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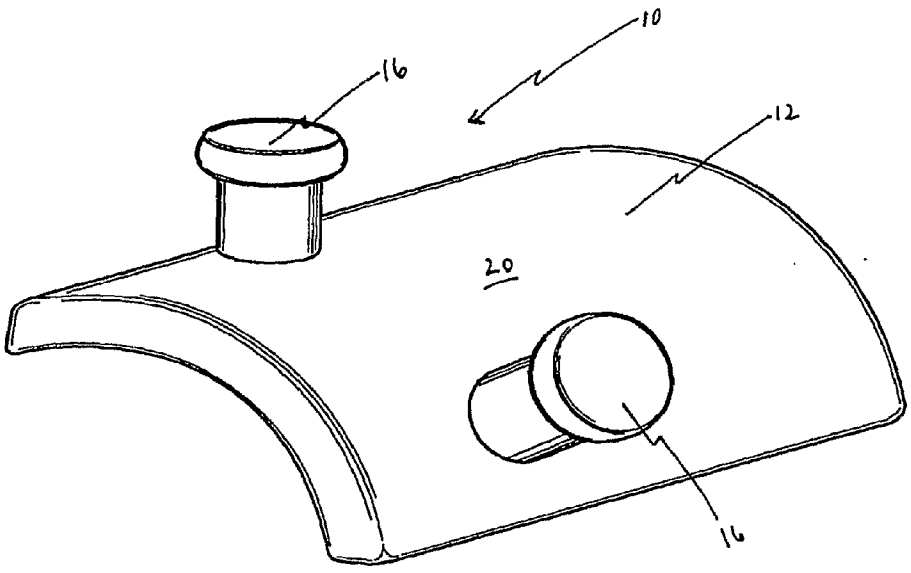
(54) **Title:** DEVICES AND METHODS TO PREVENT BLEEDING FROM NEEDLE PUNCTURE SITES OF ARTERIOVENOUS GRAFTS



(57) **Abstract:** The present disclosure is generally directed to a compressive device for occluding an arteriovenous graft needle puncture site. The compressive device includes a body and a compression ridge. The body has a first side, a second side, and a semi-curved shape such that it conforms to the contour of an arteriovenous graft. The compression ridge is positioned on the second side of the body and has a skin contacting surface able to externally compress and temporarily occlude an arteriovenous graft needle puncture site, the needle puncture site being visible from the first side of the body of the compressive device.

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DEVICES AND METHODS TO PREVENT BLEEDING FROM NEEDLE PUNCTURE SITES OF ARTERIOVENOUS GRAFTS

CROSS REFERENCE TO RELATED APPLICATION

The present application is based on and claims priority to United States Provisional Application Serial No. 60/751,004 having a filing date of December 16, 2005.

BACKGROUND

End-stage renal disease (ESRD) is characterized by a complete or near complete failure of the kidneys to function to excrete wastes, concentrate urine, and regulate electrolytes. In such cases, kidney function is so low that complications are multiple and severe, and death will occur from accumulation of fluids and waste products in the body.

A common life-sustaining treatment for patients with ESRD is hemodialysis. Hemodialysis is a process whereby large amounts of blood are rapidly removed from the body and filtered through a machine that removes wastes and extra fluid. The cleaned blood is then returned back into the body.

An important step before starting regular hemodialysis is preparing a vascular access, which is a site on the body where blood will be removed and returned during dialysis. A commonly performed operation that provides vascular access for patients receiving hemodialysis is arteriovenous (AV) graft placement. The procedure involves the surgical implantation of a tube made of material such as polytetrafluoroethylene (PTFE) into the arm or the leg. One end of the tube is attached to an artery and the other end is attached to a vein. Blood flows through the tube continuously after implantation.

However, to connect the patient to a dialysis machine, a nurse or some other medical technician must insert a large gauge needle through the skin into the graft from which blood is aspirated and passed through the dialysis machine and

cleansed blood is returned to the patient via a separate large gauge needle in the graft. Upon completion of dialysis, the needles are removed from the graft and pressure is held over the needle puncture site until hemostasis occurs. Bleeding from such needle puncture sites can be significant because large gauge needles are used to puncture the graft. In addition, dialysis patients often receive anticoagulants to prevent blood from clotting in the dialysis machine. Consequently, the residual effects of systemic anticoagulation are often present at the time the dialysis needles are removed.

A number of methods are used to occlude needle puncture sites until hemostasis is achieved. The easiest and most common is application of digital pressure by a patient or nurse/medical technician over the puncture site. However, it is difficult to reliably apply pressure for the 10-30 minutes necessary for hemostasis to occur. Typically, the nurse or medical technician must care for several patients at once and are unable to apply pressure over the needle puncture sites of each patient. Compressive devices that are currently available can cause compression of the graft leading to blockage of AV graft blood flow and potential graft thrombosis. Consequently, many dialysis units have abandoned the use of all compressive devices.

Thus, a need exists for a compressive device that applies direct pressure over a needle puncture site of an AV graft until hemostasis occurs but that will not compress the AV graft such that blood flow is impeded and graft thrombosis occurs. A need further exists for a compressive device which does not require a nurse or medical technician to administer.

SUMMARY

Objects and advantages of the invention will be set forth in part in the following description, or may be obvious from the description, or may be learned through the practice of the invention.

The present disclosure is generally directed to a compressive device for occluding an arteriovenous graft needle puncture site. The compressive device includes a body and a compression ridge. The body has a first side, a second side, and a semi-curved shape such that it conforms to the contour of an arteriovenous graft. The compression ridge is positioned on the second side of the body and has a skin contacting surface able to externally compress and

temporarily occlude an arteriovenous graft needle puncture site, the needle puncture site being visible from the first side of the body of the compressive device.

In certain embodiments, the compression ridge may be integrally connected to the body. In certain embodiments, the body and the compression ridge may have antibacterial properties. In certain embodiments, the body and the compression ridge may be plastic. In certain embodiments, the device may further include a second body, the second body having a first side and a second side, the second side having a skin contacting surface, the second body having a semi-curved shape such that it conforms to the contour of an arteriovenous graft. In certain embodiments, the first side of the body may be attached to the first side of the second body. In certain embodiments, the first side of the body may be removably attached to the first side of the second body. In certain embodiments, the device may include a strap. In certain embodiments, the device may include a needle housing.

In another exemplary embodiment, a compressive device for occluding an arteriovenous graft needle puncture site is provided. The compressive device includes a body, a compression ridge, and a second body. The body has a first side, a second side, and a semi-curved shape such that it conforms to the contour of an arteriovenous graft. The compression ridge is positioned on the second side of the body and has a skin contacting surface able to externally compress and temporarily occlude an arteriovenous graft needle puncture site, the needle puncture site being visible from the first side of the body of the compressive device. The second body has a first side and a second side with the second side having a skin contacting surface. The second body has a semi-curved shape such that it conforms to the contour of an arteriovenous graft.

In another exemplary embodiment, method for occluding an arteriovenous graft needle puncture site is disclosed. The method includes providing a compressive device having a body and a compression ridge and positioning the compression ridge over an arteriovenous graft needle puncture site such that the compression ridge temporarily occludes the puncture site with focal pressure while the body of the compressive device uniformly spreads pressure along the arteriovenous graft.

Other features and aspects of the present disclosure are discussed in greater detail below.

DESCRIPTION OF THE DRAWINGS

A full and enabling disclosure, including the best mode thereof to one of ordinary skill in the art, is set forth more particularly in the remainder of the specification, including reference to the accompanying figures in which:

FIGS. 1 – 2 depict a compressive device that applies direct pressure over a needle puncture site in accordance with certain embodiments of the present disclosure;

FIGS. 3A – 4A illustrate successive steps of positioning and operating a compressive device to prevent bleeding from a needle puncture site in accordance with certain embodiments of the present disclosure;

FIG. 4B is a cross-sectional view taken along line 4B—4B of FIG. 4A.

