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(54) INFUSION HUB ASSEMBLY AND FLUID LINE DISCONNECT SYSTEM

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(60) Provisional application No. 60/273,490, filed on Mar. 4, 2001. Provisional application No. 60/299,842, filed on Jun. 19, 2001.

Publication Classification

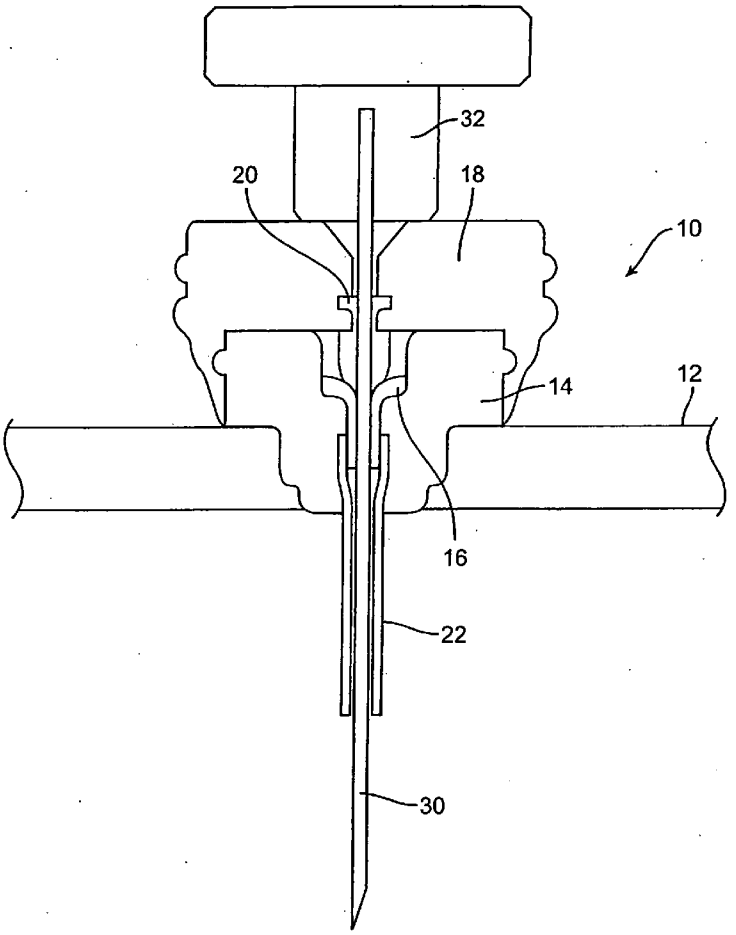
(51) **Int. Cl.**[7] **A61M 5/178**

(52) **U.S. Cl.** **604/167.05**

(57) **ABSTRACT**

An infusion hub assembly, comprising: a hub received in a hole in a wing, the hub having a bore passing therethrough, with an upper portion of the circular hub having an attachment surface thereon; an infusion cannula extending downwardly away from the wing, the infusion cannula being in fluid communication with the bore passing through the hub; a cover having a bore passing therethrough and having an inner attachment surface adapted to mate with the attachment surface on the upper portion of the hub; and a septum positioned in alignment with the bore passing through the cover.

An infusion connector set comprising: a first connector; a septum received in the first connector; a second connector; a septum received in the second connector; and a flanged needle which penetrates both the septums in the first and second connectors when the first and second connectors are connected together.



