(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 February 2005 (24.02.2005)

PCT

(10) International Publication Number
WO 2005/016176 A2

(51) International Patent Classification[7]: A61F

(21) International Application Number:
PCT/US2004/024033

(22) International Filing Date: 26 July 2004 (26.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/636,841	7 August 2003 (07.08.2003)	US
10/841,929	7 May 2004 (07.05.2004)	US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:

US	10/636,841 (CIP)
Filed on	7 August 2003 (07.08.2003)
US	10/841,929 (CIP)
Filed on	7 May 2004 (07.05.2004)

(71) Applicant and
(72) Inventor: **LEIBOFF, Arnold, R.** [US/US]; 5 Perigee Drive, Stony Brook, NY 11790 (US).

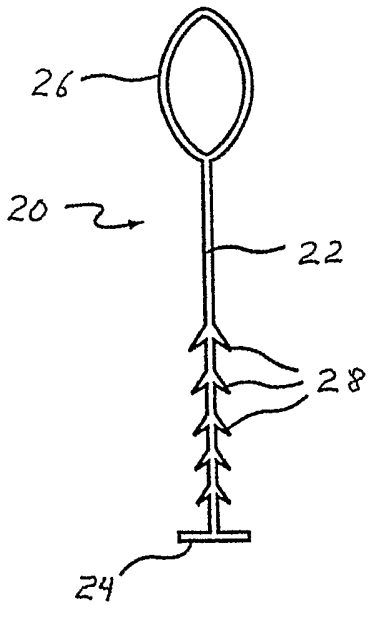
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** DEVICE AND METHOD FOR TACKING A PROSTHETIC SCREEN



(57) **Abstract:** A prosthetic screen tacking device (10, 20, 30, 40) includes a filament (12, 22, 32, 42) with at least one barb (18, 28, 38, 48) and a perpendicular foot (14, 24, 34, 44) at one end and optionally a loop (16) or needle (35, 45) at the other. When the needle (45) is present, a loop (46) can be provided between the barb(s) (48) and the needle (45). The barbs (18, 28, 38, 48) are situated near the foot (14, 24, 34, 44) and angulated in such a manner that they permit movement of the device (10, 20, 30, 40) through a prosthetic screen and body tissue in one direction, but prevent movement in the opposite direction toward the foot (14, 24, 34, 44). Methods of using the device with or without an associated button (111, 112) are also disclosed.

WO 2005/016176 A2

DEVICE AND METHOD FOR TACKING A PROSTHETIC SCREEN

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a device and method that simplifies the attachment of a prosthetic screen (also referred to as a hernia patch or mesh) to the abdominal wall during the repair of abdominal wall hernias.

2. Brief Description of the Prior Art

The layer or layers of fascia in the abdominal wall that surround the peritoneal cavity are the strong structures that maintain the integrity of the peritoneal cavity. If there is a defect in the fascia, abdominal contents may penetrate weaker layers of the abdominal wall (comprised of muscle or fat) and push ahead the abdominal cavity's thin lining (peritoneum) so that abdominal contents, such as omentum or bowel, within their envelope of peritoneum, become situated in a subcutaneous position, often causing a visible bulge.

Viscera being squeezed through a fascial defect can cause pain. When a visceral structure becomes trapped outside a fascial plane, it is said to be incarcerated. Incarcerated viscera can be strangulated by a narrow fascial defect, producing ischemic necrosis. This may lead to infection and death if not surgically repaired. Hernias are therefore usually repaired electively, before they become incarcerated or strangulated.

Historically, hernias of the abdominal wall were repaired by closing the fascial defect with sutures. Large hernias tend to recur if closed in this way. Prosthetic screens, made of plastic mesh or sheets, are now frequently used to cover large fascial defects. One way to implant the prosthetic screen is illustrated in prior art Figure 1. Here, the prosthesis 1 is attached to the fascia 2c of the abdominal wall 2 with sutures 3. This is relatively easy to do, but the repair has a high rate of failure because the sutured prosthesis often pulls away from the fascial edge.

Other ways to secure prosthetic screens are shown in prior art Figures 2-5. In each of these methods the prosthesis 1 overlaps the edge of the fascia 2c. These methods are less likely to fail. Increased intra-abdominal pressure tends to force the periphery of the prosthesis against the abdominal wall rather than pull the prosthesis away from the fascia. A gap where both prosthesis and fascia are absent is less likely to develop.

If the prosthetic screen is allowed to overlap the edges of the fascial defect, there are a number of ways it can be secured in place as illustrated in prior art Figures 2-5. The sutures 3 can secure the fascia 2c to the prosthesis 1 inward from the edge of the prosthesis as shown in prior art Figure 2. This is technically easy when the surgery is done in the conventional "open" approach. However materials such as Gortex™ or polypropylene mesh used for prosthetic screens are soft and may buckle and deform outside the suture line, so that the structural advantage of the overlap with fascia is not realized.

A better method is to secure the prosthesis 1 to the abdominal wall fascia 2c with sutures 3 as close to the edge of the prosthesis as possible, while maintaining generous overlap between prosthesis and intact fascia as shown in prior art Figure 3. However, it can be difficult to secure an overlapping intraperitoneal prosthesis at its periphery when performing surgery using a conventional approach. Access to the inside surface of the abdominal wall overlying the periphery of the prosthesis is limited. The more the overlap, the more difficult the access.

In order to achieve generous overlap the surgeon may bring the sutures through the abdominal wall as shown in prior art Figures 4 and 5. The midpoint of a suture 3 may be tied to the edge of the prosthesis 1, and the two ends brought out directly through the abdominal wall 2 near one another, through a single small separate incision 4 in the skin 2a as shown in prior art Figure 4. Both ends of this transmural suture 3 are then tied together, placing the knot 5 beneath the skin in the subcutaneous tissue 2b as shown in prior art Figure 5. The skin incision 4 is closed separately with skin sutures 6 or staples (not shown). This process is completed around the periphery of the prosthesis.

If surgery is done by a minimally invasive technique (i.e., laparoscopic surgery), the surgeon's view is from within the abdominal cavity looking up at the anterior abdominal wall. The periphery of the prosthesis can be fixed to the abdominal wall by direct suture (using a laparoscopic suture technique), or by using one of several fixation devices, such as staples or helical tacks. Alternatively, sutures can be fixed to the prosthesis before it is introduced into the peritoneal cavity. Once the prosthesis is correctly positioned, both ends of these sutures can be pulled through the abdominal wall and the same small skin incision and the ends tied together, placing the knot subcutaneously. Transmural sutures provide the most secure fixation of prosthetic screens. Hernia recurrence rates are lower when transmural sutures are used. A combination of techniques, using a few transmural sutures,

at equidistant points along the periphery of the prosthesis, with staples or helical tacks in between, is also useful.

Despite the many advances made in laparoscopic suturing techniques as well as in open hernia repair, there are still many problems to be overcome. One problem is that in order to secure the prosthesis to the abdominal wall at a single point with a transmural suture, each suture end must be pulled separately through the abdominal wall. This is time consuming. Another problem is that after placement of both ends of each suture through the abdominal wall, they must be clamped together above the body wall while other transmural sutures are placed, because it is much easier to place transmural sutures before the prosthesis is hoisted up against the abdominal wall. Clamping insures that suture ends do not inadvertently pull out of the abdominal wall during this process. Many clamps clutter the operative field and the sutures and clamps tend to entangle one another. Furthermore, multiple short skin incisions must be made to set the knot of each tied pair subcutaneously. This process is somewhat time-consuming and the multiple skin incisions produce a poor cosmetic result. Moreover, when two strands of suture are tied subcutaneously to secure a prosthetic screen, tissues of the abdominal wall are captured and partially strangulated within the ligature. This often produces postoperative pain and cosmetically undesirable dimpling of the skin at the ligature sites.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a device and method to fix a prosthetic screen to the abdominal wall.

It is another object of the invention to provide a device and method to fix a prosthetic screen to the abdominal wall that is applicable to both the open and laparoscopic methods of hernia repair.

It is still another object of the invention to provide a device and method to fix a prosthetic screen to the abdominal wall which requires penetrating the abdominal wall only once for each point of fixation.

It is yet another object of the invention to provide a device that is more easily grasped by a suture passer than is a single strand of suture.

It is a further object of the invention to provide a device that impedes accidental withdrawal once it is passed through the abdominal wall.

It is also an object of the invention to provide a device and method to fix a prosthetic

screen to the abdominal wall that does not require the tying of sutures.

It is another object of the invention to provide a device and method to fix a prosthetic screen to the abdominal wall that does not require a skin incision to obtain subcutaneous fixation.

It is still another object of the invention to provide a device and method to fix a prosthetic screen to the abdominal wall that does not strangulate tissues of the abdominal wall.

It is another object of the invention to provide a device and method to fix a prosthetic screen to the abdominal wall that is particularly applicable to open surgery.

In accord with these objects, which will be discussed in detail below, the prosthetic screen tacking device according to the invention includes a barbed filament with a perpendicular foot at one end. The foot may be a linear form, so that end of the device forms a T. The barbs are situated near the foot and angulated in such a manner that they permit movement of the device through tissue in one direction (away from the foot), but prevent movement in the opposite direction (toward the foot). Instead of a plurality of barbs, a single barb can be provided.