FIGS. 5A – 5C depict a compressive device that applies direct pressure over a needle puncture site in accordance with certain embodiments of the present disclosure;

FIG. 6 illustrates application of a hemostatic agent to the compressive device in accordance with certain embodiments of the present disclosure;

FIGS. 7A – 7C depict a compressive device that applies direct pressure over a needle puncture site in accordance with certain embodiments of the present disclosure;

FIGS. 8 – 9 depict a compressive device that applies direct pressure over a needle puncture site in accordance with certain embodiments of the present disclosure; and

FIG. 10 illustrates a compressive device that applies direct pressure over a needle puncture site in accordance with certain embodiments of the present disclosure.

DETAILED DESCRIPTION

It is to be understood by one of ordinary skill in the art that the present discussion is a description of exemplary embodiments only, and is not intended as limiting the broader aspects of the present disclosure, which broader aspects are embodied in the exemplary construction.

In general, the present disclosure is directed to devices and methods to

prevent bleeding from needle puncture sites of arteriovenous (AV) grafts. In particular, the devices and methods described herein help to occlude needle puncture sites until hemostasis is achieved while avoiding the graft thrombosis that may occur in other compressive devices.

Very generally, an AV graft provides vascular access by way of a synthetic tube implantation. An AV graft can be formed from any suitable biocompatible material. One end of the tube is connected to an artery while the other end is connected to a vein. The AV graft is typically placed either in the leg or arm of a patient.

Blood flows from the artery through the AV graft and into the vein. To connect the patient to a dialysis machine, two large hypodermic needles are inserted through the skin and into the graft. Blood is removed from the patient through one needle, circulated through the dialysis machine, and returned to the patient through the second needle. Typically, patients undergo hemodialysis approximately four hours a day, three days a week.

Hypodermic needles as shown in FIGS. 3A – 3B, for instance, usually have a relatively large diameter or gauge. Thus, when needles are removed from a graft, significant bleeding can occur where the needles have previously been. In addition, dialysis patients often receive anticoagulants to prevent blood from clotting in the dialysis machine. Consequently, the residual effects of systemic anticoagulation are often present at the time the dialysis needles are removed. Nurses and medical technicians must be careful not to compress the AV graft such that blood flow is impeded and graft thrombosis occurs. Graft thrombosis, however, continues to remain a recurring complication associated with the use of AV grafts. The present devices and methods apply focal pressure to the needle puncture site rather than over a broad surface area, thereby decreasing the possibility of such complications.

Referring now to FIGS. 1-2, a compressive device 10 in accordance with one embodiment of the present disclosure is shown. The compressive device 10 comprises a body 12 and a compression ridge 14.

The body 12 has a top surface 20 and a bottom surface 22. The body 12 is generally curved in shape, or at least the bottom surface 22 is curved in shape, to conform to the contour of an AV graft or the surface of the skin. The body 12 may

be formed from any suitable material known in the art such as a type of plastic material, an elastomeric material, or a metal. In one embodiment, the body is formed from a material or the compressive device 10 is otherwise configured so that a needle puncture site can be visualized through the body 12 so as to allow the body to be precisely positioned over the AV graft. As such, the body 12 can be formed from a clear material. In some embodiments in which a non-clear material is utilized, a window may be formed through the body 12 to allow visualization of the needle puncture site. The body 12 is preferably 1 – 3 inches in length and 0.5 – 1.5 inches in width although the overall dimensions may be larger or smaller depending on the specific application of the compressive device 10 so as to conform to the contour of an AV graft.

In some embodiments, the body 12 may be formed from a suitable material or is coated with a material that has antibacterial properties. In some embodiments, an antibacterial composition is applied to the body 12.

The compressive device 10 also comprises a compression ridge 14. The compression ridge 14 is positioned on the bottom surface 22 of the body 12. The compression ridge extends from the bottom surface of the body 12 and has a generally flat surface for contact with a needle puncture site on the skin of a patient. The compression ridge 14 should be of sufficient length and width so as to externally compress and temporarily occlude a needle puncture site of an AV graft. The compression ridge 14 should extend a sufficient distance from the bottom surface 22 so as to focally indent the AV graft at the needle puncture site. As pressure is applied to the compressive device 10, the segment of AV graft underlying the body 12 will have pressure uniformly applied, except underneath the compression ridge 14. The compression ridge 14 may focally indent the AV graft at the needle puncture site; however, the extent of the indention caused by the compression ridge 14 will be limited by the body 12 of the compressive device 10.

The compression ridge 14 may be formed from the same material as the body 12 of the compressive device 10. However, the compression ridge 14 may be formed from any suitable material known in the art such as a plastic so long as the precise location of the needle puncture device can be visualized through the compression ridge 14 and, in turn, the body 12. In some embodiments, the

compression ridge 14 may be formed from a suitable material that has antibacterial properties. An antibacterial composition may be applied to the compression ridge 14 in certain embodiments. In some embodiments, an adhesive composition may be applied to the compression ridge 14 to assist in occluding the needle puncture site.

In certain embodiments, the compression ridge 14 is integrally connected to the body 12 such that it extends from the bottom surface 22 of the body 12. In some embodiments, the compression ridge 14 is affixed to the body 12 by adhesive or other methods of affixing as would be known to one of ordinary skill in the art.

The compressive device 10 may also comprise one or more attachment elements 16. The attachment element 16 is positioned on the top surface 20 of the body 12. In one embodiment, the attachment element 16 has a generally cylindrical surface with a top cap so as to resemble a peg. The attachment element 16 is utilized to facilitate positioning of the compressive device 10 with sufficient focal pressure at a needle puncture site. However, it should be understood that the attachment element 16 can be of various shapes and sizes and can be located at any suitable location on the compressive device 10.

Referring now to FIGS. 3A – 3C, the use of the compressive device 10 for preventing bleeding from needle puncture sites of AV grafts will be described in detail. Referring now in particular to FIG. 3A, a depiction of a needle 30 puncturing an AV graft 32 to form a puncture site 34 is illustrated. As shown in FIGS. 3B – 3C, once the needle is withdrawn, an embodiment of the compressive device 10 is positioned externally above the general location of the AV graft 32 such that the compression ridge 14 can externally compress and temporarily occlude the needle puncture site 34 of the AV graft 32. In one embodiment as shown, the needle puncture site 34 can be visualized through the body 12 as well as the compression ridge 14 of the compressive device 10 allowing the compressive ridge 14 to be positioned precisely above the needle puncture site 34. The compressive device 10 is positioned such that the body 12 is placed generally longitudinal above the AV graft 32.

As depicted in FIGS. 4A – 4B, once the compressive device 10 is properly positioned, a technician holds the compressive device 10 in place and can digitally

compress the body 12 such that the compression ridge 14 externally compresses and occludes the needle puncture site 34 of the AV graft 32. Pressure is applied to the compressive device 10 such that the segment of AV graft 32 underlying the body 12 of the compressive device 10 will have pressure uniformly applied, except underneath the compression ridge 14. The compression ridge 14 may focally indent the AV graft 32 at the needle puncture site 34; however, the extent of the indention caused by the compression ridge 14 may be limited by the body 12 of the compressive device 10. As pressure on the compressive device 10 is increased, the AV graft segment will be depressed further into the subcutaneous tissue of the skin but will not be compressed. By applying pressure over a focal area rather than a broad area, less pressure on the device is needed to occlude needle puncture site 34 bleeding. Consequently, less pressure leads to less likelihood of compression of the AV graft 32 or impedance of blood flow through the AV graft 32. Pressure is applied until hemostasis of the needle puncture site 34 occurs.

In some embodiments, the compressive device 10 can be held in place utilizing the attachment element and/or strap as described in further detail below. In such embodiments, sufficient pressure can be applied until hemostasis of the needle puncture site 34 occurs. In other embodiments, other methods of attachment as described herein or as would be known in the art may be utilized to hold the compressive device 10 in place while also applying pressure to the compressive device 10.

Referring to FIG. 5A, the attachment element 16 is depicted anchoring a strap 18. The strap 18 is utilized to hold the compressive device 10 in place while also applying pressure to the compressive device 10. Any suitable material known to one of ordinary skill in the art may be utilized to form the strap 18 including elastic material, fabric material, or the like. As described previously, the strap 18 is anchored to one or more attachment elements 16.

