of the closure element 220. The elastomeric material of the needle seal 218 is, however, in this second embodiment too, compressed by the closure element 220 when it is fixedly and non-releasable connected to the needle shielding sheath 216 to form a sterile barrier 254 with the needle shielding sheath 216.

The two main procedures in assembling the cap-type closure element and the needle shielding sheath are as follows:

1. joining the closure element by a welding or bonding technique, ensuring a good seal by the assurance of a full-length jointing seam (sterile barrier 54; 254),

2. positioning the flange of the needle seal when joining or assembling closure element and needle shielding sheath so that the resulting needle space is closed off microbiologically or sterile from the environment.

For the sake of completeness the steps in assembling the aforementioned needle assemblies are listed in the following in omitting the quality inspection steps:

1. picking and placing the needle holder;
2. picking and placing the needle and positioning the needle in the needle holder;
3. dispensing the adhesive and any follow-on steps as required, such as e.g. curing;
4. picking and placing the closure element
5. picking and placing the needle seal;
6. inserting the needle seal into the closure element;
7. picking and placing the needle shielding sheath
8. inserting the needle shielding sheath onto the closure element including the needle seal;
9. jointing and mounting method: securing the closure element on the needle shield sheath by means of welding or bonding and, if applicable, follow-on steps such as e.g. curing the adhesive in producing the sterile barrier;
10. inserting the needle and the needle holder into the needle shield sheath with the closure element and needle seal.

An alternative assembly method is as follows:

1. picking and placing the needle holder;
2. picking and placing the needle and positioning the needle in the needle holder;
3. dispensing the adhesive and any follow-on steps as required, such as e.g. curing;
4. picking and placing the needle sheath;
5. inserting the needle and the needle holder into the needle sheath;
6. picking and placing the needle seal and mounting onto needle tip and/or needle sheath;

7. picking and placing the closure element and mount onto needle shield sheath;

8. jointing and mounting method: securing the closure element on the needle shield sheath by means of welding or bonding and, if applicable, follow-on steps such as e.g. curing the adhesive in producing the sterile barrier.

It will thus be appreciated that the needle assembly in accordance with the invention ensures the needle remaining sterile during storage of the prefilled injection syringe in thus rendering it safely tamperproof. In addition, the needle assembly is simple to fit to a siliconized and sterilized syringe barrel on a mass production scale. All of the various component parts are simple to manufacture and assemble.

Claims

1. A needle assembly (10; 210) for a prefilled injection syringe, comprising:

   a needle holder (12; 212) adapted to be secured to a syringe barrel of the injection syringe and a needle (14; 214) secured to the needle holder (12; 212);
   a needle sheath (16; 216), releasably connected at its distal end to the needle holder (12; 212) to form a sterile seal, and surrounding and shielding the needle (14; 214), said needle sheath (16; 216) being a tubular member (32; 232);
   a needle seal (18; 218) located on the needle tip and arranged at least in part in the proximal end of the needle sheath (16; 216);
   a closure element (20; 220) that closes off the proximal end of the needle seal, said closure element (20; 220) being a cap (56; 256) with a cylindrical shell (60; 260) having a distal rim (62; 262); and
   a closure connection between the closure element (20; 220) and the needle sheath (16; 216), configured as a non-releasable and sterile barrier (54; 254) produced by means of bonding or welding,

   characterized in that the proximal end of the needle sheath (16; 216) is provided with a ring flange (34; 234) and the distal rim (62; 262) of said cap shell (60; 260) connects said ring flange (34; 234) of said needle sheath (16; 216) to form the sterile barrier (54; 254).

2. The needle assembly as set forth in claim 1, **characterized in that** said sterile barrier (54; 254) is produced by ultrasonic welding.

3. The needle assembly as set forth in claim 1, **characterized in that** said sterile barrier (54; 254) is produced by laser welding.

4. The needle assembly as set forth in claim 1, **characterized by** the use of non-toxic acrylic-based adhesives for curing by means of UV light or at room temperature for producing said sterile barrier (54; 254) by means of a bonding technique.

5. The needle assembly as set forth in any one of the preceding claims, **characterized in that** said ring flange (34: 234) of said needle sheath (16; 216) is provided at the outer edge of its proximal side with an annular face (36; 236) for securing said distal rim (62; 262) of said cap shell (60, 260).

6. The needle assembly as set forth in claim 5, **characterized by:**

   - a supporting collar (38; 238) jutting forwards from the proximal side of said ring flange (34, 234) of said needle sheath (16; 216) radially within said outer annular securing face (36: 236) for said closure element (20; 220),
   - a flange-type extension (48; 248) of the upper end of said needle seal (18; 218) with which said needle seal (18; 218) is supported by said supporting collar (38; 238) of said needle sheath (16; 216) thereof, and
   - the distal side (70) of said closure element (20; 220) contacting a proximal end of said needle seal (18; 218).