A second embodiment includes a loop at the end of the filament opposite the foot.

Using the second embodiment of the tacking device and the open method of hernia repair, several tacking devices of the second embodiment are pulled through the prosthetic screen equidistantly along the periphery (circumference) of the prosthesis. The assembly is then positioned within the open abdominal cavity, over the viscera. A suture passer (a needle-like implement with the ability to grasp sutures) is then used to penetrate the abdominal wall at a point opposing the location where one tacking device penetrates the prosthesis, a point substantially beyond the edge of the fascial defect. The suture passer grasps the loop of the tacking device, and draws it back through the abdominal wall, so that the loop lies external to the body. The loop is then disengaged from the suture passer. The tacking device remains in place because the loop impedes accidental withdrawal from the abdominal wall. The same action is repeated until the loops of all devices are passed through the abdominal wall. Each device is then pulled further through the abdominal wall by grabbing the loop and pulling upward. The devices are pulled as far as possible using appropriate force to draw the prosthesis against the abdominal wall. This action draws the barb(s) into the abdominal wall and through at least one fascial layer. Each device is then

pulled by its loop under tension. The skin, where penetrated by the device, is simultaneously pressed downward, further compressing the abdominal wall, and the filament is severed at skin level. Pressure is released, the abdominal wall expands and the severed end of the filament recedes beneath the skin. The barb(s) on the remaining portion of the filament prevent dislodgement of the device, which prevents the prosthesis from pulling away from the abdominal wall. The abdominal wound above the prosthesis is closed as completely as possible by standard technique, and the operation is concluded.

The tacking device of the invention can be similarly utilized in a laparoscopic procedure. Here the devices are loaded onto the periphery of the prosthesis, the assembly is rolled up or folded introduced through a cannula or port site into the peritoneal cavity. Within the peritoneal cavity the assembly is unrolled or unfolded and oriented so that the loops are upward towards the abdominal wall. A suture passer is then used to penetrate the abdominal wall at a point corresponding to the preferred point of fixation of a particular device and the procedure proceeds substantially the same as described above.

Other embodiments of the invention incorporate needles, swaged or attached by other means, to the embodiments described above and are primarily used only during open surgery. One such embodiment, a third embodiment of the tacking device, includes a barbed filament with a perpendicular foot at one end and a needle at the other. The foot may be a linear form, so that end of the device forms a T. The barbs are situated near the foot and angulated in such a manner that they permit movement of the device through tissue in one direction (toward the needle), but prevent movement in the opposite direction (toward the foot).

Using the third embodiment of the tacking device and the open method of hernia repair, the needle of a tacking device is passed through the prosthetic screen at a point along the periphery of the prosthesis. The tacking device is pulled so that the filament and barb(s) pass through the prosthesis and the foot, which cannot penetrate the prosthesis, is adjacent to the prosthesis. The assembly is then positioned near or within the open peritoneal cavity. The needle is then used to penetrate the abdominal wall at a point that will oppose the location where the tacking device penetrates the prosthesis when the prosthesis is finally secured against the abdominal wall. The needle and portion of the filament is drawn up through all layers of the abdominal wall. The needle is then disengaged from the filament and the free end of the filament is clamped. A second tacking device is similarly passed

through the prosthesis at another point along the periphery of the prosthesis so that its foot is adjacent to the prosthesis. The needle and portion of the filament of this tacking device are then passed through the abdominal wall, and the needle disengaged and the filament clamped. More tacking devices are passed through the prosthesis and abdominal wall in a similar manner, so that tacking devices are distributed around the entire periphery of the prosthesis and wound, and are relatively equidistant from one another where they pass through the prosthesis and where they pass through the abdominal wall. Each device is then pulled further through the abdominal wall by grabbing the filament and pulling upward. The devices are pulled as far as possible using appropriate force to draw the prosthesis against the abdominal wall. This action draws the barb(s) into the abdominal wall and through at least one fascial layer. The skin, where penetrated by the device, is simultaneously pressed downward, further compressing the abdominal wall, and the filament is severed at skin level. Pressure is released, the abdominal wall expands and the severed end of the filament recedes beneath the skin. The barb(s) on the remaining portion of the filament prevent dislodgement of the device, which prevents the prosthesis from pulling away from the abdominal wall. The abdominal wound above the prosthesis is closed as completely as possible by standard technique, and the operation is concluded.

A second embodiment of the invention incorporating a needle includes a loop located between the barb(s) and the needle. The loop obviates the need for a clamp to hold the device in place while the other devices are installed. The loop is also useful in pulling the filament up through the abdominal wall to secure the barb(s).

One advantage of the tacking device of the invention over the conventional transmural suture is that it requires one filament rather than two suture ends to be drawn through the abdominal wall to secure the prosthesis at any point on its periphery. Thus, half the work is required.

Another advantage of the embodiments with loops is that the loop of the device provides an excellent handle that can be used to secure the barb(s).

Another advantage is that the loop of the device provides an excellent handle that a suture passer can grasp more easily than a single suture strand.

Another advantage of the embodiments with loops is that once pulled through the abdominal wall the device will not be inadvertently withdrawn, since the loop will prevent withdrawal. Conventional sutures on the other hand can be accidentally withdrawn if not

secured by a surgical clamp.

Another advantage is that no knot is required when using the device.

Another advantage is that no skin incision is required to place a knot subcutaneously.

Another advantage is that, unlike a transmural suture, this tacking device will not strangulate tissue of the abdominal wall and therefore will not produce as much postoperative pain.

Another advantage is that, unlike a transmural suture, this device will not produce cosmetically undesirable dimpling of the skin.

Another advantage of the embodiments with a needle is that a suture passer is not needed since the device includes a needle.

Furthermore, a knot below a skin incision is more likely to become infected than is the single filament of the tacking device of the invention, which retracts into the abdominal wall well below a small skin puncture site. Infectious agents are then less likely to travel down to infect the prosthetic screen. Use of the tacking device of the invention will result in fewer prosthetic screen infections, which are a major cause of morbidity, re-operation and recurrent hernia. Infected prosthetic screens must often be removed to control infection.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1-5 illustrate prior art methods of securing a prosthetic screen;

Figure 6 is a side elevational view of a first embodiment of a prosthetic screen tacking device according to the invention;

Figures 7-10 illustrate how the first embodiment of the novel prosthetic screen tacking device is used in conventional open surgery;

Figures 11 and 12 illustrate how the first embodiment of the prosthetic screen tacking device is used in laparoscopic surgery;

Figure 13 is a side elevational view of a second embodiment of a prosthetic screen tacking device according to the invention;

Figures 14-17 illustrate how the second embodiment of the novel prosthetic screen tacking device is used in conventional open surgery;

Figures 18 and 19 illustrate how the second embodiment of the prosthetic screen tacking device is used in laparoscopic surgery;

Figure 20 is a side elevational view of a third embodiment of a prosthetic screen tacking device according to the invention;

Figures 21 and 22 schematically illustrate how the third embodiment of the prosthetic screen tacking device is used in conventional open surgery;

Figure 23 is a side elevational view of a fourth embodiment of a prosthetic screen tacking device according to the invention;

Figures 24 and 25 schematically illustrate how the fourth embodiment of the prosthetic screen tacking device is used in conventional open surgery;

Figures 26-28 illustrate different embodiments of the foot of the tacking device;

Figures 29-31 illustrate different embodiments of the barbs of the tacking device;

Figure 32 is a broken side elevational view of a filament with a barb according to another embodiment of the invention;

Figure 33 is a view similar to Figure 32 rotated 90 degrees about the axis of the filament; and

Figures 34-38 illustrate embodiments of a button that can be passed over the filament in order to further secure the tacking device and prevent its withdrawal from the abdominal wall.

DETAILED DESCRIPTION

Turning now to Figure 6, a first embodiment of a prosthetic screen tacking device 10 includes a filament 12 with a perpendicular foot 14 at one end and at least one barb 18 adjacent to the foot 14. The foot 14 may be a linear (or planar) form, so that end of the device 10 forms a T or may have other configurations as described in more detail below with reference to Figures 26-28. The barb(s) 18 are angulated in such a manner that they permit movement of the device 10 through a prosthetic screen and body tissue in one direction (toward end 17), but prevent movement in the opposite direction (toward the foot 14).

Figures 7-10 illustrate how the tacking device 10 is used in the open method of hernia repair. Several devices 10 are pulled through the prosthetic screen 1 equidistantly along the periphery (circumference) of the prosthesis 1. The assembly is then positioned within the open peritoneal cavity, over the viscera (Figure 7). A suture passer 7 is then used to penetrate the abdominal wall at a point opposing the location where one device penetrates the prosthesis, a point substantially beyond the edge of the fascial defect. The suture passer

7 grasps the filament 12 towards its free end 17 and draws a portion of the filament 12 back through all layers of the abdominal wall 2, including the peritoneum 2d, fascia 2c, muscle if present (not shown), subcutaneous tissue 2b and skin 2a, so that end 17 of filament 12 lies external to the body. Filament 12 is then disengaged from the suture passer and its free end 17 clamped to prevent withdrawal back through the abdominal wall 2. The same action is repeated until the free ends 17 of filaments 12 of all devices are pulled through the abdominal wall 2.

