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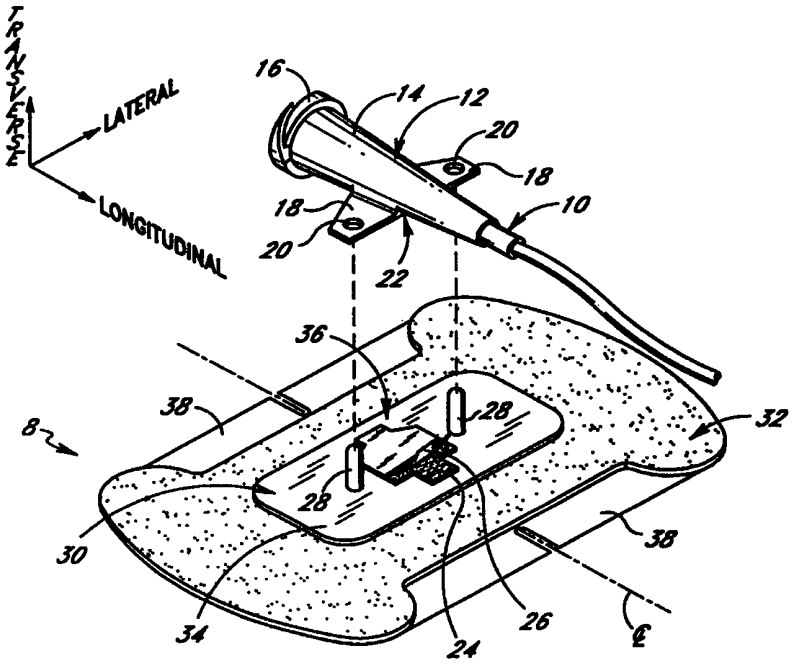
(54) Title: MEDICAL LINE SECUREMENT DEVICE

(57) Abstract

A securement device (8) includes a simply-structured retention mechanism that permits a portion of a catheter hub or a similar medical article to be easily anchored to a patient, without the use of tape or needles and suturing. A unitary retainer (30) desirably includes a base (34) defining a locator mechanism (28). The locator mechanism interacts with a fitting (12) of the medical device so as to position the medical device relative to the retainer. The locator mechanism also desirably guides the medical device fitting into contact with an adhesive member (24) mounted on an outer surface of the retainer. In one form, the locator mechanism includes one or more posts (28) that engage mating holes (20) defined in the medical device fitting (12). In other forms, the locator mechanism includes a cradle defining an arcuate channel to receive a convex surface of the medical device, or a recess shaped to matingly receive the fitting. The retainer is attached to a flexible anchor pad (32) that includes an adhesive bottom surface, which can be attached to the patient's skin. In use, a health care provider positions the medical device fitting on the retainer in a position established and guided by the locator mechanism, and attaches the fitting to the retainer via the adhesive member.



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MEDICAL LINE SECUREMENT DEVICE

Background of the Invention

Field of the Invention

The present invention relates to a securement device for securing a medical line or article to a patient.

Description of Related Art

Medical treatment of patients commonly involves the use of percutaneously inserted catheters to direct fluids directly into the bloodstream, a specific organ or an internal location within the patient, or to monitor vital functions of the patient. For instance, short, peripherally-inserted, intra-arteriovenous catheters are commonly used to direct fluids and/or medications directly into the bloodstream of the patient.

The fluid (e.g., parenteral liquid, medication, etc.) typically drains from a container positioned above the patient to feed under gravity or is delivered via an infusion pump. The fluid flows through tubing and thence into the indwelling catheter. The catheter and the fluid tubing are commonly removably attached to each other by a conventional luer-lock connector.

In common practice, a health care provider uses adhesive, foam or surgical tape to maintain the catheter in place on the skin of the patient. The health care provider wraps a thin piece of tape around the hub of the catheter and then forms a "chevron" with the tape, placing the ends next to the sides of the indwelling catheter. The health care provider then places one piece of across and over the catheter hub, forms a loop in the tubing, places another piece of tape across the tubing loop, and places yet an additional piece of tape over the catheter hub and the tubing section that has been looped around and extends next to the indwelling catheter. Subsequently, the health care provider typically covers the insertion site and the indwelling catheter with a transparent dressing.

The entire taping and dressing procedure takes several minutes of the health care provider's valuable time. In addition, the catheterization process often requires relatively frequent disconnection between the catheter and the fluid supply tube, as well as dressing changes. For instance, intravenous catheterization is frequently maintained for several days, depending upon the condition of the patient. The tubing is generally replaced every 48 to 72 hours in order to maintain the sterility of the fluid and the free-flow of the fluid through the tubing. A health care provider thus must frequently change the tubing and re-tape the connection. The health care provider also must frequently clean the insertion site about the indwelling catheter and change the dressings.

The health care provider thus uses a great deal of valuable time applying, removing and reapplying tape. The frequent application and removal of the tape also commonly excoriates the patient's skin about the insertion site.

In addition, the traditional method of intravenous catheter securement -- surgical tape and transparent dressings alone -- have not always prevented catheter migration and/or dislodgement. Taped intravenous catheters are also easily pulled out during a "routine" dressing change, especially by inexperienced health care providers. And if the catheter migrates too far or dislodgement occurs, the health care provider must replace the catheter, thus exacerbating the time and expense required to maintain the intravenous feed.

Prior securement methods also have not served the patient well. Surgical tape or foam strips are uncomfortable. Many patients also do not rest comfortably and worry about catheter dislodgement when they move, when only tape and a dressing secure the catheter in place.

Several additional drawbacks result from the use of tape to stabilize the catheter. One is contamination. Health care providers often tear off small strips of tape and place then on the hand rail on the patient's bed. Clostridium and other bacteria, however, commonly exist on these surfaces and can be transferred to the patient's skin in the proximity of the insertion site.

In addition, tape securement requires the nurse to handle the tape while wearing protective latex gloves. Tearing adhesive tape tends to produce microscopic and/or visible holes in the gloves and thus destroys glove barrier protection.

A number of catheterization systems have been developed to improved the stability of the catheter and to obviate the need for frequent application and removal of surgical tape. Prior devices, however, have generally held the connector on the IV tubing securely against the patient, rather than the catheter fitting itself.

Summary of the Invention

The present invention involves the recognition that where (i) the catheter securement device secures the connector on the tubing, rather than the catheter fitting, and (ii) the interconnection between the tube connector and the catheter fitting occurs across a bendable anatomic joint (e.g., the patient's wrist), a possibility exists for relative movement to occur between the indwelling catheter and the corresponding vessel (e.g., vein). As a result of such movement, the catheter under some circumstances may become dislodged, requiring re-catheterization of the IV catheter, re-securement of the catheter, and redressing of the insertion site. Again, such catheter migration and/or dislodgement leads to increased time and expense associated with maintaining an intravenous feed.

A need therefore exists for a simply-structured securement device that retains a medical line in a fixed position on a patient's body, but releases the medical line for dressing changes or other maintenance, even where the catheter-tubing connection spans an anatomic joint. An additional need exists for a securement device that incorporates a versatile medical line retaining mechanism, i.e. a device that can be used to attach one of a variety of medical line fittings to an insertion site on a patient's body.

One aspect of the present invention involves a securement device system for securing a medical line to a body of a patient. The securement device comprises a mounting surface that is at least partially covered by an adhesive layer for attaching the securement device to the patient's body. A receiving surface is located distal of the mounting surface. An adhesive member at least partially covers the receiving surface and is positioned to contact at least a portion of the medical line secured by the securement device. A locator mechanism interacts with the medical line and positions the medical line portion on the receiving surface relative to the adhesive member.

A preferred method of manufacturing a medical line securement device involves affixing a sheet of a backing material to a sheet of adhesive-backed foam material, then cutting a first pattern through the sheet of foam material without cutting through the sheet of backing material, the first pattern at least partially defining an anchor pad. A second pattern is then cut through both the sheet of foam material and the sheet of backing material, the second

pattern defining on the backing material a release layer for exposing the adhesive backing of the anchor pad prior to attaching the securement device to the patient's body. A retainer is formed (e.g., molded, or extracted) to include a locator mechanism that is adapted to interact with a portion of the medical line and to thereby guide the medical line into a position relative to the retainer. The retainer is attached to a surface of the anchor pad, and a patch of an adhesive material is applied to a surface of the retainer. A release layer is affixed over the adhesive patch, but is removable to expose the adhesive patch during use.

A preferred method of securing a medical line to a patient involves providing a securement device having a first adhesive member on one side, a second adhesive member on an opposite side, and a locator mechanism. The locator mechanism is engaged with a portion of the medical device so as to position the medical device portion generally over the first adhesive member. The medical device thence is engaged with the first adhesive member to secure the medical device to the securement device. The second adhesive member is placed on the patient's body to secure the securement device, and thus the retained portion of the medical line, to the patient.

Further aspects, features, and advantages of the present invention will become apparent from the detailed descriptions of the preferred embodiments that follow.

Brief Description of the Drawings

The illustrated embodiments of the securement device are intended to illustrate, and not to limit the invention, and contain the following figures:

Figure 1 is a perspective view of a medical line securement device configured in accordance with a preferred embodiment of the present invention, and illustrates an exemplary catheter hub positioned above the securement device;

Figure 2 is a top plan view of the securement device of Figure 1;

Figure 3 is a perspective view of a securement device configured in accordance with another preferred embodiment of the present invention;

Figure 4 is a perspective view of a securement device configured in accordance with an additional preferred embodiment of the present invention;

Figure 5 is a perspective view of a securement device configured in accordance with another preferred embodiment of the present invention, and illustrates an exemplary catheter hub in a retained position;

Figure 6 is a top plan view of the securement device of Figure 5 in an open position without the retained catheter hub;

Figure 7 is a cross-sectional view of a portion of the securement device of Figure 6 taken along line 7-7, and illustrates with the securement device in an open position with the catheter hub positioned above the securement device;

Figure 8 is a cross-sectional view of securement device of Figure 5 taken along line 8-8 and illustrates the securement device in a closed position receiving the catheter hub;

Figure 9 is a perspective view of a medical line securement device configured in accordance with an additional preferred embodiment of the present invention and illustrates a catheter fitting positioned above the securement device;

Figure 10 is a cross-sectional view of the securement device of Figure 9, taken along the line 10-10;

Figure 11 is a cross-sectional view of the securement device according to Figure 10, but with tangs shown in an open position;

Figure 12 is a cross-sectional view of the securement according to Figure 10, but with a fitting of the medical line in the latched position;

Figure 13 is a partially exploded perspective view of a securement device configured in accordance with another preferred embodiment of the present invention;

Figure 14 is a perspective view of the securement device of Figure 13 in an assembled form and illustrates a catheter fitting positioned above the securement device;

Figure 15 is a partially exploded perspective view of a securement device configured in accordance with an additional preferred embodiment of the present invention; and

Figure 16 is a perspective view of the securement device of Figure 15 in an assembled form and illustrates a catheter fitting positioned above the securement device.

