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(54) **CENTRAL LINE ACCESS AND SUPPORT GARMENT**

(57)

ABSTRACT

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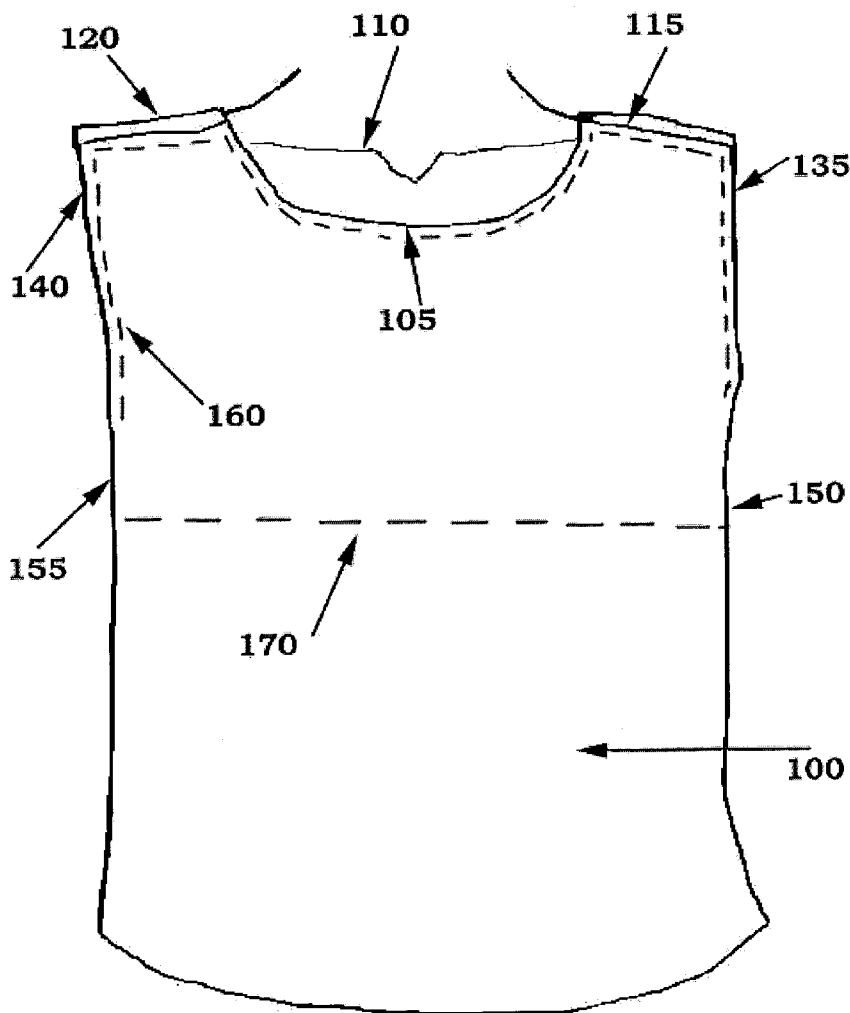
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A central line access and support garment provides a relatively tight inner layer to support and protect central line port sites and external lines. The garment protects a multitude of port site locations. Releasable shoulder closures allow for easy access to the port sites and lines while providing an easy to wear garment for the patient. An inner layer is tight enough to protect the port site, securely holding the bandage, if used at the port site, against the patient's body. The garment offers the flexibility of placing the external lines anywhere on the patient's upper torso for comfort to the patient. An elastic band around the central body cavity serves as a protective shelf to keep external lines from hanging freely and thus pulling on the port site. An outer layer serves to protect the inner layer, absorbing stresses caused by outer garment movement and providing an additional layer of protection for the port site and external lines.