Each device 10 is then pulled further through the abdominal wall by grabbing filaments 12 near their free ends 17 and pulling upward so that the barb(s) 18 engage the abdominal wall as shown in Figure 8. The devices are pulled as far as possible using appropriate force to draw the prosthesis 1 against the abdominal wall 2. When all devices have been pulled in this fashion the prosthesis is secure against the abdominal wall circumferentially.

Each device 10 is then pulled upward by its filament 12 near its free end 17 under tension. The skin 2a, where penetrated by the device, is simultaneously pressed downward as shown in Figure 9, further compressing the abdominal wall, and the filament is severed at skin level. Pressure is released, the abdominal wall 2 re-expands and the severed end of the filament recedes beneath the skin 2a as shown in Figure 10. The barb(s) 18 on the remaining portion of the filament prevent dislodgement of the device, which prevents the prosthesis 1 from pulling away from the abdominal wall 2. The abdominal wound above the prosthesis 1 is closed as completely as possible by standard technique, and the operation is concluded.

The tacking device 10 can be similarly utilized in a laparoscopic procedure. Here the devices are loaded onto the periphery of the prosthesis. The assembly of prosthesis and tacking devices is rolled up or folded and introduced into the peritoneal cavity through a cannula or, with the aid of a tool 9, through a port site 8 in the abdominal wall 2 (Figure 11). The assembly is unrolled or unfolded and oriented within the peritoneal cavity so that the free ends 17 of filaments 12 are upward towards the abdominal wall (Figure 12). The procedure continues in substantially the same manner as described above with reference to Figures 8-10.

Turning now to Figure 13, a second embodiment of a prosthetic screen tacking device 20 includes a filament 22 with a perpendicular foot 24 at one end and a loop 26 at the

other end. At least one barb 28 is provided adjacent to the foot 24. The foot 24 may be a linear form, so that end of the device forms a T or may have other configurations as described in more detail below with reference to Figures 26-28. The barb(s) 28 are angulated in such a manner that they permit movement of the device through a prosthetic screen and body tissue in one direction (toward the loop 26), but prevent movement in the opposite direction (toward the foot 24).

Figures 14-17 illustrate how the tacking device 20 is used in the open method of hernia repair. Several devices 20 are pulled through the prosthetic screen 1 equidistantly along the periphery (circumference) of the prosthesis 1. The assembly is then positioned within the open peritoneal cavity, over the viscera (Figure 14). A suture passer 7 is then used to penetrate the abdominal wall at a point opposing the location where one device penetrates the prosthesis, a point substantially beyond the edge of the fascial defect. The suture passer 7 grasps the loop 26 of the device and draws it back through all layers of the abdominal wall 2, including the peritoneum 2d, fascia 2c, muscle if present (not shown), subcutaneous tissue 2b and skin 2a, so that the loop lies external to the body. The loop is then disengaged from the suture passer. The tacking device will remain in place, because substantial force is necessary to withdraw the loop even before the barb(s) engage the abdominal wall. The same action is repeated until the loops of all devices are pulled through the abdominal wall.

Each device 20 is then pulled further through the abdominal wall by grabbing the loop 26 and pulling upward so that the barb(s) 28 engage the abdominal wall as shown in Figure 15. The devices are pulled as far as possible using appropriate force to draw the prosthesis 1 against the abdominal wall 2. When all devices have been pulled in this fashion the prosthesis is secure against the abdominal wall circumferentially.

Each device 20 is then pulled by its loop 26 under tension. The skin 2a, where penetrated by the device 20, is simultaneously pressed downward as shown in Figure 16, further compressing the abdominal wall 2, and the filament 22 is severed at skin level. Pressure is released, the abdominal wall 2 re-expands and the severed end of the filament recedes beneath the skin 2a as shown in Figure 17. The barb(s) 28 on the remaining portion of the filament 22 prevent dislodgement of the device 20, which prevents the prosthesis 1 from pulling away from the abdominal wall 2. The abdominal wound above the prosthesis 1 is closed as completely as possible by standard technique, and the operation is concluded.

The tacking device 20 can be similarly utilized in a laparoscopic procedure. Here the devices are loaded onto the periphery of the prosthesis. The assembly of prosthesis and tacking devices is rolled up or folded and introduced into the peritoneal cavity through a cannula or, with the aid of a tool 9, through a port site 8 in the abdominal wall 2 (Figure 18). The assembly is unrolled or unfolded and oriented within the peritoneal cavity so that the loops 26 are upward towards the abdominal wall 2 (Figure 19). The procedure continues in substantially the same manner as described above with reference to Figures 15-17.

Turning now to Figure 20, a prosthetic screen tacking device 30 includes a filament 32 with a perpendicular foot 34 at one end and a needle 35 at the other end. At least one barb 38 is provided adjacent to the foot 34. The foot 34 may be a linear form, so that end of the device forms a T or may have other configurations as described below. The barb(s) 38 are angulated in such a manner that they permit movement of the device through the prosthesis and body tissue in one direction (toward the needle 35), but prevent movement in the opposite direction (toward the foot 34).

Figures 21 and 22 schematically illustrate how the tacking device 30 is used in the open method of hernia repair. The needle 35 of a first tacking device 30 is passed through a prosthetic screen 1 at a point along the periphery (circumference) of the prosthesis 1. The tacking device is pulled so that the filament 32 and barb(s) 38 pass through the prosthesis and the foot 34, which cannot penetrate the prosthesis, is adjacent to the prosthesis. The assembly is then positioned near or within the open peritoneal cavity. The needle 35 is then used to penetrate the abdominal wall 2 (left side of Figure 21), at a point that will be opposing the location where the tacking device penetrates the prosthesis when the prosthesis 1 is secured against the abdominal wall 2, a point substantially beyond the edge of the fascial defect. The needle and portion of filament 32 is drawn up through all layers of the abdominal wall 2, including the peritoneum 2d, fascia 2c, muscle if present (not shown), subcutaneous tissue 2b and skin 2a, so that the needle 35 lies external to the body (right side of Figure 21). The needle 35 is then disengaged or cut-off from the filament 32 (Figure 22) and the filament 32 is held in place with a clamp (not shown).

A second tacking device 30 is similarly passed through the prosthesis 1 at another point along the periphery of the prosthesis 1, so that its foot 34 is adjacent to the prosthesis. The needle 35 and portion of the filament 32 of this tacking device 30 are then passed through the abdominal wall 2, and its needle 35 disengaged and filament clamped, as had

been done with the first tacking device. More tacking devices 30 are then passed through the prosthesis 1 and abdominal wall 2 in a similar manner, so that tacking devices 30 are distributed around the entire periphery of the prosthesis 1 and wound, and are relatively equidistant from one another where they pass through the prosthesis 1 and where they pass through the abdominal wall 2.

Each device 30 is then pulled further through the abdominal wall so that the barb(s) 38 engage the abdominal wall as shown in Figure 22. The devices 30 are pulled as far as possible using appropriate force to draw the prosthesis 1 against the abdominal wall 2 with the aid of foot 34. When all devices 30 have been pulled in this fashion, the prosthesis 1 is secure against the abdominal wall 2 circumferentially.

Each device 30 is then pulled under tension. The skin 2a, where penetrated by the device, is simultaneously pressed downward, as described above, further compressing the abdominal wall 2, and the filament 32 is severed at skin level. Pressure is released, the abdominal wall re-expands and the severed end of filament 32 recedes beneath the skin. The barb(s) 38 on the remaining portion of filament 32 prevent dislodgement of device 30, which prevents prosthesis 1 from pulling away from abdominal wall 2. The abdominal wound above prosthesis 1 is closed as completely as possible by standard or conventional techniques, and the operation is concluded.

Turning now to Figure 23, a fourth embodiment of a prosthetic screen tacking device 40 includes a filament 42 with a perpendicular foot 44 at one end and a needle 45 at the other end. At least one barb 48 is provided adjacent to foot 44. Foot 44 may be a linear form, so that end of the device forms a T or may have other configurations as described in more detail below. Barb(s) 48 are angulated in such a manner that they permit movement of the device through tissue in one direction (toward needle 45), but prevent movement in the opposite direction (toward foot 44). According to this embodiment, a loop 46 is formed in the filament at a location between barb(s) 48 and needle 45. The loop performs the same functions as does loop 26 of tacking device 20, as previously described.

Figures 24 and 25 schematically illustrate how the tacking device 40 is used in the open method of hernia repair. The needle 45 of a first tacking device 40 is passed through a prosthetic screen at a point along the periphery (circumference) of the prosthesis 1. The tacking device is pulled so that the filament 42, loop 46 and barb(s) 48 pass through the prosthesis and the foot 44, which cannot penetrate the prosthesis, is adjacent to the

prosthesis. The assembly is then positioned near or within the open peritoneal cavity. The needle 45 is then used to penetrate the abdominal wall (left side of Figure 24), at a point that will be opposing the location where the tacking device penetrates the prosthesis when the prosthesis 1 is secured against the abdominal wall, a point substantially beyond the edge of the fascial defect. The needle 45, loop 46, and portion of filament 42 is drawn up through all layers of the abdominal wall 2, including the peritoneum 2d, fascia 2c, muscle if present (not shown), subcutaneous tissue 2b and skin 2a, so that the needle 45 and loop 46 are external to the body. The needle 45 is then disengaged or cut-off from the filament 42 (right side of Figure 24). The tacking device 40 will remain in place, because substantial force is necessary to withdraw loop 46 even before the barb(s) 48 engage the abdominal wall 2.