Detailed Description of Preferred Embodiments of the Invention

The present embodiments of the medical line securement device are disclosed in the context of an exemplary intravenous (IV) catheter. The principles of the present invention, however, are not limited to IV catheters. Instead, it will be understood by one of skill in this art, in view of the present disclosure, that the securement devices and retainers disclosed herein also can be successfully utilized in connection with other types of medical lines, including tubes for fluid communication and electrical wires. For example, but without limitation, the retainers disclosed herein can be adapted to retain CVCs, PICCs, Foley catheters, and hemodialysis catheters, surgical drainage tubes, feeding tubes, chest tubes, nasogastric tubes, scopes, as well as with electrical wires or cables connected to external or implanted electronic devices or sensors. One skilled in the art may also find additional applications for the devices and devices disclosed herein. Thus, the illustrations and descriptions of securement devices disclosed herein in connection with a catheter are merely exemplary of one possible application of the device.

Each of the embodiments described herein employ the same basic concepts characteristic of the improved securement device, namely attachment of a medical line or article to a patient by use of an adhesive member that adheres to the medical line or article. The securement devices also all include interacting structure that operates between the securement devices and a portion of the medical line or article (e.g., a fitting which either is releasably attached to the medical line or article or is integrally formed with the medical line or article). The interacting structure between the retainer and the portion of the medical line or article generally inhibits relative movement between the medical line and the securement devices in at least one degree of freedom. This interaction also properly locates the portion of the medical line or article on the securement device and guides the medical line or article portion into contact with the adhesive member.

To assist in the description of the components of the securement devices and retainers disclosed herein, the following coordinate terms are used. A longitudinal axis is generally parallel to a section of the medical line to be retained by the securement device, generally in the plane of a base or pad of the securement device (discussed below). A lateral axis is generally perpendicular to the longitudinal axis within the plane of the base. A transverse axis extends transverse to both the longitudinal and lateral axes. Figure 1 illustrates this coordinate system to the side of the securement device. The illustrated coordinate system applies to the perspective views of each of the preferred embodiments illustrated herein. In addition, as used herein, the "longitudinal direction" refers to a direction substantially parallel to the longitudinal axis. "The lateral direction" refers to a direction substantially parallel to the lateral axis. And, "the transverse direction" refer to a direction substantially parallel to the transverse axis. These coordinates are used to describe structures and movement of the securement device of each embodiment. A detailed description of each embodiment, and its associated method of use, now follows.

Figures 1-2 illustrate an securement device 8 constructed in accordance with a preferred embodiment of the present invention. The securement device 8 is configured to retain a catheter 10, either directly or by way of a fitting 12, as in the illustrated embodiment. Thus, the following description first provides a brief description of the catheter fitting 12 before describing the securement device 8 in order to aid the reader's understanding of this embodiment.

Figure 1 illustrates an exemplary short, peripheral IV catheter, such as the type available from B. Braun Mesungen AG. The fitting 12 of this catheter 10 includes a conical receptacle 14 in fluid communication with the catheter 10 and having a threaded rim 16 for releasably attaching to a fluid tubing (not shown) to place the tubing in fluid communication with the catheter 10. The fitting 12 also includes a pair of lateral wings 18 that extend roughly perpendicularly from a lower portion of the fitting 12. Each wing 18 includes a through-hole 20. A medial surface 22 of the fitting 12, including portions of the lateral wings 18, has a generally flat, cruciform-shaped foot print.

The securement device 8 receives and directly anchors the catheter fitting 12 to the patient, rather than holding a point in the medical line upstream of the catheter 10 (e.g., the connector between the catheter and the fluid supply tube). For this purpose, the securement device 8 includes an adhesive member 24 against which the medial surface 22 of the catheter fitting 12 is placed. Desirably, the shape of the adhesive member 24 generally corresponds to the shape of catheter fitting's foot print, and the adhesive member 24 is coextensive with or slightly smaller than the size of the fitting's foot print. Thus, in the illustrated embodiment, the adhesive member 24 has generally a cruciform shape.

The adhesive member 24 desirably has a sufficient thickness and tackiness to either secure and/or encapsulate (at least to some degree) the catheter fitting 12 in order to inhibit relative movement between the securement device 8 and the catheter fitting 12. The adhesive member 24 can be applied to the securement device 8 in any of a variety of conventional ways, such as by transfer technology (e.g., thin film transfer tape) or by sputtering. For instance, in the illustrated embodiment, the adhesive member 24 is formed of a transfer adhesive

available from Minnesota Mining and Manufacturing Company (3M), of Minneapolis, Minnesota, as Part No. 950.

As seen in Figure 1, a release layer 26 can initially cover the adhesive layer 24 before use. In the alternative, the packaging (not shown) for the securement device 8 can function as the release layer 24. In either case, a suitable material covers the adhesive member 24 prior to the securement device's application on a patient. Such suitable material includes, for example, but without limitation, a polycoated, siliconized paper.

The securement device 8 also includes a locator mechanism to properly position the catheter fitting 12 on the adhesive member 24. Any of a wide variety of locator mechanism can be used for this purpose, as illustrated by the various embodiments described below. For instance, as seen in Figures 1 and 2, the securement device 8 desirably includes at least one post 28 which cooperates with one of the holes 20 in the catheter fitting wings 20.

In the illustrated embodiment, the securement device 8 desirably includes a pair of posts 28; however, the securement device 8 can also include additional posts to suit a specific application. For example, where the securement device is designed to secure a relatively large fitting, the securement device can include four posts arranged at the corners of a rectangle, for greater stability. As another example, three posts can be used to firmly anchor a Y-site fitting.

The posts 28 can have any of a variety of lengths and diameters, as well have a variety of distances between them, depending upon the particular application and the particular catheter fitting with which they are to interact. For applications with known catheters, each post 28 desirably has a length of about 4 mm to 20 mm, and more particularly a length of about 6 mm; however, longer or shorter lengths also are possible. The post diameter desirably is slightly smaller than the corresponding hole 20 of the catheter fitting 12 but is sufficiently large to inhibit significant bending of the post 28 under normal forces experienced on the medical line. The posts 28 desirably are of comprise a polymer plastic material, with a diameter between 0.5 mm and 3 mm, and more preferably with a diameter about 1.7 mm.

The posts 28 are laterally spaced at least wide enough to accommodate the medical line or article to be anchored, and, in the illustrated embodiment, desirably correspond to the spacing between the holes 20 in the catheter fitting wings 18. For application with most known catheters, the posts 28 are spaced apart by a distance between about 5 mm and about 40 mm, and more particularly by a distance equal to about 15 mm.

In the illustrated embodiment, as seen in Figures 1 and 2, the securement device 8 includes a retainer, generally designated by reference numeral 30, mounted on a flexible anchor pad 32. The retainer 30 includes a base 34 which supports the locator mechanism (e.g., the posts 28) and the adhesive member 24 of the retainer 30. The base 34 desirably has a planar shape that defined in part a receiving surface (generally designed by reference numeral 36) for the catheter fitting 12. The posts 28 extend generally normal to the receiving surface 36 of the base 34 with the adhesive member 24 located on the receiving surface 36 and between the posts 28.

The base 34 and the posts 28 of the retainer 30 desirably are integrally formed as a unitary piece. This can be accomplished in any of a variety of ways well known to one of skill in the art. For instance, the entire retainer 30 can be injection molded, in order to reduce fabrication costs. Suitable plastics from which the posts 28

and base 34 can be made include, for example, but without limitation, polypropylene, polyethylene, and the like. In particular, acceptable materials include Tenite™ 811 low density polyethylene (LDPE) available commercially from Eastman Chemical Company, of Kingsport, Tennessee, and polypropylene (#P6M5B-015) and polypropylene copolymer (#P6M5Z-036), both available commercially from Huntsman Chemical, Salt Lake City, Utah.

As mentioned above, the adhesive member 24 can be applied to the base 34 in a variety of ways, including, but without limitation, by transfer tape or sputtering. If applied by transfer tape, the application can be done as part of a converter process, described below.

The base 34 of the retainer 30 is attached to the anchor pad 32. The base 34 desirably is secured to the anchor pad 32 by a solvent bond adhesive, such as cyanoacrylate or other bonding material. One such adhesive is available commercially as Part No. 4693 from 3M.

The anchor pad 32 comprises a flexible structural layer for securing the retainer 30 to a patient's skin. The pad 32 desirably comprises a laminate structure with an upper foam layer (e.g., closed-cell polyethylene foam), and a bottom adhesive layer. The adhesive preferably is a medical-grade adhesive and can be either diaphoretic or nondiaphoretic, depending upon the particular application. The anchor pad 32 desirably is formed from a polyethylene foam tape (1/32 to 1/8 inch thick) with an acrylic adhesive, 40 to 120 grams/square meter thick. Such foam with an adhesive layer is available commercially from New Dimensions in Medicine of Columbus, Ohio.

