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(54) Benævnelse: **SUBKUTAN INFUSIONSANORDNING TIL INJEKTION AF MEDICINSKE STOFFER**

(56) Fremdragne publikationer:
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US-A- 3 538 915
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DESCRIPTION

BACKGROUND

[0001] The present disclosure generally relates to devices for injecting medicinal substances, and more particularly relates to a medical fluid delivery device for subcutaneously administering viscous liquid medicines into the body of a user.

[0002] Subcutaneous infusion devices are well known in the medical arts for use in the administration of a selected medicinal substance to a desired infusion site located underneath the skin of a patient or user. Commonly included in such infusion device is a tubular cannula or catheter that is supported by and protrudes from a hub for receiving the medicinal substance via a delivery tubing. Typically, the hub includes a small needle that is inserted just under the surface of the skin, and remains in place for up to several days.

[0003] More specifically, such infusion devices provide an alternative to intravenous delivery of medicines and allow the medicinal substance to be administered through a layer of skin immediately below the dermis and epidermis. As is known in the art, such use of the subcutaneous infusion devices decreases the number of times the patient must have an injection to receive frequently administered medicines. Although not all medicines can be administered through such infusion devices, they are an effective and convenient way to administer medicinal substances without having to impose multiple injections on the patient.

[0004] However, some medicinal substances are highly viscous (i.e., in the range of 3-10 cP or centipoise) and are delivered at high flow rates, and conventional subcutaneous infusion devices are not designed to deliver the highly viscous substance at these flow rates. As a result, a build-up of excessive delivery pressure during the delivery of such substances is likely to occur, and clogging may occur in the needle or its adjacent areas during infusion. Further, because the needle used in the infusion device is typically bent about 90 degrees, the risk of kinking is relatively high at or near the bent portion of the needle.

[0005] Another issue of conventional infusion devices is that movement of the hub can cause the needle to break during use. Foldable gripping wings are typically attached to the hub for securely holding the needle when inserting the needle straight into the desired infusion site at a 90 degree angle relative to the skin surface. Specifically, the wings are folded back away from the needle and pinched together between two fingers. At times, the folded wings slide against each other during the insertion step, making the insertion of the needle rather challenging. Further, if the needle is made of a smaller diameter, the needle is not supported firmly and causes it to break during use.

[0006] Therefore, there is a need for improving subcutaneous infusion devices to facilitate a more stable retention of the needle on the skin during the insertion step, and for reducing flow

resistance of highly viscous substance during the delivery step.

[0007] US3640275 discloses an intravenous needle assembly for administering medication into a patient comprising a cannula having a hub portion from the opposite sides of which extend a pair of hub wing sections. The hub wing sections are adapted to flex in either direction around said hub into abutting contact with one another to form a gripping handle for holding the cannula while it is being inserted into the vein of the patient.

[0008] US2006/047252 discloses a winged angled needle assembly having a hub to which a proximal end portion of an angled needle having a sharpened tip portion is joined and a pair of wings attached to both sides of the hub. The assembly further includes a fixing member attached so as to support the wings and an extensible, contractible needle guard disposed between the hub and the fixing member so as to connect these two members.

[0009] WO2007/137339 discloses a Huber needle assembly having a base with hinged guide members about a needle aperture. A needle assembly has a Huber needle mounted between two hinged wings. The guide members are movable between a parallel arrangement in which the needle may move vertically between the guide members and a horizontal arrangement in which the needle is locked in the in-use position.

[0010] US3538915 discloses an infusion device and method, the device including an infusion needle received by and cemented in fixed relation to a one-piece needle-holding member or inserter which has been folded as separate halves about one end of the needle and remains in the folded state when the cement or bonding agent has cured.

[0011] US2009/187153 discloses medical needle assemblies incorporating a needle cover. According to one aspect, a medical needle assembly includes a hub portion and a pair of outwardly extending wings. The hub portion may have a raised orientation member, with the wings being foldable to overlay the raised orientation member and contact the raised orientation member and each other. Alternatively, the hub portion may have an anti-rotation member adapted to cooperate with the wings to limit rotation of the wings with respect to the hub portion.

SUMMARY

[0012] The present disclosure is directed to a medical fluid delivery device for subcutaneously administering viscous liquid medicines into the body of a user or patient. The present infusion device is designed to reduce a pressure drop (or flow resistance) that occurs during the delivery step of the viscous liquid or solution into a subcutaneous space of the user's skin. As described in further detail below, the present infusion device delivers the viscous liquid at a higher flow rate than the conventional devices due to the geometry of a hub and a needle.