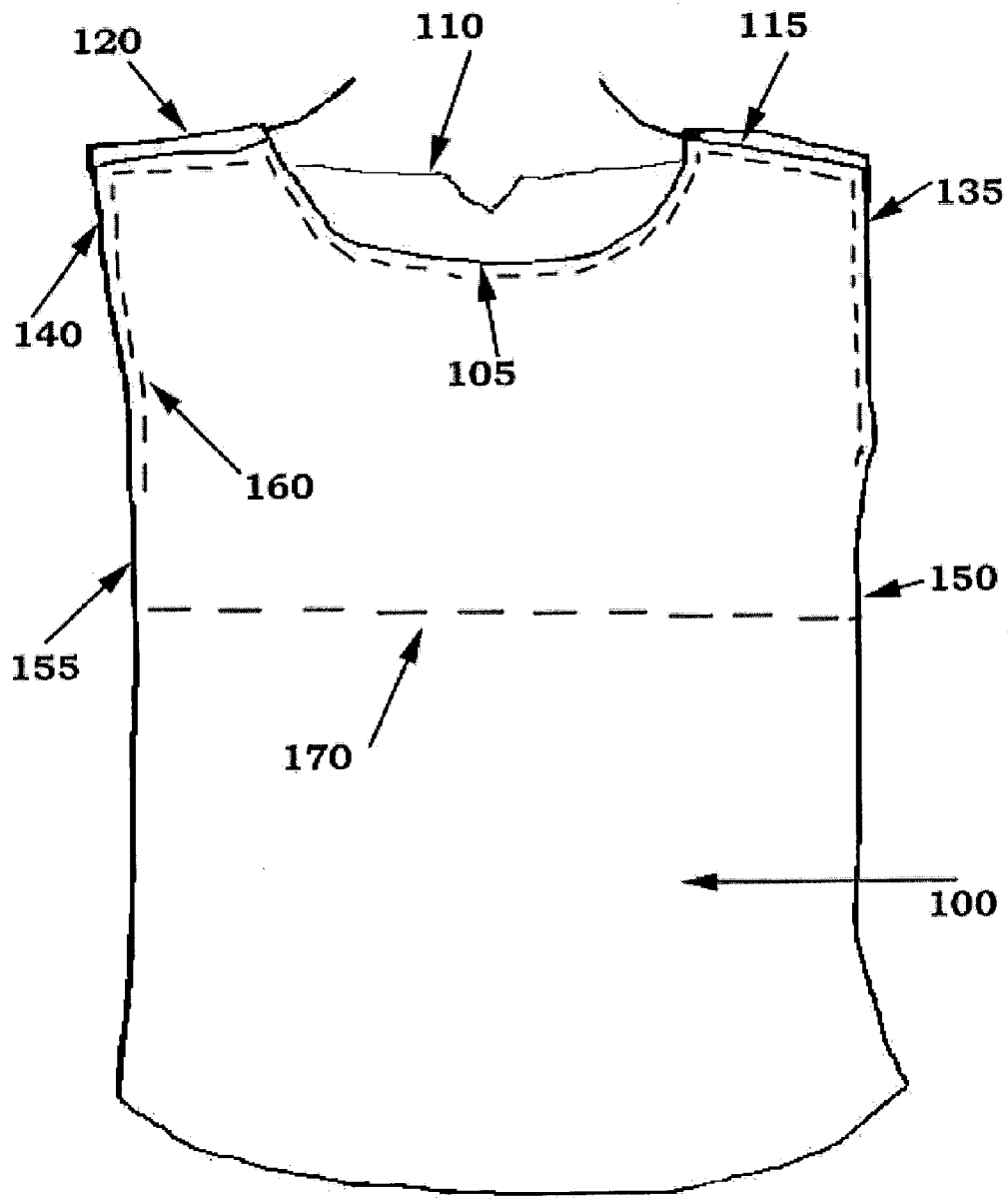


Figure 1

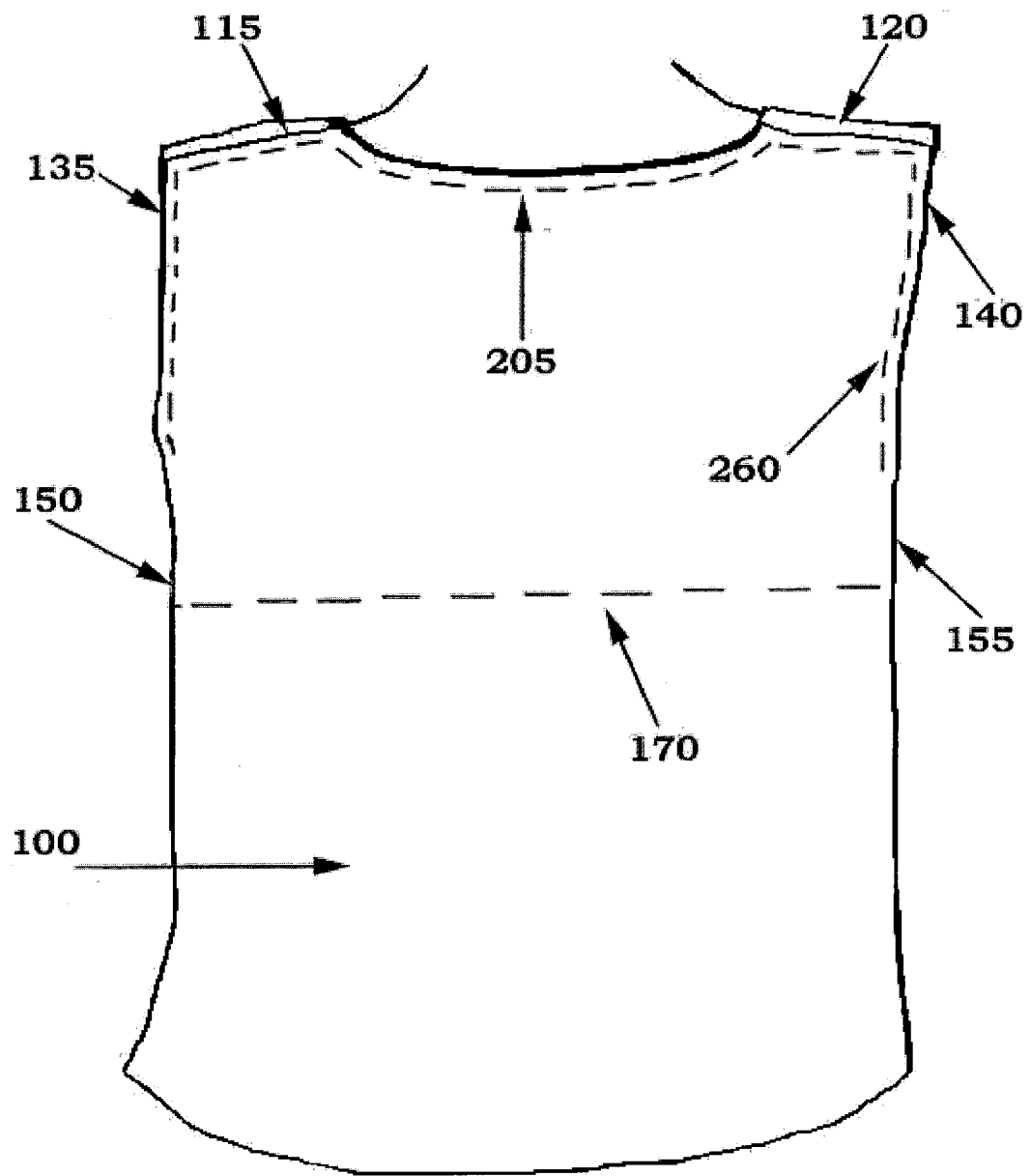


Figure 2