An upper surface of the foam layer of the anchor pad 32 is roughened by corona-treating the foam with a low electric charge. The roughened or porous upper surface of the anchor pad 32 improves the quality of the adhesive joint formed by the cyanoacrylate (or by another type of adhesive or bonding material) between the base 34 and the anchor pad 32. In the alternative, the flexible anchor pad 32 can comprise a medical-grade adhesive bottom layer, an inner foam layer and an upper paper or other woven or non-woven cloth layer.

A removable paper or plastic backing or liner 38 desirably covers the bottom adhesive surface before use. This release layer 38 preferably resists tearing and is divided into a plurality of pieces to ease attachment of the pad to a patient's skin. In the illustrated embodiment, the backing is a polycoated, siliconized paper.

The backing desirably is split along a center line C_L of the flexible anchor pad 32 in order to expose only half of the adhesive bottom surface at one time. The backing 38 also advantageously extends beyond at least one edge of the anchor pad 32, as illustrated, to facilitate removal of the backing 38 from the adhesive layer.

Although not illustrated, the retainer 30 and/or the anchor pad 32 can include suture holes in addition to the adhesive layer to further secure the anchor pad to the patient's skin.

In the illustrated embodiment, the anchor pad 32 also desirably includes a pair of opposing concave sections that narrows the center of the anchor pad 32 proximate to the retainer base 34. As a result, the peripheral ends of the anchor pad 32 have more contact area to provide greater stability and adhesion to a patient's skin, while allowing the retainer 30, which is located at center section of the anchor pad 32, to be placed adjacent to a catheter insertion site.

The anchor pad 32 and release layer 38 (i.e., backing) are formed using a converter process. A sheet of backing material is initially applied onto the adhesive surface of the foam material. (The foam is purchased with

a backing; however, a new backing desirably is applied which includes printed indicia that identifies the manufacturer of the securement device 8.)

A first pattern is cut multiple times in the sheet of adhesive-backed foam material through the conversion process. This may be done using a die-cut technique which "kiss-cuts" only the foam material in the first patters without cutting the backing material. The cut first pattern desirably corresponds to at least a portion of the anchor pad 32. That is, the first pattern, which is cut into the foam material, at least partially defines the shape of the anchor pad 32.

A second pattern is then cut multiple times into the sheet of adhesive-backed material (i.e., the foam material) and the backing material. The second pattern defines the balance of the anchor pad shape, as well as the exposed portion of the release layer 38. This process likewise can be done by die-cutting.

The release liner 38 also is cut into its two halves without cutting the foam layer. This process can be done either before or after the second pattern is cut and also can be accomplished by a die cut. Multiple anchor pads thus are produced from a single sheet the foam/adhesive/backing laminate structure through this conversion process.

In use, the health care provider removes the securement device from its protective, sterile packaging (not shown) and peals off the release layer 26 from the adhesive member 24 if provided separate from the packaging. Otherwise, the adhesive member 24 emerges uncovered from the packaging. The health care provider then aligns the posts 28 with suture holes 20 in the catheter fitting wings 18 and inserts the posts 28 into the holes 20. The interaction between the holes 20 and the posts 28 properly positions the catheter fitting 12 on the retainer 30. The health care provider then moves the catheter fitting 12 into contact with the adhesive member 24 and presses the catheter fitting 12 against the retainer 30 to ensure good contact between the adhesive member 24 and the medial surface 22 of the catheter fitting 12. As a result of the corresponding shapes of the adhesive member 24 and medial surface 22 of the catheter fitting 12, the medial surface 22 completely covers the adhesive member 24, thereby inhibiting exposure of the adhesive member 24. Because exposed adhesive can become sites for bacterial growth, minimizing such exposure substantially reduces the risk of a insertion site infection.

The health care provider desirably secures the anchor pad 32 to the patient after attaching the catheter fitting 12 to the retainer 30. This step can be done before catheter fitting attachment, but it requires placing the anchor pad 32 on the patient in a position precisely aligning the retainer 30 beneath the catheter fitting 12. Regardless of the order of these acts, the health care provider secures the anchor pad to the patient by first removing one half of the release layer and pressing the anchor pad against the patient's skin, adhesive side face down. The health care provider then removes the other half of the release layer and smooths the anchor pad 32 against the patient. The securement device 8 in this position securely anchors the catheter fitting 12 to the patient.

Figure 3 illustrates a medical line securement device 8a in accordance with another embodiment of the present invention. The above description in relation to Figures 1 and 2 applies equally to the embodiment of Figure 3, unless otherwise indicated. In addition, like reference numerals are used to indicate like features among the embodiments, with the letter "a" added as a suffix to refer to features of the present embodiment.

The securement device 8a comprises a retainer 30a. The retainer 30a is similar to the retainer illustrated in Figures 1-2, except that the base 34a of the retainer 30a comprises a raised pedestal 40 extending upwardly from the base 34a and defining a portion of the receiving surface 36a. The raised pedestal 40, the base 34a and the posts 28a desirably are all integrally formed in an unitary retainer 30a.

The adhesive member 24a is formed on an upper surface of the raised pedestal 40, and a release layer 26a covers the adhesive member 24a. Alternatively, the packaging (not shown) functions as the release layer, as described above.

The raised pedestal 40 of the retainer 30a preferably has a planar upper surface on which the adhesive layer 24a is located. Desirably, the plane generally defined by the upper surface of the raised pedestal 40 desirably forms an acute angle with the planar surface of the base 34a. The angled upper surface imparts an angular orientation to the catheter fitting relative to the patient's skin. The resulting incident angle desirably ranges between about 0° and 15°, depending upon the application of the catheter securement device 8, as known in the art.

An anchor pad 32a supports the retainer 30a. A release layer (not shown) covers an adhesive underside of the anchor pad 32a prior to application of the anchor pad 32a to the patient, as described above.

Figure 4 illustrates a medical line securement device 8b in accordance with another embodiment of the present invention. The above description with respect to the embodiment of Figures 1 and 2 applies equally to the embodiment of Figure 4, unless otherwise indicated. In addition, like reference numerals are used to indicate like features among the embodiments, with the letter "b" added as a suffix to refer to features of the present embodiment of Figure 4.

The retainer 30b is similar to the retainer of Figure 1, except that the retainer 30b includes a cradle 42 extending upwardly from the base 34b of the retainer 30b. The adhesive member 24b desirably lies within the cradle 42 and covers at least a portion of the receiving surface 38b defined by the cradle 42. A release layer 26b can initially cover the adhesive member 24b, or the packaging can serve this function, as described above.

In addition, a foam layer 46 desirably is interposed between the surface of the channel 44 and the adhesive layer 24b. The foam layer 46 provides for good contact between the adhesive layer 24b and the surface of the catheter fitting, despite the presence of protuberances on the surface of the catheter fitting. That is, the foam layer 46 allows the adhesive layer 24b to follow the contours of the juxtaposed catheter fitting surface.

The cradle 42 preferably has a concave, arcuate upper surface that forms a channel 44 and functions as the receiving surface of the retainer 30b. Desirably, the surface of the channel 44 conforms substantially to a portion of a surface of a cone, thereby allowing the channel to mate easily with a conically-shaped catheter fitting, such as the fitting illustrated in Figure 1. Because the arcuate surface of the channel 44 can be used to guide a catheter fitting into a desired position relative to the retainer 30b and onto the adhesive layer 24b, posts 28b (shown in phantom lines in Figure 4) are optional in the present embodiment. Such posts 28b, in conjunction with corresponding suture holes, such as the holes 20 in the catheter fitting wings (see Figure 1), may make it easier for a health care provider to position a catheter fitting relative to the retainer 10c and therefore may be used if desired.

In this embodiment, both the shape of the channel 44 and the posts 28b, if included, function as the locator mechanism of the retainer 30b.

An anchor pad 32b supports the retainer 30b. A release layer (not shown) desirably covers an adhesive underside of the anchor pad 32b prior to application of the anchor pad 32b to the patient, as described above.

Figures 5-8 illustrate a medical line securement device 8c in accordance with another embodiment of the present invention. The above description with respect to the embodiment of Figures 1 and 2 applies equally to the embodiment of Figures 5-8, unless otherwise indicated. Like reference numerals are used to indicate like features among the embodiments, with the suffix "c" added to refer to features of the present embodiment.

The retainer 30c and anchor pad 32c of securement device 8c are similar to those illustrated in Figure 1, except that the locator mechanism takes the form of a cradle 48 with movable walls 50. The adhesive member 24c desirably lies within the cradle 48 and covers at least a portion of the receiving surface as defined by the cradle 48. A release layer (not shown) can initially cover the adhesive member 24c or the packaging can serve this function, as described above.

As best understood from Figures 6, 7 and 8, the cradle includes a channel 52 of tapering width, which includes an arcuate surface that functions as the receiving surface of the retainer 30c. Desirably, the shape of the channel 52 conforms substantially to a portion of a cone (i.e., has a frusto-conical shape), thereby allowing the channel 52 to mate easily with a conically-shaped section of the catheter fitting 12c.

The channel 52 is defined in part by the opposing wall sections 50. Each wall section 50 has an arcuate shape of a radius of curvature that generally matches the catheter fitting 12c. Each wall section 50 also extends through an arc length of generally greater than 90° such that together the wall sections 50 surround at least 180° of the conical-shaped catheter fitting 12c.

A flexible coupling, generally identified by reference numeral 54, interconnects the wall sections 50 of the cradle 48 and supports the cradle 48 about retainer base 34c. In the illustrated embodiment, the flexible coupling 54 is integrally formed with the base 34c, as well as with the wall sections 50. The flexible coupling 54 includes a pair of generally parallel rails 56. Each rail 56 includes a necked-down section formed between the base 34c and the corresponding wall section 50. This neck section is flexible and permits the corresponding wall section 50 to move relative to the base 34c.

The wall sections 50 thus are movable relative to each other and to the base 34c. Desirably, the flexible coupling 54 normally holds the wall sections 50 in an open position, as illustrated in Figure 7, in which the upper ends (distal of the base 34c) of the wall sections 50 are spaced apart. The flexible coupling 54 permits the wall sections 50 to move toward each other into a closed position, as seen in Figure 8. In this position, the upper ends of the wall sections 50 are spaced closely together, and the channel's shape and size generally matches that of the retained section of the catheter fitting 12c. The cradle 48 in the closed position thus extends more than 180° around the circumference of the catheter fitting 12c.