In another embodiment, as depicted in FIG. 5B, a strap 18 can also be utilized without the need for an attachment element 16. For example, the strap 18 can be formed from adhesive tape and can be utilized to hold the compressive device 10 in place while also applying pressure to the compressive device 10.

In yet another embodiment, as depicted in FIG. 5C, the strap 18 may be

formed from a material such as Velcro® and held in place by a buckle shaped attachment element 16. The Velcro® holds the compressive device 10 in place while also applying pressure to the compressive device 10.

In still other embodiments, other attachment devices may be utilized such as a C-clamp or the like. Such other embodiments can hold the compressive device 10 in place while also applying pressure to the compressive device 10.

Referring to FIG. 6, in some embodiments, a hemostatic agent 40 may be applied to the compression ridge 14 of the compressive device 10 to help facilitate thrombosis of the needle puncture site 34. Any suitable hemostatic agent 40 may be utilized as would be known to one of ordinary skill in the art including Gelfoam® or Surgicel®. As described previously, in some embodiments, an adhesive composition may be applied to the compression ridge 14 to help facilitate occlusion of the needle puncture site 34.

In certain embodiments, the compressive device of the present disclosure includes a second body. As stated previously, an AV graft provides vascular access by way of a synthetic tube implantation. One end of the tube is attached to an artery and the other end is attached to a vein. In this regard, the second body can be utilized to prevent compression of the portion of the graft adjacent to the needle puncture site. With reference to FIGS. 7A – 7C, the second body 24 can be similar to body 12 and generally curved in shape, or at least the bottom surface 26 is curved in shape, to conform to the contour of an AV graft or the surface of the skin. As with body 12, the second body 24 can be formed from any suitable material known in the art such as a type of plastic material, an elastomeric material, or a metal. The second body 24 is preferably 1 – 3 inches in length and 0.5 – 1.5 inches in width although the overall dimensions may be larger or smaller depending on the specific application of the compressive device 23 so as to conform to the contour of an AV graft.

Referring to FIG. 7C, in certain embodiments, the body 12 and second body 24 can be attached to a cuff 28. The cuff 28 can be formed of any suitable material and is configured for positioning on the side of the arm opposite from the needle puncture site 34. One or both the body 12 and second body 24 can be attached to the cuff 28 by any suitable method as would be known in the art. For example, as illustrated in FIG. 7C, the body 12 and the second body 24 are each

attached to the cuff 28 by tether 29. The tether 29 can be formed of any suitable material and the tether 29, cuff 28 and second body 24 can all be formed from an antibacterial material or coated with a material that has antibacterial properties.

In application, the body 12 can be positioned over needle puncture site 34, the second body 24 can be positioned adjacent to the body 12 so as to prevent compression of the portion of the graft adjacent to the needle puncture site 34, and the cuff can be positioned on the opposite side from the needle puncture site 34. As described previously, a strap 18 or other suitable method can be utilized to hold the various components of the device in place while also applying pressure. In certain embodiments, an additional body 12 and an additional second body 24 can also be attached to cuff 28 and can be used in connection with additional an needle puncture site.

Referring to FIG. 8, in certain embodiments of the present disclosure, second body 24 can be affixed to body 12. Second body 24 can be affixed to body 12 by any conventional method as would be known in the art including adhesives or the like. In certain embodiments, second body 24 and body 12 are also connected to a strap 18. In certain embodiments, second body 24 can be removably affixed to body 12 so that second body 24 can be removed from body 12. In this regard, referring again to FIG. 8, in application, second body 12 can be removed from body 12 so that body 12 can be positioned over needle puncture site 34, while the second body 24 can be positioned adjacent to the body 12 so as to prevent compression of the portion of the graft adjacent to the needle puncture site 34. Again, a strap 18 or other suitable method can be utilized to hold the various components of the device in place while also applying pressure.

With regards to FIG. 9, second body 24 can also remain affixed to body 12 in application so that body 12 can be positioned over needle puncture site 34 while second body 24 remains unused. In certain embodiments, body 12 and second body 24 can be integrally connected to one another. An additional device can be utilized so that the second body 24 of such an additional device can be positioned adjacent to the body 12 of the first device so as to prevent compression of the portion of the graft adjacent to the needle puncture site 34 while body 12 of the second device remains unused. Again, a strap 18 or other suitable method can be utilized to hold the various components of the device in place while also applying

pressure.

The present disclosure can also be provided a needle such as a standard dialysis needle or the like. Referring to FIG. 10, a needle 30 can be positioned in a housing 36. The housing 36 can be provided to prevent inadvertent needle sticks after a needle 30 is retracted from a patient. As illustrated in FIG. 10, a compression device of the present disclosure can be affixed to housing 36. In certain embodiments, a compression device 10 can be removably affixed to housing 36 by any suitable method as would be known in the art. This can allow the compression device to be detached from the housing and utilized after the needle is removed from the needle puncture site of a patient. The device 10 can then be used with the needle puncture site 34.

These and other modifications and variations to the present disclosure may be practiced by those of ordinary skill in the art, without departing from the spirit and scope of the present disclosure, which is more particularly set forth in the appended claims. In addition, it should be understood that aspects of the various embodiments may be interchanged both in whole or in part. Furthermore, those of ordinary skill in the art will appreciate that the foregoing description is by way of example only and is not intended to limit the disclosure so further described in such appended claims.

What is claimed is:

1. A compressive device for occluding an arteriovenous graft needle puncture site, said compressive device comprising:

a body, said body having a first side and a second side, said body having a semi-curved shape such that it conforms to the contour of an arteriovenous graft; and

a compression ridge, said compression ridge positioned on said second side of said body, said compression ridge having a skin contacting surface able to externally compress and temporarily occlude an arteriovenous graft needle puncture site, said needle puncture site being visible from said first side of said body of said compressive device.

2. A device as in claim 1, wherein said compression ridge is integrally connected to said body.

3. A device as in claim 1, wherein said body and said compression ridge have antibacterial properties.

4. A device as in claim 1, wherein said body and said compression ridge are plastic.

5. A device as in claim 1, further comprising a second body, said second body having a first side and a second side, said second side having a skin contacting surface, said second body having a semi-curved shape such that it conforms to the contour of an arteriovenous graft.

6. A device as in claim 5, wherein said first side of said body is attached to said first side of said second body.

7. A device as in claim 5, wherein said first side of said body is removably attached to said first side of said second body.

8. A device as in claim 5, further comprising a strap.

9. A device as in claim 1, further comprising a needle housing.

10. A compressive device for occluding an arteriovenous graft needle puncture site, said compressive device comprising:

a body, said body having a first side and a second side, said body having a semi-curved shape such that it conforms to the contour of an arteriovenous graft;

a compression ridge, said compression ridge positioned on said second side of said body, said compression ridge having a skin contacting surface able to

externally compress and temporarily occlude an arteriovenous graft needle puncture site, said needle puncture site being visible from said first side of said body of said compressive device; and

a second body, said second body having a first side and a second side, said second side having a skin contacting surface, said second body having a semi-curved shape such that it conforms to the contour of an arteriovenous graft.

11. A device as in claim 10, wherein said first side of said body is attached to said first side of said second body.

12. A device as in claim 10, wherein said first side of said body is removably attached to said first side of said second body.

13. A device as in claim 10, further comprising a strap, said strap positioned between said first side of said body and said first side of said second body.

14. A device as in claim 10, further comprising a needle housing.

15. A method for occluding an arteriovenous graft needle puncture site comprising:

providing a compressive device having a body and a compression ridge;

positioning said compression ridge over an arteriovenous graft needle puncture site such that said compression ridge temporarily occludes said puncture site with focal pressure while said body of said compressive device uniformly spreads pressure along said arteriovenous graft.

16. A method as in claim 15, further comprising:

providing a second body and a strap;

positioning said second body over a portion of said arteriovenous graft and adjacent to said body; and

positioning said strap to hold said body and said second body in place while also applying pressure.