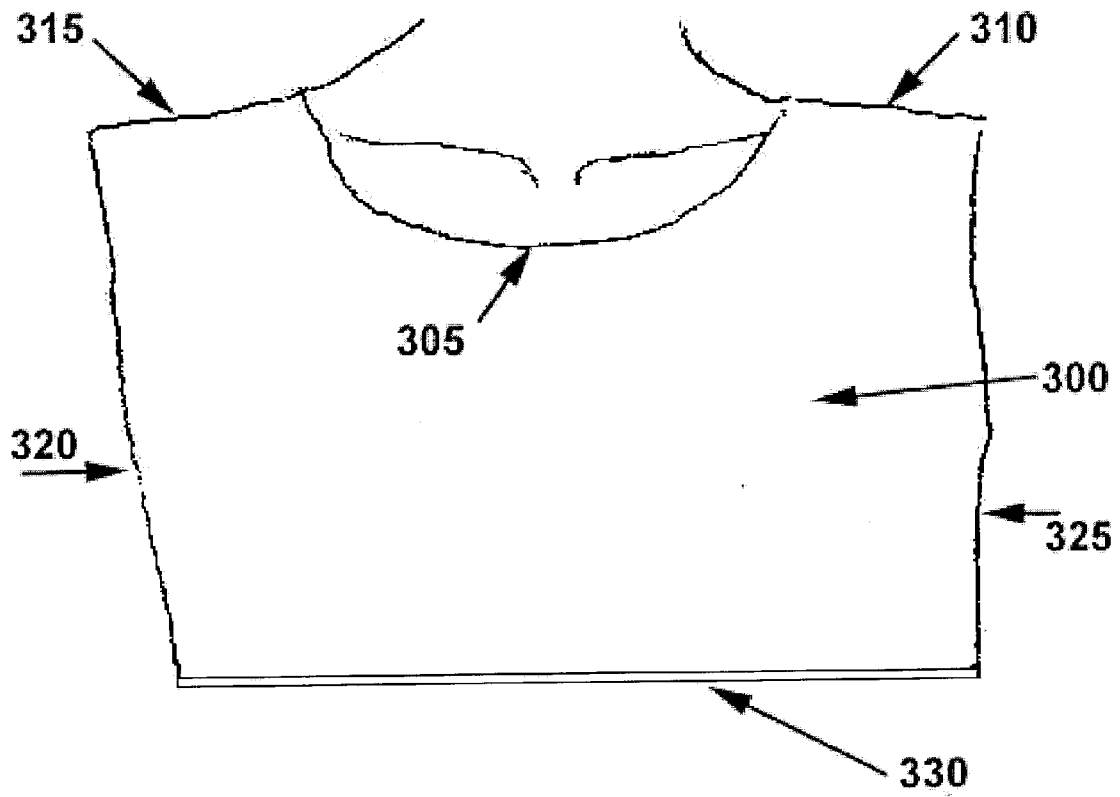


Figure 3

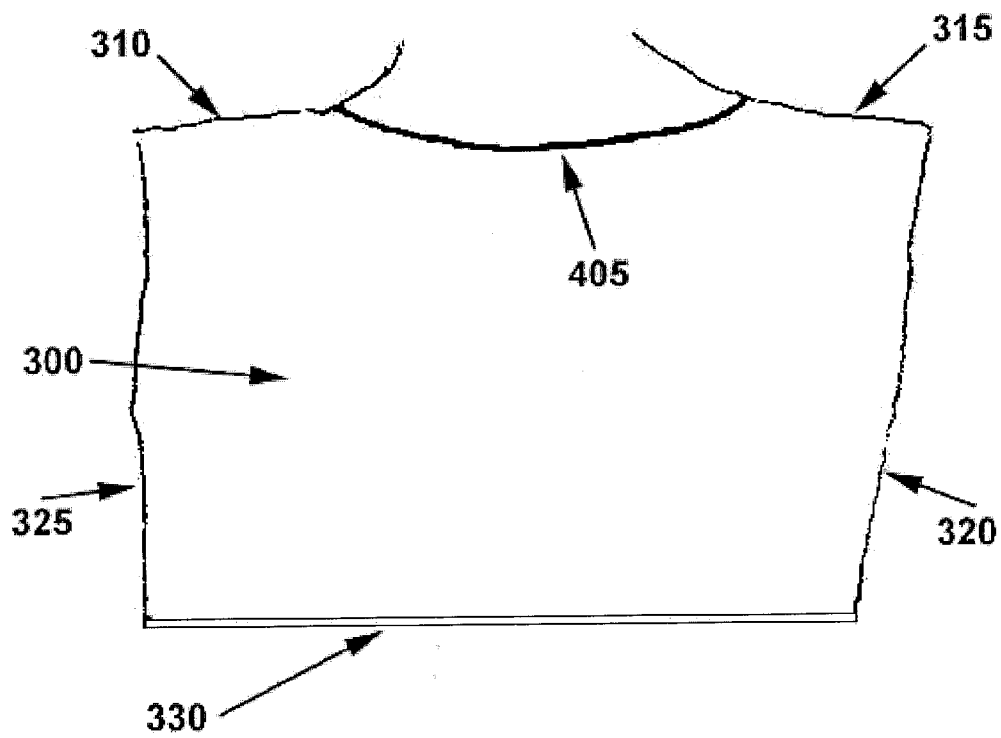
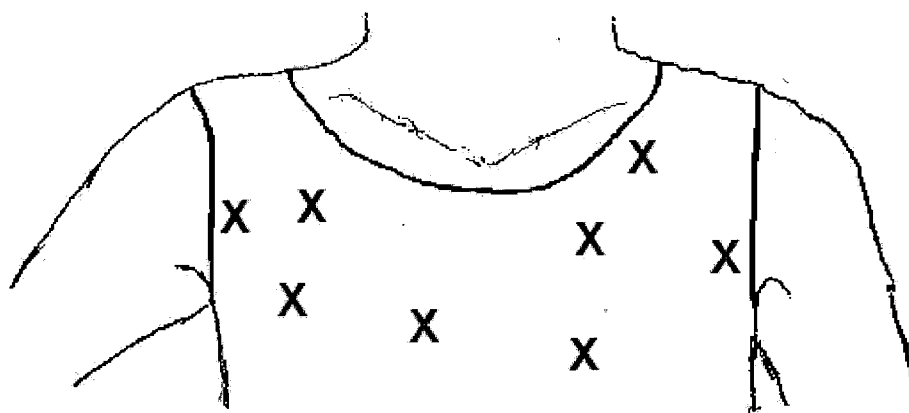