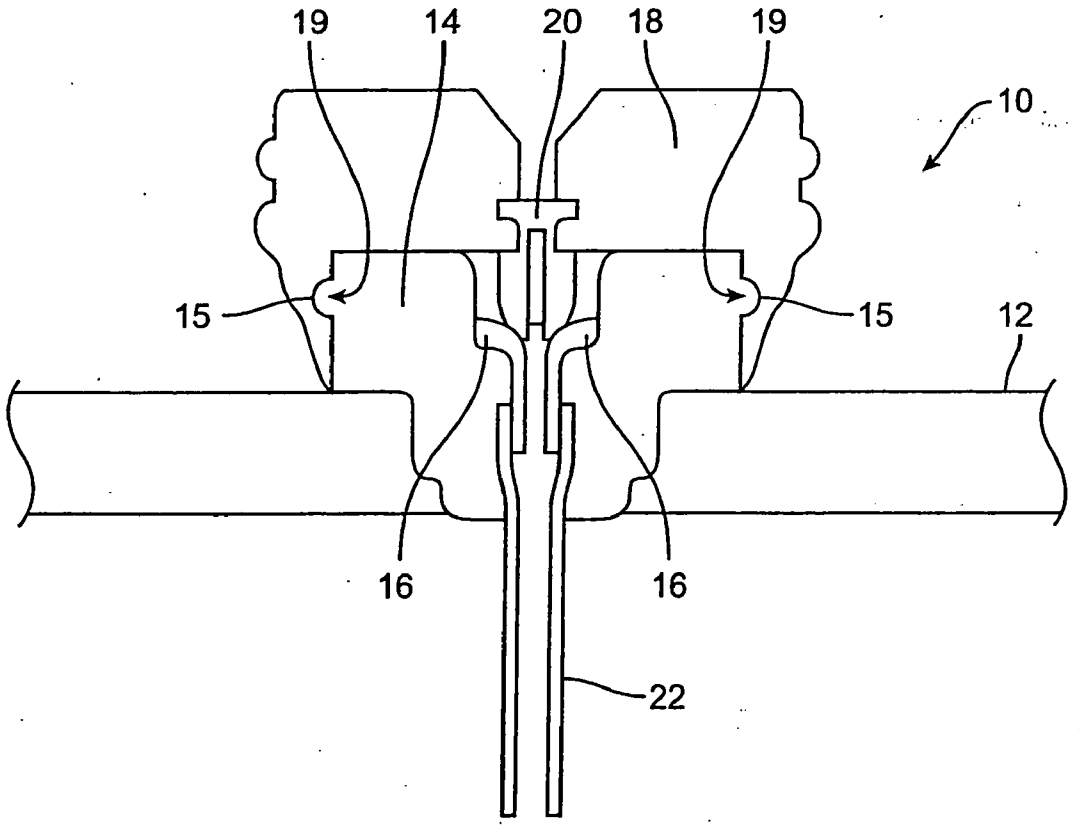


FIG. 1

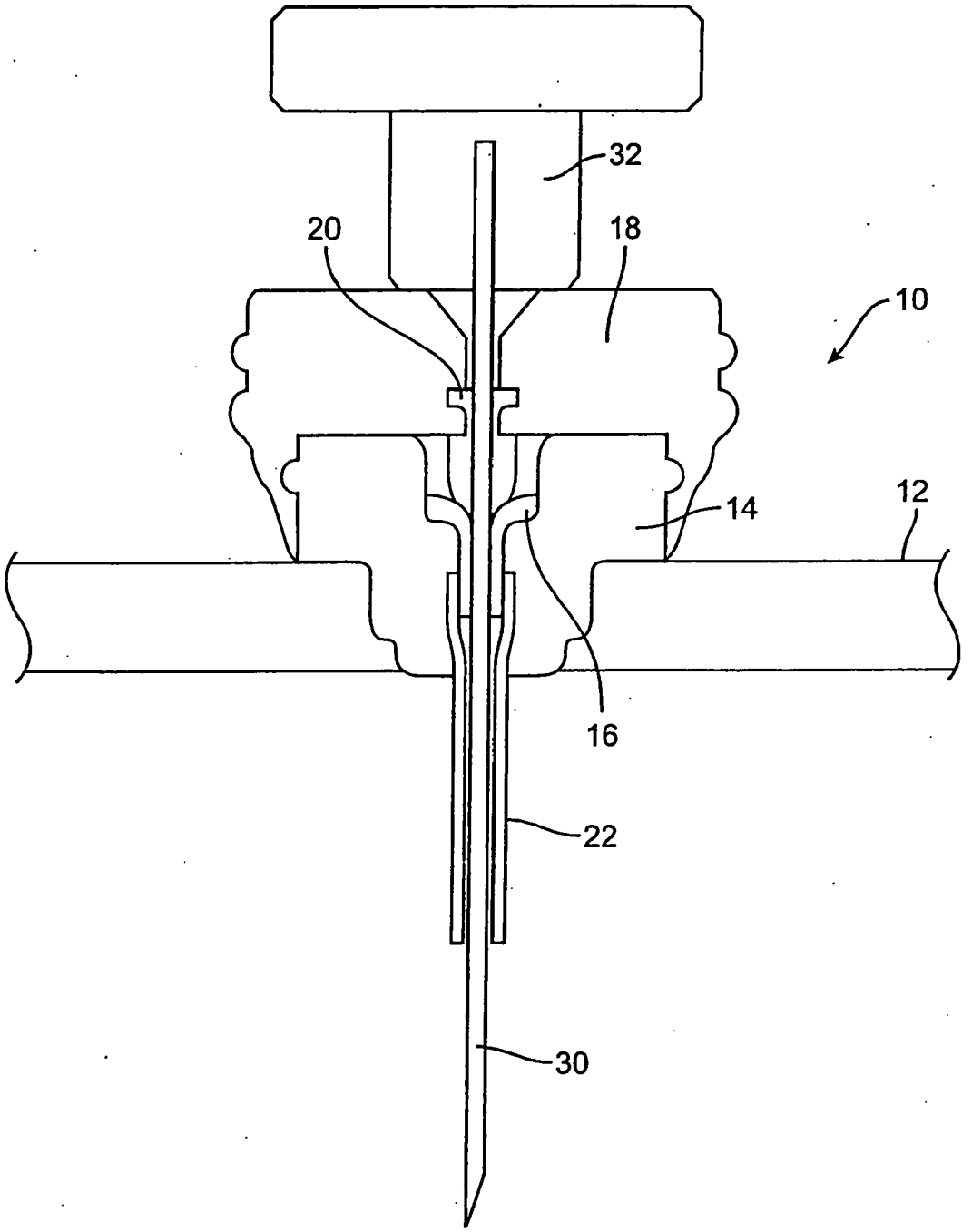


FIG. 2

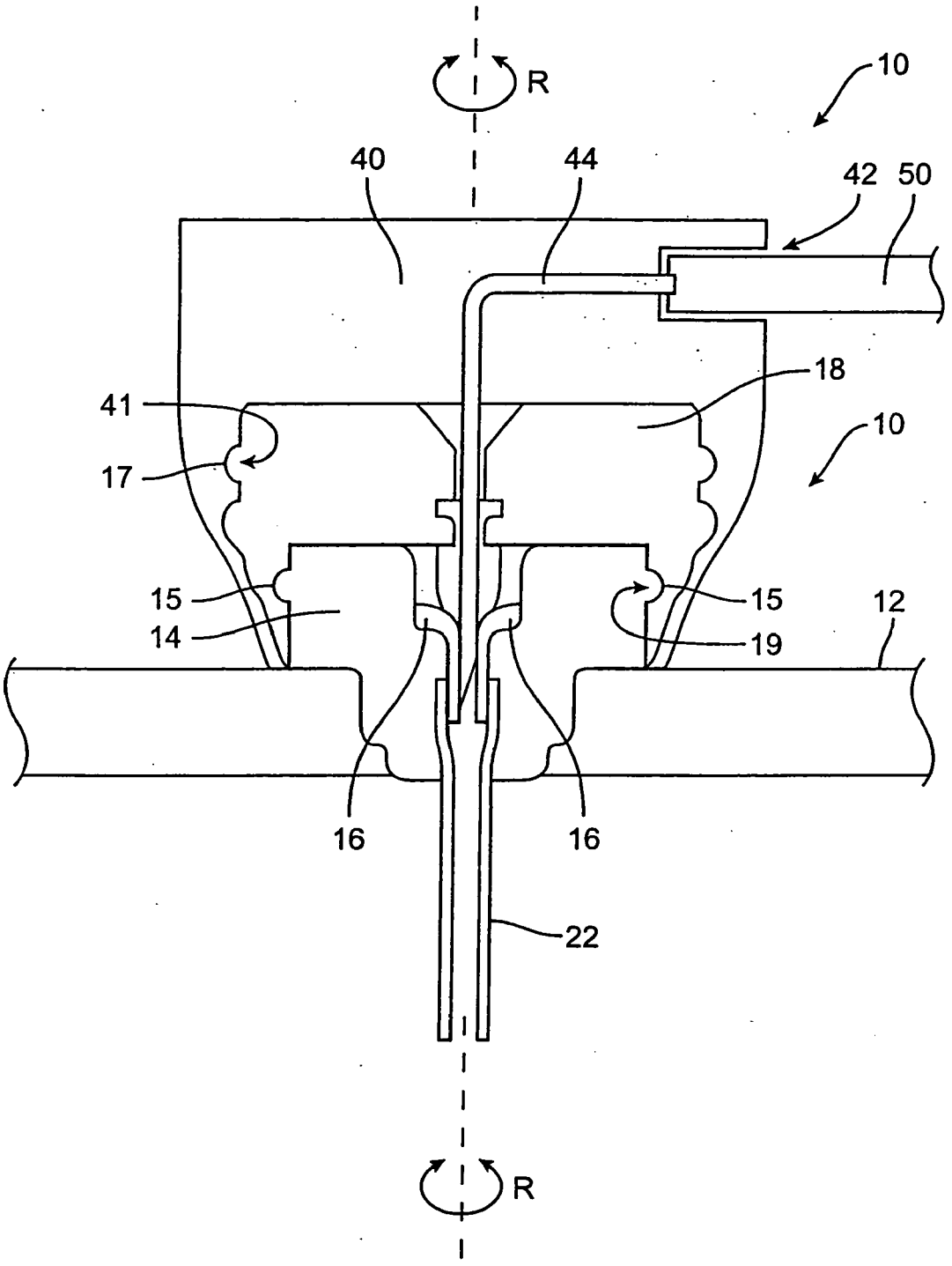


FIG. 3

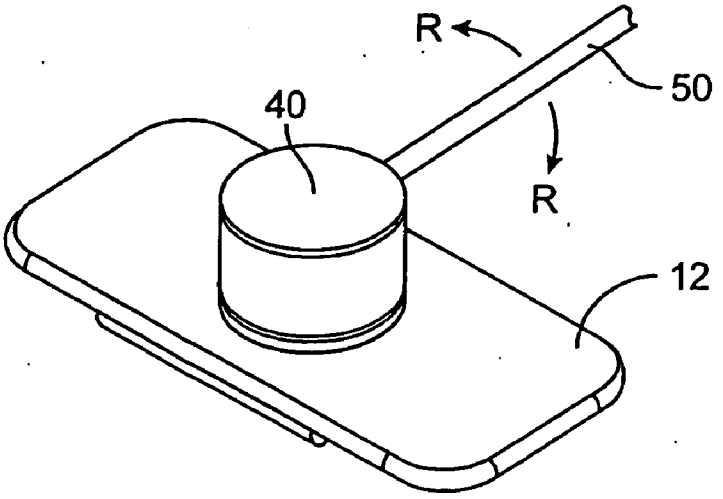


FIG. 4

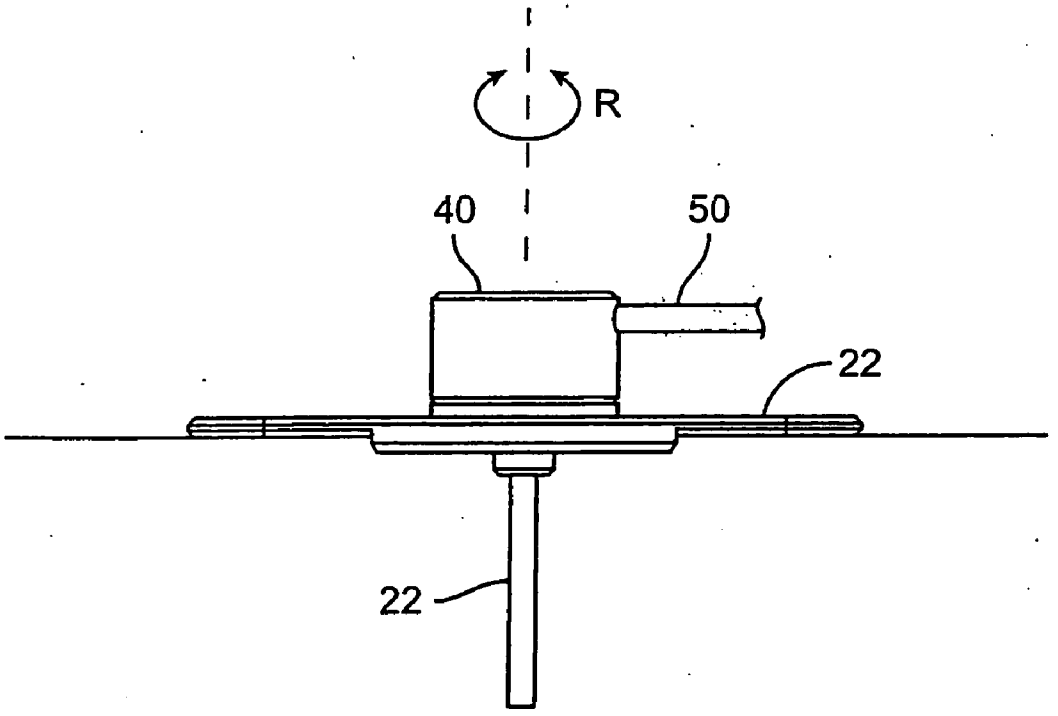


FIG. 5

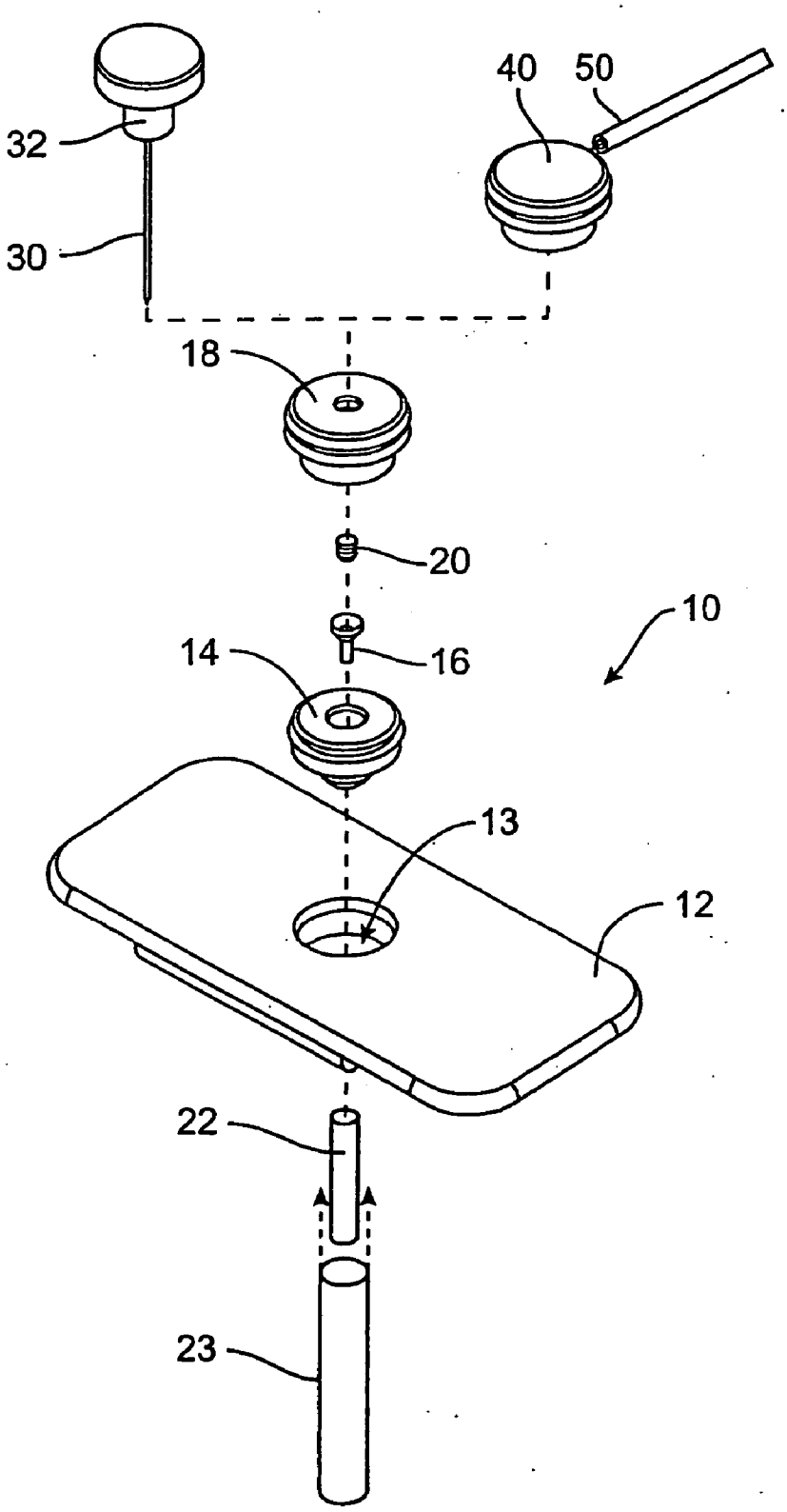


FIG. 6

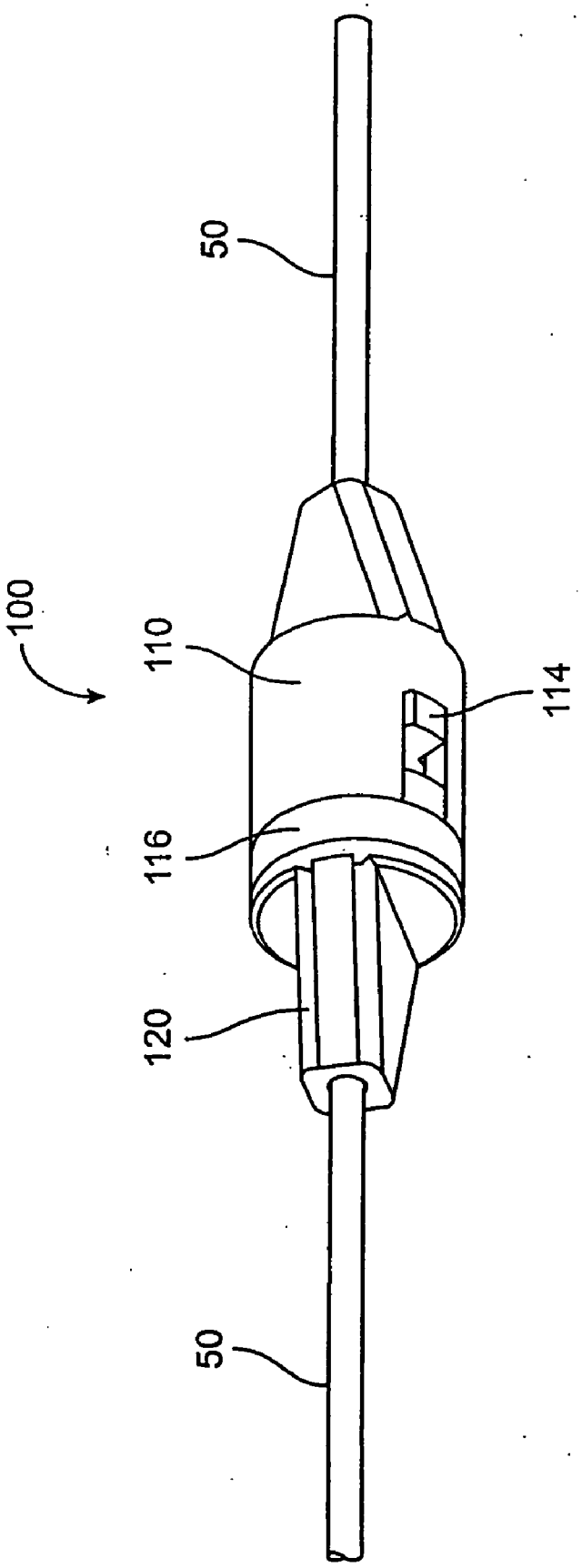


FIG. 7

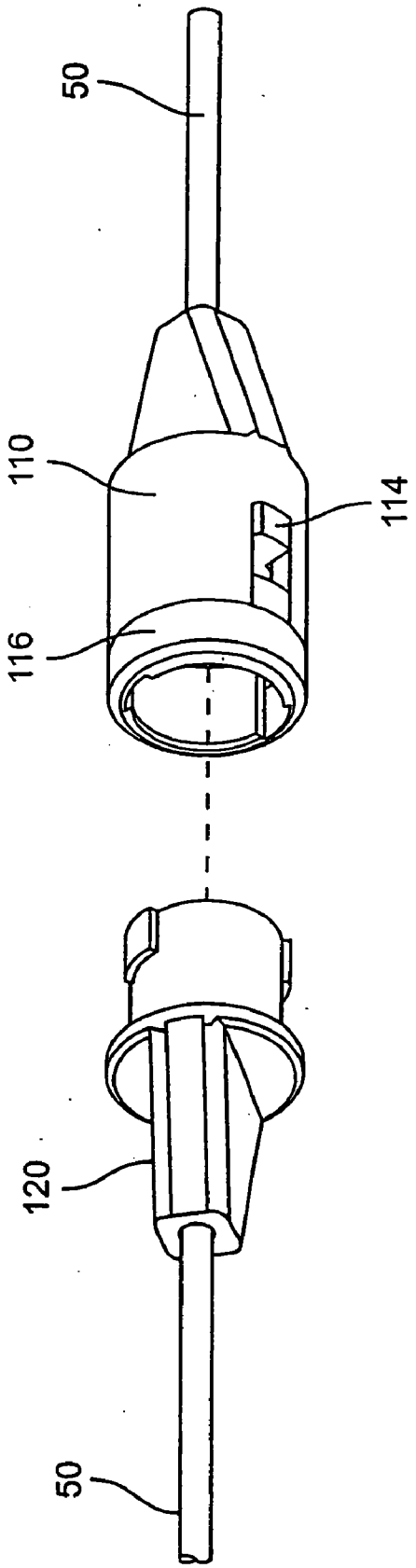


FIG. 8

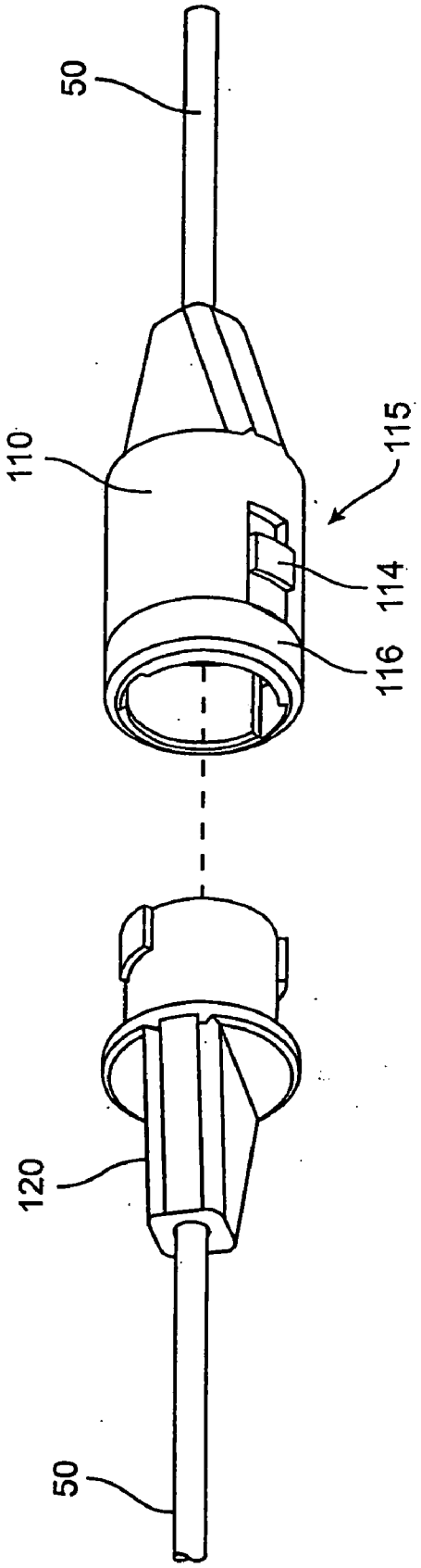


FIG. 9

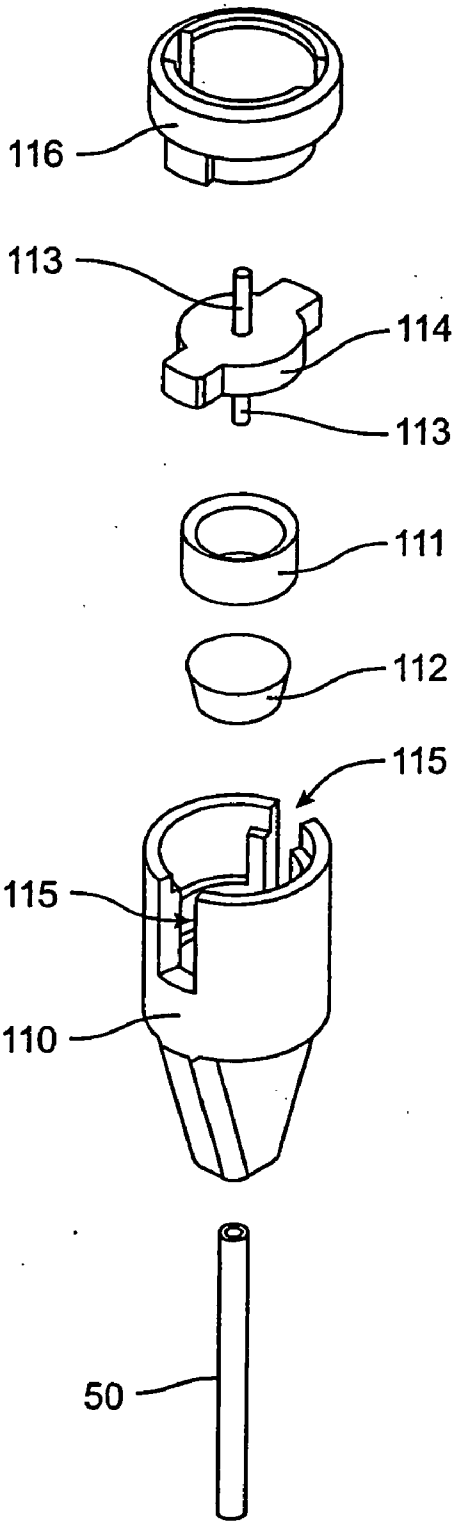


FIG. 10

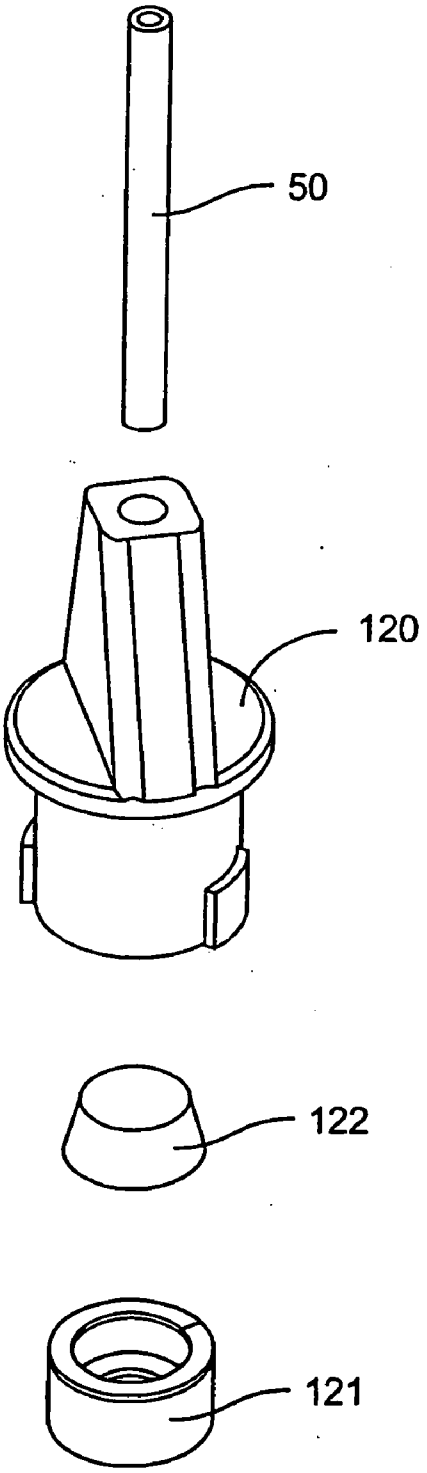


FIG. 11

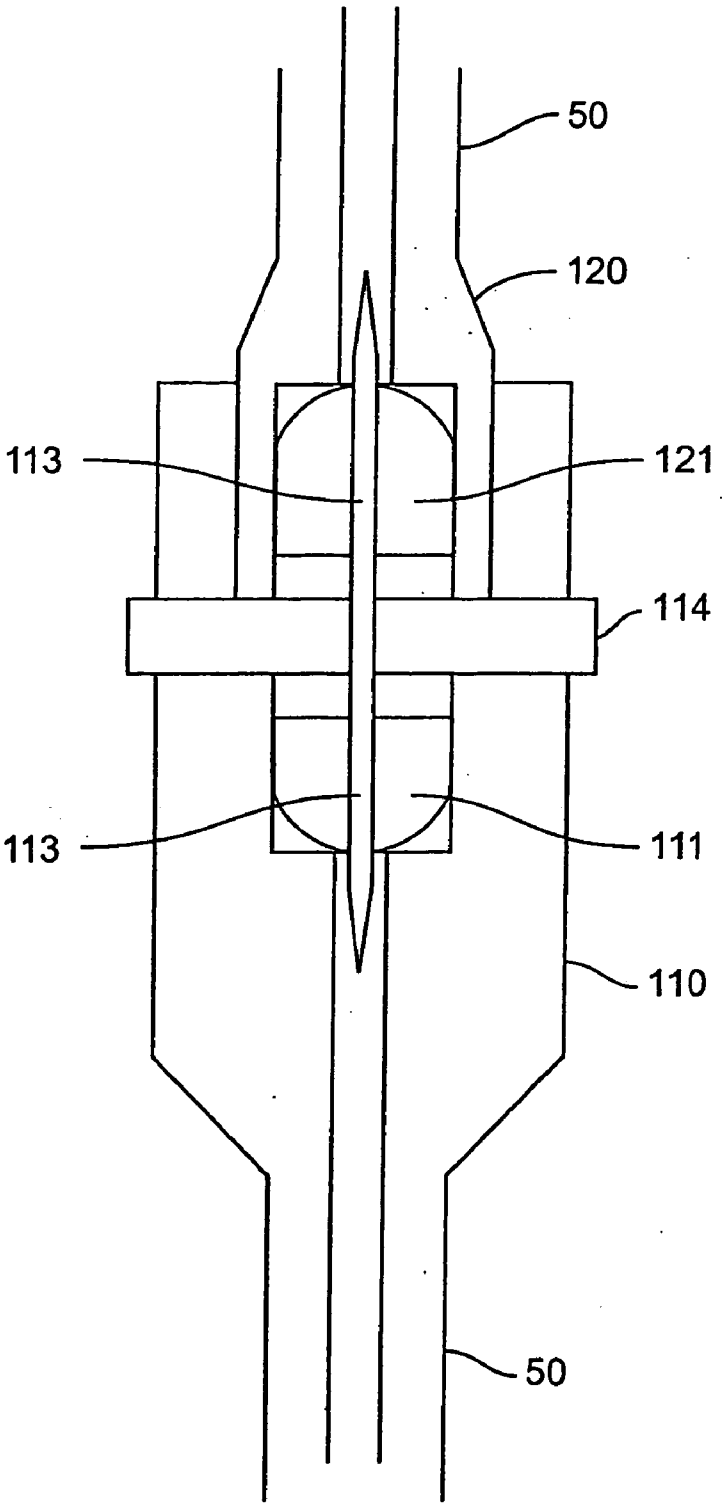


FIG. 12

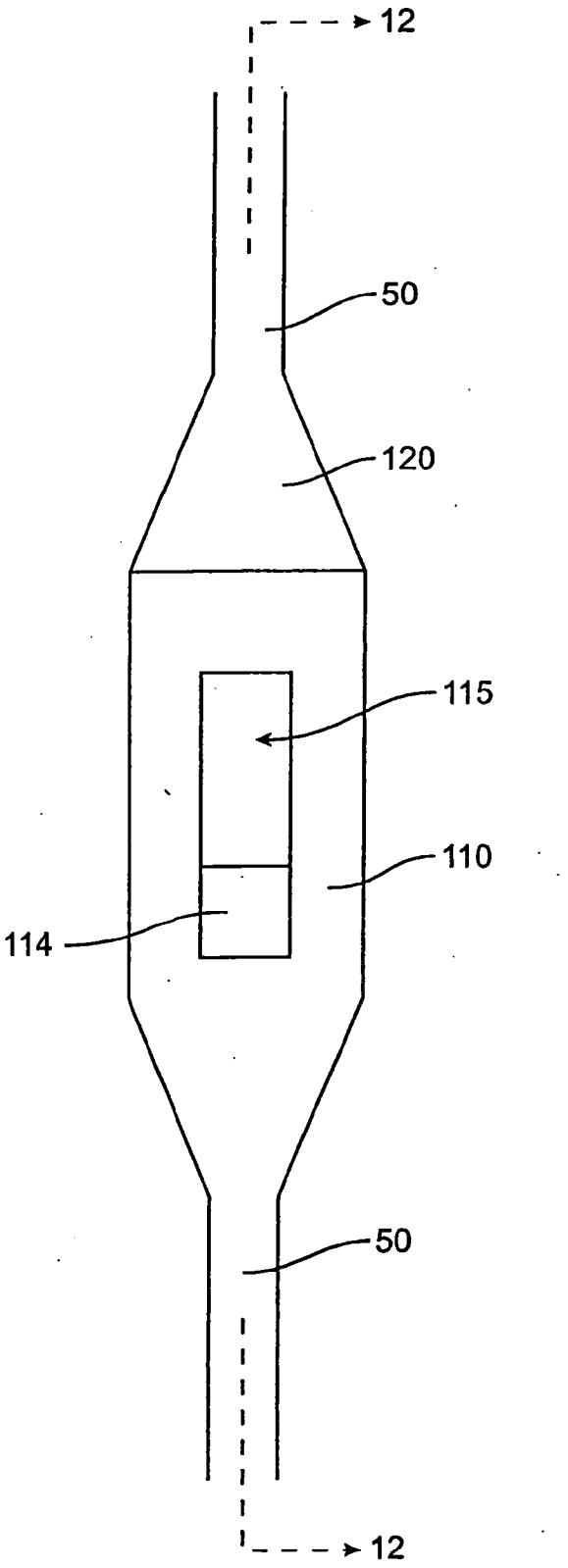


FIG. 13

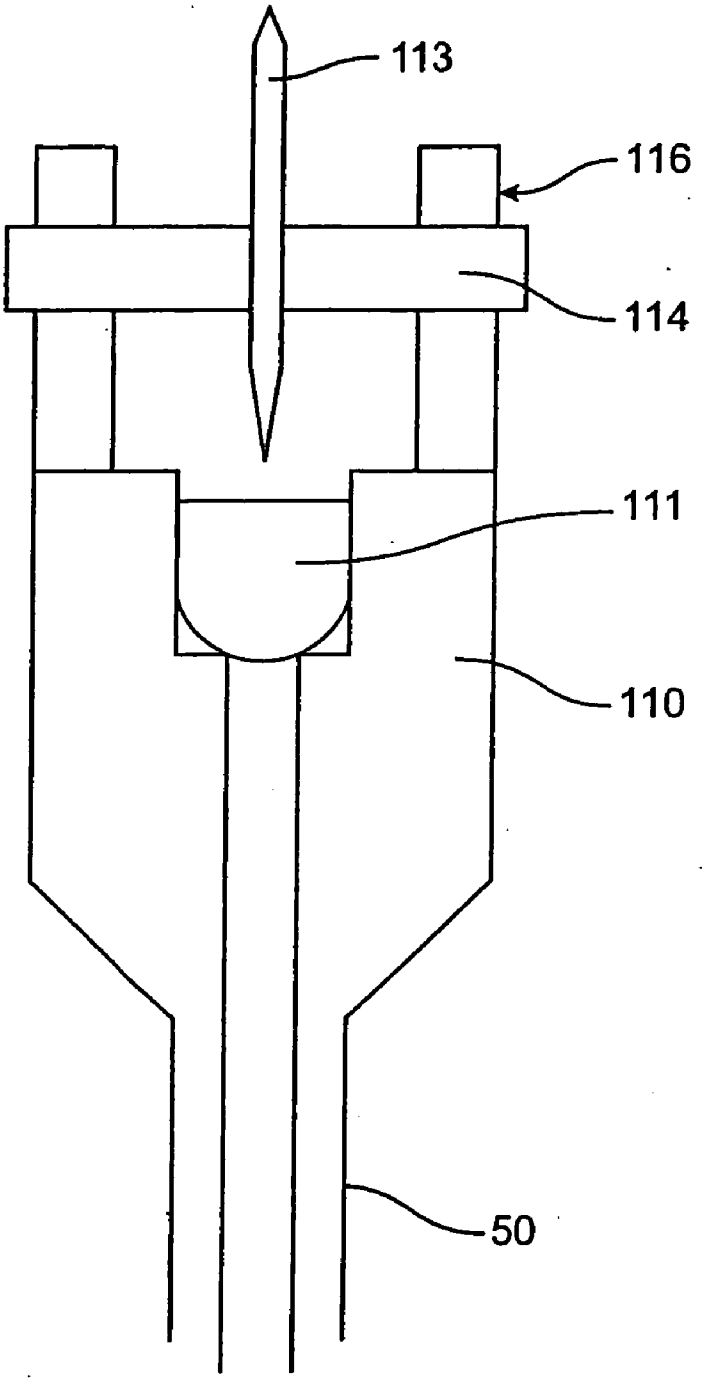


FIG. 14

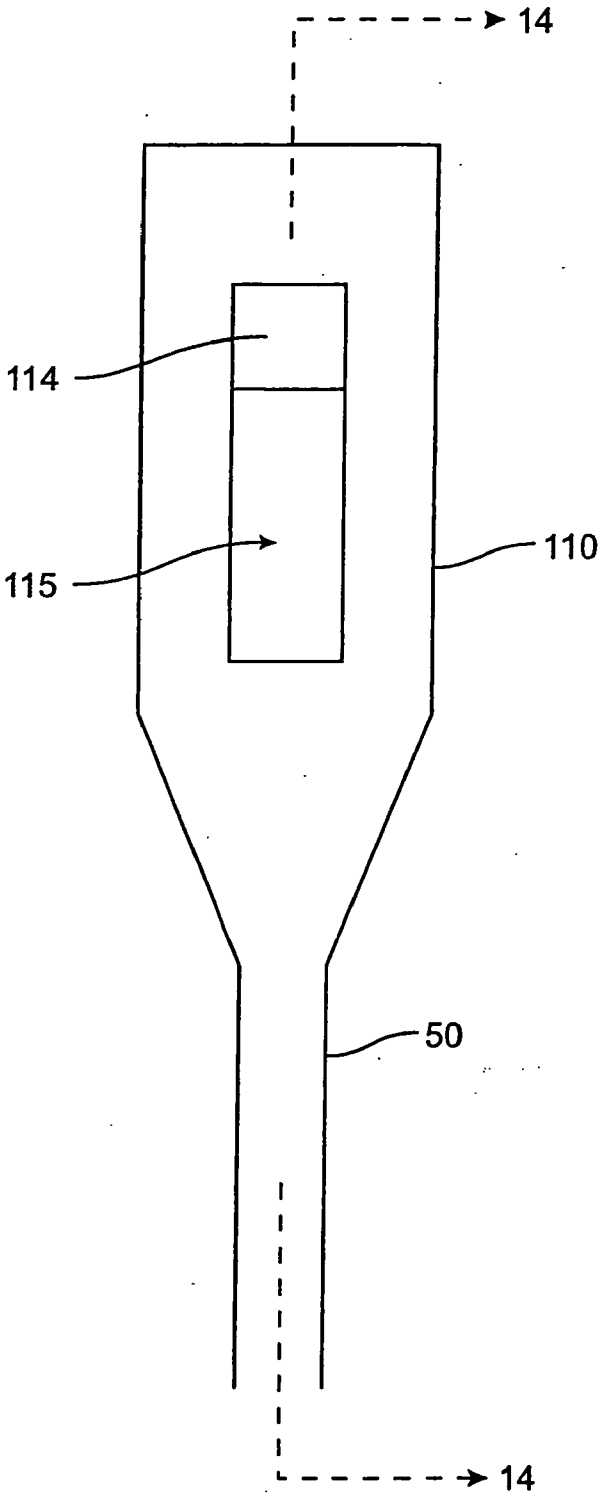


FIG. 15

INFUSION HUB ASSEMBLY AND FLUID LINE DISCONNECT SYSTEM

RELATED APPLICATION