The flexible coupling 54 also includes an actuator mechanism to move the wall sections into the closed position once the channel 52 has received the catheter fitting 12c. In the illustrated embodiment, the actuator

mechanism includes a pair of lugs 58 that extend from the lower ends of the wall sections 50 between the rails 56. Each lug 58 has an inner surface (i.e., a surface within the channel 52) with an arcuate shape that generally matches that of the corresponding wall section 50. The lugs 50 are also oriented and sized to have a slight upwardly orientation when the cradle 48 is in the open position,, as seen in Figure 7. But when the catheter fitting 12c is pressed into the channel 52, the lugs 58 move downward. The downward movement of the lugs 58 causes the attached wall section 50 to pivot about the corresponding rail 56 with the neck section of the rail 56 flexing, as seen in Figure 8.

A foam layer 60 is placed within the channel 52 and lines at least a portion of the channel's surface. The foam layer 60 not only compensates for irregularities in the catheter fittings surface, but it also acts as a substrate for the adhesive member 24c. In the illustrated embodiment, the foam layer 60 and the adhesive layer 24c line the entire inner surface of the cradle's channel 52.

In use, the conical section of the catheter fitting 12c is inserted into the cradle 48 while the flexible coupling 54 holds the cradle walls 50 in the open position. The opposing walls 50 of the cradle 48 then close about the fitting 12c, placing the adhesive member 24c in contact with the outer surface of the fitting 12c thereby securing the fitting 12c to the retainer 30c.

Figures 9-12 illustrate a medical line securement device 8d in accordance with another embodiment of the present invention. The above description with respect to the embodiment of Figures 1 and 2 applies equally to the embodiment of Figures 9-12, unless otherwise indicated like reference numerals are used to indicate like features among the embodiments, with the letter "d" added to refer to features of the present embodiment.

The retainer 30d comprises a clamping mechanism formed by a pair of opposing latches 62. The latches 62 are spaced apart from each other on the base 34d, and the adhesive member 24d is located between the latches 62. In the illustrated embodiment, the latches 62 and base 34d are integrally formed together in the form of a unitary retainer 30d, such as, for example, but without limitation, by molding, extracting, or thermal forming, and the adhesive member 24 is applied in any of the above-described manners.

Each latch 62 includes a tang 64, which projects toward the other latch 62, and a generally upright support 66, which suspends the tang 64 above the base 34d. An actuator or lug 68 is attached to the support 66 at a point above the base 34d. The actuator 68 desirably includes a roughened upper surface and/or friction ridges in order to enhance frictional contact between the actuator 68 and the user's finger tips. In the illustrated embodiment, each actuator 68 lies to the outer lateral side of the corresponding tang 64 at the top of the upright support 66. In this position, movement of the actuator 68 toward the base 34d causes the support 66 to flex and moves the tang 64 away from the other latch 66, as seen in Figure 11.

In the illustrated embodiment, the upright supports 66 have elongated shapes and are arranged on the base 34d generally parallel to each other. The supports 66, together with the base 34d, define a generally rectangular channel 70. The opposing tangs 64 of the latches 62 reduce the size of the channel's upper opening. The floor of the channel 70 defines at least a portion of the receiving surface 36d of the retainer 30d.

The channel 70 is sized to receive the catheter fitting wings 18d, and the latches 62 are arranged on the base 34d to snap over the wings 34d to latch the catheter fitting 12d within the channel 70.

In operation, both actuators 68 are depressed by finger pressure, as schematically illustrated in Figure 11, causing the supports 66 to bend laterally outward. This outward bending of the supports 66 allows lateral wings 18d of the catheter fitting to be placed between the supports 66, thereby bringing a medial surface 22d of the fitting 12d in contact with the adhesive pad 24d. After insertion of the catheter fitting wings 18d into the channel 70, the finger pressure on the actuators 68 can be released, thereby allowing the tangs 64 to partially cover an upper surface of the catheter fitting wings 18. Accordingly, the fitting 12d is secured to the retainer 30d in two ways: first, by the adhesive force of the adhesive member 24d to the medial surface 22d of the fitting 12d; and second, by the placement of tangs 64 over top of the fitting wings 18d.

Figures 13-14 illustrate a medical line securement device 8e in accordance with another embodiment of the present invention. The above description with respect to the embodiment illustrated in Figures 1 and 2 applies equally to the embodiment of Figures 13-14, unless otherwise indicated. Like reference numerals are used to indicate like features among the embodiments, with the suffix "e" added to refer to features of the present embodiment.

The retainer 30e comprises plate with a recess or well formed therein. The plate can be formed of any of a wide variety of materials, including a plastic polymer. In the illustrated embodiment, however, the retainer 30e comprises a foam pad defining an aperture 72 therethrough. As shown in Figure 14, the aperture 72 has a shape corresponding to the shape of a catheter fitting's foot print, and thereby locates the catheter fitting 12e relative to the retainer 30e.

An adhesive member 24e is applied to an anchor pad 32e generally at the center of the pad 32e. The size and shape of the adhesive member 24e desirably matches the size and shape of the foam pad 30e. The adhesive member 24e desirably has a uniform thickness and covers the entire area within its perimeter. As a result, a portion of the adhesive member 24e is exposed through the opening. A release layer (not shown) or the product packaging desirably covers the adhesive ember 24e prior to use, as described above.

The foam pad retainer 30e and its aperture 72 can be formed during a conversion process during a die cut procedure. The application of the adhesive member 24e and the attachment of the foam pad retainer 30e to the adhesive member 24e can also occur as steps during the conversion process.

Although not illustrated, the well or recess need not extend entirely through the foam pad, but rather can take the form of an embossment. In this form, the adhesive member can be applied to the floor of the recess so as to be accessible from a side of the anchor pad opposite of the patient's skin. Again, at least a portion of the recess is configured to correspond to the secured portion of the catheter fitting wings in shape and size.

In operation, the catheter fitting 12e is moved toward and placed into the recess 72 so as to position a medial surface 22e of the fitting 12e relative to the adhesive member 24e. The medial surface 22e is thence pressed into contact with the adhesive member 24e to secure the catheter fitting 12e to the securement device 8e. The anchor pad 32e is secured to the patient's skin in the manner described above.

Figures 15-16 illustrate a medical line securement device 8f in accordance with another embodiment of the present invention. The description of the embodiment of Figures 1 and 2 applies equally to the embodiment of Figures 15-16, unless otherwise indicated. Like reference numerals are used to indicate like features among the embodiments, with the suffix "f" added to refer to features of the present embodiment. This embodiment is also similar to that illustrated in Figures 13-14, except that the need for a retainer. The retainer illustrated in Figure 13 is eliminated in the present embodiment, and a recess or well 74 is defined in the anchor pad 32f itself. In the illustrated embodiment, the recess 74 extends entirely through the anchor pad 32f; however, the recess can take the form of an indentation in the pad 32f. In either case, the recess 74 desirably has a similar shape and size to at least a portion of the catheter fitting 12f. And preferably, the recess 74 generally matches the foot print of the catheter fitting 12f in shape and size.

The adhesive member 24f is located on the bottom of the recess. In the illustrated embodiment, though, where the recess extends through the pad 32f, a substrate 76 supports the adhesive member 24f at this location. The adhesive member 76 desirably covers the entire substrate 76 and secures it to a side of the anchor pad on which the adhesive layer is formed. Thus, the substrate can include adhesive layers on both of its sides.

The use of the present securement device 8f is similar to that associated with the securement device illustrated in Figures 13 and 14. The catheter fitting 12f is moved toward and placed into the recess 74 so as to position a medial surface 22f of the fitting 12f relative to the adhesive member 24f. The medial surface 22f is thence pressed into contact with the adhesive member 24f to secure the catheter fitting 12f to the securement device 8f. The anchor pad 32f is secured to the patient's skin in the manner described above.

As common to all of the embodiments described above, the securement device includes adhesive layers on two sides. One side adheres to the patient, while the other side adheres to the medical line or article. In order to properly position the medical line on the securement device and to enhance the speed and ease of applying the securement device, each of the above-described securement devices also include a locator mechanism. Proper positioning promotes good contact between the adhesive member and the medical line or article to enhance securement, as well as ensures that the medical line or article completely covers the adhesive member. As a result, the adhesive tends not to become a sites for bacterial growth. The locator mechanism also allows the health care provider to properly position the medical line or article on the securement device with minimum time and effort.

For use with catheter type devices, each of the securement devices described above secures the catheter fitting to the patient, rather than secures the connector on the tubing to the patient as done by prior devices. The catheter thus does not move with movement of an anatomic joint when an interconnection between the catheter and the tubing spans across the joint.

Also as common to each of the above-described embodiments, the securement device provides a sterile, stable, efficient way to anchor a medical line or article to a patient. The securement device is quickly and easily applied to the medical line or article by using the locator mechanism, and is equally quickly and easily applied to the patient's skin. During the application process, the health care provider need not contact the adhesive layers with

his or her gloves. Use of the securement device thus does not degrade glove protective. Once secured, the securement device stabilizes the catheter and substantially prevents catheter movement and migration.

Although not illustrated, each of the above-described securement devices can include one or more tube clips, especially for use with intravenous catheters. An exemplary tube clip is described and illustrated in U.S. Patent No. 5,578,013, issued in the name of Steven F. Bierman, on November 26, 1996, and to the assignee hereof, which is hereby incorporated by reference. The tube clip can have a plate-like base adhered to the anchor pad and be located on either side of the retainer to accommodate left or right hand mounting.

The tube clip desirably defines a channel having a generally circular cross-sectional configuration truncated to form an upper orifice. The diameter of the channel is desirably slightly less than that of the fluid supply tube so as to ensure a secure interconnection. The channel receives a portion of the fluid supply tube through the orifice upon application of gentle pressure or by pulling the tubing across and through the orifice of the tube clip. The clip surrounds a substantial portion of the tubing with the tubing positioned within the channel.

