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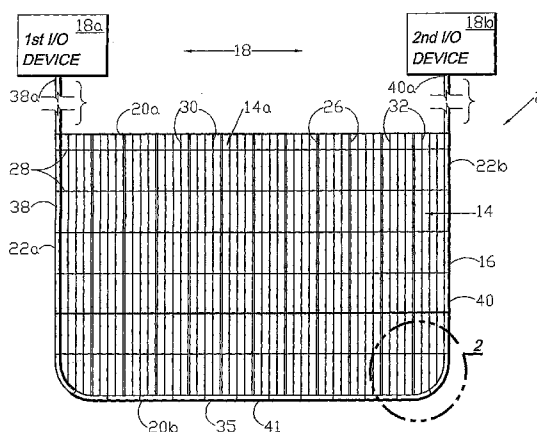
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(54) Title: MEDICAL CLOSURE SCREEN INSTALLATION SYSTEMS AND METHODS



(57) Abstract: A medical closure screen device for a separation of first and second tissue portions is provided, which includes a mesh screen comprising tubular vertical risers, vertical strands with barbed filaments, and horizontal spacers connecting the risers and strands in a grid-like configuration. An optional perimeter member partly surrounds the screen and can comprise a perimeter tube fluidically coupled with the vertical risers to form a tubing assembly. Various input/output devices can optionally be connected to the perimeter tube ends for irrigating and/or draining the separation according to methodologies of the present invention. Separation closure, irrigation and drainage methodologies are disclosed utilizing various combinations of closure screens, tubing, sutures, fluid transfer elements and gradient force sources. The use of mechanical forces associated with barbed strands for repositionably securing separated tissues together is disclosed. The use of same for eliminating or reducing the formation of subcutaneous voids or pockets, which can potentially form hematoma and seroma effects, is also disclosed. Further disclosed are alternative embodiment medical closure screen installation systems and methods.

WO 2007/120138 A2

Medical Closure Screen Installation Systems and Methods

5 Technical Field

The present invention relates generally to medical closure and wound fluid management devices, and in particular to installation systems and methods for screen closure members and devices for closing tissue separations, such as incisions and wounds, which closure members and devices are optionally
10 bioabsorbable.

Background Art

In the medical field, which is broadly defined to include dentistry, veterinary medicine, etc., cutaneous incisions are commonly performed in surgery to provide
15 access to underlying tissue, organs, joints, skeletal structure, etc. Incision and closure techniques are an important part of surgery in general. They tend to occupy surgical teams and other resources for significant portions of many surgical procedures.

Surgeons generally strive to minimize the traumatic and scarring effects of
20 surgery on their patients by both minimizing the incisions, and by employing a variety of closure techniques which tend to reduce postoperative swelling, bleeding, seroma, infection and other undesirable postoperative side effects. For example, the fields of endoscopic-assisted surgery, microscopic surgery, and computer-enhanced instrumentation (e.g., the DaVinci System available from Intuitive Surgical, Inc. of
25 Sunnyvale, Calif.) are generally concerned with minimally invasive surgery ("MIS") procedures and techniques, which have proven to be increasingly popular. Such popularity is at least partly due not only to the minimally-sized scars left by such techniques, but also to the minimal trauma to the fascia and muscle layers and the correspondingly faster recoveries this allows. However, surgeons must balance such
30 considerations with providing adequate access to perform various surgical procedures. A typical surgical procedure involves a cutting or dissecting phase and a closing phase. In recent years, considerable progress has been made in minimizing surgical cutting, dissecting and shaping. Surgical closing techniques involve sutures,

clips, staples and adhesives. However, suturing can be time-consuming and tedious. Moreover, the tissue structures to be joined may not be amenable to other closure techniques. MIS often restricts access to the separated tissue structures, thus making it more difficult to approximate and close same.

5 In contrast to MIS, some surgical procedures, by their nature, must include long incisions. Examples include cutaneous excisional procedures such as "lifts" and reduction procedures, flap procedures for closure of defects, and many bariatric procedures. Suturing in these extensive defects can be time-consuming and tedious.

The "first intention" (primary intention healing) in surgery is to "close" the
10 incision. For load-bearing tissues, such as bone, fascia, and muscle, this requires substantial material, be it suture material, staples, or plates and screws. For the wound to be "closed," the epithelial layer must seal. To accomplish this, the "load bearing" areas of the cutaneous and subcutaneous layers (i.e., the deep dermal elastic layer and the superficial fascia or fibrous layers of the adipose tissue,
15 respectively) must also at least be held in approximation. Important considerations include controlling infection and bleeding, reducing scarring, eliminating the potential of hematoma, seroma, and "dead-space" formation and managing pain. Dead space problems are more apt to occur in the subcutaneous closure. Relatively shallow incisions can normally be closed with surface-applied closure techniques, such as
20 sutures, staples, glues, and adhesive tape strips. However, deeper incisions may well require not only skin surface closure, but also time-consuming placement of multiple layers of sutures in the load-bearing planes. Absorbable sutures are commonly used for this purpose and comprise an important class of surgical sutures. Depending on various factors, absorbable sutures typically dissolve over a period of
25 a few days to a few months. Commercially available examples include Monocryl.RTM. monofilament absorbable synthetic sutures comprising a poliglecaprone and PDS.RTM. (polydioxanone) and Vicryl.RTM. (polyglactin) sutures, all available from Ethicon, Inc., of Somerville, N.J.

Surgical mesh is commonly used to span or reinforce load-bearing planes or
30 defects in them. When coupled with sutures or fasteners, surgical mesh represents another important class of surgical closure devices. Applications include reconstruction, hernia repair, and organ repair. In such procedures, surgical mesh fabric prostheses are inserted into patients through either open surgery or

endoscopic (MIS) procedures. Knitted surgical mesh for hernia repair is disclosed in the Agarwal et al. U.S. Pat. No. 6,287,316, which is assigned to Ethicon, Inc. Another Ethicon, Inc. patent, Duncan U.S. Pat. No. 4,548,202, discloses mesh tissue fasteners including various fastening members with spaced-apart legs for passing
5 through tissue portions. Another closure procedure involves the placement of pins or rods through skin edge or bone followed by the placement of an external clamp or fixator device spanning the wound and frequently incorporating a worm-screw apparatus capable of progressive tightening over time to effect closure, stabilization or distraction.

10 Fluid management represents another important aspect of both open and minimally invasive surgery. Postoperative fluid drainage can be accomplished with various combinations of tubes, sponges, and porous materials adapted for gathering and draining bodily fluids. The prior art includes technologies and methodologies for assisting drainage. For example, the Zamierowski U.S. Pat. No. 4,969,880; U.S. Pat.
15 No. 5,100,396; U.S. Pat. No. 5,261,893; U.S. Pat. No. 5,527,293; and U.S. Pat. No. 6,071,267 disclose the use of pressure gradients, i.e., vacuum and positive pressure, to assist with fluid drainage from wounds, including surgical incision sites. Such pressure gradients can be established by applying porous foam material either internally or externally to a wound, covering same with a permeable, semi-
20 permeable, or impervious membrane, and connecting a suction vacuum source thereto. Fluid drawn from the patient is collected for disposal. Such fluid control methodologies have been shown to achieve significant improvements in patient healing. Another aspect of fluid management, postoperative and otherwise, relates to the application of fluids to wound sites for purposes of irrigation, infection control,
25 pain control, growth factor application, etc. Wound drainage devices are also used to achieve fixation and immobility of the tissues, thus aiding healing and closure. This can be accomplished by both internal closed wound drainage and external vacuum devices. Fixation of tissues in apposition can also be achieved by bolus tie-over dressings (Stent dressings), taping, strapping and (contact) casting.