[0013] One aspect of the present infusion device is that low flow resistance is achieved for high

viscosity liquids (e.g., 3-20 cP) in flow rates ranging 40 to 400 ml/hr (or milliliter/hour) during subcutaneous delivery. Specifically, a 24G (or gauge) needle having a thin tubular wall is provided for accommodating the viscous liquid, and a mid- region of the needle is slightly bent at a predetermined radius of curvature, such that the mid-region surrounds a support region located at an outer end of the hub.

[0014] Another important aspect is that the present infusion device provides secure placement of the needle that reduces disturbance to the desired infusion site, and enhances comfort during infusion. A plurality of substantially diagonally disposed ribs is provided on a bottom side of the hub for preventing unwanted movement of the hub while worn by the user. More specifically, the diagonal bottom ribs are angled in such a manner that a forward movement toward the sharp end of the needle is prevented while a backward movement away from the sharp end of the needle is allowed. Furthermore, the diagonal pattern also stabilizes the hub for lateral disturbances after installation of the needle. This arrangement reduces shear and/or normal stress on the bent portion of the needle.

SUMMARY

[0015] According to the present invention there is provided a medical delivery device for delivering a medicinal substance into a user's body according to claim 1. Embodiments of the invention are defined in the dependent claims.

[0016] The present disclosure is directed to a medical fluid delivery device for subcutaneously administering viscous liquid medicines into the body of a user or patient. The present infusion device is designed to reduce a pressure drop (or flow resistance) that occurs during the delivery step of the viscous liquid or solution into a subcutaneous space of the user's skin. As described in further detail below, the present infusion device delivers the viscous liquid at a higher flow rate than the conventional devices due to the geometry of a hub and a needle.

[0017] Also described is an infusion device in which low flow resistance is achieved for high viscosity liquids (e.g., 3-20 cP) in flow rates ranging 40 to 400 ml/hr (or milliliter/hour) during subcutaneous delivery. Specifically, a 24G (or gauge) needle having a thin tubular wall is provided for accommodating the viscous liquid, and a mid-region of the needle is slightly bent at a predetermined radius of curvature, such that the mid-region surrounds a support region located at an outer end of the hub.

[0018] In one embodiment, the present infusion device provides secure placement of the needle that reduces disturbance to the desired infusion site, and enhances comfort during infusion. A plurality of substantially diagonally disposed ribs is provided on a bottom side of the hub for preventing unwanted movement of the hub while worn by the user. More specifically, the diagonal bottom ribs are angled in such a manner that a forward movement toward the sharp end of the needle is prevented while a backward movement away from the sharp end of the needle is allowed. Furthermore, the diagonal pattern also stabilizes the hub for lateral

disturbances after installation of the needle. This arrangement reduces shear and/or normal stress on the bent portion of the needle.

[0019] In another embodiment, a top side of the hub includes at least two ribs, each one of which is respectively located on a left wing and a right wing of the hub. Each rib is asymmetrically disposed on the wings, such that when the wings are folded back away from the needle and pinched together, the two ribs prevent twisting and/or sliding of the wings relative to each other during an insertion of the needle into the skin. Accordingly, the needle remains stable and straight during the insertion, preventing a breakage of the needle due to undesirable movement of the wings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020]

FIG. 1 is a top perspective view of the present infusion device featuring a winged hub having top ribs;

FIG. 2 is a vertical cross-section taken along the line 2-2 of FIG. 1 and in the direction generally indicated;

FIG. 3 is a top view of the present hub featuring angled bottom ribs;

FIG. 4 is a vertical cross-section taken along the line 4-4 of FIG. 3 and in the direction generally indicated;

FIG. 5 is a front view of the winged hub folded away from a needle in preparation of an insertion of the needle into an infusion site;

FIG. 6 is a perspective view of the present infusion device being inserted into the infusion site;

FIG. 7 is a perspective view of the present infusion device during infusion; and

FIG. 8 is an enlarged perspective view of the winged hub after the needle is inserted into the infusion site.

DETAILED DESCRIPTION

[0021] Referring now to FIGs. 1-2, the present subcutaneous infusion device is generally designated 10 and is designed for subcutaneously delivering a medicinal substance below the dermis and epidermis. An exemplary medicinal substance may include nutritional products and Chinese herbal medicinal products. It is contemplated that the device 10 is disposable.

Included in the device 10 is a luer cap 12 configured for receiving the liquid at one end, and at an opposite end, is attached to a female luer connector 14 using complementary helically threaded portions for threadably fastening the cap and connector together. For carrying a viscous liquid medicine to an infusion site, a flexible elongated tube 16 is attached at one end to the female luer connector 14, and at an opposite end to a foldable hub 18 having a left or first wing 20 and a right or second wing 22.