[0001] The present application claims the benefit of priority to U.S. utility patent application Ser. No. 10/091,123, filed Mar. 4, 2002 and U.S. provisional patent application Nos. 60/273,490, filed Mar. 4, 2001; and 60/299,842, filed Jun. 19, 2001.

SUMMARY OF THE INVENTION

[0002] In various embodiments, the present invention provides an infusion hub assembly, comprising: a wing having a hole passing therethrough; a hub received in the hole in the wing, the hub having a bore passing therethrough, with an upper portion of the circular hub having an attachment surface thereon; an infusion cannula extending downwardly away from the wing, the infusion cannula being in fluid communication with the bore passing through the hub; a cover having a bore passing therethrough with an inner attachment surface adapted to mate with the attachment surface on the upper portion of the hub; and a septum positioned in alignment with the bore passing through the cover.

[0003] In various embodiments, the upper portion of the hub is circular and has an attachment surface extending circumferentially therearound. In various embodiments, this attachment surface comprises a lip extending circumferentially therearound.

[0004] The present infusion hub assembly comprises a cover having a bore through which an insertion needle is positioned when initially positioning the wing of the assembly on a patient's skin with the infusion cannula extending subcutaneously. In various embodiments, the cover holds a septum therein to advantageously seal the pathway into the patient (when the insertion needle is not piercing therethrough).

[0005] In various embodiments, the cover is dimensioned to be snap-fit over the infusion hub. In various embodiments, the cover has a central bore through which the insertion needle passes when the assembly is positioned subcutaneously.