30 Heretofore, there has not been available a medical closure screen assembly with the advantages and features of the present invention, including the combination of same with negative pressure wound therapy ("NPWT").

Disclosure of Invention

In the practice of one aspect of the present invention, a medical closure screen device is provided, which includes a mesh screen comprising tubular vertical risers, barbed filaments therebetween and horizontal spacers. Integral or separate sutures can be provided. An optional perimeter member partly surrounds the screen member and can comprise a perimeter tube fluidically coupled with the vertical risers to form a tubing assembly. The tubing assembly cooperates with the vertical risers to extract fluid from the tissue separation in a drain mode and to introduce fluid therein in an irrigate mode.. In one embodiment of the invention the tubing assembly is fluidically coupled to a vacuum source to facilitate drainage. In another embodiment of the invention, the perimeter tube is passed through the surrounding tissue to secure the screen member in place. Fluid transfer elements, such as sponges, are optionally placed adjacent to and over an extension of the screen for fluid transfer, for example, in conjunction with a vacuum or pump source. Another embodiment of the invention includes a suture connected to the screen and adapted for securing same in a tissue separation. Alternative embodiment vertical risers are also disclosed, and can provide active fluid transfer utilizing the patient's body dynamics. Yet another alternative embodiment of the present invention utilizes the screen barbs for mechanical fixation in a separation for closure of same. Separation closure, irrigation and drainage methodologies are disclosed utilizing various combinations of closure screens, tubing, sutures, fluid transfer elements and gradient force sources. The closure screen of the present invention uses mechanical and other forces associated with screens and barbed strands for securing separated tissues together and for eliminating or reducing the formation of subcutaneous voids or pockets, which can potentially form hematoma and seroma effects.

Brief Description of Drawings

FIG. 1 is a side elevational view of a medical closure screen device embodying the present invention.

FIG. 2 is an enlarged, fragmentary, side elevational view thereof, taken generally within circle 2 in FIG. 1.

FIG. 3 is an enlarged, fragmentary, side elevational view thereof, taken generally along line 3-3 in FIG. 2, and particularly showing a barbed strand.

FIGS. 4a-f show alternative perimeter tube end closures comprising: 4a) subdermal termination; 4b) knotted end; 4c) Leur lock; 4d) transfer element (i.e., sponge); 4e) vacuum source; and 4f) clamped end.

FIGS. 5a-e show a tissue separation closure procedure embodying the method
5 of the present invention.

FIG. 6a is an enlarged, fragmentary, cross-sectional view of the closure screen in a tissue separation, with skin hooks shown in hidden lines for positioning the separated tissue portions along the closure screen.

FIG. 6b is an enlarged, fragmentary, cross-sectional view of the closure screen
10 in a substantially closed tissue separation.

FIGS. 7a-f show a tissue separation closure procedure embodying the method of the present invention and utilizing optional sponge or foam fluid transfer elements and a tubing placement tool.

FIG. 8 is a cross-sectional view of a tissue separation closure utilizing tubing for
15 securing the closure screen with a fluid transfer subassembly connected to an upper edge of the closure screen.

FIG. 9 shows a needle mounting a length of drain tubing and adapted for passing same through tissue.

FIG. 10 is a side elevational view of a closure screen comprising an alternative
20 embodiment of the present invention, with a perimeter suture.

FIG. 11a is an enlarged, fragmentary, side elevational view thereof, taken generally within circle 11a in FIG. 10.

FIG. 11b is an enlarged, fragmentary, side elevational view thereof, showing
modified vertical risers.

FIG. 12 is a side elevational view of a screen-only closure screen comprising
25 an alternative embodiment of the present invention.

FIG. 13a is an enlarged, fragmentary, side elevational view thereof, taken generally within circle 13a in FIG. 12.

FIG. 13b is an enlarged, fragmentary, side elevational view thereof, showing
30 modified vertical risers.

FIGS. 14a-g show a tissue separation closure procedure utilizing the screen-only embodiment of the closure screen.

FIG. 15a is a side elevational view of a modified vertical riser with flexible, multi-tube risers forming a fluid passage.

FIG. 15b is a cross-sectional view thereof, taken generally along line 15b-15b in FIG. 15a.

5 FIG. 16a is a fragmentary, side elevational view thereof, shown in a compressed configuration.

FIG. 16b is a cross-sectional view thereof, taken generally along line 16b-16b in FIG. 16a.

10 FIG. 17 is a cross-sectional view of another modified vertical riser construction with risers bundled in a different configuration, with barbs.

FIG. 18 is a cross-sectional view of a modified vertical riser or perimeter element, comprising a fluted tube.

FIG. 19 is an enlarged, fragmentary, side elevational view of a modified barbed strand configuration.

15 FIG. 20 is an enlarged, fragmentary, side elevational view of another modified barbed strand configuration.

FIG. 21 is an enlarged, cross-sectional view of a closure screen comprising an alternative embodiment of the present invention, with barbs formed by cutting off the ends of looped filaments.

20 FIG. 22 is an enlarged, cross-sectional view of a closure screen comprising an alternative embodiment of the present invention, with barbs forming hooks and constructed by cutting looped filaments.

FIG. 23 is an enlarged, cross-sectional view of a closure screen comprising yet another alternative embodiment of the present invention, with barbs formed by
25 cutting off the ends of looped filaments, which are laid over in a common direction or orientation.

FIG. 24 is an enlarged, cross-sectional view of a closure screen comprising a further alternative embodiment of the present invention, with barbs forming hooks and constructed by cutting looped filaments, which are laid over in a common
30 direction or orientation.

FIG. 25 is a perspective view of a closure screen comprising a further alternative embodiment or aspect of the invention, comprising individual links forming

flexible strands and including a pre-installation enclosure assembly adapted for holding the screen to length and protectively covering the links.

FIG. 26 is a perspective view showing the closure screen with the pre-installation enclosure assembly being placed in a tissue separation.

5 FIG. 27 is a perspective view showing a pair of the closure screens embedded in a tissue separation, with an excess portion of one of the closure screens being trimmed away.

FIG. 28 is a perspective view showing a cover strip over the closure screens and the tissue separation.

10 FIGS. 29-30 show a sequential procedure for approximating a tissue separation using the closure screen and its enclosure assembly.

FIG. 31 is a perspective view of another alternative embodiment closure screen.

FIG. 32 is exploded view thereof.

15 FIG. 33 is a perspective view of another alternative embodiment closure screen system.

FIG. 34 is an exploded view thereof.

FIGS. 35-46 show approximating tissue separations using a closure screen system embodying the present invention.

20 FIG. 47 is a perspective view of an alternative embodiment closure screen, with a partially-exposed, positioning row of prongs.

FIGS. 48a-c show another alternative embodiment closure screen including a base clip and further show a sequential procedure for approximating separated tissue portions.

25 FIG. 49 is a perspective view of another alternative embodiment closure device, comprising discrete closure clips individually mounted on a backing sheet.

FIG. 50 is a perspective view of yet another alternative embodiment closure device, comprising discrete curved-prong closure clips individually mounted on a backing sheet.

30 FIG. 51 is a front view of a patient, particularly showing an abdominal surgical site with a flexible closure screen installed for closing an incision.

FIG. 52 is a cross-sectional view of the abdominal surgical site with the flexible screen installed in the abdominal cavity in the intraperitoneal position.