17. A method as in claim 15, wherein said compression ridge is integrally connected to said body.

18. A method as in claim 15, wherein said body and said compression ridge have antibacterial properties.

19. A method as in claim 15, wherein said body and said compression ridge are plastic.

20. A method as in claim 15, wherein said compressive device is connected to

a needle housing.

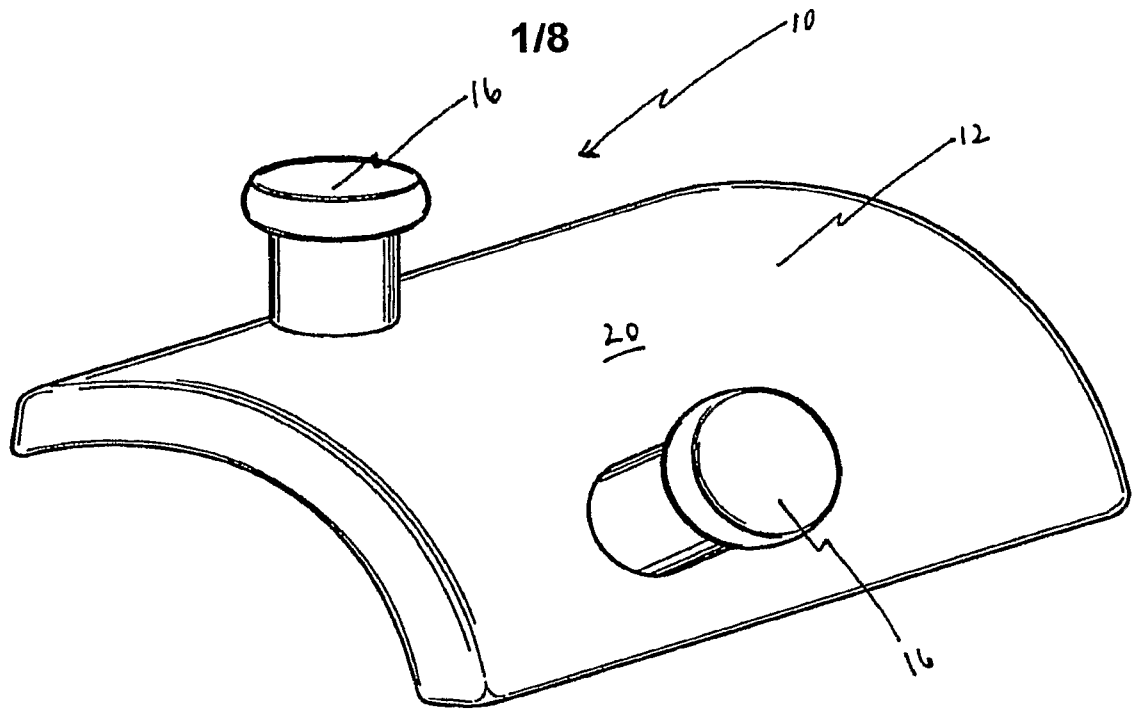

FIG. 1

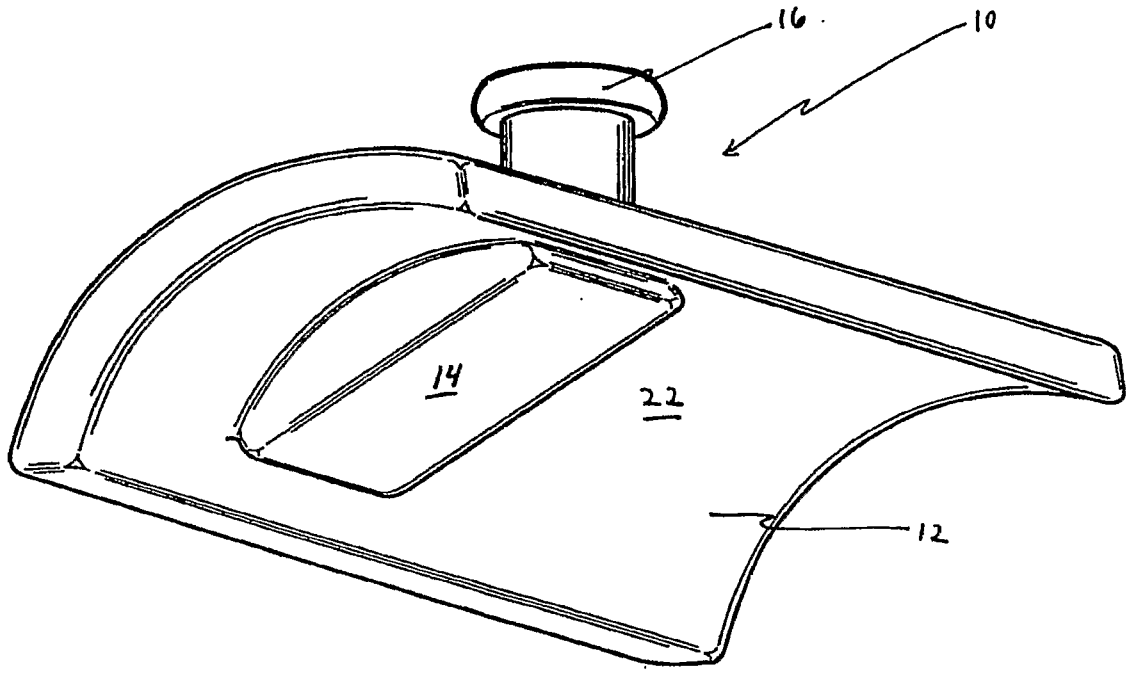