[0006] Thereafter, the novel rotatable infusion housing is attached onto the top of the cover. In various embodiments, the rotatable housing has an attachment surface adapted to mate with an outer attachment surface on the upper portion of the cover. Thus, in various embodiments, the rotatable housing is also dimensioned to be snap-fit over the cover, which is in turn snap-fit over the infusion hub.

[0007] In various aspects, the attachment surface on both the cover and the rotatable housing comprises a recess extending circumferentially therearound. These recesses mate with lips extending from an upper portion of the infusion hub and the cover, respectively. In various aspects, the infusion hub and the rotatable housing are circular such that the rotatable housing can turn freely, while still providing continuous infusion of medication (or other desired fluid substances) subcutaneously into the patient.

[0008] In various embodiments, the rotatable housing comprises a curved needle passing at least partially through a radial bore in the rotatable housing, wherein a first end of the curved needle is positioned to extend downwardly into the bores in the cover and the hub when the rotatable housing is attached to the cover. Additionally, an infusion tube is received into the radial bore of the rotatable housing in fluid communication with the curved needle.

[0009] Advantages of having a rotatable infusion housing which can turn freely, while still providing continuous infusion subcutaneously into the patient include: (i) avoiding kinks in the infusion tube, and (ii) avoiding having to tape the infusion housing to the patient, thus (iii) permitting the patient to position an infusion pump (which feeds fluid into the infusion tube) at different locations one the patient's body.