Best Mode for Carrying Out the Invention

I. Introduction and Environment

As required, detailed embodiments of the present invention are disclosed
5 herein; however, it is to be understood that the disclosed embodiments are merely
exemplary of the invention, which may be embodied in various forms. Therefore,
specific structural and functional details disclosed herein are not to be interpreted as
limiting, but merely as a basis for the claims and as a representative basis for
10 teaching one skilled in the art to variously employ the present invention in virtually
any appropriately detailed structure.

Certain terminology will be used in the following description for convenience in
reference only and will not be limiting. For example, the words "upwardly",
"downwardly", "rightwardly" and "leftwardly" will refer to directions in the drawings to
which reference is made. The words "inwardly" and "outwardly" will refer to directions
15 toward and away from, respectively, the geometric center of the embodiment being
described and designated parts thereof. The words "horizontal" and "vertical"
generally mean side-to-side and top-to-bottom, respectively. Said terminology will
include the words specifically mentioned, derivatives thereof and words of a similar
import.

20 Referring to the drawings in more detail, the reference numeral 2 generally
designates a medical closure screen device or system embodying the present
invention. Without limitation on the generality of useful applications of the closure
screen system 2, the primary application disclosed herein is for assistance with the
closing, draining, irrigating and healing of a separation of first and second tissue
25 portions, such as a wound or incision 4. As shown in FIG. 5a, the wound 4 extends
from and is open at the dermis 6, through the deep dermal layer 7 and the
subcutaneous layer 8, and to approximately the fascia 10. The wound 4 displays
edges 12a,b, which correspond to first and second tissue portions. The closure
screen device 2 generally comprises a screen 14, a screen perimeter member 16
30 and an input/output (I/O) subsystem 18.

II. Screen 14

The screen 14 includes upper and lower margins 20a,b; first and second ends
22a,b; and first and second faces 24a,b. The screen 14 generally forms a grid

configuration with vertical, hollow, perforated tubular risers 26 cross-connected by horizontal spacer members 28. Multiple barbed strands 30 are positioned between the risers 26. The risers 26, the spacers 28 and the strands 30 are preferably joined at their respective intersections. As shown in FIG. 3, each strand 30 includes a
5 filament 32 with multiple, pointed barbs 34 extending upwardly and outwardly on both sides in staggered, spaced relation. The barbs 34 generally project outwardly from the screen faces 24a,b, for purposes which will be described in more detail hereinafter.

The screen or mesh 14 material can be either dissolvable (absorbable) or non-
10 dissolvable (non-absorbable) and can be chosen from a number of commercially-available, biocompatible products, which are commonly used in medical applications for sutures, implantable meshes, and similar medical devices.

Examples of absorbable materials include, but are not limited to: aliphatic polyesters, which include, but are not limited to: homo polymers and copolymers of
15 lactide, epsilon.-caprolactone, p-dioxanone, trimethylene carbonate, alkyl derivatives of trimethylene carbonate, delta.-hydroxyvalerate, 1,4-dioxepan-2-one, 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one and polymer blends thereof. Examples of nonabsorbable materials include, but are not limited to: cotton, linen, silk, polyamides, polyesters, fluoropolymers, polyolefins, polyethylene, metals and
20 combinations thereof.

III. Screen Perimeter Member 16

The optional screen perimeter member 16 can comprise, for example, a flexible, perforated, hollow tube 35 with multiple orifices 36. As shown in FIG. 1, the tube 35 includes first and second legs 38, 40 extending generally along the screen
25 first and second ends 22a,b, and a base leg 41 extending generally along the screen lower margin 20b. The tubing first and second legs 38, 40 terminate in respective first and second ends 38a, 40a. The tube 35 can be secured to the screen 14 by multiple ties 42, which can comprise extensions of the horizontal spacer members 28 and the strands 30. By providing dissolvable ties 42, the tube 35 can be designed for
30 separation from the remainder of the closure screen 2 after a relatively short period of time. For example, the dissolvable material can dissolve into the patient's body after a few days, whereafter the tube 35 can be removed.

Optionally, portions of the tube 35 can be cut away from the screen 14. For example, the screen 14 can be separated along each screen end 22a,b, or it can be separated completely from the tube 35. In this manner the screen 14 and the tube 35 can be configured to accommodate a variety of conditions and tissue separation configurations.

The vertical risers 26 are optionally fluidically coupled to the tube 35 at respective T intersections 44. In this configuration the tube 35 and the vertical risers 26 cooperate to provide a manifold for fluid handling, i.e. either extraction or irrigation, as indicated by the fluid flow arrows 45.

IV. Input/Output (I/O) Subsystem 18

The input/output subsystem 18 is designed for extraction and/or irrigation of the patient's bodily fluids and/or external fluids. As shown in FIG. 1, the input/output subsystem 18 includes first and second I/O devices 18a,b attached to the tubing first and second leg ends 38a,b, which in this configuration are considered the "port" ends of the tube 35. One or both of the I/O devices 18a,b can comprise a pressure differential source, such as the NPWT device, The V.A.C..RTM. System.TM., available from Kinetic Concepts, Inc. of San Antonio, Tex. The use of such units for wound treatment and fluid management is disclosed in the Zamierowski U.S. Pat. No. 4,969,880; U.S. Pat. No. 5,100,396; U.S. Pat. No. 5,261,893; U.S. Pat. No. 5,527,293; and U.S. Pat. No. 6,071,267, which are incorporated herein by reference.

Alternatively, the tubing port ends 38a,b can be connected to various other sources of pressure differential and various drainage and irrigation devices. For example, they can be cut short below the dermis 6 and left within the separation 4 for sealing by the adjacent tissue portions 12a,b. FIG. 4a shows a truncated tubing end 38b. The tubing ends 38a/40a can be knotted (as shown at 48 in FIG. 4b), clipped, tied (e.g., with a suture) or otherwise closed off either above or below the dermis 6. FIG. 4c shows a Leur lock coupling 46 mounted on a tubing end 38a/40a. Still further, a transfer element comprising a piece of foam or sponge 50 can be coupled to the tube 35 at an end 38a/40a (FIG. 4d). Examples of such foam and sponge materials and configurations are discussed in the Zanierowski U.S. patents identified above. A pressure differential source, such as a vacuum source 51, can be connected to a tube end 38a/40a and to a fluid receptacle 66, as shown in FIG. 4e. A clamp 62 is shown in FIG. 4f and closes the tube end 38a/40a. The clamp 62 can be

chosen from among several suitable clamps, which are commonly used for medical applications.

Either tube end 38a/40a can function as either an inlet port or an outlet port with respect to the system 2. For example, suction can be applied for pulling fluid from the patient through the system 2 through either tube end 38a/40a. Still further, fluid can be pulled in both directions through the system 2 by alternately or jointly applying suction to the tube ends 38a/40a. For example, suction can be simultaneously applied to both tube ends 38a/40a.

V. Operation And Closure Method

FIGS. 5a-e show an installation methodology utilizing the system 2 of the present invention. In FIG. 5a, the closure screen 2 is placed in the separation 4 with the tubing base 41 located at the bottom of the separation (e.g., wound or incision) 4 and in proximity to the fascia layer 10. As shown, the tissue portions or wound/incision edges 12a,b are spaced apart. The screen upper margin 20a can protrude outwardly from the dermis 6. FIG. 5b shows the tissue separation edges 12 being pushed together as indicated by the force arrows 52. FIG. 5c shows the separation edges 12 engaged at the dermis 6, and spaced apart somewhat within the subcutaneous layer 8. The edges 12 can be pushed together as indicated by the force arrows 52. Moreover, the screen 2 can be held or positioned inwardly in order to advance the barbs 34 in the separation edges 12, as indicated by the inward or downward force arrows 54a. FIG. 5d shows the separation edges 12a,b substantially closed on the screen 2. Tugging on the screen 14 in the general direction of the outward force arrow 54b sets the mesh barbs 34.