[0022] An exemplary length of the tube 16 is approximately 61 cm (24 inches), but it is also contemplated that any length of tube can be utilized to suit different applications. Regulating a flow of the viscous liquid medicine in the tube 16 is achieved by transversely adjusting a slide clamp 24 relative to a longitudinal axis of the tube. As an example, a movable release slot 26 is provided in a center of the slide clamp 24 such that the clamp can transition between an occluding position and a non-occluding position by selectively sliding the release slot relative to the tube 16.

[0023] In a preferred embodiment, the winged hub 18 is molded, as by injection molding or the like, such that the hub and its connecting elements are integrally formed. However, it is also contemplated that the hub 18 is attachable to the connecting elements by chemical adhesives, solvent boding, ultrasonic welding or other conventional fastening techniques. More specifically, the hub 18 is attached at one end to the tube 16, and at an opposite end to a needle 28, which is slidably fitted into and safeguarded by a needle protector 30 when not in use. It is contemplated that after the hub 18 is molded, the needle 28 is assembled onto the hub 18 using an adhesive. Alternatively, the hub 18 may be over-molded over the needle 28.

[0024] An exemplary needle size is approximately 24G for ensuring comfort during infusion, and an exemplary needle length may be one of 6, 9, or 12 mm (or millimeter) depending on an application. Preferably, the needle 28 has a thin tubular wall for accommodating the viscous liquid medicine.

[0025] An important aspect of the present hub 18 is that each of the foldable left and right wings 20, 22 of the hub has at least one top rib 32, 34 extending along an entire longitudinal length of a corresponding wing. Each top rib 32, 34 is disposed on an upper surface 36 of the corresponding wing 20, 22, such that when the wings are folded, the top ribs 32, 34 are directly in contact with the upper surface 36 of a corresponding opposite wing. As a result, the top rib 32 disposed on the left wing 20 engages the upper surface 36 of the right wing 22, and conversely the top rib 34 disposed on the right wing 22 engages the upper surface 36 of the left wing 20.

[0026] As illustrated in an exemplary FIGs. 1 and 5 embodiment, a left or first top rib 32 is asymmetrically disposed from a right or second top rib 34 such that the first top rib 32 is juxtaposed with the second top rib 34 when the wings 20, 22 are folded back away from the needle 28 and pinched together (FIG. 5). More specifically, the first top rib 32 is spaced in parallel from an elongated center section 38 of the hub 18 at a first predetermined distance D_A (FIG. 1), but the second top rib 34 is spaced in parallel from the center section at a second

predetermined distance D_B (FIG. 1), where the first distance D_A is different from the second distance D_B.

[0027] For example, as best shown in the FIG. 5 embodiment, the first distance D_A is longer than the second distance D_B, and the first rib 32 goes over the second rib 34 such that the ribs 32, 34 are adjacently positioned with each other when the wings 20, 22 are folded back. As a result, this particular configuration of the top ribs 32, 34 prevents the wings 20, 22 from twisting or sliding relative to each other, thereby reducing the risk of breakage of the needle 28 during the insertion of the needle into the skin.

[0028] Returning now to FIGs. 1-2, a first insertion opening 40 at a first end of the center section 38 is configured for accommodating insertion of the needle 28, and a second insertion opening 42 at a second opposite end of the center section in fluid communication with the tube 16 is configured for accommodating insertion of the tube. In a preferred embodiment, the tube 16 is inserted into the first insertion opening 40 approximately half a length of the center section 38 to reduce a total length of the needle 28 (FIG. 2).

[0029] Both openings 40, 42 provide a passage way for the delivery of the liquid medicine. This passage way provides low flow resistance for high viscosity liquids (e.g., 3-20 cP) in flow rates ranging 40 to 400 ml/hr during subcutaneous delivery without dropping a fluid pressure more than 68.9 kPa (10 psi or pounds per square inch). More specifically, an exemplary 24G stainless needle 28 having the thin tubular wall is configured for accommodating the viscous liquid medicine, and a mid-region 44 of the needle 28 is slightly bent at a predetermined radius of curvature (e.g., 3.175 mm (0.125") typically and not less than 1.524 mm (0.060") or more than 5.08 mm (0.200")), such that the mid-region of the needle surrounds a support region 46 located at or near the first insertion opening 40 of the center section 38.