Figure 4



X = port site options

Figure 5

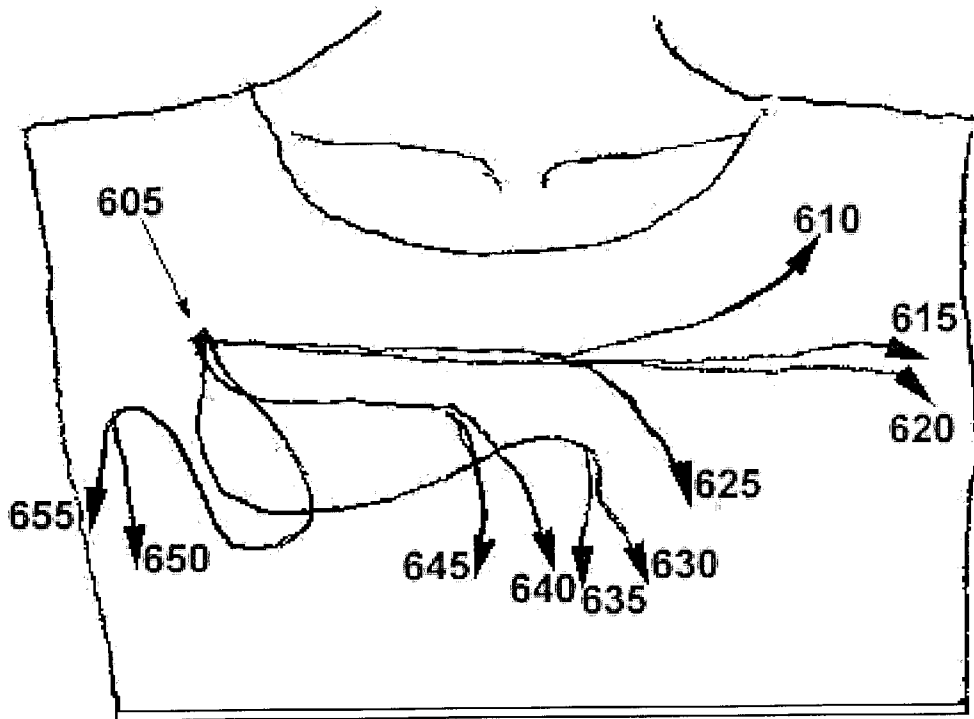


Figure 6

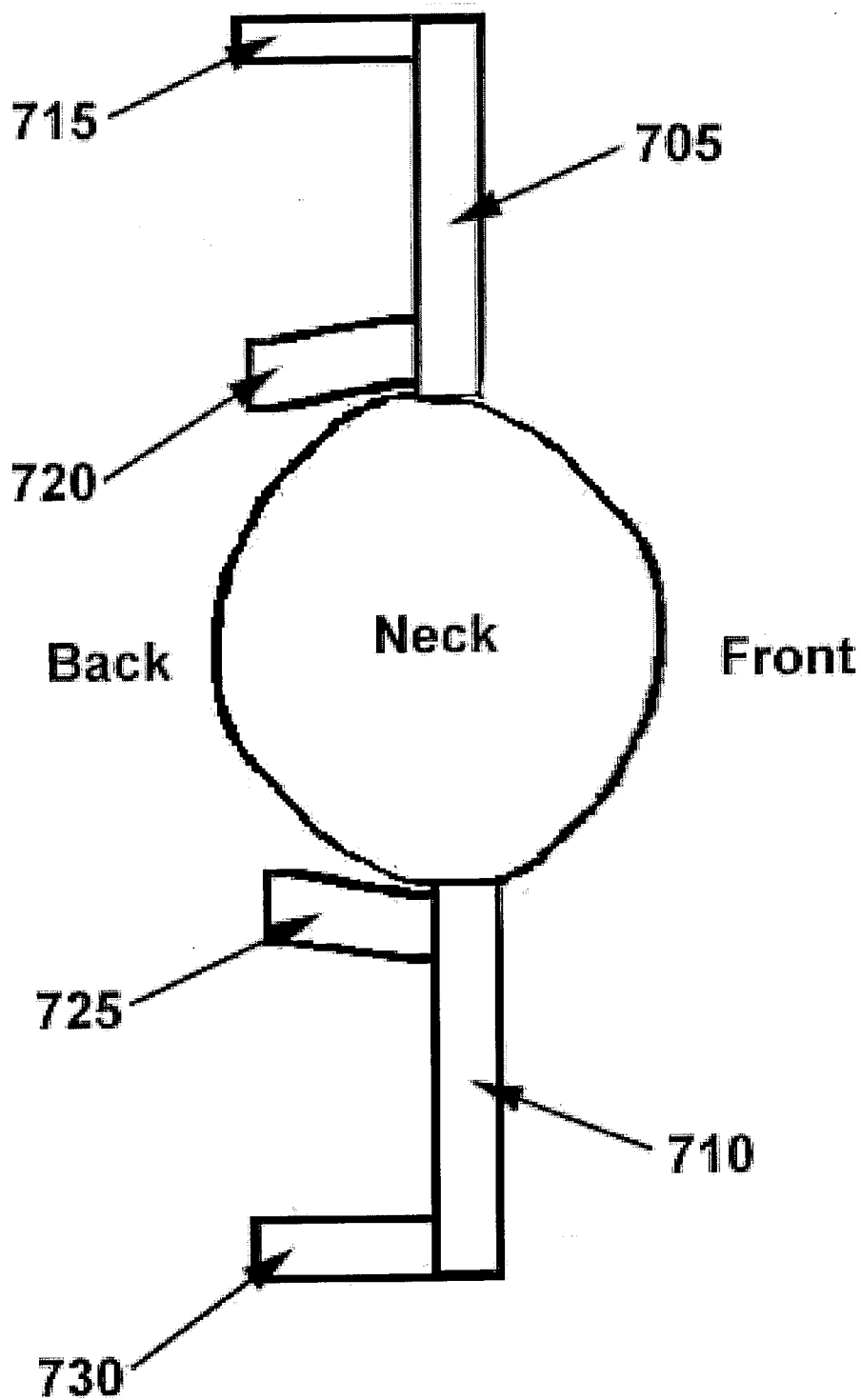


Figure 7

CENTRAL LINE ACCESS AND SUPPORT GARMENT

FIELD OF INVENTION

[0001] The invention relates to the field of medicine. More particularly, this invention relates to garments for providing access and support to central line catheters for safety, maintenance, comfort, and decreased exposure of an implantation site.

BACKGROUND

[0002] A central line catheter is a surgically implanted line having one end threaded into a vein. The other end, which remains outside the body, provides access for administering medication, performing blood transfusions and intravenous infusions and taking blood for tests. Catheters may remain in place for a varied length of time and possibly permanently. A small cuff around the central line is typically located under the skin just above the exit or port site. Scar tissue under the skin eventually grows around the cuff to hold the line in place. Until this happens a stitch may hold the line in place. A bandage may also be used as a temporary or daily dressing to protect the port site from infection, damage to the site, and premature or accidental removal of the catheter. A port (i.e., access port) at the end of the external portion of the catheter line enables access for injections and desired procedures. A catheter may contain a plurality of lines (lumens) where multiple fluids will be infused. In such case, an access port is provided at the end of each lumen.

[0003] It is important to secure the port or line site in patients with central lines. These sites require daily maintenance for the proper functioning of the catheter. Doctors have generally used gauze pads, various forms of adhesives, plastic shields, and garments, such as jog bras, to secure the catheter to the patient. Without such security, the patient runs the risk of infection, snagging of the line and causing damage and/or accidental or unintentional removal of the line prematurely, and increased scarring due to the movement of the catheter. It is especially important during the first few weeks after the implantation of the catheter that it be held securely to the body of the patient to allow for the scar tissue to form on the catheter cuff which ensures long term security and use of the catheter device.