FIG. 5e shows the separation 4 closed on the closure screen 2, with the tubing 35 removed from the screen 14. The tubing 35 can be removed either pre-installation by cutting the ties 42, or post-installation by allowing the ties 42 to dissolve, whereafter the unsecured tubing 35 can be extracted.

FIG. 6a shows the barbs 34 compressed by engagement with the separation edges 12a,b. As shown, the separation edges 12 can be manually closed by pressing along the horizontal force arrows 52. The barbs 34 allow the separation edges 12a,b to slide upwardly or outwardly along the screen 14. This process can be repeated until the separation 4 is closed, as shown in FIG. 6b. Any protruding length of the screen 14 can be cut close to the dermis 6. In the final configuration (FIGS. 5e

and 6b), the barbs 34 are embedded in the tissue adjacent to the separation edges 12a,b and thus secure the separation 4 in a closed position. The fluid conducting properties of the screen 14 facilitate extracting fluid. An outward or upward force arrow 54b indicates a force direction whereby the screen barbs 34 are set in the adjoining tissue. It will be appreciated that the screen 14 can be securely set in place with the barbs 34, yet the separation edges 12a,b will remain capable of sliding up on the screen 14 by disengaging the barbs 34 with lateral forces, as shown in FIG. 6a. Skin hooks 55 can be used for engaging the tissue portions 12a,b and tugging same outwardly as shown in FIG. 6a. The skin hooks 55 can facilitate positioning and repositioning the screen 14.

VI. Alternative Embodiment Closure Screen Systems and Methodologies

FIGS. 7a-f show an alternative procedure for mounting the closure screen 2 in a wound drainage application utilizing pressure differential. As shown in FIG. 7a, the tubing 35 can pass through the tissue adjacent to the wound 4 and exit the dermis 6 for termination of the tubing end 38a/40a as described above. An optional layer of a suitable, biocompatible adhesive 64 is shown applied to the closure screen first face 24a for securing same to the first wound edge 12a. FIG. 7b shows the screen 14 extending upwardly from the dermis 6 with the wound edges 12a,b brought together in a manner similar to that described above.

The input/output subsystem 18 includes a pair of optional fluid transfer elements comprising foam or sponge members 56a,b placed on the dermis 6 on either side of a protruding portion 14a of the screen 14. The screen 14 is then cut to a level generally flush with the upper surfaces of the sponges 56a,b, as shown in FIG. 7c. An optional sponge bridge 58 is placed over the sponge members 56a,b (FIG. 7d). Examples of suitable transfer element materials are discussed in the Zamierowski patents noted above and include open-cell, porous foam materials (e.g., polyurethane ester (PUE)) chosen for their hydrophobic properties and passage of liquids. Polyvinyl acetate (PVA) material can be used for its hydrophilic properties. The transfer element subassembly 59 formed by the sponge members 56a,b and 58 can be connected to a vacuum source, a fluid irrigation source, etc. Moreover, it can be connected to additional fluid transfer elements and covered with various flexible membranes and drapes, which can be semi-permeable or impervious, as indicated for the closure and treatment of particular separations and wounds.

FIG. 7e shows a tubing placement tool 120 with a handle 122, a shaft 124 and a hook 126 terminating at a pointed or rounded, bullet-shaped tip 128. FIG. 7f shows the tool 120 passing tubing 35 through tissue in the subcutaneous layer 8 and into proximity with the dermis 6. The tip 128 is received in a blind end 134 of the tubing 35 through a notch 136 formed therein. The thrust of the tool 120 causes tenting of the dermis 6, as shown at 138, whereat the dermis 6 can be opened with a scalpel 140 and the tubing 35 can exit the patient for suitable termination arrangements, such as those shown in FIGS. 4a-f above.

FIG. 8 shows a modified embodiment closure system 202 with a pair of screens 14 positioned generally end-to-end in a separation 204. A transfer element subassembly 59 is placed over the separation 204 and a membrane drape 205 is placed thereover. The tube 35 is passed through tissue on either side of the separation 204 (e.g., using the procedure and the tubing placement tool 120 described above) and exits the dermis 6 on either side of the transfer element subassembly 59. The tube 35 lengths are knotted at 206. The tube 35 lengths thus function as sutures or retainers for securing the closure system 202 in the separation 204. The tube ends 38a or 40a can be utilized for this purpose, thus leaving the other tubing ends available for fluid communication with one or more of the input/output subsystems 18 described above.

The tube 35 can be secured by suitable fasteners, such as clips and the like, located above the dermis 6. Moreover, the screens 14 can be overlapped, abutted, spaced slightly and otherwise configured and positioned as necessary for particular tissue separations. Still further, the screens 14 are adapted to be trimmed as necessary.

FIG. 9 shows a modified embodiment tubing/suture subassembly 220 with a Trocar instrument 222 including a sharpened, distal end 224 and a proximate end 226 with multiple, annular ridges 226a. A length of flexible tubing 228 combines the functions of screen perimeter member and suture. The flexible tubing 228 terminates at an end 228a adapted for releasably mounting on the needle proximate end 226, whereat it is retained in place by the ridges 226a. The tubing 228 is optionally connected to the screen 14 as described above and can include perforations 228b for fluid drainage and/or irrigation in conjunction with input/output subsystems 18, also as described above. The tubing/suture subassembly 220 is adapted for securing

the screen 14 in place and for closing the separation 4 by passing the tubing 228 through adjacent tissue. The tubing/suture subassembly 220 and the screen 14 can be prepackaged and presterilized for closing and treating separations, which can include wounds and incisions.

5 FIGS. 10, 11a and 11b show modified embodiment closure screen systems 302 with first and second suture subassemblies 304, 306 comprising the screen perimeter member. The suture subassemblies 304, 306 include respective curved needles 304a, 306a which are swaged or adhesively connected to opposite ends 304b, 306b of a common length of suture thread 307. The suture thread 307 can be
10 absorbable or nonabsorbable. As shown in FIG. 10, the screen closure system 302 can be preassembled with the suture thread length 307 releasably secured to the perimeter 308a of a screen 308. Prior to installation of the screen 308, the suture 307 can be disconnected or severed therefrom, either partly or completely. For example, the suture 307 can be separated along the screen ends 310a, 310b
15 respectively, thereby leaving the suture thread lengths secured only along a screen lower margin 312.

 In operation, the suture subassemblies 304, 306 facilitate installation of the suture/screen closure system 302, thereby providing a preassembled device which incorporates the necessary components for securing same in a separation 4. For
20 example, the screen 308 can be secured at the bottom alone by passing the suture subassemblies 304, 306 through tissue portions located at the bottom of the separation 4. Alternatively, the suture subassemblies 304, 306 can be passed through the adjacent tissue and exit the surface of the dermis 6, whereby the suture subassemblies 304, 306 can be used for closing the separation 4 at the dermis 6.
25 Barbed strands 320 can interact with the tissue portions 12a,b as described above, whereby the screen 308 provides a relatively secure mechanical connection between the separated tissue portions 12a,b. The suture subassemblies 304, 306 can be utilized for various purposes in the separation 4, including attachment and tacking of the dermis 6, the deep dermal layer 7, the subcutaneous layer 8 and the fascia 10.
30 Still further, all or part of the suture subassemblies 304, 306 can be removed, and additional suture subassemblies can be mounted on or sutured to the screen 308.