A second tacking device 40 is similarly passed through the prosthesis 1 at another point along the periphery of the prosthesis 1, so that its foot 44 is adjacent to the prosthesis. The needle 45, loop 46 and portion of the filament 42 of this tacking device 40 are then passed through the abdominal wall 2, and the needle 45 disengaged and the filament 42 clamped, as had been done with the first tacking device. More tacking devices 40 are then passed through the prosthesis 1 and abdominal wall 2 in a similar manner, so that tacking devices 40 are distributed around the entire periphery of the prosthesis 1 and wound, and are relatively equidistant from one another where they pass through the prosthesis 1 and where they pass through the abdominal wall 2.

Each tacking device 40 is then pulled further through the abdominal wall by grabbing loop 46 and pulling upward so that the barb(s) 48 engage the abdominal wall 2 as shown in Figure 25. The devices 40 are pulled as far as possible using appropriate force to draw the prosthesis 1 against the abdominal wall 2 with the aid of foot 44. When all devices 40 have been pulled in this fashion, the prosthesis 1 is secure against the abdominal wall 2 circumferentially.

Each device 40 is then pulled by its loop 46 under tension. The skin 2a, where penetrated by the device, is simultaneously pressed downward as described above, further compressing the abdominal wall 2, and the filament 42 is severed at skin level. Pressure is released, the abdominal wall 2 re-expands and the severed end of filament 42 recedes beneath the skin. The barb(s) 48 on the remaining portion of the filament 42 prevent dislodgement of the device, which prevents the prosthesis 1 from pulling away from the

abdominal wall 2. The abdominal wound above the prosthesis 1 is closed as completely as possible by standard or conventional techniques, and the operation is concluded.

Devices 10, 20, 30 and 40 may be color coded so that they may be more easily identified for handling in the proper sequence. They may be made of a biodegradable and absorbable material (e.g., polylactic acid, polydioxanone, polyglycolide, etc.) so that they disintegrate and disappear after the prosthetic screen is naturally integrated into the abdominal wall and no longer able to dislodge.

As mentioned above, the geometry of feet 14, 24, 34 and 44 can vary. Three examples are shown in Figures 26, 27 and 28. Figure 26 shows a linear foot 14a. Figure 27 shows a circular foot 14b, and Figure 15 shows an elliptical foot 14c.

As mentioned above, the configuration of barbs 18, 28, 38 and 48 may also vary. Figure 29 shows bilateral barbs 18a. Figure 30 shows unilateral barbs 18b, which may alternate on different sides of the filament, or be positioned along different planes with respect to the axis of the filament. Figure 31 shows conical barbs 18c.

Another barb configuration, barb 18d, is illustrated in Figures 32 and 33. Barb 18d has an upper end 101 and a lower end 102. The barb 18d is flared in two directions from the upper end 101 to the lower end 102. As shown in Figures 32 and 33, the two directions are mutually orthogonal. This results in a wedge-shaped barb having a generally triangular cross-sectional profile (see Figure 33) with a relatively large lower end 102 as compared to the upper end 101, i.e., with a tapered form. This barb 18d penetrates tissue more easily and provides greater holding strength.

The tacking devices of the invention may also be used in conjunction with a button 111 as shown in Figures 34 and 35. After the filament or loop is pulled through the body tissue, the filament or loop is pulled through the button 111 and the button 11 is advanced downward along the filament until it locks behind barb(s), e.g., barb 18c as shown in Figure 35. It will be appreciated that the button 111 may be used with any of the barbs described above. The button 111 preferably has an outer diameter that is substantially larger than the width of the barbs. This makes it even more difficult for the tacking device to be withdrawn in the direction of the foot, securing the prosthesis even more. The button 111 may be allowed to sit on the surface of the skin, or be buried subcutaneously through a small skin incision. The button 111 shown in Figures 34 and 35 is a simple perforated disk, sufficiently plastic so that the barb 18c can be passed through the disk in one direction, but

not the other.

A different kind of button 112 is shown in Figures 36-38. The button 112 is provided with a slot 120. The slot 120 allows button 112 to pass over the barbs 18, 28, 38 and 48 when rotated to a first orientation shown in Figure 37. When the button is rotated to a second orientation, shown in Figure 38, it cannot be withdrawn.

There have been described and illustrated herein a device and method for affixing a prosthesis to the abdominal wall. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.

CLAIMS

1. A surgical tacking device suitable for the fixation of a prosthetic screen, said device comprising:

a filament having a first end and a second end;

at least one barb arranged on said filament between said first and second ends, each of said at least one barb being configured to allow said filament to pass through body tissue when said first end is pulled but to prevent said filament from passing through body tissue when said second end is pulled; and

a foot on said second end of said filament, said foot being arranged to prevent said second end of said filament from passing through a prosthetic screen.

2. The surgical tacking device according to claim 1, wherein said at least one barb comprises a plurality of barbs, said barbs being arranged in side by side pairs.

3. The surgical tacking device according to claim 1, wherein said at least one barb comprises a plurality of barbs, said barbs being arranged in an alternating configuration.

4. The surgical tacking device according to claim 1, wherein said at least one barb comprises a plurality of barbs, said barbs being arranged in a random configuration.

5. The surgical tacking device according to claim 1, wherein said at least one barb is substantially conical.

6. The surgical tacking device according to claim 1, wherein said at least one barb is tapered and has a relatively wide lower end and a relatively narrow upper end.

7. The surgical tacking device according to claim 1, wherein said at least one barb is wedge-shaped and has a generally triangular cross-sectional profile.

8. The surgical tacking device according to claim 1, wherein said foot is substantially linear, substantially circular or substantially elliptical.

9. The surgical tacking device according to claim 1, further comprising a button arranged to slide over said at least one barb when moved over said filament from said first end toward said second end but unable to slide over said at least one barb when moved from said second end toward said first end.

10. The surgical tacking device according to claim 1, further comprising a button configured to slide over said at least one barb when rotated to a first position but unable to slide over said at least one barb when rotated to a second position.

11. The surgical tacking device according to claim 1, wherein said device is made of a non-biodegradable material.

12. The surgical tacking device according to claim 1, wherein said device is made of a biodegradable material.

13. The surgical tacking device according to claim 1, further comprising a loop arranged at said first end of said filament.

14. The surgical tacking device according to claim 1, further comprising a needle on said first end of said filament.

15. The surgical tacking device according to claim 14, further comprising a loop arranged between said at least one barb closest to said first end and said needle.

16. A method for affixing a prosthetic screen to the wall of the abdomen, said method comprising:

attaching a plurality of surgical tacking devices to the screen, the tacking devices including a filament having a first end and a second end with a foot at said second end and at least one barb between said first and second ends;

delivering the screen with attached tacking devices to the peritoneal cavity; and

pulling the filament of each tacking device through the abdominal wall so that the at

least one barb of the device lodges in the abdominal wall and affixes the screen to the abdominal wall.

17. The method according to claim 16, further comprising cutting said tacking devices at a point between said first end and the barb closest to said second end so that when the surgical procedure is concluded, no parts of the tacking devices penetrate into or through the skin.

18. The method according to claim 16, wherein said step of delivering includes delivering the screen and attached tacking devices into the peritoneal cavity through a port site when performing laparoscopic hernia repair.

19. The method according to claim 16, wherein the tacking devices further include a loop at said first end, and the step of pulling the filament through the abdominal wall comprises pulling the loop of each tacking device through the abdominal wall, and the step of fixing the screen to the abdominal wall by pulling the loop away from the abdominal wall.

20. The method according to claim 16, wherein the tacking devices further include a needle at said first end, the step of pulling the filament through the abdominal wall comprising

passing the needle of the surgical tacking devices through the abdominal wall from inside to outside,

further comprising separating the needles from the filaments.

21. The method according to claim 20, wherein the tacking devices further include a loop arranged between said at least one barb closest to said first end and said needle, and the step of fixing the screen to the abdominal wall by pulling the loop away from the abdominal wall.