FIG. 2

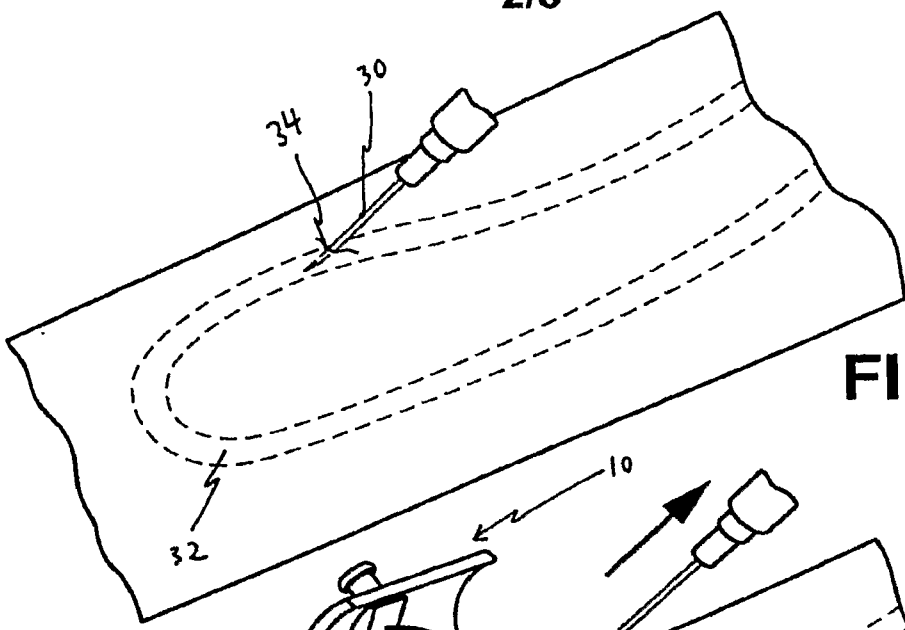

FIG. 3A

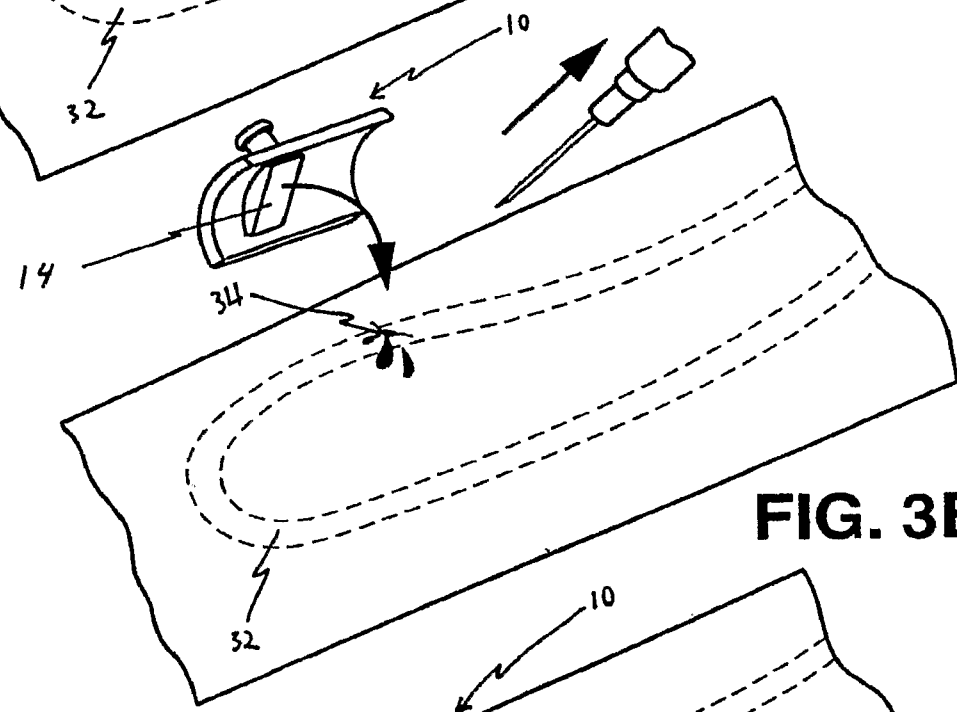

FIG. 3B

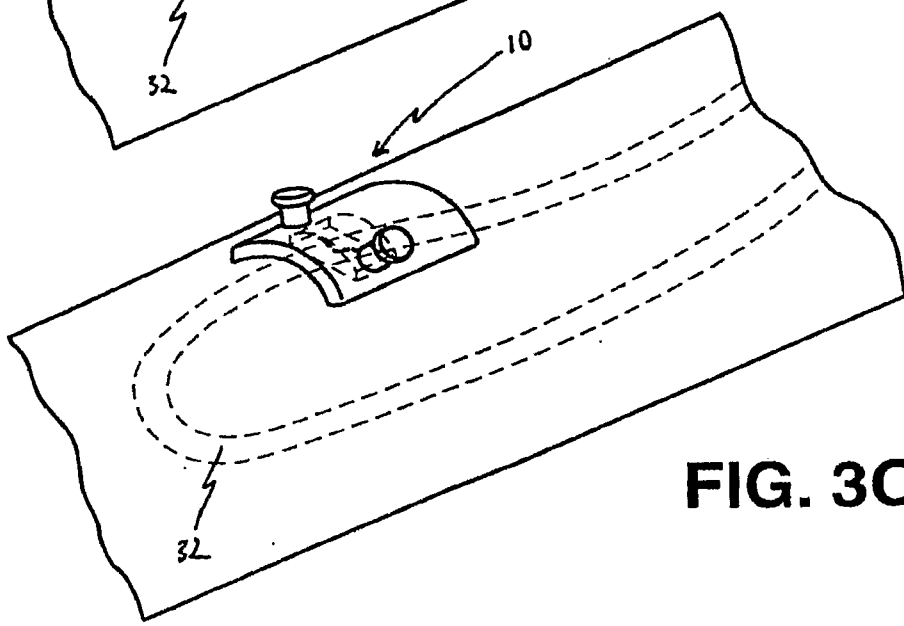

FIG. 3C

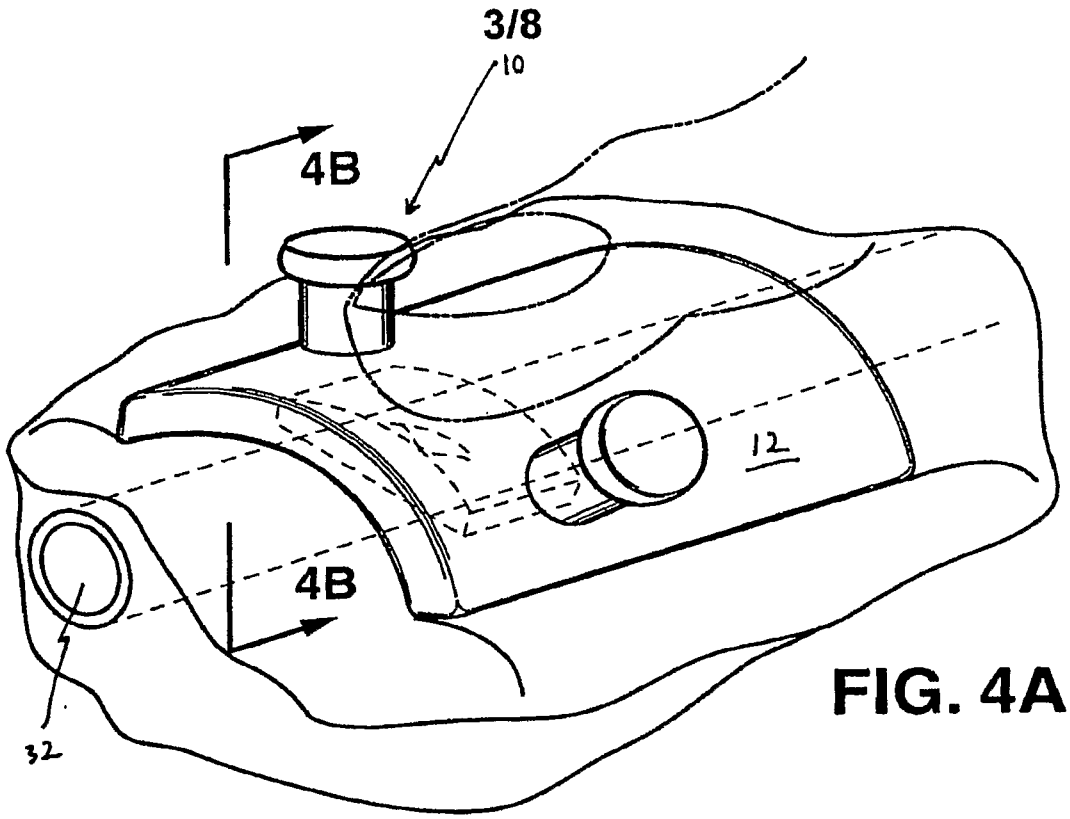

FIG. 4A

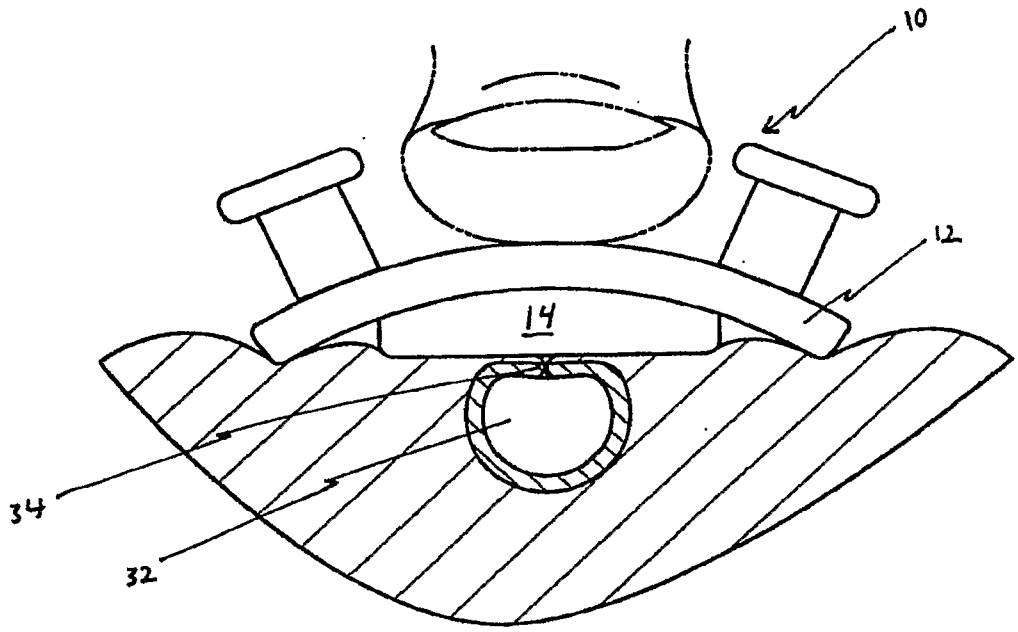