[0030] It is preferred that the mid-region 44 of the needle 28 is bent gradually at an angle of 45 to 90 degrees (nominally close to 90 degrees), such that the support region 46 buttresses against the bent mid-region of the needle. A sharp end of the needle 28 extends outwardly from the first insertion opening 40 of the center section 38 so that the sharp end of the needle is disposed transverse to a longitudinal axis of the center section. Consequently, the support region 46 reduces the risk of needle breakage, and provides integrated support for the bent mid-region 44 not only during the insertion of the needle 28 into the skin but also while being attached to the user's body.

[0031] Referring now to FIGs. 2-4 and 8, a plurality of substantially diagonally disposed bottom ribs 48a, 48b is provided on a lower or bottom surface 50 of each wing 20, 22 for preventing unwanted movement of the hub 18 during use. It is preferred that the bottom ribs 48a, 48b are generally evenly spaced in parallel, and extend along a full diagonal length of a corresponding wing 20, 22. The bottom ribs 48a, 48b are angled or slanted in such a manner that a forward movement toward the sharp end of the needle 28 is prevented, while a backward movement away from the sharp end of the needle is allowed. This particular arrangement reduces shear

and/or normal stress on the bent mid-region 44 of the needle 28 during use.

[0032] In a preferred embodiment, both the first and second wings 20, 22 of the hub 18 have the bottom ribs 48a, 48b positioned on the lower surface 50 at an angle of approximately 45 degrees relative to the longitudinal axis of the center section 38. An important aspect of the ribs 48a, 48b is, however, that each bottom rib 48a disposed on the lower surface 50 of the first wing 20 is inclined or sloped upwardly from a left side of the first wing to a right side of the first wing toward the center section 38. In a mirrored orientation, each bottom rib 48b disposed on the lower surface 50 of the second wing 22 is declined or sloped downwardly from a left side of the second wing adjacent the center section 38 to a right side of the second wing. As a whole, the bottom ribs 48a, 48b are constructed and arranged in a chevron or herringbone pattern, thereby preventing unwanted movement of the hub 18 while being attached to the user's body.

[0033] This enhanced friction provided by the ribs 48a, 48b prevents slippage of the hub 18 from the skin during use. While diagonally arranged ribs 48a, 48b are shown for illustration purposes, any type of knurling or textured ribs, ridges, grooves, or bumps are contemplated for disposition as a friction formation on the lower surface 50 of the wings 20, 22 for enhancing friction in this manner. Further, the angular orientation and/or spacing of the ribs 48a, 48b is variable to suit the situation.

[0034] Referring now to FIGs. 5-7, an exemplary use of the present infusion device is illustrated in greater detail. Before inserting the needle 28 into the skin, the user folds the wings 20, 22 back away from the needle 28 and pinches the wings together between two fingers. Then, the user subsequently removes the needle protector 30 from the needle 28, and discards the protector (FIG. 5). In preparation of the insertion, the user pinches an inch of the cleansed skin at the desired infusion site, and inserts the needle 28 with a darting motion, straight into the infusion site at a 90 degree angle (FIG. 6). Next, the user checks a needle placement with a syringe 52 by pulling a plunger 54 backward. If blood is seen in the syringe 52, then the present device 10 is removed and discarded in case of a disposable device. Otherwise, the user repeats the process of preparing the present device 10 and the infusion site. If no blood is seen in the syringe 52, the user secures the needle 28 in place, and starts infusion as directed by a healthcare professional (FIGs. 7-8).

[0035] While a particular embodiment of the present infusion device has been shown and described, it will be appreciated by those skilled in the art that changes and modifications may be made thereto without departing from the present disclosure in its broader aspects and as set forth in the following claims.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not

form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US3640275A [0007]
- US2006047252A [0008]
- WO2007137339A [0009]
- US3538915A [0010]
- US2009187153A [0011]

Patentkrav

1. Medicinsk administrationsanordning til admnistration af et medicinsk stof i en brugers krop, som omfatter:
en foldbar muffe (18) med en venstre vinge (20) og en højre vinge (22), hvilken muffe er fastgjort i den ene ende til en slange (16) og fastgjort i en modsat ende til en kanyle (28); og
hvor der er disponeret mindst én første ribbe (32) på den venstre vinge, og der er disponeret mindst én anden ribbe (34) på den højre vinge, således at når vingerne er foldet tilbage væk fra kanylen og klemt sammen, så forhindrer den første og anden ribbe, at vingerne snor og/eller glider i forhold til hinanden under indføring af kanylen i en bruger hud og forhindrer derved beskadigelse af kanylen som følge af uønsket bevægelse af vingerne, og
hvor den mindst ene første ribbe (32) er adskilt parallelt fra en midtersektion (38) af muffen (18) med en første forudbestemt afstand, og den mindst ene anden ribbe (34) er adskilt parallelt fra midtersektionen med en anden forudbestemt afstand, idet den første afstand er forskellig fra den anden afstand;
hvor kanylen (28) har en tynd rørformet væg, der er konfigureret til at rumme det medicinske stof, hvor et midterområde (44) af kanylen er let bøjet med en forudbestemt krumningsradius, således at midterområdet omgiver et støtteområde (46), der er placeret i en ydre ende af muffen, og hvor midterområdet (44) af kanylen er bøjet gradvist ved en vinkel på 45 til 90 grader, således at støtteområdet (46) støtter mod det bøjede midterområde af kanylen.