ANY REFERENCE TO FIGURES 7 AND 8 SHALL BE CONSIDERED NON-EXISTANT

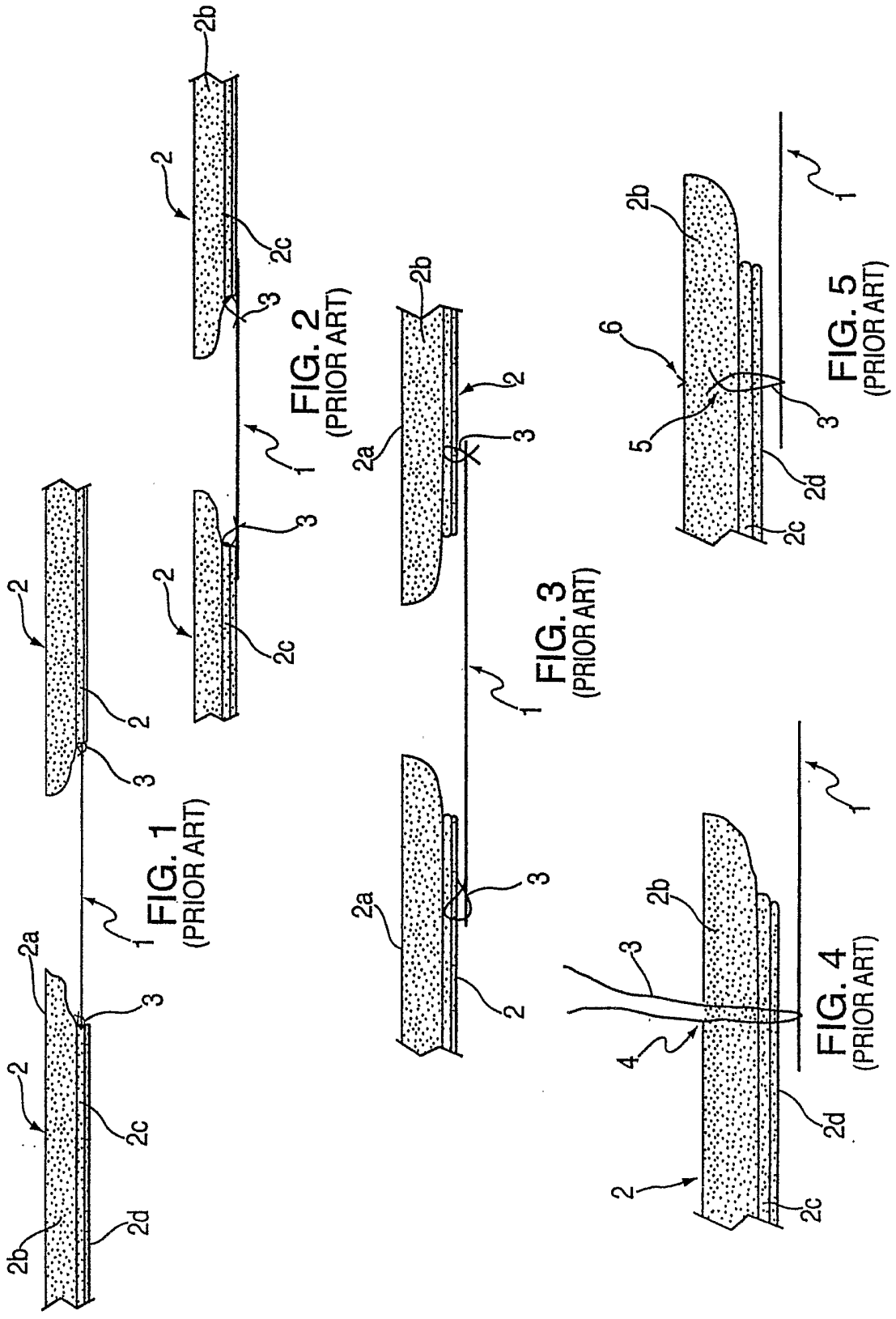


FIG. 1 (PRIOR ART)

FIG. 2 (PRIOR ART)

FIG. 3 (PRIOR ART)

FIG. 4 (PRIOR ART)

FIG. 5 (PRIOR ART)