In use, a health care provider loops the IV supply tubing around from the insertion site and insert a portion of the tubing into the tube clip. The looped section has sufficient slack to form a conventional safety loop. The safety loop absorbs any tension applied to the fluid supply tube to inhibit pulling of the catheter.

The skilled artisan will also recognize the interchangeability of various features from different embodiments. For instance, the angular orientation of the receiving surface illustrated in Figure 3 can be employed with the cradles illustrated in Figures 4 and 5. Thus, various features of the embodiments can be combined in order to adapt the securement device to a particular application.

Although this invention has been described in terms of certain preferred embodiments, other embodiments apparent to those of ordinary skill in the art are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by the claims that follow.

WHAT IS CLAIMED IS:

1. A securement device system for securing a medical line to a body of a patient, comprising a mounting surface at least partially covered by an adhesive layer for attaching the securement device to the patient's body, a receiving surface located distal of the mounting surface, an adhesive member at least partially covering the receiving surface and positioned to contact at least a portion of the medical line secured by the securement device, and a locator mechanism configured to interact with the medical line and to position the medical line portion on the receiving surface relative to the adhesive member.

2. A securement device as in Claim 1, wherein the adhesive member is sized so as to be completely covered by the secured medical line portion.

3. A securement device as in Claim 2, wherein the shape of the member generally matches the shape of the portion of the medical line to be secured.

4. A securement device as in Claim 2, wherein the adhesive member is generally planar, the receiving surface is arranged to receive the medical line in a manner generally aligning an axis of the medical line with a longitudinal axis of the securement device, and a length of the adhesive member, as measured parallel to the longitudinal axis, is greater than a width of the adhesive member, as measured perpendicular to the longitudinal axis and generally parallel to the adhesive member.

5. A securement device as in Claim 4, wherein the adhesive member has generally a cruciform shape.

6. A securement device as in Claim 1 additionally comprising a flexible anchor pad, the mounting surface being defined on one side of the anchor pad and the receiving surface being accessible from an opposite side of the anchor pad.

7. A securement device as in Claim 6, wherein the anchor pad comprises a flexible foam layer, and the adhesive layer covers at least a portion of one side of the foam layer.

8. A securement device as in Claim 6, wherein the locator mechanism comprises a recess formed in the anchor pad.

9. A securement device as in Claim 8, wherein said recess extends through the anchor pad and the adhesive layer is formed at least in part over at least a portion of a substrate, the substrate being positioned over one side of the recess.

10. A securement device as in Claim 9, wherein said adhesive member being located within said recess.

11. A securement device as in Claim 8, wherein at least a portion of the recess is configured to correspond to the secured portion of the medical line in shape and size.

12. A securement device as in Claim 6 additionally comprising a retainer attached to an upper side of the anchor pad, the retainer including the locator mechanism with the receiving surface being defined on a side of the retainer facing away from the anchor pad.

13. A securement device as in Claim 12, wherein the locator mechanism includes a recess formed in the retainer.

14. A securement device as in Claim 13, wherein said recess extends through the retainer and the adhesive member is located between the anchor pad and the retainer with a portion of the member being exposed within the recess.

15. A securement device as in Claim 13, wherein at least a portion of the recess is configured to correspond to the secured portion of the medical line in shape and size.

16. A securement device as in Claim 12, wherein the locator mechanism comprises at least one post.

17. A securement device as in Claim 16, wherein the locator mechanism comprises at least a pair of posts spaced apart from each other.

18. A securement device as in Claim 17, wherein the adhesive member is positioned between the pair of posts.

19. A securement device as in Claim 18, wherein the retainer includes an inclined surface positioned between the posts, and the adhesive member is located on the inclined surface.

20. A securement device as in Claim 12, wherein the locator mechanism comprises a cradle with the receiving surface being formed within the cradle.

21. A securement device as in Claim 20, wherein the adhesive member is positioned within the cradle and covers at least a portion of the receiving surface.

22. A securement device as in Claim 21, wherein a foam layer is interposed between the adhesive member and the cradle.

23. A securement device as in Claim 20, wherein the cradle comprises a contoured surface configured to mate with a complementary contoured surface defined by the secured portion of the medical line.

24. A securement device as in Claim 20, wherein the cradle includes an arcuate channel.

25. A securement device as in Claim 24, wherein at least a portion of the surface of the channel extends about a central axis of the channel by more than 180 degrees.

26. A securement device as in Claim 25, wherein the channel has a tapering frusto-conical surface.

27. A securement device as in Claim 25, wherein the cradle includes a flexible coupling interconnecting sides of the channel to permit movement of the sides relative to each other at least between an open position and a closed position.

28. A securement device as in Claim 27, wherein the flexible coupling comprises an actuation mechanism which causes the channel sides to move from the open position to the closed position when a portion of the medical line presses against the flexible coupling within the channel.

29. A securement device as in Claim 12, wherein the retainer comprises a base and a raised pedestal extending upwardly from the base, and the receiving surface is defined on the raised pedestal.

30. A securement device as in Claim 12, wherein the retainer includes a base and a pair of latches spaced apart from each other on the base, and the adhesive member is located between the latches.

31. A securement device as in Claim 30, wherein each latch includes a tang, which projects toward the other latch, a generally upright support, which suspends the tang above the base, and an actuator, which is

attached to the support at a point above the base, whereby moving the actuator toward the base causes the support to flex and moves the tang away from the other latch.

32. A securement device as in Claim 31, wherein each support has an elongated shape, and the supports are arranged on the base generally parallel to each other so as to define a generally rectangular channel between the supports and the base.

33. A securement device as in Claim 32, wherein the channel is sized to receive the secured portion of the medical line, and the latches are arranged on the base to engage a portion of the medical line to secure, at least in part, within the channel.

34. A securement device as in Claim 30, wherein a release line covers the adhesive member.

35. A securement device as in Claim 12, wherein the retainer is attached to the anchor pad by a solvent bond adhesive.

36. A securement device as in Claim 28, wherein the solvent bond adhesive comprises cyanoacrylate.

37. A securement device as in Claim 12 additionally further comprising a foam pad interposed between the retainer and the adhesive member, the adhesive member covering at least a portion of one side of the foam pad.

38. A securement device for anchoring a medical device to the body of a patient, comprising a mounting surface at least partially covered by an adhesive layer for attaching the securement device to the patient's body, a receiving surface located distal of the mounting surface, adhering means for securing a portion of the medical device to receiving surface, and guide means for locating the medical device relative to the adhering means in a position wherein a portion of the medical device attaches to and generally completely covers the adhering means.

39. A securement device as in Claim 38 additionally comprising a flexible foam pad on which said adhesive layer and which supports said adhering means and said guide means.

40. A method of manufacturing a securement device for retaining a medical line to the body of a patient comprising:

affixing a sheet of a backing material to a sheet of adhesive-backed foam material;

cutting a first pattern through the sheet of foam material without cutting through the sheet of backing material, the pattern at least partially defining an anchor pad;

cutting a second pattern through both the sheet of foam material and the sheet of backing material, the second pattern defining a release layer for exposing the adhesive backing of the anchor pad prior to attaching the securement device to the patient's body;

forming a retainer that defines a locator mechanism adapted to interact with a portion of the medical line and thereby guide the medical line into a position relative to the retainer;

attaching the retainer to the upper surface of the anchor pad; and

applying a patch of an adhesive material to an upper surface of the retainer.

41. A method of manufacturing an securement device as in Claim 40, wherein the adhesive patch is applied by spray-sputtering an adhesive onto the upper surface of the retainer.

42. A method of manufacturing an securement device as in Claim 40, wherein the adhesive patch is applied by transferring the adhesive patch to the retainer using transfer tape.

43. A method of manufacturing an securement device as in Claim 40 additionally involving of corona-treating the upper surface of the anchor pad with a low electric charge before attaching the retainer to the anchor pad.

44. A method of manufacturing an securement device as in Claim 40 wherein attaching the retainer to the anchor pad involves adhering the retainer onto a surface of the pad using a solvent bond adhesive.

45. A method of securing a medical device to the body of a patient comprising:

providing a securement device having a first adhesive member on one side of a securement device, a second adhesive member on an opposite side of the securement device, the securement device comprising a locator mechanism adapted to engage the medical device so as to guide the medical device into a position relative to the first adhesive member;

engaging the medical device with the locator mechanism so as to position a portion of the medical device over the first adhesive member,

engaging the portion of the medical device with the first adhesive member thereby releasably securing the medical device to the securement device; and

placing the second adhesive member on the patient's body to secure the securement device thereto.

46. A method as in Claim 45, wherein engaging the locator mechanism with a portion of the medical line involves inserting at least one post of the locator mechanism through a hole of a fitting of the medical device.

47. A method as in Claim 45, wherein engaging the medical device with the locator mechanism involves placing a portion of the medical device within a cradle of the locator mechanism.

48. A method as in Claim 45, wherein engaging the medical device with the locator mechanism involves placing a mating portion of the medical device within a recess of the securement device.

49. A method as in Claim 45, wherein the provided securement device comprises a pair of cooperating latches with a channel defined between the latches, and engaging the medical device with the locator mechanism involves placing a portion of the medical device within a channel.

50. A method as in Claim 49 additionally comprising latching the portion of the medical device to the securement device using the latches.

51. A method as in Claim 45, wherein engaging the medical device with the locator mechanism means placing the to-be-retained portion of the medical device within a cradle of the retainer, pressing the medical device portion against a flexible coupling, and moving opposing sides of the cradle around the portion of the medical device.

52. A method as in Claim 52, wherein engaging the medical device with the first adhesive member involves bringing the opposing sides of the cradle into contact with the medical device with the first adhesive member covering at least portions of opposing sides.