 FIG. 11a shows the screen 308 attached to the suture thread 307. FIG. 11b shows an alternative construction screen 318 with hollow tubular vertical risers 324

located between adjacent, respective vertical strands 320, all connected by the spacers 322 and adapted for communicating fluid with the separation 4 through the open riser ends 324a and the perforations 324b, as indicated by the fluid flow arrows 326. All or part of the screen/suture system 302 can comprise absorbable material.

5 FIGS. 12, 13a and 13b show a modified embodiment screen-only closure screen system 402 and application methodology. A screen or mesh 404, similar to the screen 14 with barbed strands 30 described above, is placed in a separation 4 against the first tissue portion 12a. The second tissue portion 12b is then placed against the screen 404 whereby the separation 4 is closed and can be secured by
10 the mechanical action of the screen 404. The screen 404 can be supplemented with sutures, drainage tubing, I/O devices, and other auxiliary components for purposes of closing the wound edges 12, draining the inside of the tissue separation 4, fighting infection, pain management and all other functionalities associated with the present invention, as discussed elsewhere herein. For example, the screen 404 can be
15 secured with sutures at the subcutaneous level 8. Various fluid interconnecting devices can be utilized as necessary, and can be designed for removal after they serve their initial purpose. External drainage can also be achieved at the dermis level 6 utilizing transfer element subassemblies, such as the example designated 59 and described above (FIG. 7d). Moreover, drainage and irrigation tubing can be installed
20 within the wound 4 alongside or adjacent to the screen 404. It will be appreciated that a screen-only version of the invention can comprise various suitable biocompatible absorbable and non-absorbable materials, including the materials disclosed above.

FIG. 13a is an enlarged view of the screen 404 and particularly shows barbed
25 strands 406 and horizontal spacers 408, which are connected together in a grid pattern forming the screen 404. FIG. 13b shows an alternative embodiment with a modified screen 410 including vertical risers 412 comprising hollow tubing, which are connected to and spaced by horizontal spacers 408. Fluid flows into and out of the vertical risers 412 through open riser ends 412a and perforations 412b, as indicated
30 by the fluid flow arrows 420.

FIGS. 14a-g show the screen 404 installed in a tissue separation 4 and closing same, utilizing the methodology of the present invention. The methodology shown in FIGS. 14a-g is similar to the methodology shown in FIGS. 5a-e and 6a,b. FIG. 14c

shows a downward/inward force arrow 54a indicating a direction in which the screen 404 is pushed or guided into the separation.

FIGS. 15a,b and 16a,b show a modified vertical riser 502 comprising bundled tubes 504 secured together at spaced intervals by connectors 506. The normal movement of the patient tends to alternately compress and expand the vertical risers 502, thus providing a "pumping" action for transferring fluid from the wound 4, as indicated by the fluid flow arrows 510. FIGS. 15a,b show a riser 502 in an extended configuration. Compressing the screen 14 longitudinally (i.e., end-to-end) compresses the bundled risers 504 to the configuration shown in FIGS. 16a,b, whereby fluid is drawn into the interstitial space 508 and pumped therefrom when the risers 502 extend.

FIG. 17 shows yet another configuration of a vertical riser 602 with bundled tubes 604, which are closely bunched and define passages 606 for conveying fluid. Such fluid conveyance can be enhanced by a pumping action associated with normal patient movements. Barbs 608 project outwardly from the tubes 604. It will be appreciated that various other bundled tube configurations, such as twisted, braided, etc., can be utilized.

FIG. 18 shows yet another vertical riser/perimeter member 702 alternative embodiment configuration. The member 702 has a configuration which is commonly referred to as a "fluted" drain and includes longitudinally-extending passages 704. This configuration can substitute for the perimeter members described above and can function to communicate fluid to and from the wound 4 with the input/output subsystem 18.

As additional alternative embodiment configurations for the vertical risers, they can comprise either barbed monofilament strands, similar to strand 30 shown in FIG. 3, or unbarbed monofilament strands. Such monofilament vertical risers can function as passive drains with fluid flowing alongside same. They can extend above the dermis 6 and abut or connect to transfer elements formed in various configurations with suitable absorbent materials. Examples include gauze dressings and transfer element subassemblies, such as 59 shown in FIG. 7d.

FIG. 19 shows an alternative embodiment strand 802 constructed by twisting and braiding multiple, individual filaments 804. Barbs 805 are formed by respective individual filaments 804a, which terminate at blunt ends 806. The barbs 805 project

generally outwardly from the strand 802 and form acute angles with respect to its longitudinal axis. They are adapted for penetrating tissue within a separation 4, as described above. In use, the barbs 805 would normally be oriented in directions generally pointing outwardly from the patient and the tissue separation 4.

5 FIG. 20 shows another alternative embodiment strand 902 comprising multiple twisted and braided filaments 904. Barbs 905 are formed from individual filaments 904a and have notches 908 and pointed ends 910. The notches 908 and the ends 910 are configured to allow the barbs 905 to easily extract from the separation edge tissues, whereby the screen is adapted for sliding along the separation edges in
10 order to achieve the proper position.

FIG. 21 shows a further modified screen 1002 with barbs 1004 formed by looping individual filaments 1006 and cutting same at cut locations 1010 spaced inwardly from respective apexes 1008 of the filament loops. In operation, the barbs 1004 slightly penetrate the tissue and are imbedded therein. It will be appreciated
15 that the filaments 1006 are relatively thin in diameter, similar to microfibers, whereby patient comfort is optimized.

FIG. 22 shows yet another modified screen 1102 with barbs 1104 formed by looping individual filaments 1106 and cutting same at locations 1110 spaced inwardly from respective apexes 1108 of the filament loops whereby respective
20 hooks 1112 are formed. The hooks 1112 operate in a manner similar to hook-and-loop fasteners, with the adjacent tissue forming the loop parts of the connections. In operation, the hooks 1112 slightly penetrate the tissue and are imbedded therein. The configurations of the hooks 1112 tend to retain them in the tissue adjacent to the separation 4 whereby the separated first and second tissue portions 12a,b can be
25 closed.

FIG. 23 shows a screen 1202 with a configuration similar to the screen 1002 discussed above, with additional fiber elements or filaments 1204. The additional filaments 1204 tend to lay the filament barbs 1206 over whereby the screen 1202 can be directionally oriented within the wound separation 4 and operate in a manner
30 similar to the screen 14 described above. The barbs 1206 are formed by cutting the apexes 1208 at cut locations 1210.

Similarly, FIG. 24 shows a screen 1302 with additional filaments 1304, which engage the filament loops 1306 and orient same in a direction towards the right as

shown in FIG. 24. The slanted orientations of the filament loops 1306 facilitate setting same in the tissue portions 12a,b adjacent to the separation 4 by tugging outwardly on the screen 1302. Repositioning the screen 1302 is also possible, as described above. The filament loops 1306 can be cut at cut locations 1310, which
5 are spaced inwardly from filament loop apexes 1308 whereby hooks 1312 are formed.

It will be appreciated that FIGS. 21-24 disclose screens with barbs and hooks extending from one face thereof. The present invention also includes screens with barbs and hooks extending from both faces.

10 A closure screen comprising a further modified aspect or embodiment of the invention is shown in FIGS. 25-30 and is generally designated by the reference numeral 1402. The screen 1402 generally comprises a highly flexible panel 1404, which engages and approximates adjacent tissue portions across a separation by the semi-independent action of multiple, individual links 1406, which are strung
15 together in respective strands 1408.