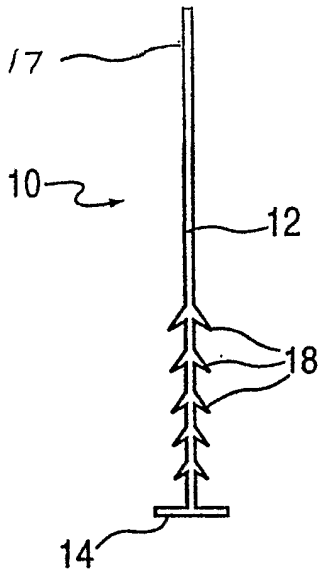


FIG. 6

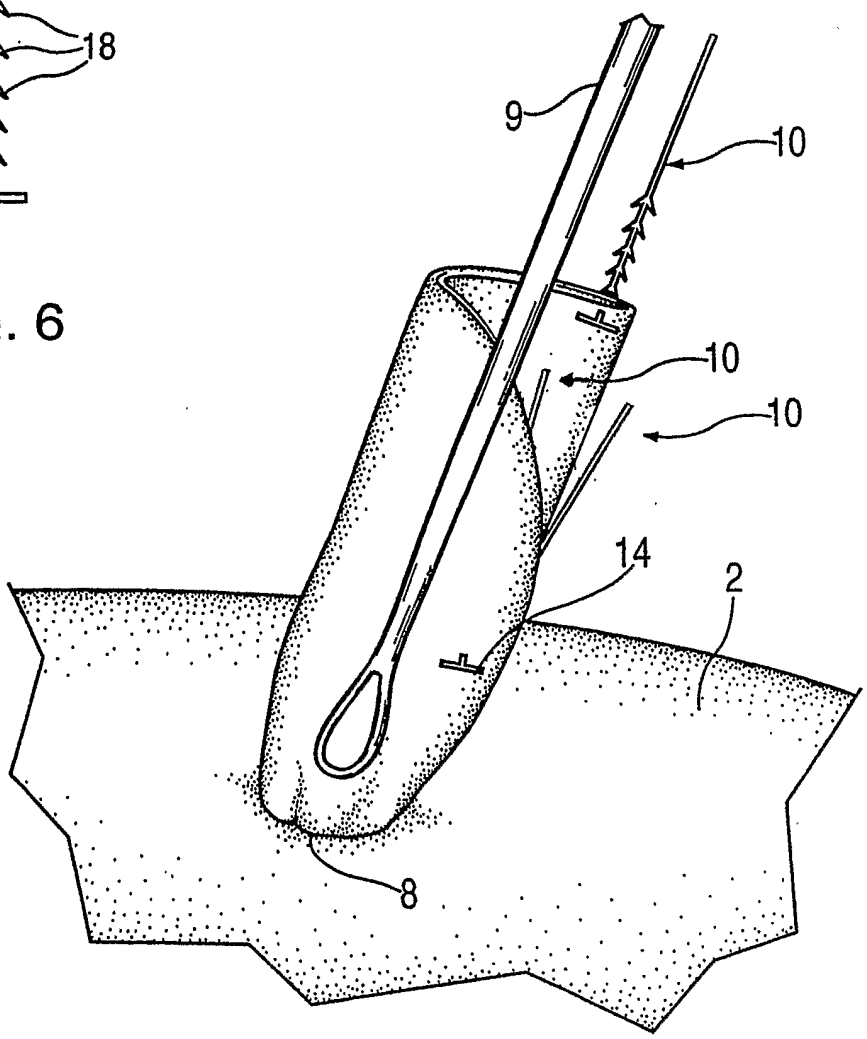


FIG. 11

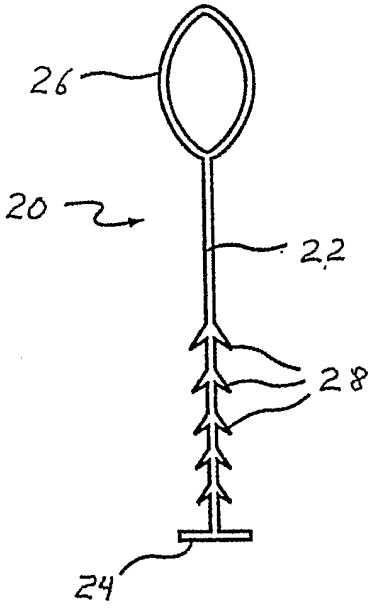


FIG. 13

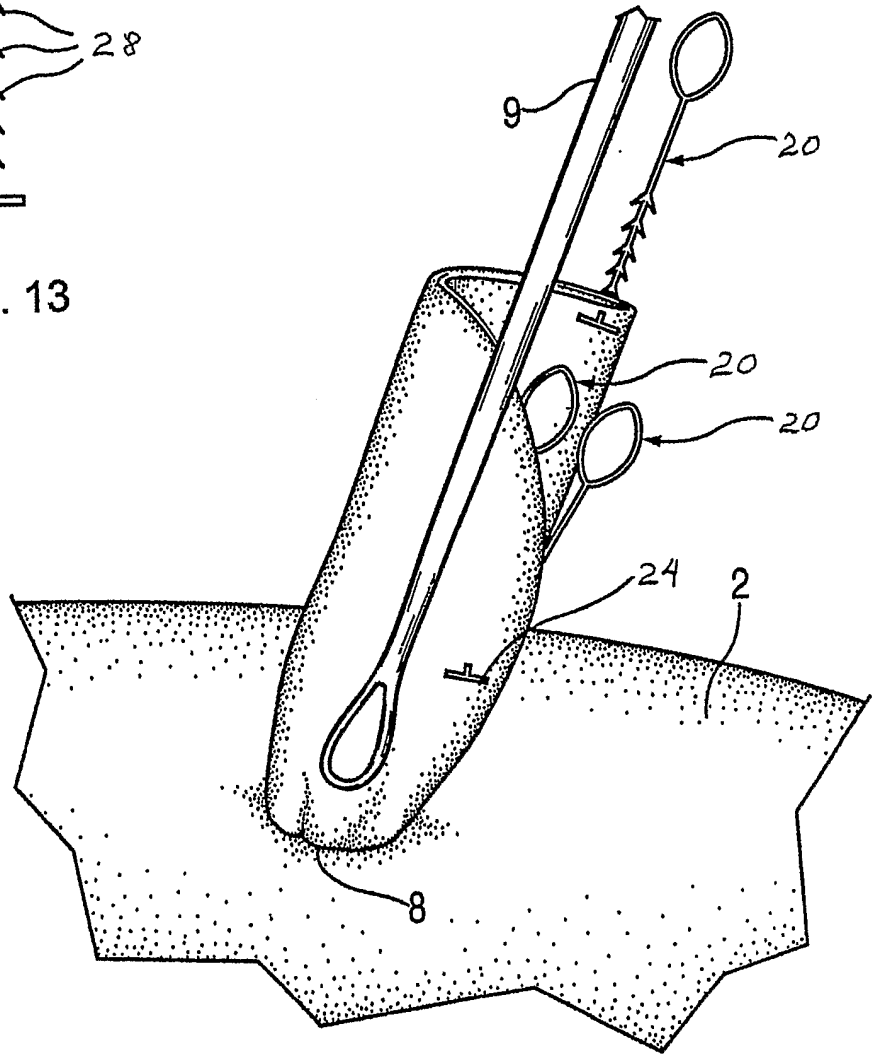


FIG. 18

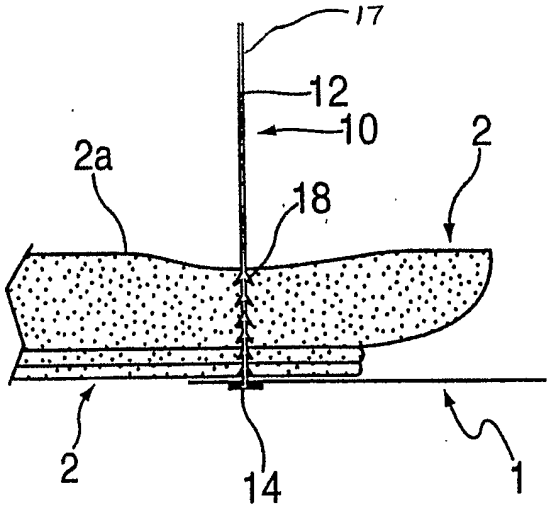


FIG. 9

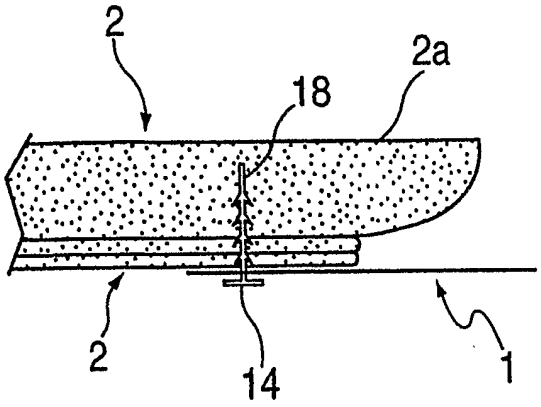


FIG. 10

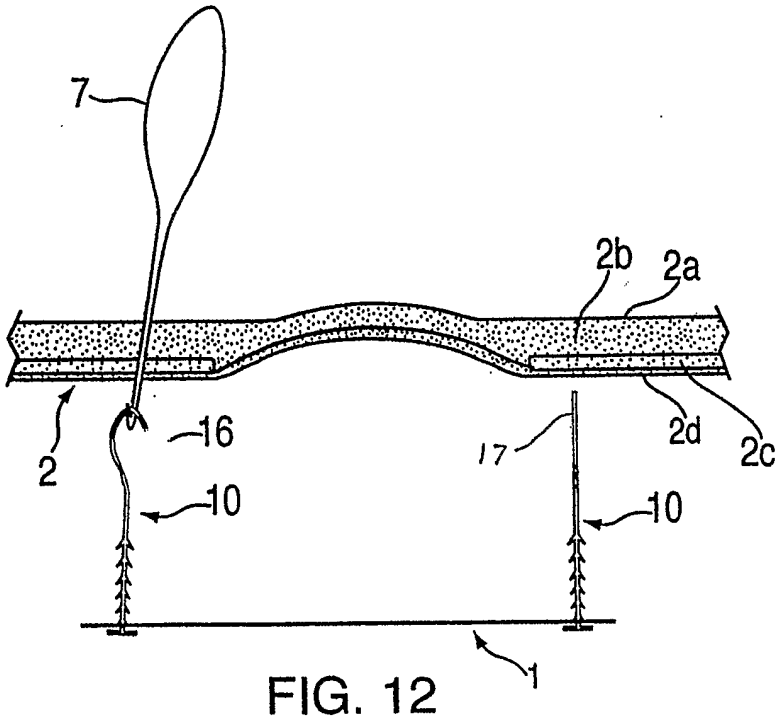


FIG. 12

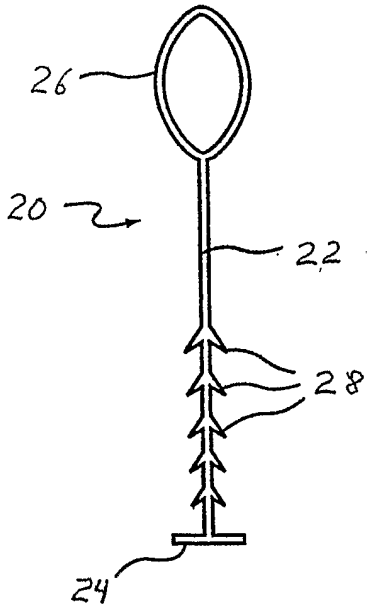


FIG. 13

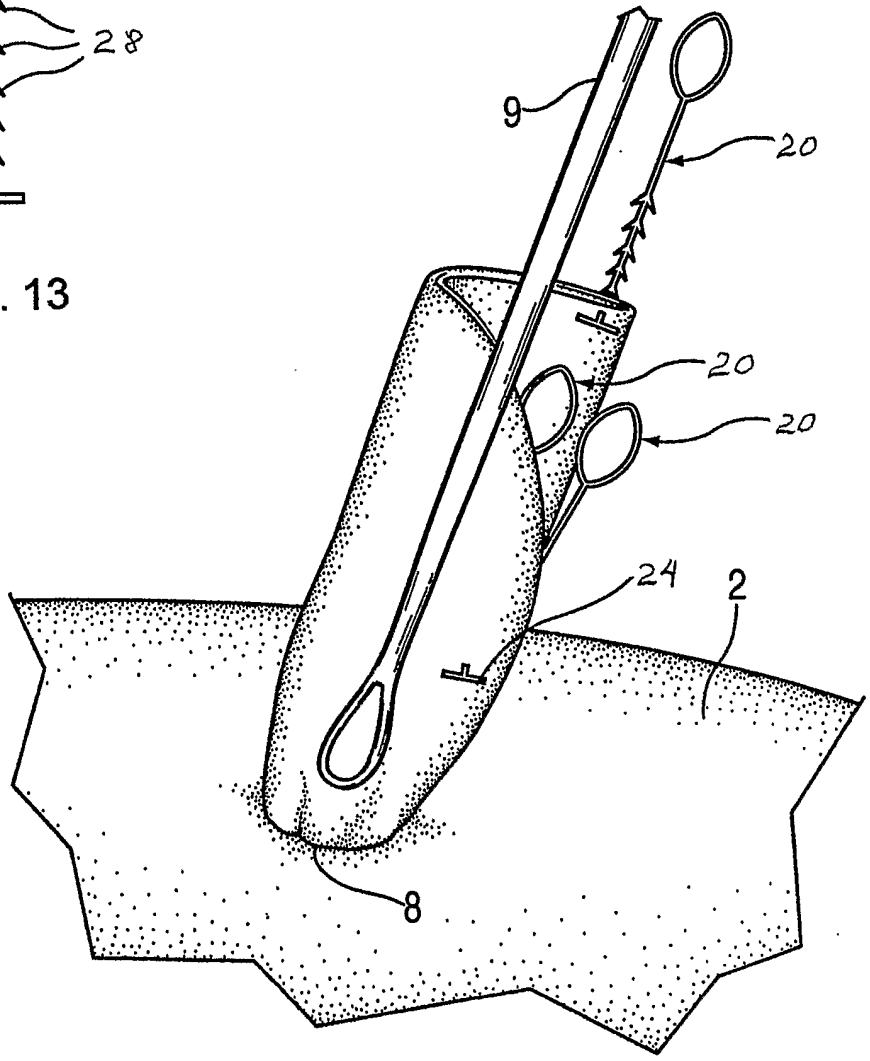


FIG. 18

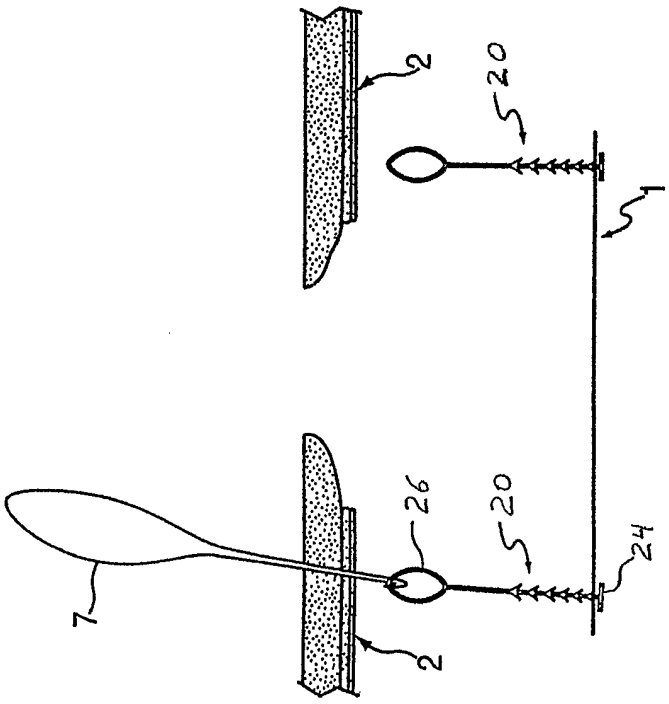