[0010] In another aspect of the invention, the present invention provides an infusion connector set comprising: a proximal connector; a septum received in the proximal connector; a distal connector; a septum received in the distal connector; and a flanged needle which penetrates both the septums in the proximal and distal connectors when the proximal and distal connectors are connected together.

[0011] It is to be understood, however, that reference made herein to a "proximal" and "distal" connector is only exemplary. Thus, the flanged needle may instead move to various positions within the distal connector rather than within the proximal connector. Accordingly, the present invention refers to a "first" and a "second" connector. In various embodiments, the "first" connector is the "proximal" connector and the "second" connector is the "distal" connector. In alternate embodiments, the connectors are reversed such that the "first" connector is the "distal" connector and the "second" connector is the "proximal" connector.

[0012] In various embodiments, the flanged needle is slidably movable within a slot in the distal connector. In various aspects, the flanged needle may be moved to a position at which the needle does not penetrate the proximal septum in the proximal connector, yet is still held within the proximal connector.

[0013] Thus, when the proximal and distal connectors are fastened together, the needle provides a fluid path therethrough. When the distal connectors is uncoupled from the proximal connector, the septum in the distal connector will seal (since the flanged needle is held within the proximal connector, and thus is no longer in contact with the septum in the distal connector).

[0014] In various embodiments, the flange of the flanged needle protrudes through the slot in the distal connector such that an operator may grab onto the flange and move the flanged needle along in the slot in the distal connector. Thus, the flanged needle may conveniently be moved to a position in which the needle no longer penetrates the septum in the proximal connector. Thus, the septum in the proximal connector will seal itself, preventing contamination or exposure to the substance being delivered through the infusion tubing.

[0015] An advantage of having the proximal and distal connector easily disconnectable from one another (with their respective septums sealing the fluid path through both connectors) is that it facilitates switching between different infusion lines.

[0016] A further advantage of providing the distal connector with its own septum is that a patient can manually

disconnect the proximal and distal connectors and then inject a syringe (containing an alternate medication or substance) through the septum in the distal connector, and into the patient.

[0017] In various embodiments, the infusion connector set further comprises a retainer mounted at the distal end of the proximal connector. In various embodiments, this retainer closes the distal end of the slot in the proximal connector, such that movement of the flanged needle is retained to back and forth movement within the proximal connector.

[0018] In various embodiments, the proximal and distal connectors are dimensioned such that one connector may be inserted into the other, and then rotated into an interlocked position. This may be achieved by providing one of the connectors with at least one tab extending therefrom, and the other of the connectors with at least one recess therein. The at least one recess is dimensioned to receive the at least one tab therein when the proximal and distal connectors are connected together. In various embodiments, the connector comprising the at least one tab is the proximal connector, and the connector comprising the at least one slot is the distal connector.

[0019] Still other features and advantages of the present invention will become apparent to those skilled in the art from a reading of the following detailed description of embodiments constructed in accordance therewith, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] **FIG. 1** is a sectional side elevation view of an infusion hub assembly according to the present invention.

[0021] **FIG. 2** is a sectional side elevation view similar to **FIG. 1**, but with an insertion needle passing therethrough.

[0022] **FIG. 3** is a sectional side elevation view similar to **FIGS. 1 and 2**, but with the insertion needle removed, and replaced by a rotatable infusion housing.

[0023] **FIG. 4** is a perspective view of the assembled infusion hub assembly.

[0024] **FIG. 5** is a side elevation view of the assembled infusion hub assembly.

[0025] **FIG. 6** is an exploded perspective view of the present infusion hub assembly, showing alternate positioning of the insertion needle passing through the cover and of the rotatable infusion housing fit over the cover.

[0026] **FIG. 7** is a perspective view of an infusion connector set according to the present invention.

[0027] **FIG. 8** is a perspective view similar to **FIG. 7**, showing the proximal and distal connector disconnected from one another.

[0028] **FIG. 9** is a view similar to **FIG. 8**, but with the flanged needle moved such that it does not penetrate the proximal septum.

[0029] **FIG. 10** is an exploded perspective view of the proximal connector assembly.

[0030] **FIG. 11** is an exploded perspective view of the distal connector assembly.

[0031] **FIG. 12** is a schematic sectional view corresponding to **FIG. 7**. (Corresponding to a view taken along line **12-12** in **FIG. 13**).

[0032] **FIG. 13** is a side elevation view corresponding to **FIG. 12** (showing the slot in which the flange supporting the flanged needle moves).

[0033] **FIG. 14** is a schematic sectional view of the proximal connector of the system of **FIG. 12**, after the distal connector has been uncoupled and removed and the flanged needle has been moved in the slot such that it does not penetrate the septum in the proximal connector. (Corresponding to a view taken along line **14-14** in **FIG. 15**).

[0034] **FIG. 15** is a side elevation view corresponding to **FIG. 14**.

DETAILED DESCRIPTION OF THE DRAWINGS

[0035] FIGS. **1** to **6** illustrate an infusion hub assembly according to the present invention. FIGS. **7** to **15** illustrate an infusion connector set according to the present invention.

[0036] Referring first to FIGS. **1** to **6**, an infusion hub assembly **10** is provided. A large wing or patch **12** having a hole **13** passing therethrough is provided. Wing **12** is positioned on the surface of a patient's skin. In various embodiments, the underside of wing **12** has an adhesive surface, securing it to a patient's skin. In alternate embodiments, the wing **12** is instead taped directly onto the patient's skin.

[0037] As shown in **FIG. 1**, assembly **10** comprises wing **12**, hub **14** and cover **18**. In various aspects, all, or at least the upper portion of hub **14** is circular. Hub **14** is received into a circular shaped hole **13** in wing **12**. In various embodiments, hole **13** is stepped in diameter, and circular hub **14** also has a stepped diameter such that hub **14** fits into hole **13**, as shown. Circular hub **14** has a central bore passing vertically therethrough. A needle guide **16** is positioned within this bore through circular hub **14** as also shown. Needle guide **16** may be funnel-shaped, and may be made of metal.

[0038] In various aspects, an upper portion of circular hub **14** has an attachment surface onto which cover **18** can be snap fit. For example, various aspects, circular hub **14** has a lip **15** extending at least partially circumferentially therearound. In various embodiments, cover **18** has an interior groove **19** extending at least partially circumferentially therearound. In various embodiments, as well, cover **18** is made of a flexible material such that it can be easily snap-fit over the upper portion of circular hub **14**.

[0039] As can also be seen, a septum **20** is also provided. Septum **20** may be held by cover **18** (such that when cover **18** is removed from hub **14**, septum **20** is also removed). As can also be seen, septum **20** may be positioned such that it is received within needle guide **16** when cover **18** is positioned over infusion housing **14**. Septum **20** may be made from a plug of self-sealing elastomeric material.

[0040] A infusion cannula **22** extends downwardly from wing **12**. Thus, infusion cannula **22** is positioned subcutaneously when wing **12** rests on the patient's skin. Infusion cannula **22** is thus used for subcutaneously infusing medication into the patient. In various embodiments, the proximal end of infusion cannula **22** may be positioned to be received within the lower portion of circular hub **14**, and

may also be received around an end of needle guide **16**, as shown, however, the present invention is not so limited. Many other systems for attaching infusion cannula **16** such that it extends downwardly from wing **12** are also contemplated within the scope of the present invention.

[**0041**] Referring next to **FIG. 2, a** various system for positioning assembly **10** such that infusion cannula **22** is positioned subcutaneously is also provided. Specifically, an insertion needle **30**, (which is supported by a handle **32**) is inserted through the central bores of protective cover **18** and circular hub **14**. Thus, needle **30** passes through septum **20**, and extends downwardly, passing out the bottom distal end of infusion cannula **22**. When needle **30** is inserted through infusion cannula **22**, as shown in **FIG. 2**, the operator simply applies pressure downwardly onto handle **32** such that wing **12** is pushed down into contact with the patient's skin and infusion cannula **22** is subcutaneously inserted.

[**0042**] After assembly **10** has been positioned with its wing **12** resting against the patient's skin, and with infusion cannula **22** positioned subcutaneously, (i.e.: as shown in **FIG. 2**), the operator then simply removes needle **30** by pulling upwardly on handle **32**. When needle **30** is initially removed, septum **20** will self-seal, ensuring no contamination enters from the atmosphere through cannula **22** and thus into the subcutaneous pathway under the patient's skin.