[0004] Although during the day many women can use bras and men can use necklaces with clamps to hold the catheter in place, comfort and safety during sleeping has continually posed problems. Necklaces tend to shift with the patient during the night, and wearing a bra at night is not comfortable. Neither of these options offers any security to the port site or external catheter lines when in a reclined mode, such as sleeping, thus posing a threat to damaging the site, premature or accidental removal of the catheter, and discomfort from rolling over onto the ends (i.e., access ports) of the external lines.

[0005] Patients have been encouraged to purchase sports bras and other women's accessories as a method for keeping the catheter line secure and the site protected. The negatives of these alternatives are many. For example, a large male will not find even the largest sports bra comfortable. A female, with a sports bra fitted to her size, can also find these very uncomfortable as they cross over the neck area in a

sensitive place where the internal catheter is close to the skin. Sports bras are extremely tight against the body as a whole. The sports bra design, although very secure, often crosses over the clavicular area of the patient, the site where most central lines cross into the neck. This not only causes discomfort around the mid-section of the patient, but also in the neck area which is often affected by the central line placement. A sports bra is also very difficult to take on and off. This would even be more difficult for a patient with limited range of upper body motion or upper body weakness.

[0006] T-shirts, a few sizes too small, are also used to keep the line tight against the body of the patient and the dressing on the implantation site secure. However, as with sports bras, getting these garments on and off can be difficult for patients with a limited range of upper body motion. Such garments also do not facilitate access to the implant area or the lines themselves. Furthermore, standard t-shirts lack a containment and support means for keeping the external catheter lines above the midsection. Thus, increased tension can be placed on the port site due to the lack of support for the weight of the external lines.

[0007] Shoulder straps, spaghetti straps, or thinner shoulder pieces have the disadvantage of either not covering the port site or irritating the port site by either rubbing it or getting under the bandage designed to protect the site. If the port site is located centrally on the patient's chest, these types of garments might not even cover the port site thus serving no purpose other than holding the external catheter lines against the body and/or above the midsection.