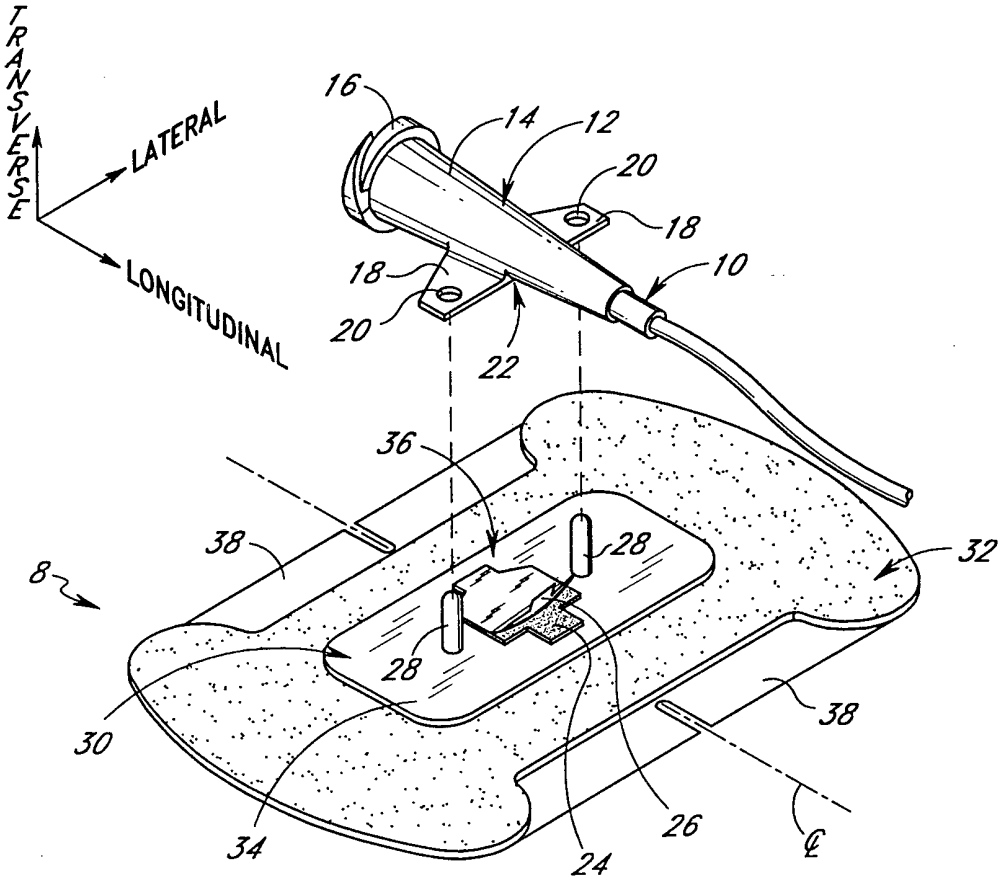
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FIG. 1

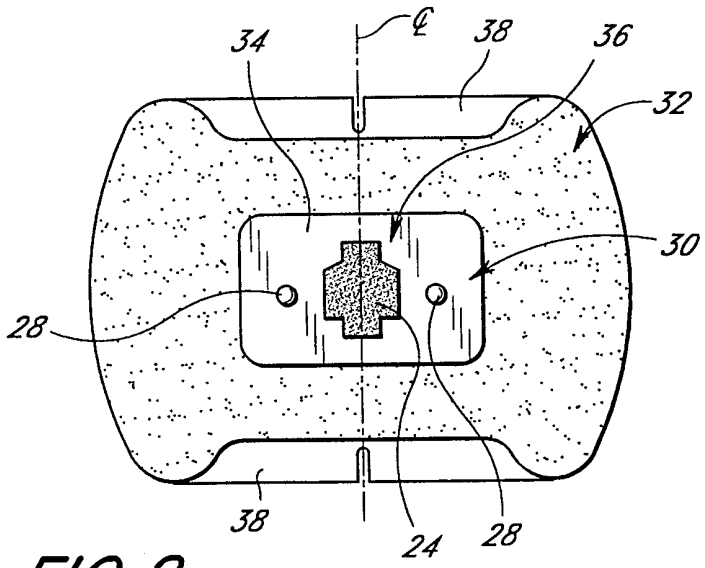
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FIG. 2

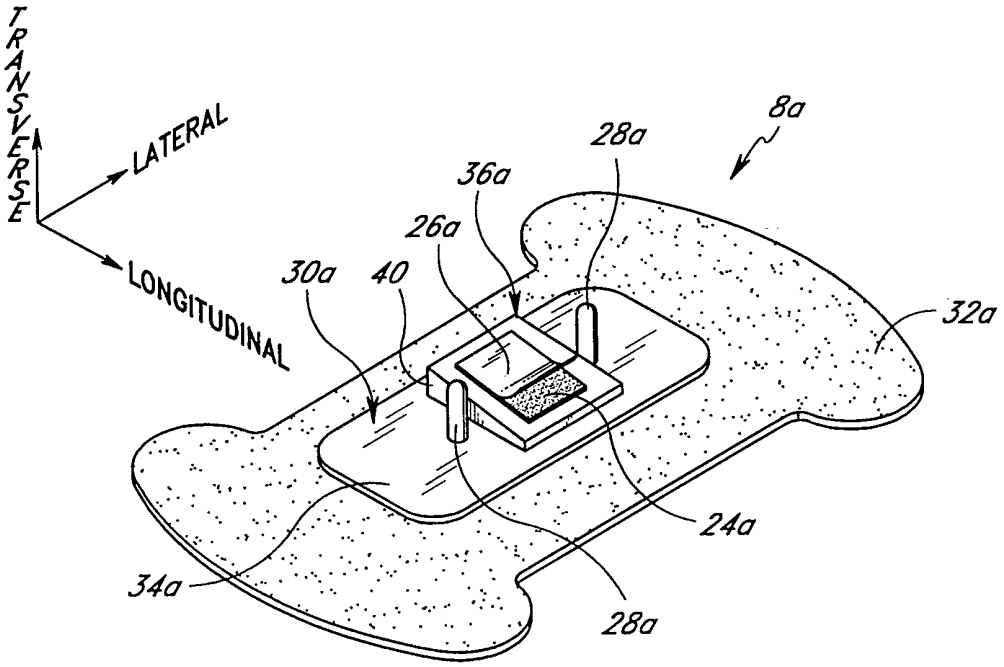
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FIG. 3

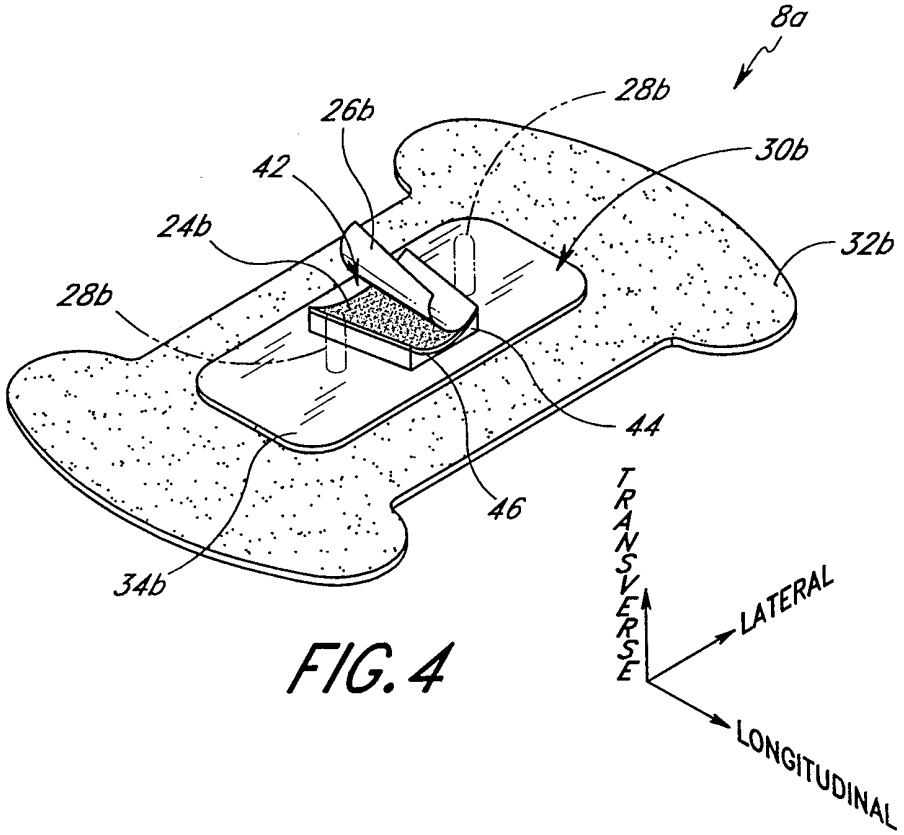
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FIG. 4