2. Medicinsk administrationsanordning ifølge krav 1, hvor den mindst ene første og anden ribbe (32, 34) strækker sig langs en hel længdegående længde af en tilsvarende vinge (20, 22).

3. Medicinsk administrationsanordning ifølge krav 1, hvor hver af den mindst ene første og anden ribbe (32, 34) er

disponeret på en øvre overflade (36) af en tilsvarende vinge (20, 22), således at når vingerne er foldet, så er den mindst ene første og anden ribbe direkte i kontakt med den øvre overflade en tilsvarende modsat vinge.

4. Medicinsk administrationsanordning ifølge krav 1, hvor den mindst ene første ribbe (32) er asymmetrisk disponeret fra den mindst ene anden ribbe (34), således at den mindst ene første ribbe er placeret ved siden af den mindst ene anden ribbe, når vingerne er foldet tilbage væk fra kanylen og klemt sammen.

5. Medicinsk administrationsanordning ifølge krav 1, hvor en første indføringsåbning (40) i en første ende af midtersektionen (38) er konfigureret til at rumme indføring af kanylen (28), og en anden indføringsåbning (42) i en anden modsat ende af midtersektionen, der er i fluidforbindelse med slangen (16), er konfigureret til at rumme indføring af slangen.

6. Medicinsk administrationsanordning ifølge krav 5, hvor slangen (16) er indført i den første indføringsåbning (40) ca. halvdelen af længden af midtersektionen (38) for at reducere den samlede længde af kanylen.

7. Medicinsk administrationsanordning ifølge krav 1, der yderligere omfatter en luerhætte (12), der er konfigureret til at modtage det medicinske stof i den ene ende og er fastgjort til en hun-luerkonnektor (14) i den modsatte ende.

8. Medicinsk administrationsanordning ifølge krav 1, der yderligere omfatter en fleksibel aflang slange (16), der er fastgjort i den ene ende til en hun-luerkonnektor (14) og er fastgjort i den modsatte ende til den foldbare muffe (18), og en glideklemme (24), der er konfigureret til at regulere strømningen af det medicinske stof i slangen ved tværgående justering af klemmen i forhold til en længdeakse af slangen.

9. Medicinsk administrationsanordning ifølge krav 1, hvor hver af den mindst ene første og anden ribbe (32, 34) er disponeret på en øvre overflade (36) af en tilsvarende vinge (20, 22), og hvor anordningen yderligere omfatter en flerhed af i det væsentlige diagonalt disponerede ribber (48) på en bundoverflade (50) af hver vinge, hvilken flerhed af ribber er konfigureret til at forhindre uønsket bevægelse af muffen (18) under infusion, hvor ribberne er vinklet, således at en bevægelse fremad mod en skarp ende af kanylen forhindres, mens en bevægelse bagud væk fra den skarpe ende af kanylen er mulig.

10. Medicinsk administrationsanordning ifølge krav 9, hvor ribberne (48) på bundoverfladen (50) af hver vinge er anbragt med overvejende lige store mellemrum parallelt og strækker sig langs en hel diagonal længde af en tilsvarende vinge (20, 22).

11. Medicinsk administrationsanordning ifølge krav 9, hvor ribberne (48) på bundoverfladen (50) af hver vinge (20, 22) er placeret i en vinkel på ca. 45 grader i forhold til længdeaksen af en midtersektion (38) af muffen.

12. Medicinsk administrationsanordning ifølge krav 9, hvor en første indføringsåbning (40) i en første ende af muffen (18) er konfigureret til at rumme indføring af kanylen (28), og en anden indføringsåbning (42) i en anden modsat ende af muffen, der er i fluidforbindelse med slangen (16), er konfigureret til at rumme indføring af slangen.

13. Medicinsk administrationsanordning ifølge krav 11, hvor hver ribbe (48) på bundoverfladen af den venstre vinge (20) skråner eller hælder udad fra venstre side af den venstre vinge mod højre side af den venstre vinge mod midtersektionen (38).