[0008] Other garments addressing this issue have been designed to assist in the external care of the catheter lines. For example, *Intravenous Catheter Holder*, Schneider, U.S. Pat. No. 4,578,062 (Mar. 25, 1986), describes a pouch to contain the catheter and access through the shoulders for maintaining the site. Another example, *Garment for Concealing Patient Medical Appliances*, Ojoyeyi, U.S. Pat. No. 6,477,710 B1 (Nov. 12, 2002) describes several pockets to hold catheter lines, however, it does not offer the easy shoulder access as the garment described in U.S. Pat. No. 4,578,062 (Mar. 25, 1986). The pouch and pocket both offer an area to store the line versus having it hang free or attached to clothing or a necklace by a clip. However, there is no option as to the placement of the pouch or pocket and, thus, this can be uncomfortable to some patients. The clips can be cold and hard, the necklaces can hang around the sensitive areas of the neck. The pouches and pockets do not offer any options in the placement of the lines against the body, therefore causing discomfort when hard clamps and access ports are pressed against the body.

[0009] Thus, an improved garment is needed to secure the line and implantation site, provide comfort to the patient, accessibility to medical staff, and ease in cleaning the port site.

SUMMARY

[0010] A garment in accordance with an exemplary embodiment of the present invention includes an inner layer of fabric relatively tightly fitted to the body to secure the dressing to a port site. The garment includes an inner shelf lining of elastic to allow the patient flexibility in locating the end(s) of the catheter in the garment, but keeping the end(s) from falling low enough to pull at the implantation site. In

a preferred embodiment, an outer layer is attached to the inner layer, such as at the shoulders, arms and neck, to provide comfort and to reduce stress on the inner layer, lines and port site from movement of outer garments. Also in a preferred embodiment, releasable closures are provided at the shoulders to enable access for easy cleaning, treatment procedures, and putting on and taking off the garment. The neck is preferably high enough to protect any port site a doctor may choose when inserting a catheter into the patient, but low enough not to press on the clavicular area. The inner garment and elastic band are preferably tight enough to secure the port site, dressing, and lines, but also provide the patient with options of locating the end(s) of the catheter line where it is most comfortable for that patient.

[0011] It is, therefore, an object of the present invention to provide a garment that will secure central catheter lines or other similar devices, including the external portion of lines and port sites.

[0012] It is another object of the present invention to provide a garment that facilitates access by medical staff and care givers for cleaning and treating, and placing on and removing the garment, especially for patients with limited range of upper body motion.

[0013] It is also another object of the present invention to provide a garment that allows a patient to choose where a catheter line is held against the body.

[0014] It is yet another object of the present invention to provide a garment that accommodates a range of port sites, thereby enhancing doctors' flexibility in site selection.

[0015] It is another object of the present invention to provide a garment that is comfortable to a patient in a reclined position, such as sleeping, and enables the patient to change positions while reclined without damaging the catheter, prematurely or accidentally removing it, or incurring discomfort. For example, patients can comfortably sleep in any position.

[0016] It is a further object of the present invention to provide a garment that protects catheter lines and a port site while providing security of the line and comfort to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The foregoing and other objects, features and advantages of the present invention will become better understood with reference to the following description, appended claims, and accompanying drawings where:

[0018] **FIG. 1** conceptually depicts the front of an outer layer of a garment in accordance with an exemplary embodiment of the present invention. The outer layer is designed as a sleeveless t-shirt with releasable closures at the shoulders. The closures are preferably adjustable to allow for a customized fit of the patient. The length is preferably long enough to tuck into pants, skirts, pajama bottoms, shorts, or any other lower body garment.

[0019] **FIG. 2** conceptually depicts the back of an outer layer of the garment in accordance with an exemplary embodiment of the present invention. The outer layer design is the same as in **FIG. 1**.

[0020] **FIG. 3** conceptually illustrates the front of an inner layer of a garment in accordance with an exemplary embodi-

ment of the present invention. The inner layer is preferably secured to the outer layer at the neck, shoulder and arm seams. The shoulder seams are preferably adjustable for a customized fit. The material is a relatively tight, stretchable fabric, tighter in fit than the outer layer, providing security to the port site. An elastic body band is attached to the inner layer and sits low enough on the patient for comfort yet high enough to inhibit the catheter lines from falling downward and pulling on the port site.

[0021] **FIG. 4** conceptually illustrates the back of an inner layer of the garment in accordance with an exemplary embodiment of the present invention.

[0022] **FIG. 5** conceptually illustrates the front of a garment in accordance with an exemplary embodiment of the present invention along with a variety of possible placements (each denoted with an X), but not limited to these shown, for a catheter port, demonstrating versatility of the garment. The garment is low enough not to interfere with clavicular areas, yet high enough to provide security to a wide variety of port sites.

[0023] **FIG. 6** conceptually illustrates the front of a garment in accordance with an exemplary embodiment of the present invention along with various positions of a catheter line (each position being represented by a curved line ending with an arrow) to provide comfort to a patient. A garment in accordance with the present invention permits a patient to place the lines under an arm, between breasts, or along the chest area, or to separate them to avoid rubbing, pressure points, and discomfort.

[0024] **FIG. 7** conceptually illustrates releasable closures for the shoulder regions of an outer layer of a garment in accordance with an exemplary embodiment of the present invention.

DETAILED DESCRIPTION

[0025] Referring now to **FIG. 1**, a front view of an outer layer **100** of a central line access and support garment in accordance with an exemplary embodiment of the present invention is shown. The outer layer **100** comprised of material such as cotton, a stretchable synthetic fiber material (e.g., Lycra® by E. I. du Pont de Nemours and Company), jersey knit, or other fabric, provides an undershirt garment for appearance. It also protects an inner layer (discussed below) by reducing or eliminating frictional motion from movement of outer clothing worn by a patient. The outer layer **100** preferably has a neck line **105** just below the patient's clavicular region **110** to avoid contact with a catheter line which may cross into the neck region. The shoulders **115** and **120** of the outer layer **100** are preferably broad enough to provide security without being uncomfortably tight.