[**0043**] After needle **30** is removed, it is replaced by rotatable infusion housing **40**, as follows.

[**0044**] As shown in **FIG. 3**, rotatable housing **40** is then attached over cover **18**. Rotatable housing **40** may be made of a flexible material such that it can be snap-fit over cover **18** (similar to how cover **18** fits over hub **14**). Specifically, rotatable housing **40** may also have an inner attachment surface such as an interior grooves **41** which extend at least partially circumferentially therearound.

[**0045**] An advantage of interior grooves **41** extending at least partially circumferentially around lip **17** of cover **18** is that housing **40** is therefore rotatable with respect to circular housing **14**. Thus, as shown in **FIGS. 4 and 5**, housing **40** may freely be rotated in direction R.

[**0046**] Referring back to **FIG. 3**, an infusion tube **50** may be used to deliver medication (or any other desired substance) subcutaneously to the patient. Tube **50** may be received into a radially extending bore **42** in housing **40**. A curved needle **44** may be attached to the end of tube **50**, and is positioned such that its downwardly facing distal end is received directly into needle guide **16** in the bore of circular housing **14**. Since the distal end of curved needle **44** points downwardly from the center of rotatable housing **40**, and is positioned in the central bores passing through cover **18** and circular housing **14**, housing **40** is free to rotate in direction R about its central axis while medication or any other desired substance is infused through tube **50**.

[**0047**] **FIG. 6** shows an exploded view of the present system in which either: (i) the introducing needle **30** or, (ii) the rotatable housing **40** and infusion tube **50** are attached to cover **18** and pass through septum **20**, into circular housing **14**. As can also be seen, in various embodiments, an optional removable protective cylinder **23** can be received over infusion cannula **22**, to protect the cannula and keep the cannula free of contamination prior to its use.

[**0048**] Turning now to FIGS. **7** to **15**, an infusion connector set is also provided. In various aspects, connector assembly **100** comprises a proximal connector **110** and a distal connector **120**. It is to be understood that connector **110** could instead be the distal connector and connector **120** could instead be the proximal connector, according to the user's preferences.) As illustrated herein, assembly **100** is used to provide a detachable coupling link mid-way along infusion tube **50**. It is to be understood, however, that while connector assembly **100** (FIGS. **7** to **15**) may be used in conjunction with the infusion hub assembly **10** (FIGS. **1** to **6**), it need not be. Rather, each of connector assembly **100** and infusion hub assembly **10** may be used separately. Thus, the tube numbered "**50**" in FIGS. **1** to **6** may, or may not, be the same or different from the tubes numbered "**50**" in FIGS. **7** to **15**.

[**0049**] **FIG. 7** shows proximal connector **120** and distal connector **110** coupled together. **FIG. 8** shows proximal connector **120** and distal connector **110** uncoupled from one another. As will be explained, the present connector set provides a system in which, when the proximal and distal connectors are fastened together, fluid flows freely through the assembly. When the proximal and distal connectors are no longer fastened or coupled together, the present invention provides a novel self-sealing system which prevents contamination from entering the flow path through either of the proximal or distal connectors. Specifically, as will be explained, a self-sealing septum is positioned in each of the proximal and distal connectors. Also, the proximal connector supports a flanged needle assembly which can be moved such that a septum in the proximal needle self-seals as desired.

[**0050**] Referring to **FIG. 10**, proximal connector **110** has a septum housing **111** received therein. A self-sealing septum **112** is held in position by septum housing **111**. A flanged needle assembly comprising a flange **114** and a needle **113** is then received therein. As will be explained, flange **114** can be moved up and down in slots **115** in proximal connector **110** (thereby moving needle **113** to different positions). A retainer **116** is then received over flanged needle assembly **113/114**. Retainer **116** prevents flange **114** from escaping from slot **115**. Thus, needle **113** remains supported within proximal connector **110** at all times.

[**0051**] Referring to **FIG. 11**, distal connector **120** has a septum housing **121** received therein. A self-sealing septum **122** is held in position by septum housing **121**.

[**0052**] When assembled together, as shown in **FIG. 7** (and as illustrated schematically in **FIGS. 12 and 13**), needle **113** penetrates both of septums **111** and **121**, permitting flow through tubes **50**.

[**0053**] When the connectors are disconnected from one another, (i.e.: when distal connector **120** is detached from proximal connector **110**) needle **113** (which is held within proximal connector **110**) will no longer penetrate distal septum **121** in distal connector **120**. Thus, distal septum **121** will self-seal, such that the subcutaneous pathway into the patient (i.e.: the path through distal connector **120**, tube **50** and rotatable housing **40** into the patient) will be sealed. However, should a user so desire, a separate syringe injection needle may be inserted through distal septum **121** in distal connector **120** such that different or additional medication (or other substances) can be subcutaneously introduced into the patient.

[0054] In accordance with the present invention, a novel system of sealing proximal septum **111** in proximal connector **110** is also provided. Referring to **FIG. 9** (and to schematic **FIGS. 14 and 15**), flange **114** is moved distally along slot **115** such that it carries needle **113** to a position at which it no longer penetrates proximal septum **111**.

[0055] In various embodiments, flange **114** protrudes slightly through slots **115** on opposite sides of proximal connector **110**, to permit an operator to grasp onto flange **114** and slide it into a position against retainer **116** (such that needle **113** no longer pierces septum **111**).

What is claimed is:

1. An infusion hub assembly, comprising:

a wing having a hole passing therethrough;

a hub received in the hole in the wing, the hub having a bore passing therethrough, with an upper portion of the circular hub having an attachment surface thereon;

an infusion cannula extending downwardly away from the wing, the infusion cannula being in fluid communication with the bore passing through the hub;

a cover having a bore passing therethrough and having an inner attachment surface adapted to mate with the attachment surface on the upper portion of the hub; and

a septum positioned in alignment with the bore passing through the cover.

2. The assembly of claim 1, wherein the upper portion of the hub is circular.

3. The assembly of claim 2, wherein the attachment surface on the upper portion of the circular hub comprises a lip extending circumferentially therearound.

4. The assembly of claim 1, wherein an underside surface of the wing comprises an adhesive layer.

5. The assembly of claim 1, wherein the hole in the wing is a stepped hole and the hub has a stepped outer dimension which fits into the stepped hole in the wing.

6. The assembly of claim 5, wherein both the stepped hole and the hub are circular and the hub has a stepped outer diameter.

7. The assembly of claim 1, further comprising:

a needle guide received in the bore of the hub.

8. The assembly of claim 7, wherein the needle guide is funnel shaped.

9. The assembly of claim 7, wherein the infusion cannula is attached to the needle guide.

10. The assembly of claim 1, wherein the upper portion of the cover is circular.

11. The assembly of claim 1, wherein the inner attachment surface on the cover comprises a recess extending circumferentially around an internal surface of the cover.

12. The assembly of claim 1, wherein the cover further comprises an outer attachment surface.

13. The assembly of claim 12, wherein the outer attachment surface on the cover comprises a lip extending circumferentially therearound.

14. The assembly of claim 13, further comprising:

a needle guide received in the bore of the hub, wherein the septum is received into the needle guide when the cover is attached to the hub.

15. The assembly of claim 13, further comprising:

a removable insertion needle passing through the bore in the cover, the septum and the infusion cannula, wherein a distal end of the insertion needle extends downwardly out of the distal end of the infusion cannula.

16. The assembly of claim 1, further comprising:

a rotatable housing having an attachment surface adapted to mate with the outer attachment surface on the upper portion of the cover.

17. The assembly of claim 16, wherein the attachment surface on the rotatable housing comprises a recess extending circumferentially around an internal surface of the rotatable housing.

18. The assembly of claim 16, wherein the rotatable housing has a radial bore.

19. The assembly of claim 18, further comprising:

a curved needle passing at least partially through the radial bore in the rotatable housing, wherein a first end of the curved needle is positioned to extend downwardly into the bores in the cover and hub when the rotatable housing is attached to the cover.

20. The assembly of claim 19, further comprising:

a tube received into the radial bore of the rotatable housing in fluid communication with the curved needle.

* * * * *