7. The needle assembly as set forth in claim 6, **characterized in that** the proximal end of said flange-type extension (48; 248) of said needle seal (18; 218) is provided with a ring collar (50; 250) contacting the distal side (70; 270) of said header plate (58; 258) of said closure element (20; 220).

8. The needle assembly as set forth in claim 6 or claim 7, **characterized in that** said ring flange (34) of said needle sheath (16) and said supporting collar (38) each comprise at said ring flange (34) of said needle sheath (16; 216) a cylindrical inner surface area (46) whose bore corresponds to the bore of said cylindrical inner surface area of said needle sheath (16).

9. The needle assembly as set forth in claim 8, **characterized in that** said inner surface area (246) of said supporting collar (238) of said needle sheath (216) is flared conically proximally and that said flange-type extension (248) of said needle seal (218) has a circumferential surface area which at least over a portion (249) of its distal end matches the shape of said conical inner surface area (246) of said supporting collar (238) and is supported by this conical partial portion (248) at said inner surface area (246) of said supporting collar (238).

10. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** the distal end of said needle seal (18) receiving said needle tip contains a central opening (42) for said needle (14).

11. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** a portion (40; 240) of said needle seal (18; 218) arranged distally of said flange-type extension (48; 248) extends into said supporting collar (38; 238) into the proximal end of said needle sheath (16; 216), and comprises a diameter substantially equal to that of the inner space of said needle sheath (16; 216).

12. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said needle sheath (16; 216) is integrally connected at its distal end by a designed frangible connection (52; 252) to a proximal portion of said needle holder.

13. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said closure element (20; 220) and said needle sheath (16; 216) are made of an amorphous or partly crystalline thermoplastic, such as polypropylene or polythene.

14. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said needle seal (18; 218) is made of a pharmaceutical rubber or a thermoplastic elastomer.

15. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said needle (14; 214) is made of a stainless steel.

16. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said needle (14; 214) is fixedly bonded in said needle holder (12; 212) coaxially to said needle sheath (16; 216).

17. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said needle (14; 214) is fixedly connected to said needle holder (12; 212) by a plastics potting.

18. The needle assembly as set forth in one or more of the preceding claims, **characterized in that** said needle holder (12; 212) is made of a thermoplastic such as polycarbonate, polypropylene or polyamide.

19. A method of manufacturing a needle assembly (10; 210) for a prefilled injection syringe, comprising:

securing a needle to a needle holder (12; 212) that is adapted to be secured to a syringe barrel of the injection syringe;
releasably connecting a distal end of a needle sheath (16; 216) to the needle holder (12; 212) to form a sterile seal, and to surround and shield the needle (14; 214), said needle sheath (16; 216) being a tubular member (32; 232);
locating a needle seal (18; 218) on the needle tip and at least in part in the proximal end of the needle sheath (16; 216); and
closing off a proximal end of the needle seal with a closure element (20; 220), said closure element (20; 220) being a cap (56; 256) with a cylindrical shell (60; 260) having a distal rim (62; 262);

characterised by:

forming a closure connection between the distal rim (62; 262) of said cap shell (60; 260) and a ring flange (34; 234) provided on the proximal end of the needle sheath (16; 216), configured as a non-releasable and sterile barrier (54; 254), by means of bonding or welding.

20. The method of claim 19, in which:

a first subassembly of the needle seal (18; 218), closure element (20; 220) and needle sheath (16; 216) is formed, in which the needle seal (18; 218) is arranged at least in part in the proximal end of the needle sheath (16; 216) and the closure element (20; 220) closes off the proximal end of the needle seal;
a second subassembly is formed by securing the needle (14; 214) to the needle holder (12; 212); and
the first and second subassemblies are offered up to one another so that the needle sheath (16; 216) releasably connects at its distal end to the needle holder (12; 212) to form a sterile seal, and surrounds and shields the needle (14; 214), and the needle seal (18; 218) locates on the needle tip.

21. A method according to claim 19, in which:

a first subassembly is formed by securing the needle (14; 214) to the needle holder (12; 212);
a second subassembly is formed by inserting the first subassembly into the needle sheath (16; 216);
a third subassembly is formed by mounting the needle seal (18, 218) onto needle tip and needle sheath (16; 216) of the second subassembly; and
the needle assembly is completed by forming the closure connection between the closure element (20; 220) and the needle sheath (16; 216) of the third subassembly.