14. Medicinsk administrationsanordning ifølge krav 11, hvor hver ribbe (48) på bundoverfladen af den højre vinge (22) skråner eller hælder nedad fra venstre side af den højre vinge

tilstødende midtersektionen (38) mod højre side af den højre vinge.

15. Medicinsk administrationsanordning ifølge krav 9, hvor flerheden af ribber (48), der er disponeret på bundoverfladen (50) af vingerne, er konstrueret og anbragt i et vinkel- eller sildebensmønster.

DRAWINGS

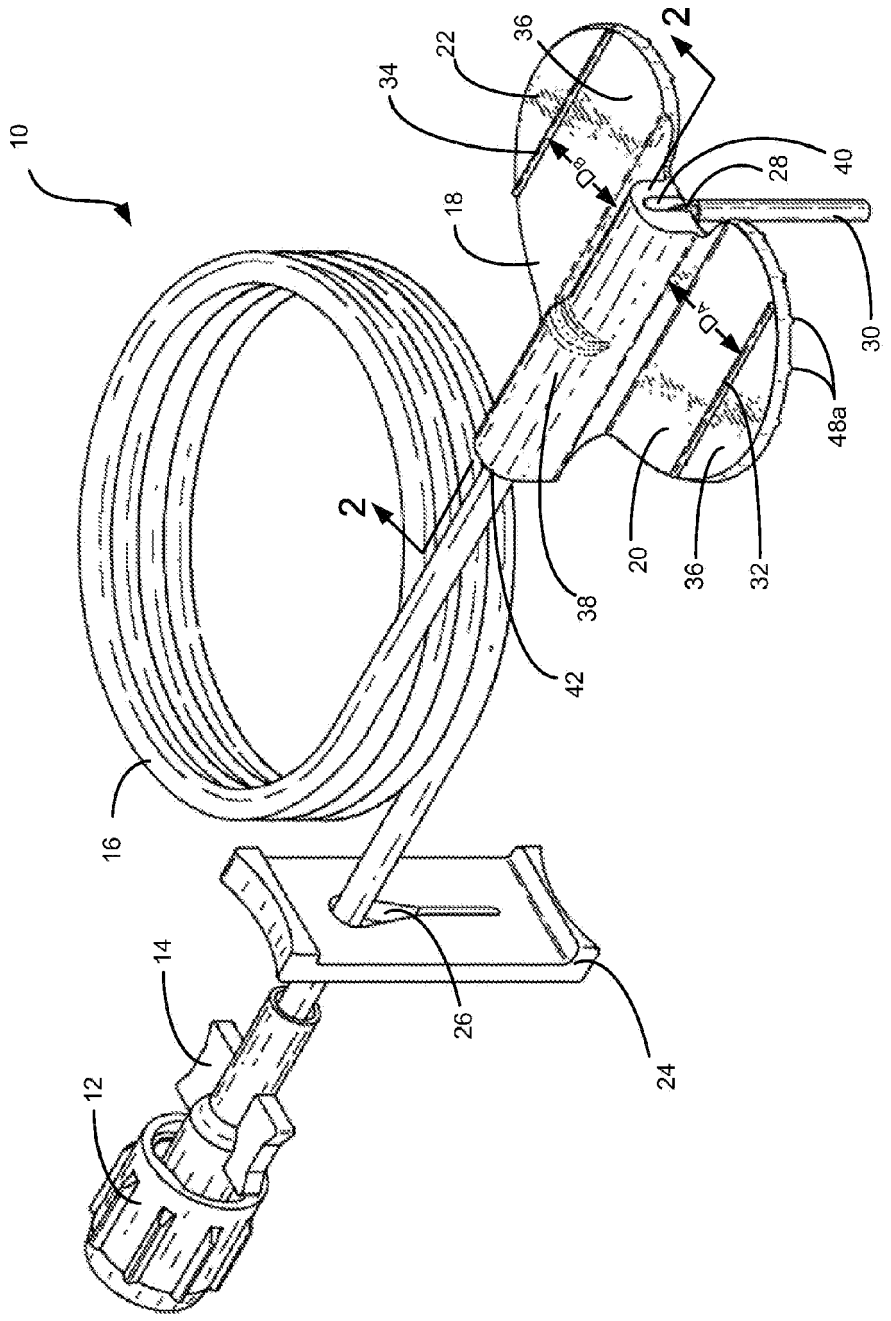
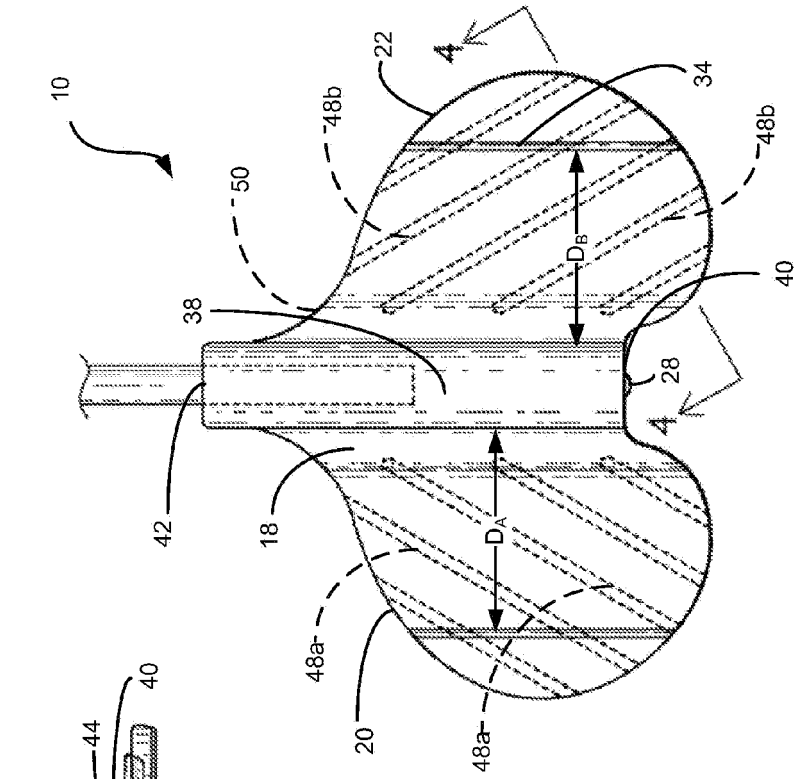