The screen 1402 includes a pre-installation enclosure assembly 1424 comprising front and back backing sheets 1426, 1428, which can be provided with a suitable releasable adhesive 1429. The backing sheets 1426, 1428 preferably
20 comprise paper or other material (e.g., Styrofoam.RTM. material), which is relatively stiff (as compared to the relatively flimsy panel 1404) for maintaining the flat shape of the closure screen 1402 during handling and placement in the patient and for protection from the sharpened prong tips. An outer edge handling strip 1430 is mounted on the upper edge of perimeter 1432 of the panel 1404 (FIG. 25) and is adapted for grasping manually or with instruments in order to facilitate handling,
25 alignment and placement.

FIG. 26 shows a closure screen 1402 being placed in a tissue separation 4 with a suitable instrument, such as forceps 1434. FIG. 27 shows the panels 1404 of two closure screens 1402 in place with the backing pieces 1426 and 1428 removed and with the separated tissue portions 12a,b pushed together and approximated by the
30 panels 1404. Selvage edges 1436 can be trimmed flush with the skin surface and removed along with the handling strips 1430. The closed separation 4 can be covered with a suitable cover strip 1438, which can provide tensile retaining strength

for securing the tissue portions 12a,b together, as well as protecting the separation 4 during healing (FIG. 28).

FIG. 29 shows a closure screen 1502 in place in a tissue separation 4. FIG. 30 shows extracting a back backing sheet 1508, whereby the panel 1504 is placed
5 against the tissue portion 12b for engaging same by penetrating its prongs into the tissue approximately 1-2 mm or whatever length is dictated by particular tissue requirements.

FIGS. 31-46 show the construction and operation of another modified embodiment or aspect of a closure screen 1502 embodying the present invention.

10 FIG. 31 shows the closure screen 1502 assembled, with front and back backing sheets 1506, 1508 enclosing a tissue approximation panel 1504. FIG. 32 is an exploded view thereof, with the tissue approximation panel 1504 adapted for placement between the front and back backing sheets 1506, 1508. The backing sheets 1506, 1508 have upper margins 1510, 1512 respectively, with the back
15 backing sheet upper margin 1512 extending higher than the front backing sheet upper margin 1510, which facilitates gripping the back sheet 1508 at its upper margin 1512 with forceps or some other similar instrument. The back backing sheet upper margin 1512 is preferably printed with a color for high visibility, to further facilitate grasping same with forceps or manually. FIGS. 33 and 34 show another
20 embodiment closure screen 1513 with a square closure panel 1514 with a similar construction to the rectangular panel 1504.

FIG. 35 shows the tissue separation 4 with first and second separated tissue portions or edges 12a,b. FIG. 36 shows the placement of a closure screen 1513 with dashed lines indicating panels 1514, which are already in place in the tissue
25 separation 4. As shown in FIG. 36, a tissue separation 4 can be "tiled" with the closure panels 1514, which can be of any suitable size and number depending upon the configuration of the separation 4. FIG. 37 shows the screen 1502 (FIG. 31) in place with its back backing sheet 1508 removed, whereby the prongs are exposed to and penetrate the tissue portion 12b. The opposite tissue portion 12a can be pushed
30 in the direction of directional arrow 1516 to approximate closure. FIG. 38 shows the lower (innermost) portion of the tissue separation 4 approximated, with the front backing sheet 1506 being removed in FIG. 39, resulting in the condition shown in FIG. 40 with the lower portion of the tissue separation 4 secured or "approximated"

against the closure panel 1504. FIGS. 41-46 show securing an upper (or outer/distal) portion of the tissue separation 4 with another closure screen 1502 by essentially repeating the procedure described above. A protruding distal selvage margin 1518 is removed from the outermost panel 1504 as shown in FIG. 44 substantially flush with the skin surface. A suitable cover 1520 is placed over the tissue separation as shown in FIG. 45. FIG. 46 shows the prong-tissue engagement whereby the tissue edges 12a,b are approximated, with the upwardly-and-outwardly orientation of the prongs 1522 tending to draw together at the tissue edges 12a,b in response to outward tugging on the panel 1504. The prongs of the various embodiment closure screens and clips can have various suitable sizes and configurations, including curved, straight, barbed, etc. Closure and approximation of the tissue separation 4 can be augmented with tape, adhesive, staples, sutures or other closure devices, including a pressure differential source, such as the NPWT device, The V.A.C..RTM. System.TM., available from Kinetic Concepts, Inc. of San Antonio, Tex., which can be chosen to promote wound closure in conjunction with a closure screen or screens.

FIG. 47 shows another alternative embodiment closure screen 2302 with a backing sheet 2304 having a lower removable strip 2306, which exposes a lowermost row 2308 of clips for initially positioning the screen 2302, whereafter an upper portion 2310 of the backing sheet 2304 can be removed.

FIGS. 48a-c show another embodiment closure screen 2352 with a row of closure clips 2354, which can be mounted along a bottom edge 2356 of a panel 2358 of the closure screen 2352. Each closure clip 2354 includes first and second rows of laterally-projecting hooks 2360a,b, which are adapted and positioned for penetrating respective tissue portions 12a,b. A sequential procedure for closing a lower or inner portion of a tissue separation 4 can begin with the closure clips 2354 positioned within the tissue separation 4 as shown in FIG. 48a. The first row of hooks 2360a can be embedded in the first tissue portion 12a, for example by tilting and manipulating the panel 2358 (FIG. 48b). Closure can be accomplished by embedding the second row of hooks 2360b in the second separated tissue portion 12b (FIG. 48c), for example, by tilting and manipulating the panel 2358. The closure screen 2352 with the closure clips 2354 can be used in conjunction with the enclosure assembly of the closure screen 2302, whereby the lower row of links 2308

can be exposed for supplementing the closure clips 2354 in connection with initially anchoring the closure screen. The clips 2354 can be provided in any suitable number and spacing, including a clip 2354 at the lower end of each column of links, at the lower end of every other column of links, etc.

5 FIG. 49 shows an additional alternative embodiment closure screen 2402, which is constructed by mounting discrete clips 2404 on a backing 2406, which can retain the clips 2404 by a suitable adhesive or some other means pre-installation. FIG. 50 shows yet another alternative embodiment closure screen 2502, which is similar to the screen 2402 but with fewer and different clips 2504. The clips 2504
10 have prongs 2506, which are curved in an outwardly-convex direction with respect to bodies 2508 of the clips 2504. The curvature of the prongs 2506 can facilitate penetration and closure of the separated tissue portions 12a,b. The prongs 2506 can also be straight, barbed, etc., and can be oriented at any suitable angle with respect to the bodies 2508 of the clips 2504.

15 FIGS. 51 and 52 show a closure screen 1902 applied to an abdominal incision 1904. Such incisions are typically involved in abdominal surgery procedures and can result in various complications, including infection and difficulties in closure and healing. The abdominal tissues are exposed within the abdominal cavity to a perimeter 1906. The screen 1902 can be provided with multiple rigid or semi-rigid
20 non-collapsible members 1908 for maintaining its general shape and facilitating its placement in the abdominal cavity, preferably to approximately the perimeter 1906. The screen 1902 includes prongs 1910, which can be oppositely-oriented towards a centerline 1916 for directing the opposite sides of the incision 1904 towards medial closure. The screen 1902 can be provided with a perimeter member 1912, which is
25 preferably sized and configured to place and maintain the screen in proximity to the tissue separation perimeter 1906. Relatively extensive coverage of the abdominal tissue separation can thus be achieved, particularly with the positioning effects of the non-collapsible members 1908 and the perimeter member 1912 in combination. With appropriate dissection and direction of prongs, this device can also be placed in pre-
30 peritoneal positions and on the musculature, in addition to placement intra-abdominally below the musculature, as shown.