FIG. 14

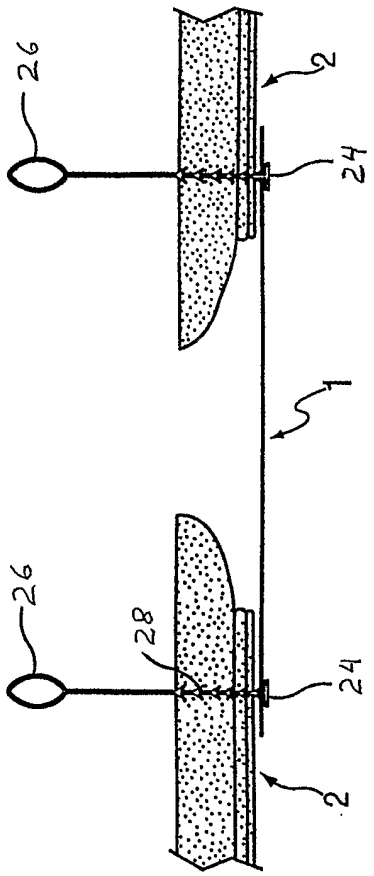


FIG. 15

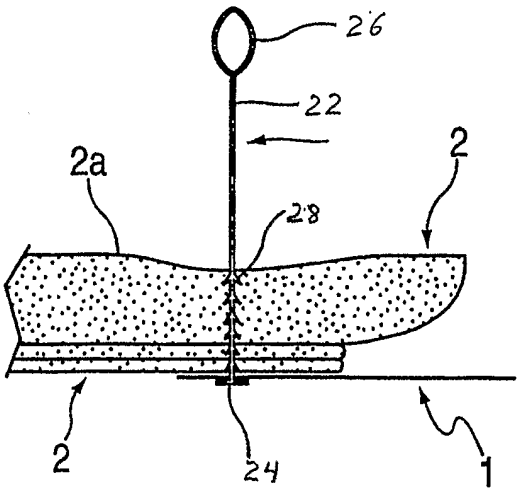


FIG. 16

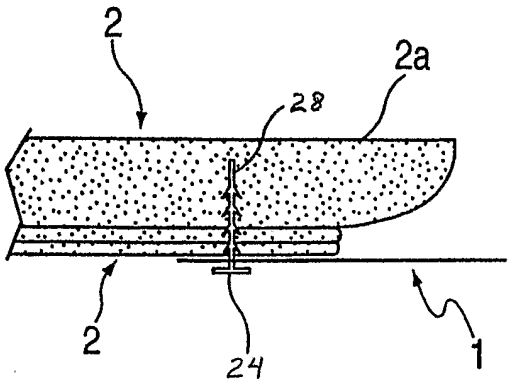


FIG. 17

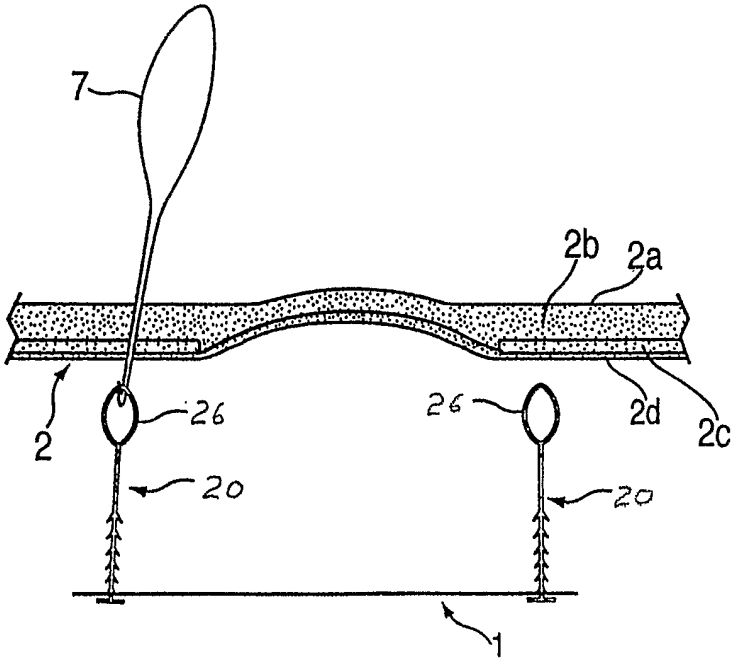


FIG. 19

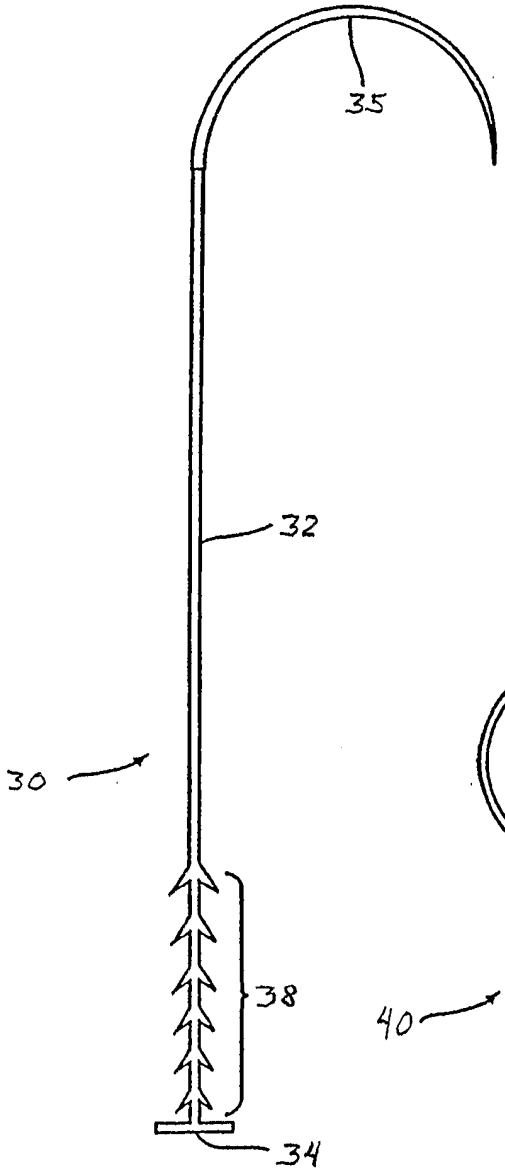


FIG. 20

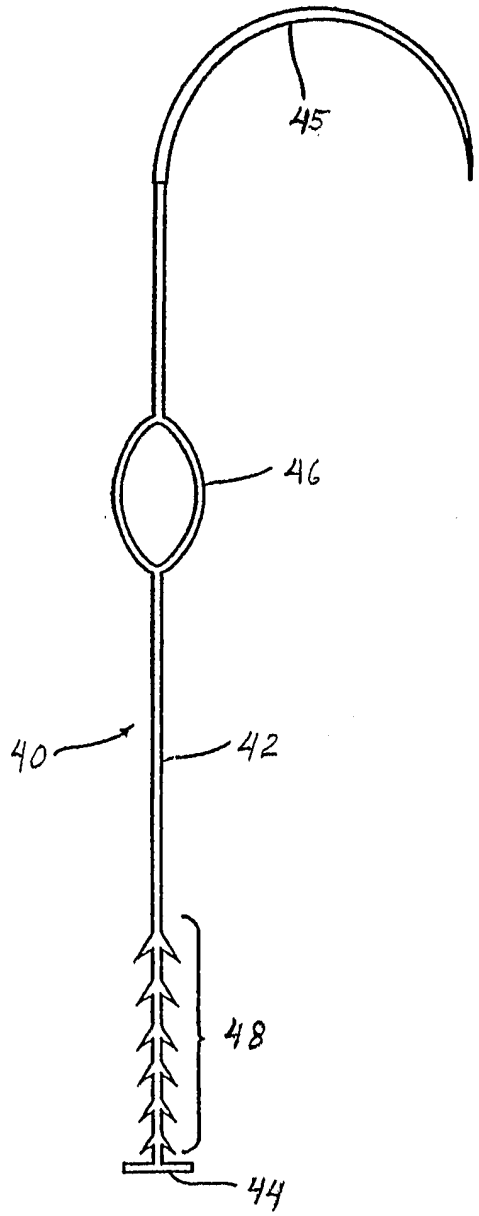


FIG. 23

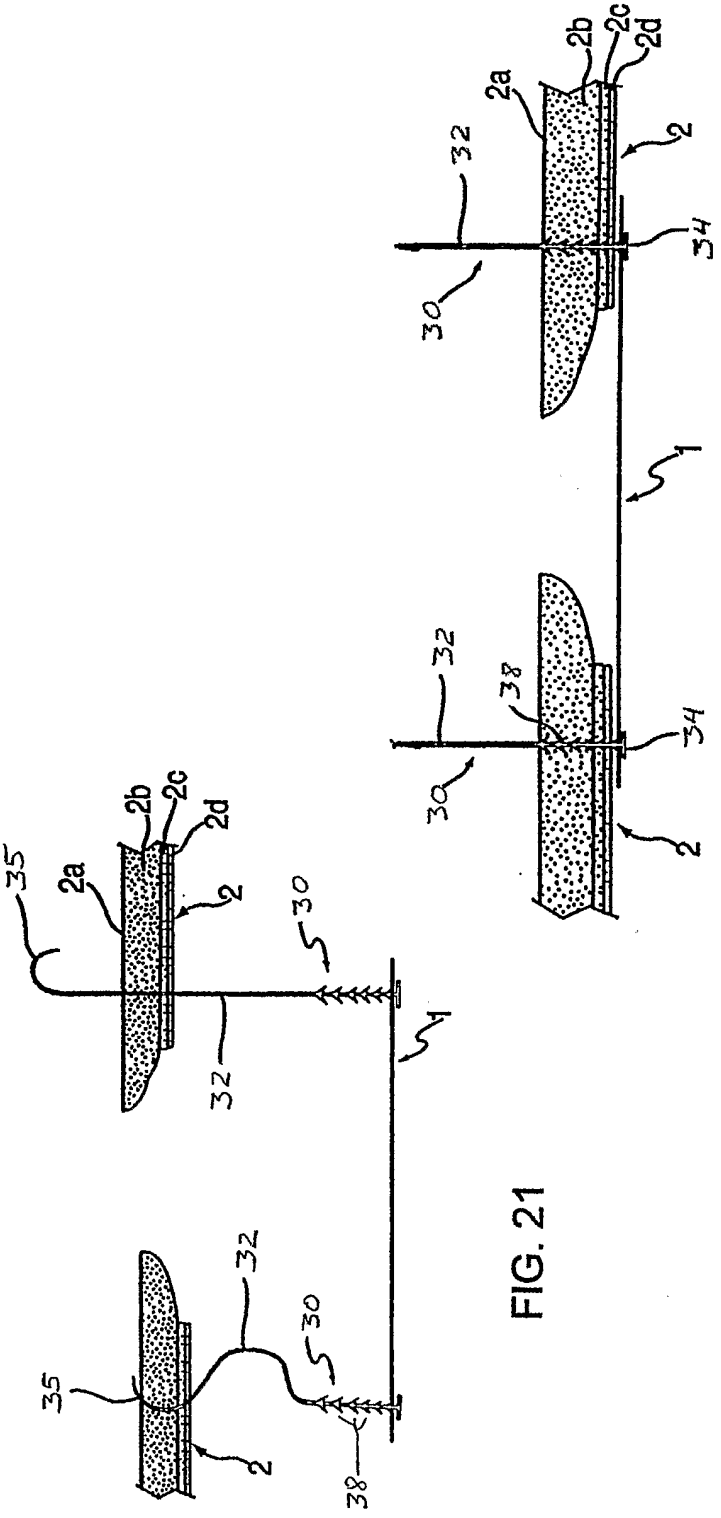


FIG. 21

FIG. 22

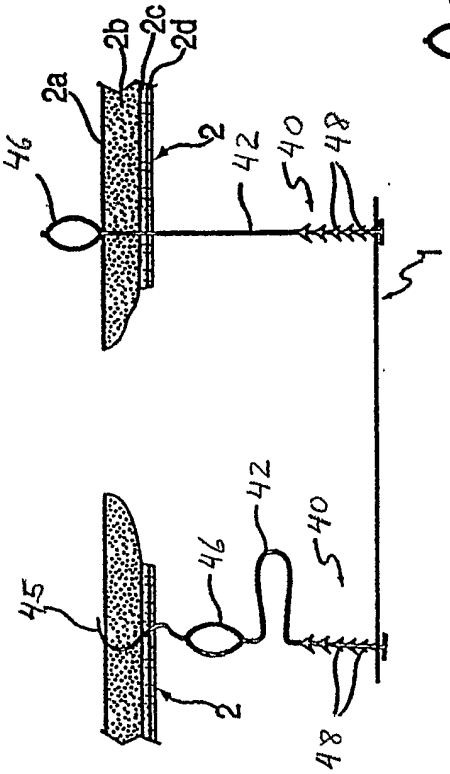


FIG. 24

FIG. 25

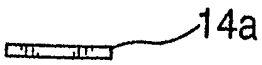


FIG. 26

FIG. 27

FIG. 28