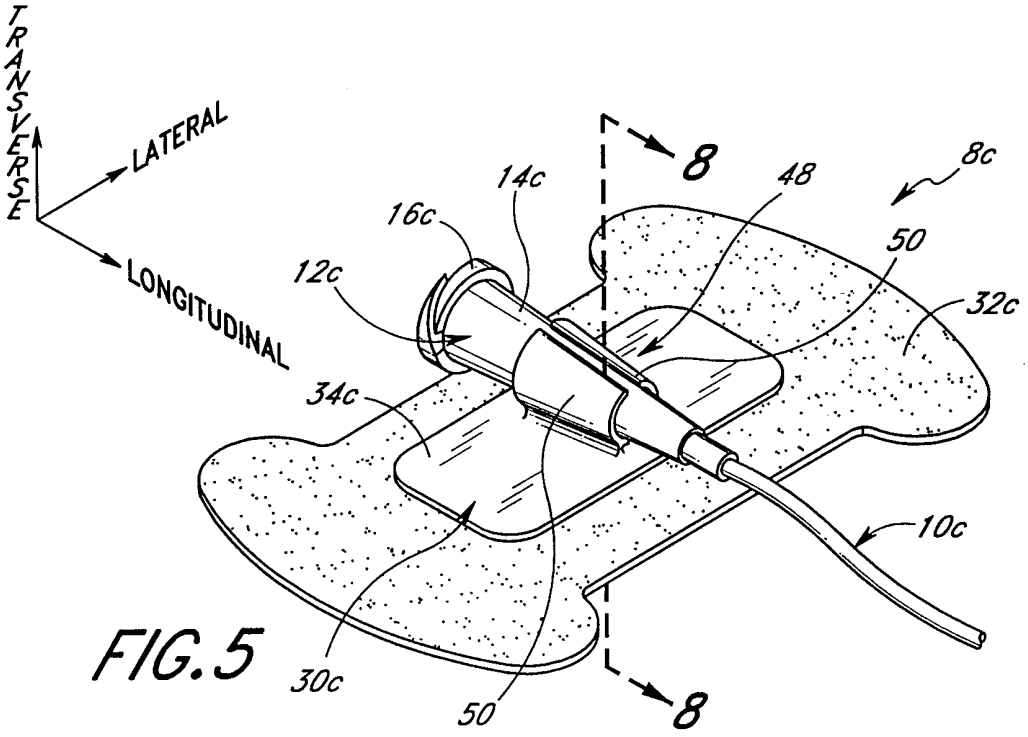

FIG. 5

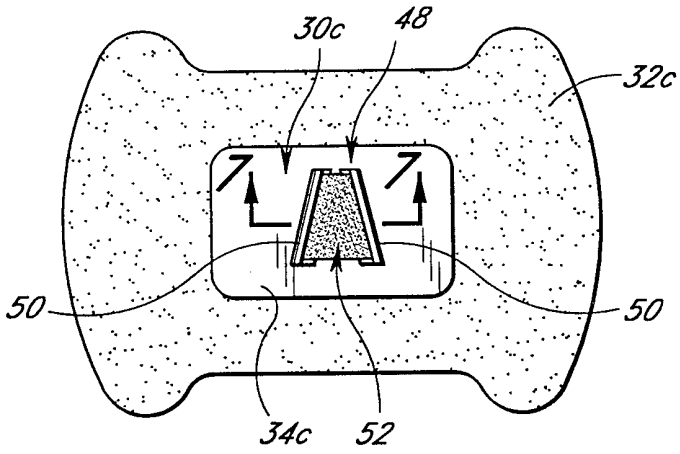

FIG. 6

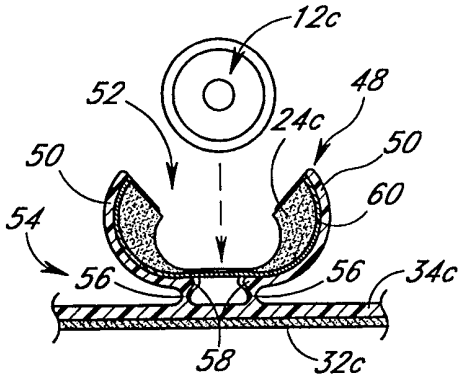

FIG. 7

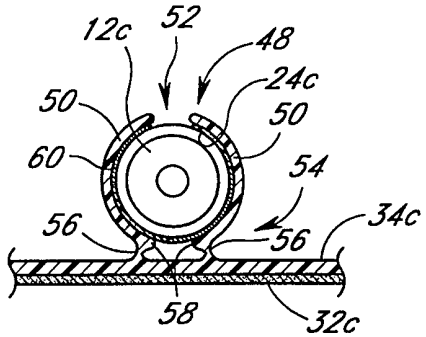

FIG. 8

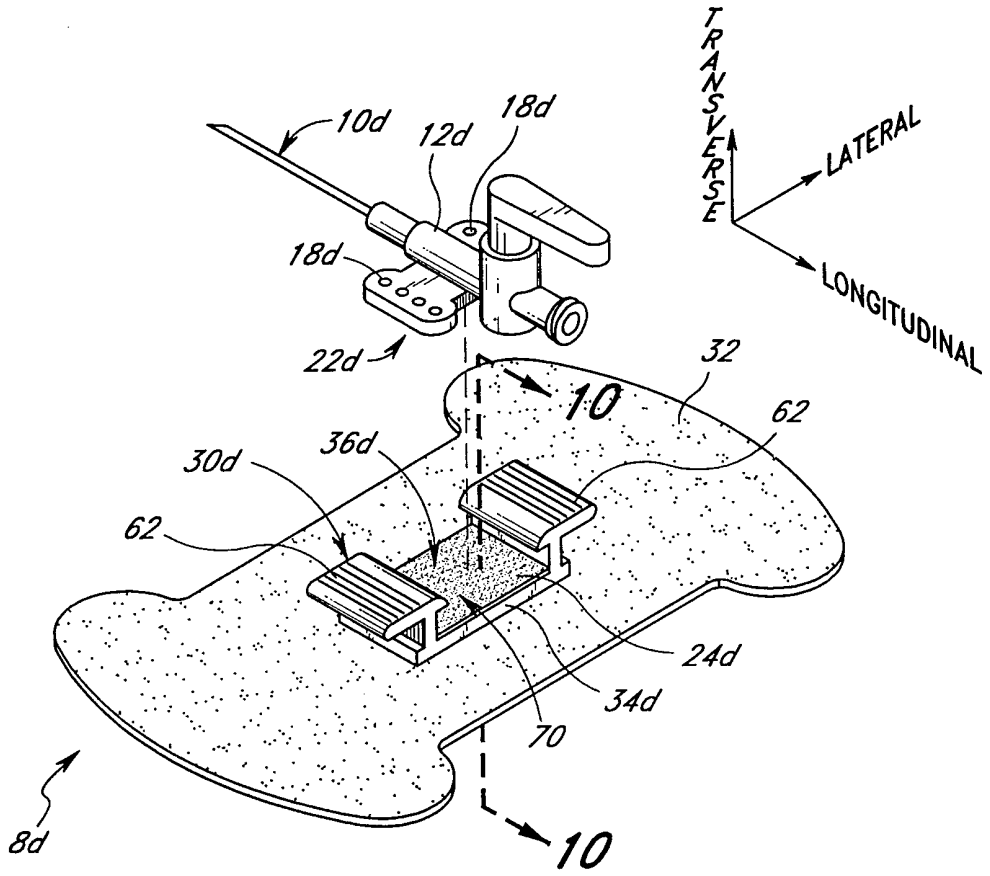
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FIG. 9

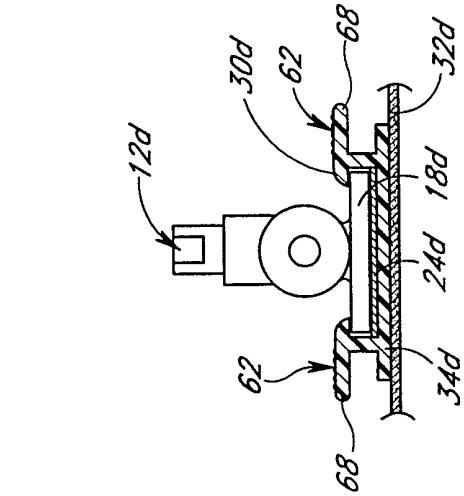

FIG. 12

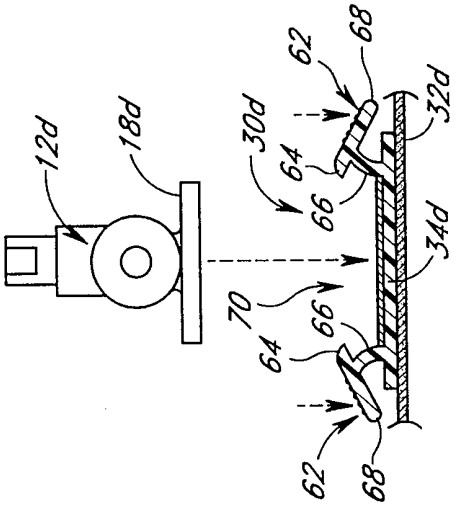

FIG. 11

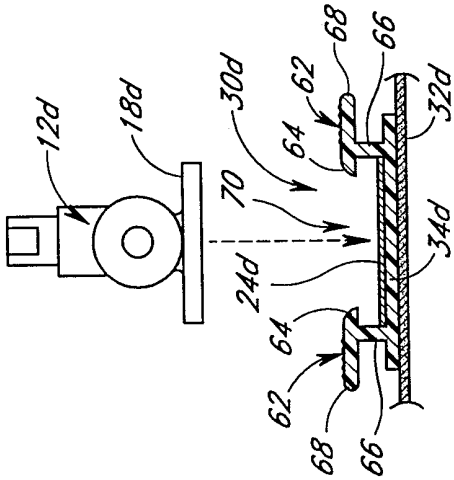

FIG. 10

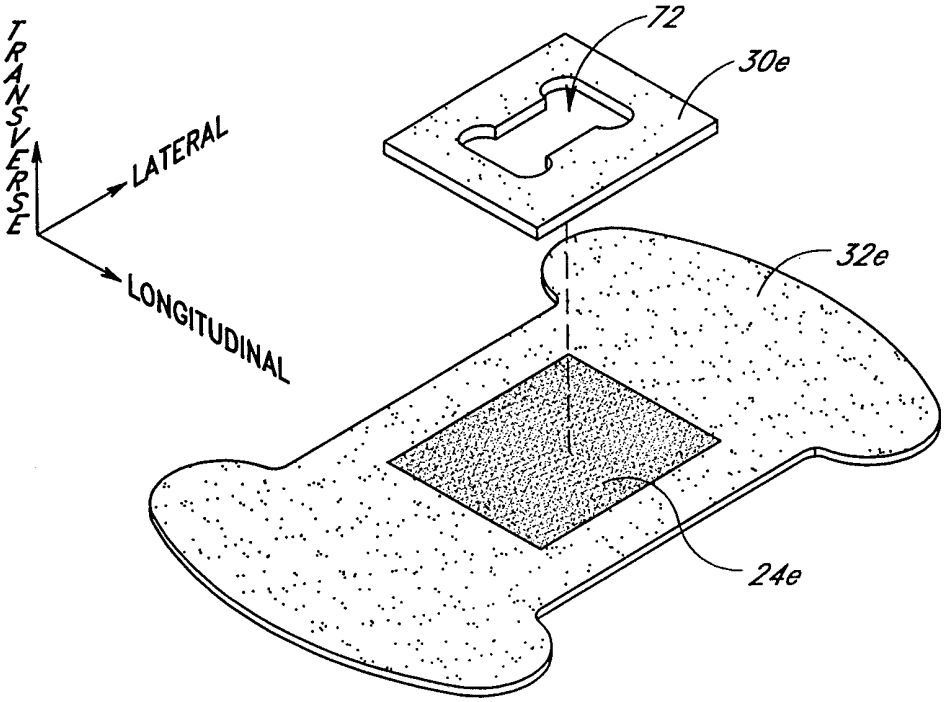
TRANSVERSE
LATERAL
LONGITUDINAL
72
30e
32e
24e