[0026] The outer layer **100** is preferably comprised of a front panel and a back panel, discussed below, as in a conventional manner for shirts. The front panel and back panel may be joined by stitching along sides **150** and **155** in a conventional manner.

[0027] Left and right shoulder portions or sections (**115** and **120**, respectively), each having front panel and back panel portions (or sections), are provided. The shoulder portions **115** and **120** of the front panel are preferably releasably joined to the shoulder portions of the back panel

using releasable closure means, such as hook and loop fasteners (e.g., Velcro® hook and loop fasteners by Velcro Industries B.V.); though other releasable closure means (e.g., buttons, snaps and zippers) may be used without departing from the scope of the present invention. The releasable closure means may allow adjustment of the shoulder portions to accommodate a range of patient physiques and preferences. By way of example and not limitation, the shoulder portions **115** and **120** of the front panel of the outer layer may have loop portions of a hook and loop closure **705** and **710**, as shown in **FIG. 7**, horizontally across the width of the shoulder seams **115** and **120**. The back panel may have cooperating hook portions of hook and loop closures **715**, **720**, **725**, **730** vertically along the sides of the shoulder strap to allow for customized adjustment.

[0028] In use, a patient may open the releasable closures **715-730** at the shoulder sections to facilitate removing and placing on the garment. Additionally, a patient may open the releasable closures for one or both shoulders to facilitate access to the catheter line and/or port site.

[0029] The outer garment preferably provides arm holes **135** and **140** large enough to comfortably accommodate a patient's arms, but small enough to provide security for the catheter. Adjustment of the releasable closure means **715-730**, preferably adjusts the sizes of the arm holes, allowing the garment to accommodate various physiques and preferences.

[0030] The outer layer **100** is joined to the inner layer **300** shown in **FIG. 3**, along the arm holes **135** and **140**, the shoulders **115** and **120**, and the neckline **105** as indicated by the dotted line **160**. The inner layer **300** is shorter in length than the outer layer **100** as indicated by the dotted line **170**.

[0031] In **FIG. 2**, a rear view of the outer layer **100** of the central line access and support garment in accordance with an exemplary embodiment of the present invention is shown. The outer layer **100** remains the same as described in **FIG. 1**. The neckline **205** is closer to the base of the neck of the patient to provide enhanced fit, comfort, and security. Arm holes **135** and **140** remain the same as described in **FIG. 1**. The shoulder closures **115** and **120** remain the same as described in **FIG. 1**, and the inner layer **300** is joined to the outer layer **100** as indicated by the dotted line **260**. The front panel and the back panel may be joined by stitching along sides **150** and **155** in a conventional manner. The inner layer **300** is shorter in length than the outer layer **100** as indicated by the dotted line **170**.

[0032] The inner layer **300** of a garment, as shown in **FIGS. 3 and 4**, in accordance with an exemplary embodiment of the present invention is of a similar shirt design as the outer layer. However, the inner layer is preferably smaller in width below the arm holes to allow for a relatively tight fit against the body and shorter in length, so as to be concealed by the outer layer. The material of the inner layer is preferably a stretchable fabric (e.g., Lycra® by E. I. Du Pont de Nemours and Company), a tight jersey knit, a polyester stretch, a cotton, a blend of the above fabrics, or other suitable fabrics. The material should be chosen with patient comfort in mind, especially for patients with sensitive skin. The inner layer may otherwise follow the same general shirt pattern as the outer layer.

[0033] In a preferred embodiment the inner layer **300** is attached to the inside of the outer layer **100**. For example, the neckline **305** of the inner layer may be stitched to the

neckline **105** of the outer layer. Shoulder seams for a front panel of the inner layer **310** and **315** may be attached to shoulder seams for a front panel of the outer layer **115** and **120**. Likewise, shoulder seams for a rear panel of the inner layer may be attached to shoulder seams for a rear panel of the outer layer. Preferably, upon opening releasable closure means **715-730** provided at the shoulders of the outer layer, the shoulders of the outer layer and the shoulders of the inner layer may be opened. Thus, in an exemplary embodiment, the releasable closure means for the outer layer operate as releasable shoulder closure means for the inner layer.

[0034] The sides **320** and **325** of the inner layer **300** are joined from the arm holes to the bottom hem **330** in a conventional manner, but independently from the outer layer **100** and sides **150** and **155**.

[0035] A bottom hem **330** for the inner layer **300** is preferably comprised of an elastic band. For example, a ¾-1" inch width band may be used, though narrower or wider elastic can also be used. Lingerie or cotton elastic is preferred for comfort. The elastic is preferably smaller than the chest dimension for the size of the garment. For example; a woman's large may measure thirty inches at the chest and twenty-seven inches at the bottom hem. Preferably, the elastic band provides a comfortable but secure fit to prevent the free ends of the catheter lines from falling below the hem under normal conditions, while protecting the catheter port site and lines.

[0036] **FIG. 4** demonstrates the rear panel of the inner layer **300**. As described in **FIG. 3**, the rear panel of the inner layer **300** remains the same with the exception that neckline **405** has been raised to the same level as the outer layer neckline **205** and is stitched in the same manner as **105** and **305** of the front panels.

[0037] Referring now to **FIG. 5**, various potential port sites are conceptually illustrated, although not limited to, each by an X. A garment in accordance with an exemplary embodiment of the present invention conceals, and therefore secures, port sites within the boundaries of the garment. Thus, the garment accommodates a wide range of port sites. It does not have openings or pockets that require certain specific port site locations.