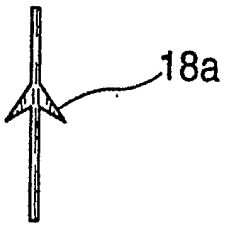


FIG. 29

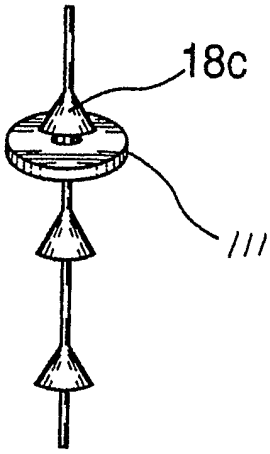


FIG. 35

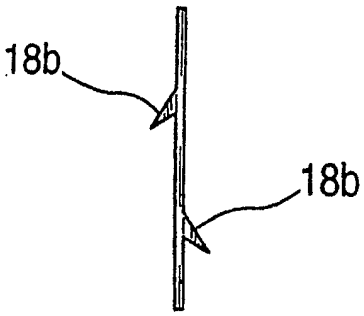


FIG. 30

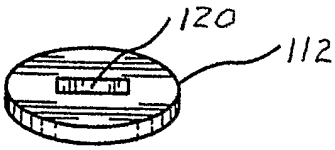


FIG. 36

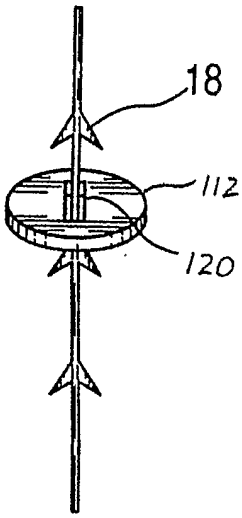


FIG. 38

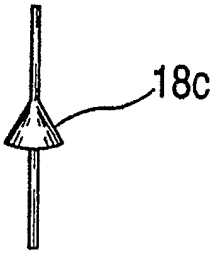


FIG. 31

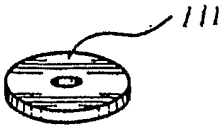


FIG. 34

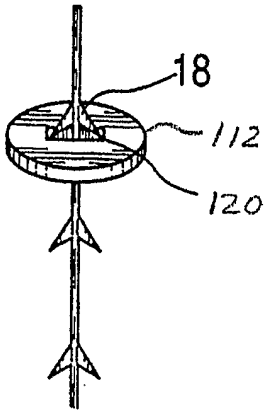


FIG. 37

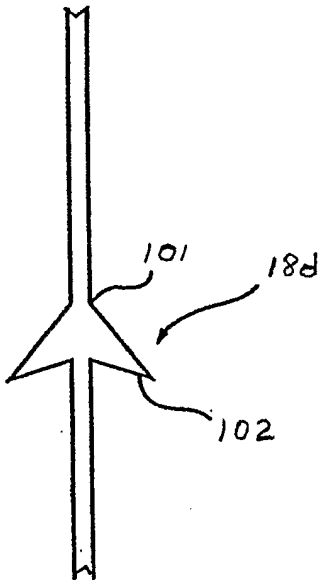


FIG. 32

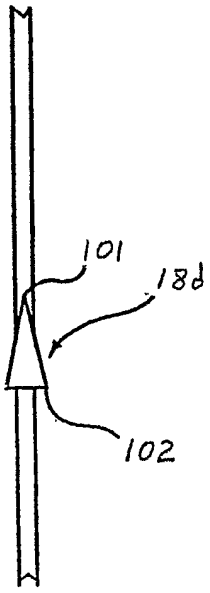


FIG. 33