FIG. 13

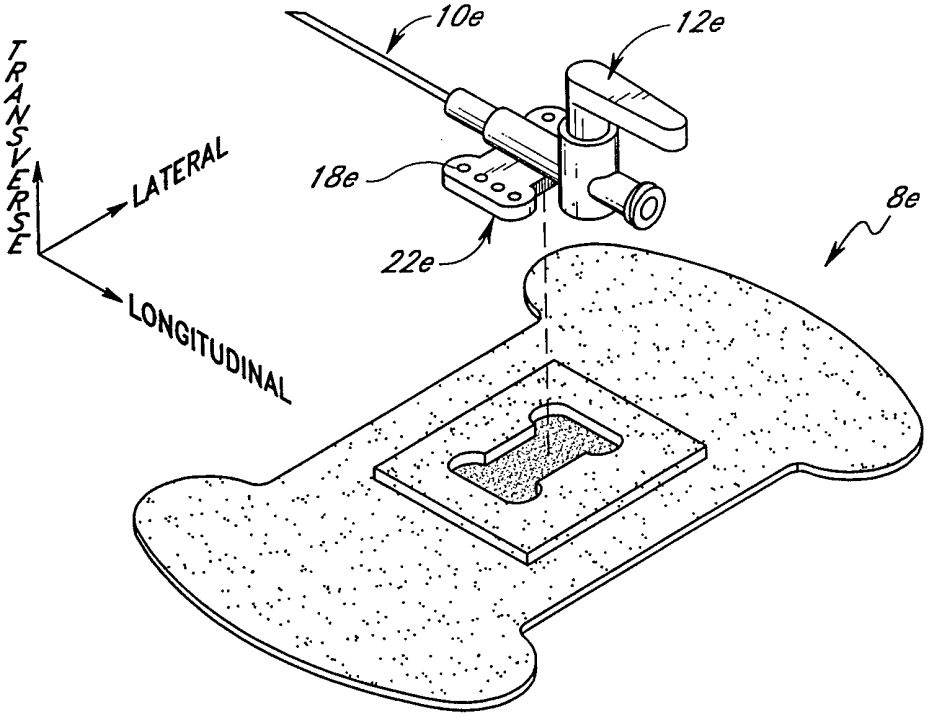
TRANSVERSE
LATERAL
LONGITUDINAL
10e
12e
18e
22e
8e

FIG. 14

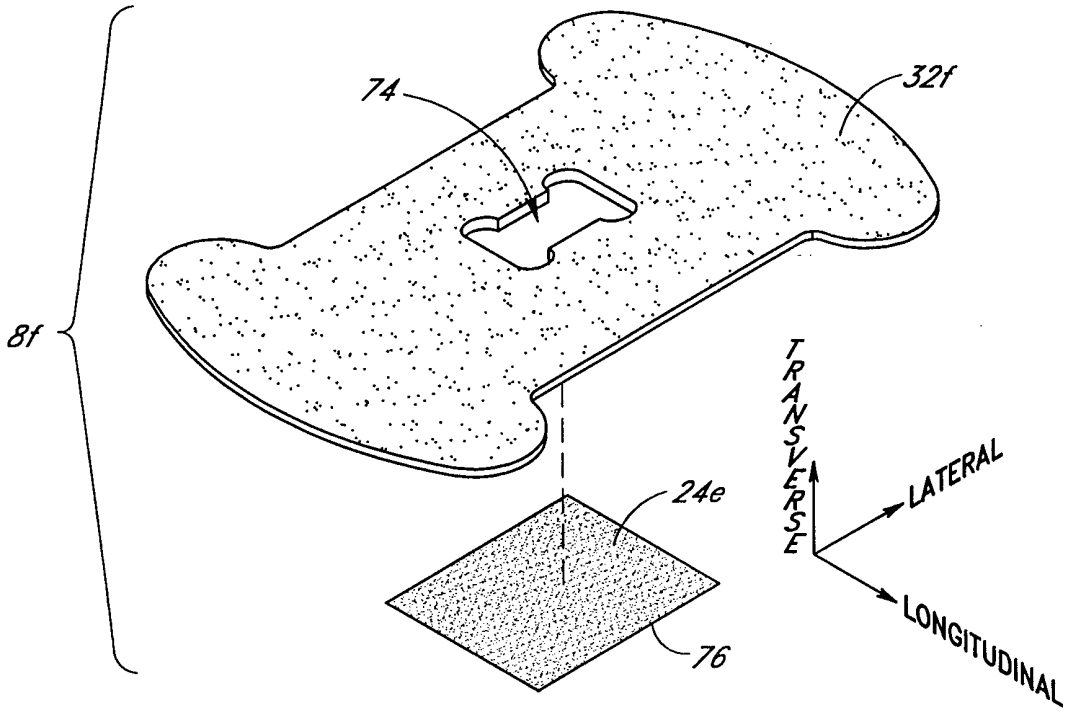
74
32f
8f
24e
76
TRANSVERSE
LATERAL
LONGITUDINAL

FIG. 15

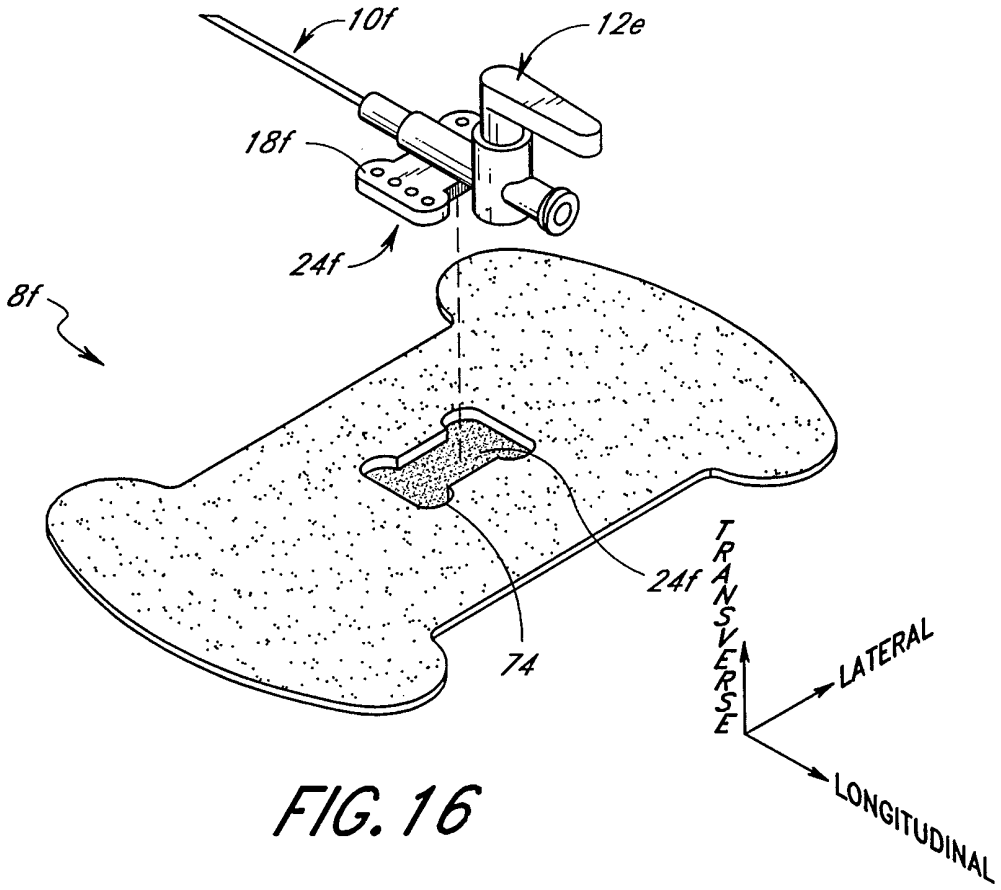
10f
12e
18f
24f
8f
24f
74
TRANSVERSE
LATERAL
LONGITUDINAL

FIG. 16

INTERNATIONAL SEARCH REPORT

Intern :al Application No
PCT/US 98/24239

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/00 A61M5/32 A61C3/00 B32B31/00 A61M5/14
A61M25/02 B65H37/00 A61F13/02

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61C B32B B65H A61F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 333 468 A (GEIST ROBERT W) 8 June 1982 see column 2, line 13 - column 3, line 51 see figure 2 ---	1,6,7, 12,13, 38,39, 45,48
Y	US 4 919 654 A (KALT GLENDA G) 24 April 1990 see column 1, line 42-45 see column 3, line 8 - column 4, line 34 see figure 2 --- -/--	1-7, 10-13, 15,18, 20,21, 23-26, 35,36

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 January 1999	11/02/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bichlmayer, K-P

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INTERNATIONAL SEARCH REPORT

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PCT/US 98/24239

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97 15337 A (VENETEC INT INC) 1 May 1997 see page 3, line 24-27 see page 4, line 17 - page 6, line 27 see page 8, line 30 - page 9, line 2 see figure 2	1-5,10, 18,21
A	see page 6, line 28 - page 7, line 14 see page 7, line 18-24	16-19, 35,36, 43,44
Y	WO 97 15342 A (VENETEC INT INC) 1 May 1997 see page 1, line 35 - page 2, line 27 see page 4, line 6 - page 5, line 3 see page 6, line 22-28 see page 8, line 8-20 see figure 2	1-7, 10-13, 15,20, 21, 23-26, 35,36
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