FIG. 1


10
22
4
34
48b
50
48b
38
D_B
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4
42
18
D_A
48a
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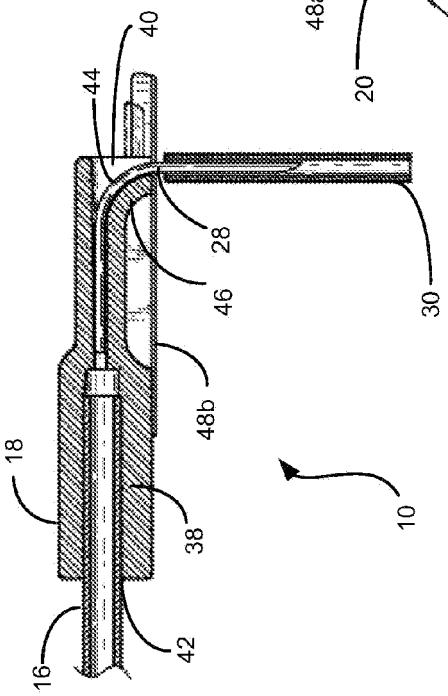
48a

FIG. 3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30
48b
18
38
42
16
10

FIG. 2

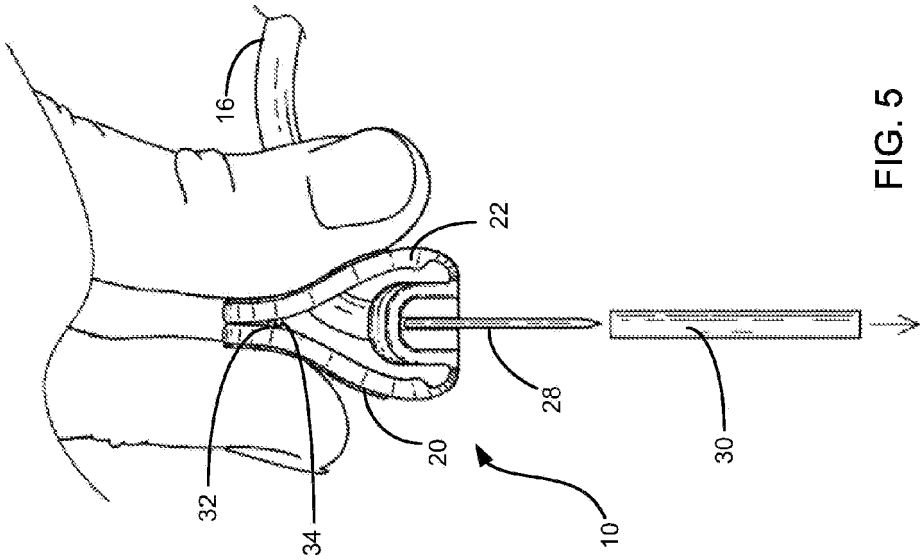

FIG. 5

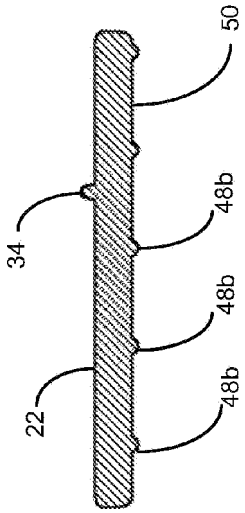

FIG. 4

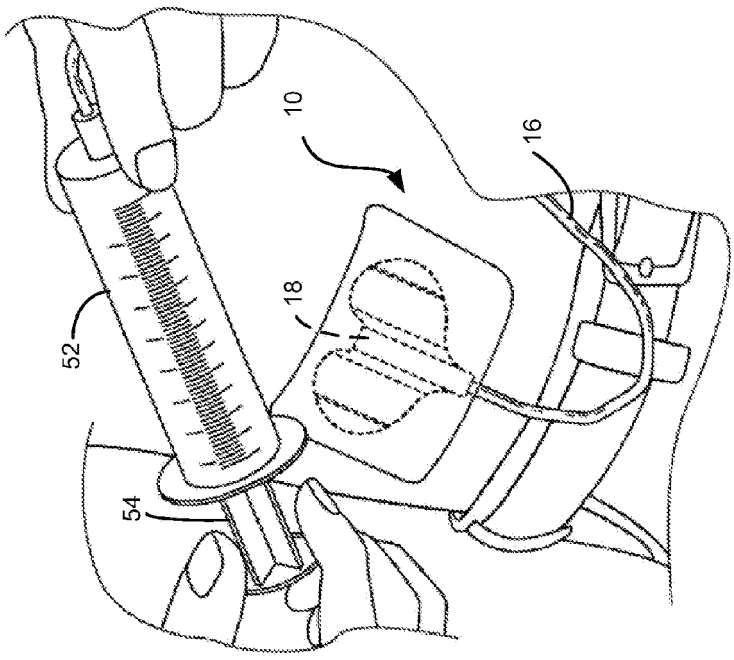

FIG. 7

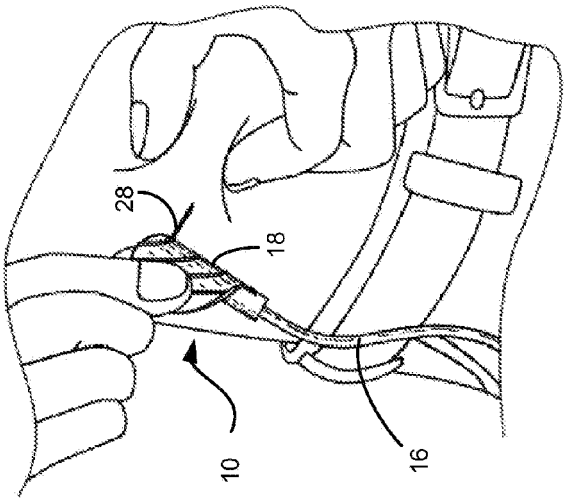

FIG. 6

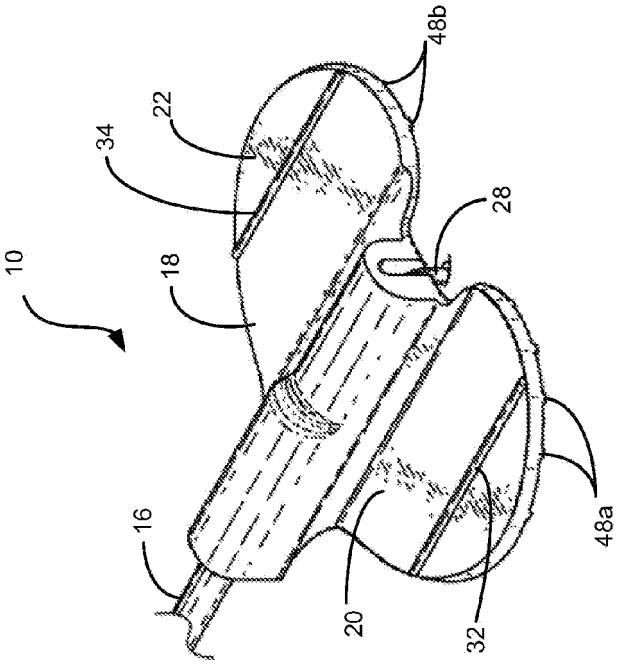

FIG. 8