[0038] Referring now to **FIG. 6**, various locations and positioning of the external line portion of a catheter are conceptually illustrated, each by a curved line with an arrow. The external portion of each line starts at a port site **605** and ends with an access port (denoted by an arrow). Though lines with a plurality of lumens or single lumen may be used, double lumen lines are conceptually shown in **FIG. 6** to illustrate a range of placements for a given port site. For clarification, lumens **610** and **625** stem from the same catheter line, as do **615** and **620**, **630** and **635**, **640** and **645**, and **650** and **655**. Clips, which are commonly used with lines/lumens, are also not shown in **FIG. 6**. Of course, the port site shown in **FIG. 6** is but one example of a port site. Other port sites within the boundaries of the garment may be used without adversely reducing the efficacy of the garment.

[0039] A garment in accordance with an exemplary embodiment of the present invention conceals and secures lines in a wide range of positions, as demonstrated but not limited to, **610-655** within the boundaries of the garment. Thus, the garment allows positioning of a line to maximize comfort. By way of example, a patient wishing to sleep on his or her side or stomach may position the line (and particularly the access ports and any clips, both of which can

be hard), in a location that enhances comfort. Advantageously, the garment does not depend upon immovable openings or pockets for locating the line.

[0040] Although an inner layer could be utilized alone without departing from the scope of the present invention, use with an outer layer is preferred. Advantageously, the outer layer helps insulate the inner layer from stresses and strains attributed to movement of a patient's outer clothing. Without an outer layer, movement of outer clothing could possibly cause the inner layer to move against the patient's body and thus cause complications with the port site and catheter lines. The outer layer is designed to reduce that risk allowing the inner layer to do what it is designed to do—protect and secure the port site and line.

[0041] As used herein, the terms “relatively tight” and “relatively tight fit” and like phrases refer to a fit that is not loose. A loose fit is one that provides substantial excess space between the garment and the person for whom the garment size is intended. Any fit that does not provide substantial excess space between the garment being worn and an intended wearer may qualify as a relatively tight fit. Those skilled in the art will appreciate that a garment in accordance with the present invention when worn by a person for whom the garment size is not intended (e.g., an extra large garment worn by a petite person or child) will not fit the wearer properly. Nevertheless, such a garment is still considered to provide a relatively tight fit if it provides a relatively tight fit when worn by a person for whom the garment size is intended.

[0042] In a preferred embodiment, for example, the inner layer provides a relatively tight fit that is sufficiently tight to secure a catheter line in a desired position, between the patient and the inner layer, without causing appreciable discomfort. Inner layers that provide a looser or tighter fit, nevertheless a fit that qualifies as relatively tight, also come within the scope of the present invention.

[0043] The foregoing detailed description of particular preferred embodiments of the present invention, which should be read in conjunction with the accompanying drawings, is not intended to limit the enumerated claims, but to serve as particular examples of the invention. Those skilled in the art should appreciate that they can readily use the concepts and specific embodiments disclosed as bases for modifying or designing other garments carrying out the same purposes of the present invention.

[0044] By way of example, and not limitation, garments without an outer layer but with an inner layer having releasable shoulder closure means; garments with an inner layer and/or an outer layer formed of more panels or fewer panels than a front and back panel; garments comprised of inner layers without shoulder sections; and garments with various additional pockets, pouches, and accessories; come within the scope of the present invention. Also by way of example and not limitation, garments comprised of other materials than those identified above, e.g., breathable, lightweight and sheer materials, as well as synthetic materials or blended materials whether now known or later developed are intended to come within the scope of the present invention. Those skilled in the art should also realize that such equivalent garments do not depart from the spirit in scope of the invention as claimed.

1. A garment for protecting a catheter line and port site, said garment comprising an inner layer providing a relatively tight fit and being configured to secure the catheter line at any point between the inner layer and a wearer's body, said inner layer having a bottom and an elastic band at or adjacent to the bottom, said elastic band providing a relatively tight fit.

2. A garment according to claim 1, said inner layer further comprising a left shoulder section, a right shoulder section and means for releasable closure of the left and right shoulder sections.

3. A garment according to claim 2, said garment further comprising an outer layer having an exterior side and an interior side, said inner layer being attached to the interior side of the outer layer.

4. A garment according to claim 3, said inner layer being comprised of at least one material from the group consisting of cotton, stretchable synthetic material, jersey knit and polyester.

5. A garment according to claim 3, said outer layer being comprised of at least one material from the group consisting of cotton, stretchable synthetic material, jersey knit and polyester.

6. A garment for protecting a catheter line and port site, said garment comprising:

an inner layer providing a relatively tight fit, said inner layer having a left open shoulder section, a right open shoulder section, a bottom and an elastic band at or near the bottom, said elastic band providing a relatively tight fit, said inner layer being configured to secure the catheter line at any point between the inner layer and a wearer's body; and

an outer layer having an interior side, an exterior side, a left shoulder section, a right shoulder section and releasable closure means for releasably closing the left and right shoulder sections;

said inner layer being attached to the interior side of the outer layer.

7. A garment according to claim 6, wherein the left shoulder sections of the inner layer are attached to the left shoulder sections of the outer layer, such that releasably closing the left shoulder sections of the outer layer releasably closes the left shoulder sections of the inner layer.

8. A garment according to claim 6, wherein the right shoulder sections of the inner layer are attached to the right shoulder sections of the outer layer, such that releasably closing the right shoulder sections of the outer layer releasably closes the right shoulder sections of the inner layer.

9. A method for protecting a central catheter implanted in a patient, said method comprising steps of:

placing a garment on the patient, said garment comprising an inner layer providing a relatively tight fit and being configured to secure the catheter line at any point between the inner layer and a wearer's body, said inner layer having a bottom and an elastic band at or adjacent to the bottom, said elastic band providing a relatively tight fit, and

positioning between the inner layer of the garment and the patient's body a portion of the central catheter that is outside the patient's body.