It is to be understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangement of parts described and shown.

Claims

1. A medical closure method for closing a separation of first and second tissue portions, which method comprises the steps of: providing a flexible screen with outwardly-projecting prongs; configuring said prongs for retaining said tissue thereon; configuring said screen for placement in said tissue separation; placing said screen in said tissue separation and penetrating at least one of said tissue portions with said prongs; and closing said tissue separation.
2. The method of claim 1, which includes the additional steps of: providing said screen with multiple clips; providing each said clip with at least one of said prongs; and providing said screen with a panel comprising a flexible matrix mounting said clips.
3. The method of claim 2, which includes the additional steps of: forming said matrix with multiple, flexible interwoven filaments; providing said screen with a pre-installation enclosure assembly with front and back backing sheets mounted on opposite sides of said panel pre-installation; and removing said backing sheets from said screen, exposing said prongs and engaging said tissue portions with said prongs.
4. The method of claim 3, which includes the additional steps of: providing said panel with an outer edge; mounting a handling strip on said panel projecting from said outer edge thereof; and grasping said handling strip during installation of said panel; and applying an outward force to said panel at said outer edge thereof.
5. The method of claim 3, which includes the additional steps of: providing said panel with an inner edge; providing said panel with a row of base prongs along said inner edge; providing said enclosure assembly with a removable

strip adjacent to said panel inner edge; removing said enclosure assembly removable strip and exposing said row of base prongs; and anchoring said panel by engaging said row of base prongs with one of said tissue portions at an inner portion of said tissue separation.

6. The method of claim 2, which includes the additional steps of: applying said screen panel across a longitudinal tissue separation; applying tension across said first and second tissue portions; approximating said tissue portions; and closing said tissue separation.

7. The method of claim 2, which includes the additional steps of: installing multiple said panels in said tissue separation; locating at least some of said panels adjacent to the skin surface with outer edges of said panels located exteriorly to the patient; removing protruding portions of said panels approximately flush with the skin surface; and covering said tissue separation with a dressing applied to the skin surface.

8. The method according to claim 2, which includes the additional steps of: applying a negative pressure to said tissue separation with a negative pressure wound therapy device; fluidically connecting said closure screen panel with said negative pressure wound therapy device; draining said tissue separation with negative pressure; and closing said tissue separation with negative pressure.

9. The method according to claim 5, which includes the additional steps of: providing a row of closure clips along said panel inner edge; providing each said closure clip with first and second hooks extending from first and second faces of said panel respectively; penetrating said first tissue portion at an inner location of the separation with said first hooks; penetrating said second tissue portion at an inner location of the separation with said second hooks;

and closing said tissue separation at said inner location with said closure clips.

10. The method according to claim 2, which includes the additional steps of: providing each said clip with a body and multiple said prongs extending therefrom; providing a pre-installation enclosure assembly with front and back backing sheets mounted on opposite sides of said screen pre-installation; removing said backing sheets from said screen, exposing said prongs and engaging said tissue portions with said prongs; independently mounting each said clip on a respective enclosure backing sheet; removing said backing sheets from said screen, exposing said prongs and engaging said tissue portions with said prongs; penetrating and securing said first and second tissue portions at respective fixation points with said clips; and closing said tissue separation with multiple said clips.
11. The method according to claim 10 wherein said clips have constructions chosen from among the list consisting of: stamped sheet metal; bioabsorbable; formed wire; plastic; barbed-prong; and curved-prong.
12. The method according to claim 3, which includes the additional steps of: sequentially removing said first and second backing sheets and engaging said prongs protruding from said first and second panel faces in said first and second tissue portions respectively; and pulling said panel outwardly and thereby further embedding said prongs and closing said tissue separation.
13. A medical closure method for closing a separation of first and second tissue portions, which method comprises the steps of: providing a flexible screen with outwardly-projecting prongs; configuring said prongs for retaining said tissue thereon; configuring said screen for placement in said tissue separation; placing said screen in said tissue separation and penetrating at least one of said tissue portions with said prongs; closing said tissue

separation; providing said screen with multiple clips having constructions chosen from among the list consisting of: stamped sheet metal; bioabsorbable; formed wire; plastic; barbed-prong; and curved-prong; providing each said clip with at least one of said prongs; providing said screen with a panel comprising a flexible matrix mounting said clips; forming said matrix with multiple, flexible interwoven filaments; providing said screen with a pre-installation enclosure assembly with front and back backing sheets mounted on opposite sides of said panel pre-installation; removing said backing sheets from said screen, exposing said prongs and engaging said tissue portions with said prongs; installing multiple said panels in said tissue separation; locating at least some of said panels adjacent to the skin surface with outer edges of said panels located exteriorly to the patient; removing protruding portions of said panels approximately flush with the skin surface; covering said tissue separation with a dressing applied to the skin surface; applying a negative pressure to said tissue separation with a negative pressure wound therapy device; fluidically connecting said closure screen panel with said negative pressure wound therapy device; draining said tissue separation with negative pressure; and closing said tissue separation with negative pressure.

14. A method of closing an abdominal incision, which includes the steps of: providing a closure screen with a panel including opposite faces, multiple prongs projecting from said faces and a perimeter; placing said panel between first and second abdominal tissue layers exposed by said abdominal incision; penetrating said abdominal tissue layers with said prongs; applying tension to said panel; and closing said incision.
15. The method according to claim 14, which includes the additional steps of: providing said panel with first and second portions and a medial line dividing said first and second portions; orienting said prongs at said first and second portions oppositely towards said medial line; and placing said panel within

-27-

said patient with said medial line thereof located below said abdominal incision.

16. The method according to claim 15, which includes the additional steps of:
pulling said panel at said medial line; further embedding said prongs with said pulling force; and closing said incision with said pulling force.
17. The method according to claim 14, which includes the additional steps of:
providing said panel with a flexible, semi-rigid perimeter member at said perimeter; locating said perimeter member at a perimeter of said abdominal tissue layer separation; and maintaining the shape of said panel with said perimeter member.
18. The method according to claim 14, which includes the additional steps of:
providing said panel with multiple, semi-rigid, non-collapsible members oriented longitudinally, transversely or diagonally with respect to said panel; and maintaining the shape of said panel with said members.
19. The method according to claim 14, which includes the additional step of placing the panel in a pre-peritoneal position on the abdominal musculature.
20. The method according to claim 14, which includes the additional step of placing the screen intra-abdominally below the abdominal musculature.
21. The method of claim 14, which includes the additional steps of: providing multiple clips and providing each said clip with a body and multiple said prongs extending therefrom; providing a pre-installation enclosure assembly with front and back backing sheets mounted on opposite sides of said screen pre-installation; and removing said backing sheets from said screen, exposing said prongs and engaging said tissue portions with said prongs.

22. The method of claim 14, which includes the additional steps of: applying a negative pressure to said tissue separation with a negative pressure wound therapy device; fluidically connecting said closure screen panel with said negative pressure wound therapy device; draining said tissue separation with negative pressure; and closing said tissue separation with negative pressure.
23. A flexible medical closure screen for closing a separation between first and second tissue portions, which screen includes: a flexible material forming multiple prongs adapted for penetrating the tissue portions; and a configuration adapted for facilitating the closure of the tissue portions.
24. The screen according to claim 23, which includes: said flexible material comprising multiple strands with said prongs projecting therefrom; and connecting filaments connecting said strands and forming a flexible screen therewith.
25. The screen according to claim 24, which includes: said strands and said prongs comprising a continuous, flexible, linear material; and said prongs being formed by looping said material on itself and by securing said loops with connections chosen from the group comprising connecting filaments, weldments and adhesive.
26. The screen according to claim 23 wherein said prongs terminate at ends with configurations chosen from the group comprising diagonal cut, transverse cut and tapered.
27. The screen according to claim 23 wherein each said strand includes a longitudinal axis and said prongs of said strand form acute angles with respect to said axis and are generally oriented in a common direction along said strand.