FIG. 4B

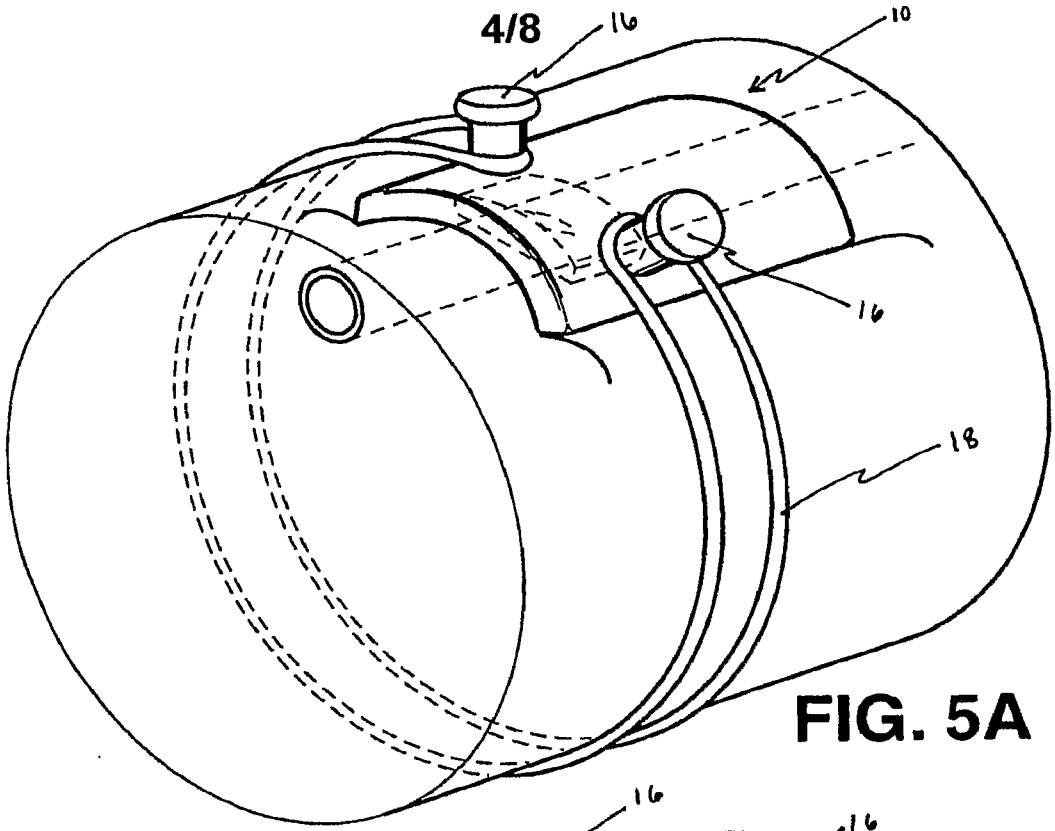

FIG. 5A

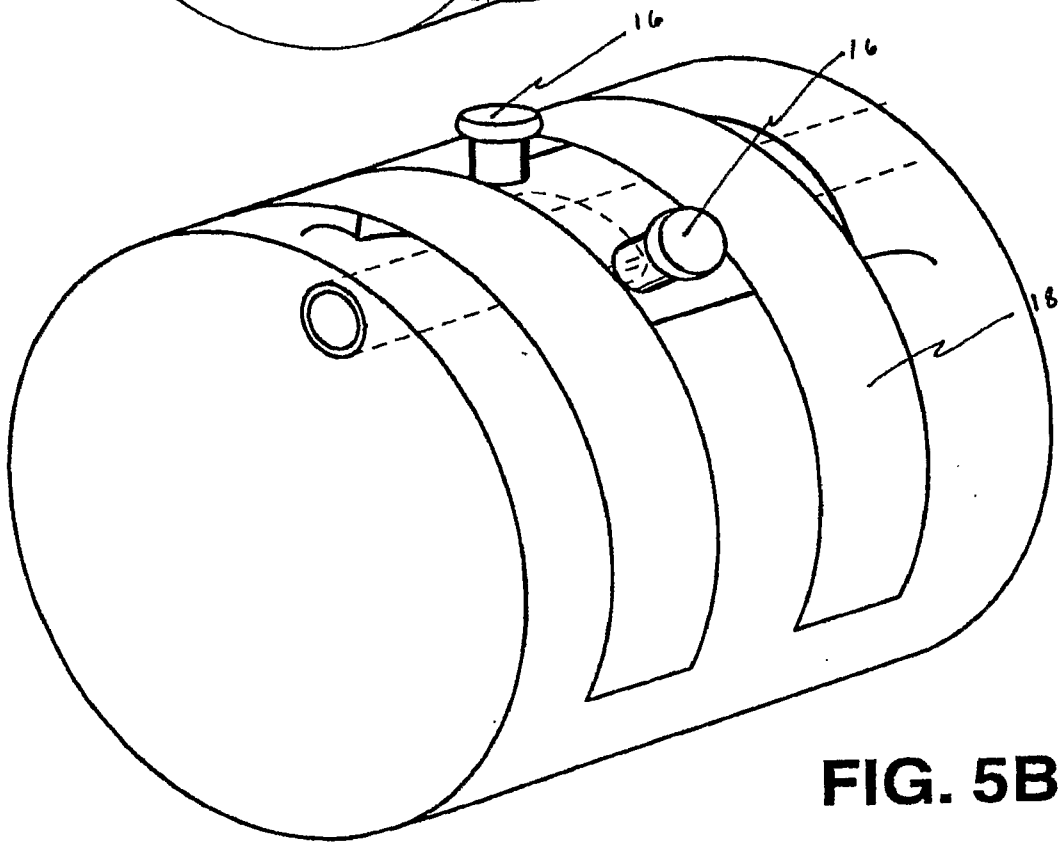

FIG. 5B

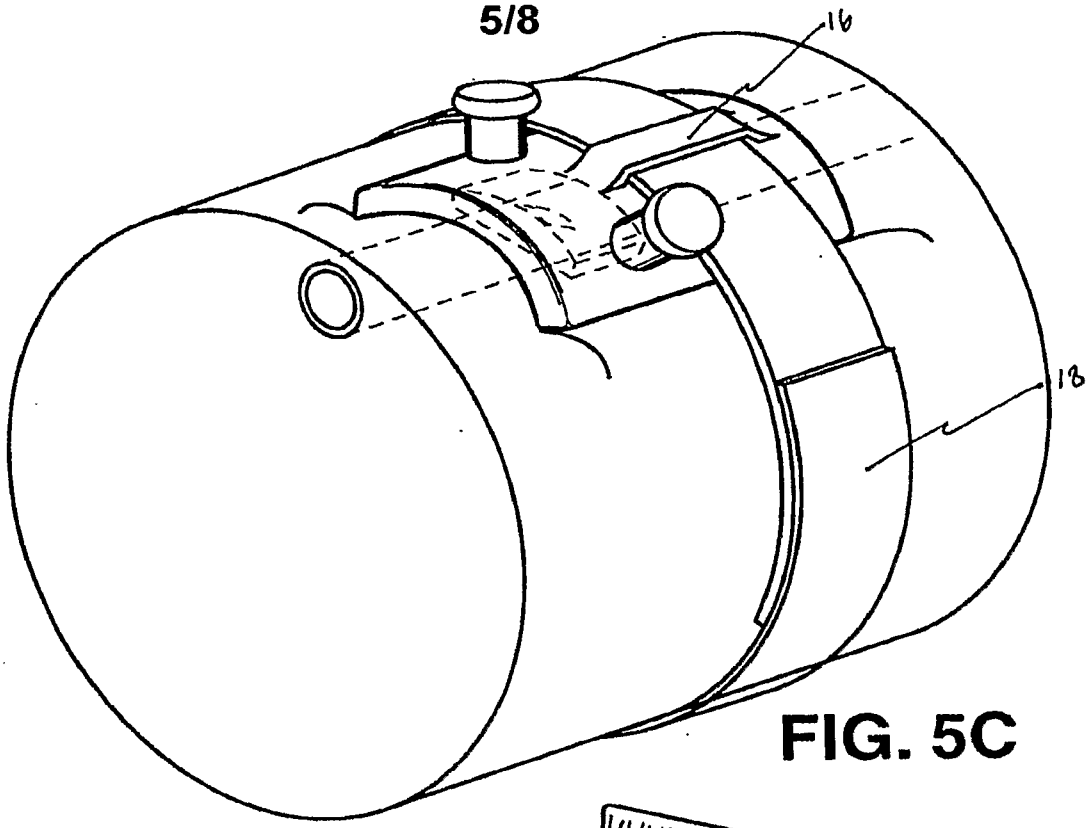

FIG. 5C

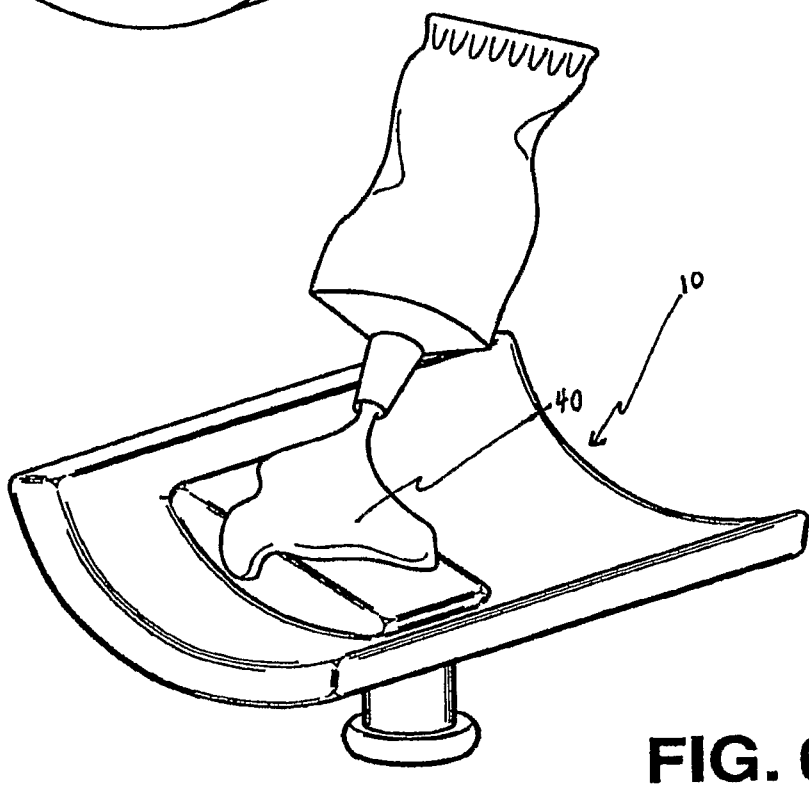

FIG. 6

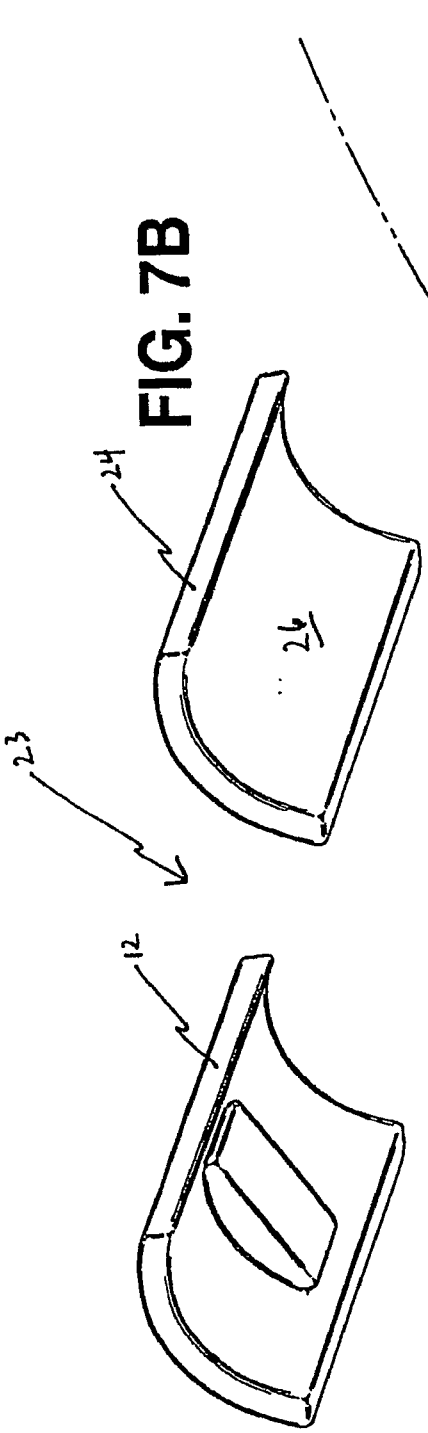

FIG. 7B

FIG. 7A

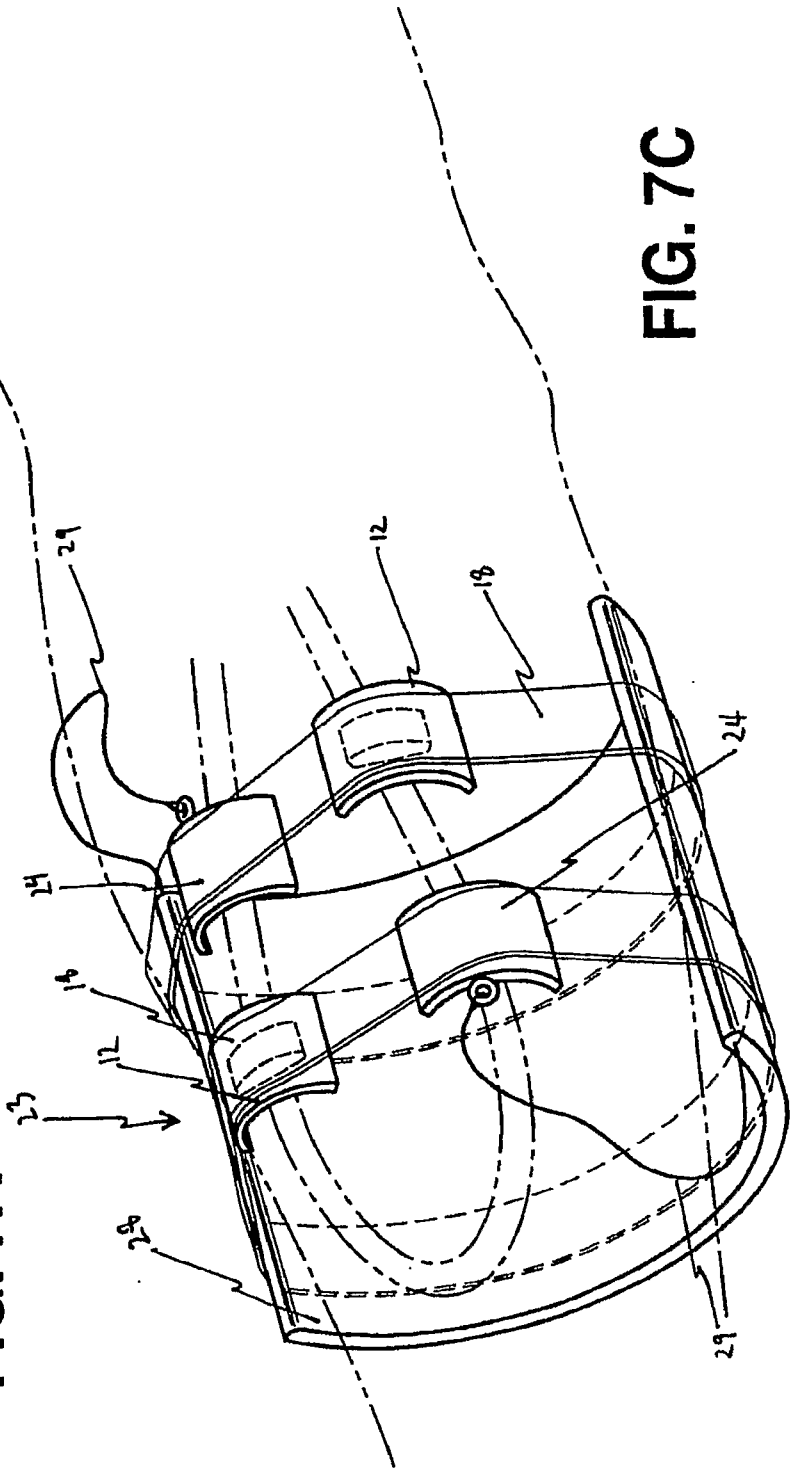

FIG. 7C

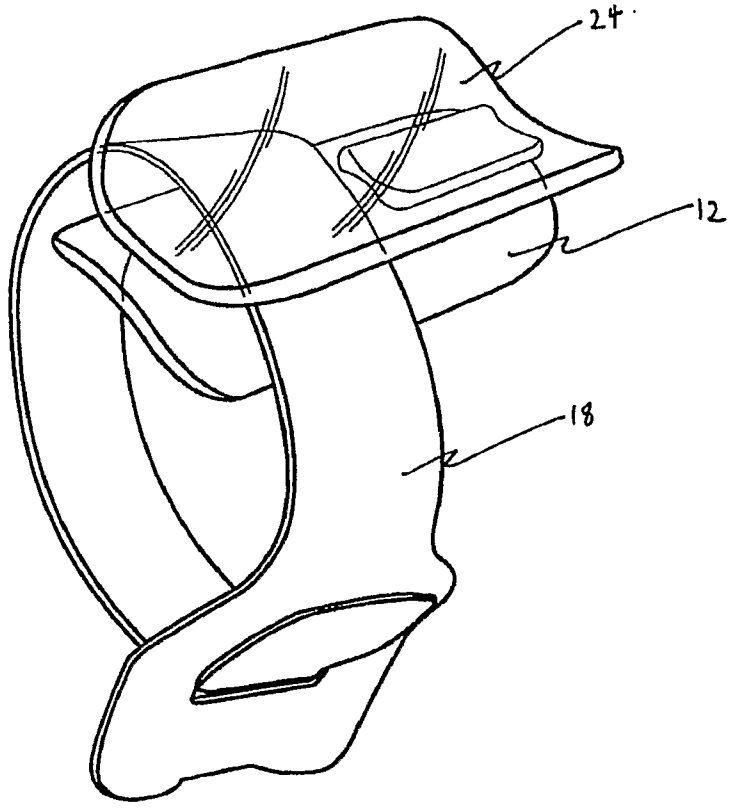

FIG. 8

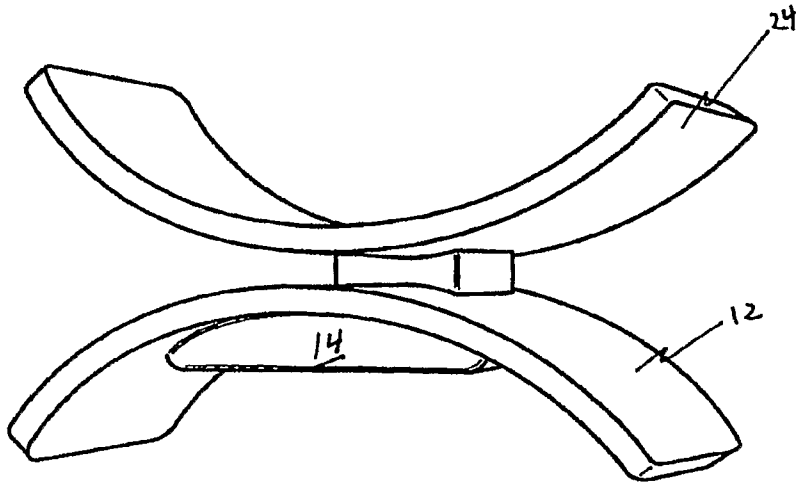

FIG. 9

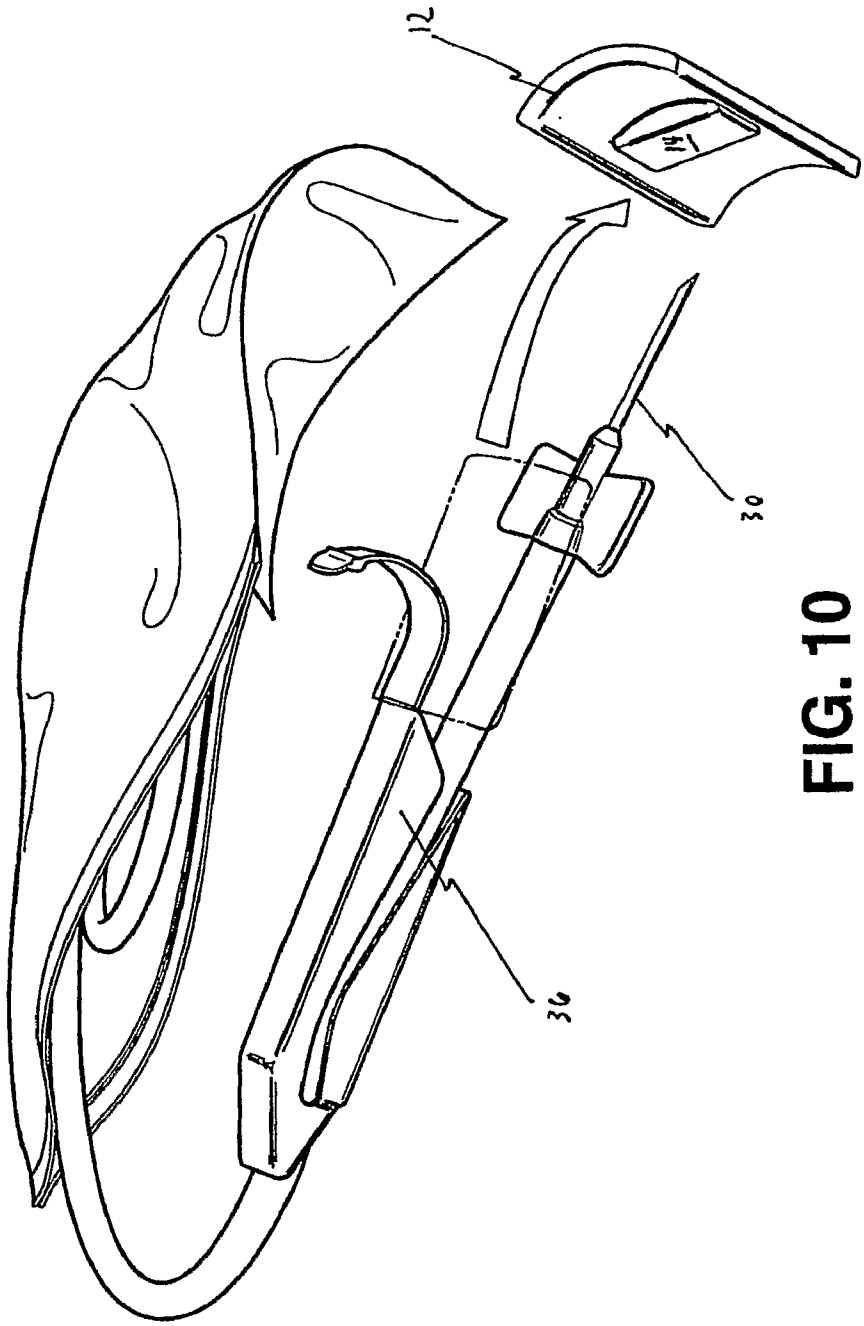

FIG. 10