28. The screen according to claim 23, which includes: each said strand having a semicircular cross-sectional configuration forming a relatively flat face along one side and a convex face along an opposite side, said convex face being notched to form said prongs.
29. The screen according to claim 28, which includes: each said strand including a medial point, with said prongs on either side of said medial point converging towards same; and multiple filaments extending between and connected to said strands and forming a flexible screen therewith.
30. The screen according to claim 23 wherein said material comprises porous, open-cell, reticulated foam and said screen includes a panel of said foam with opposite faces forming respective prongs with random orientations adapted for penetrating the first and second tissue portions respectively.
31. The screen according to claim 24, which includes: first and second panels; each said panel having an inner face with multiple prongs projecting therefrom and an outer face; said panel inner faces being positioned in opposed relationship; a disengaged configuration with said prongs of said panels in opposed relation and said panels in spaced relation; an engaged configuration with said prongs of each said panel penetrating the other panel and said panels in adjacent, closely-spaced, opposed positioned; and said panels being adapted for shifting relative to each other with said screen system in said engaged configuration whereby said prongs form acute angles with respect to respective panel outer faces.
32. The screen according the claim 31, which includes: each said strand including: primary and secondary lines positioned in generally parallel, juxtaposed sliding relation with respect to each other; multiple prongs mounted on said primary line; and said prongs being adapted for engagement

by said secondary line whereby said prongs can be reoriented by sliding said lines relative to each other.

33. The screen according to claim 24, which includes: an externally-applied vacuum dressing connected to said screen; and a negative pressure source connected to said dressing.
34. A flexible medical closure screen for closing a separation between first and second tissue portions, which screen includes: a flexible material forming multiple prongs adapted for penetrating the tissue portions; a configuration adapted for facilitating the closure of the tissue portions; said flexible material comprising multiple strands with said prongs projecting therefrom; connecting filaments connecting said strands and forming a flexible screen therewith; said strands and said prongs comprising a continuous, flexible, linear material; said prongs being formed by looping said material on itself and by securing said loops with connections chosen from the group comprising connecting filaments, weldments and adhesive; said prongs terminate at ends with configurations chosen from the group comprising diagonal cut, transverse cut and tapered; first and second panels; each said panel having an inner face with multiple prongs projecting therefrom and an outer face; said panel inner faces being positioned in opposed relationship; a disengaged configuration with said prongs of said panels in opposed relation and said panels in spaced relation; an engaged configuration with said prongs of each said panel penetrating the other panel and said panels in adjacent, closely-spaced, opposed positioned; said panels being adapted for shifting relative to each other with said screen system in said engaged configuration whereby said prongs form acute angles with respect to respective panel outer faces; each said strand including: primary and secondary lines positioned in generally parallel, juxtaposed sliding relation with respect to each other; multiple prongs mounted on said primary line; and said prongs being adapted for engagement by said secondary line whereby said prongs can be

reoriented by sliding said lines relative to each other; an externally-applied vacuum dressing connected to said screen; and a negative pressure source connected to said dressing.

35. A method of closing first and second separated tissue portions, which includes the steps of: providing a medical closure screen comprising a flexible material; providing said screen with a face; forming prongs of said flexible material and projecting same from said face; providing prongs projecting from said screen; and penetrating at least one of said tissue portions with said prongs.
36. The method of claim 35, which includes the additional steps of: providing multiple strands; providing each said strand with a convex surface; notching said convex surface to form said prongs; and mounting said strands on a flexible screen to form a screen panel.
37. A circumferential medical closure device for closing a separation between first and second tissue portions, which device includes: a flexible screen adapted for forming a circumferential configuration; and said screen having multiple projecting prongs adapted for penetrating tissue.
38. The device according to claim 37, which includes: multiple strands; said prongs being formed by said strands; and a flexible matrix including said strands.
39. The device according to claim 38 wherein said strands have orientations with respect to said matrix, said orientations being chosen from the group consisting of: longitudinal; transverse; circumferential; diagonal; helical; and/or double helical.

40. The device according to claim 38, which includes: each said strand including a first, smooth face and a second, convex face with said prongs projecting therefrom.
41. The device according to claim 38, which includes: said prongs having multiple orientations with respect to said strands.
42. The device according to claim 38, which includes: an externally-applied vacuum dressing connected to said matrix; and a negative pressure source connected to said dressing.
43. The device according to claim 38, which includes: prongs oriented both inwardly and outwardly with respect to said screen; said device being adapted to receive a first elongated tissue portion therein with said inwardly-oriented prongs engaging same; and said device being adapted to be received in a second elongated tissue portion with said outwardly-oriented prongs engaging same.
44. The device according to claim 38 wherein each said strand includes: primary and secondary lines positioned in generally parallel, juxtaposed sliding relation with respect to each other; multiple prongs mounted on said primary line; and said prongs being adapted for engagement by said secondary line whereby said prongs can be reoriented by sliding said lines relative to each other.
45. The device according to claim 44 wherein said strands have orientations chosen from the group consisting of: longitudinal; transverse; circumferential; diagonal; helical; and/or double helical.
46. The device according to claim 37, which includes: said screen having a generally tubular configuration with opposite first and second ends and a

passage extending between and open at said ends; and said prongs comprising first and second sets of teeth adjacent to and oriented inwardly from said first and second ends respectively, said prongs projecting into said passage.

47. The device according to claim 37, which includes: said screen having a generally tubular configuration with opposite first and second ends and a passage extending between and open at said ends; and said prongs comprising first and second sets of annular ridges adjacent to and oriented inwardly from said first and second ends respectively, said ridges projecting inwardly into said passage.
48. The device according to claim 38 wherein each said strand includes first and second faces and said prongs project from said first face, said second face or both.
49. A circumferential medical closure device for closing a separation between first and second tissue portions, which device includes: a flexible screen adapted for forming a circumferential configuration; said screen having multiple projecting prongs adapted for penetrating tissue; said screen comprising multiple strands; said prongs being formed by said strands; a flexible matrix including said strands; said strands having orientations with respect to said matrix, said orientations being chosen from the group consisting of: longitudinal; transverse; circumferential; diagonal; helical; and/or double helical; each said strand including: primary and secondary lines positioned in generally parallel, juxtaposed sliding relation with respect to each other; multiple prongs mounted on said primary line; and said prongs being adapted for engagement by said secondary line whereby said prongs can be reoriented by sliding said lines relative to each other; said screen having a generally tubular configuration with opposite first and second ends and a passage extending between and open at said ends; an externally-applied

vacuum dressing connected to said matrix; and a negative pressure source connected to said dressing.

50. A method of circumferentially closing a separation between first and second tissue portions, which method comprises the steps of: providing a flexible screen; approximating said first and second tissue portions; configuring and positioning said screen circumferentially with respect to said tissue portions; providing said screen with multiple prongs projecting from a face thereof; and penetrating said first and second tissue portions with said prongs.
51. The method according to claim 50, which includes the additional steps of: wrapping said screen around said approximated tissue portions; trimming or overlapping excess screen material; releasing said tissue portions; placing said screen in tension; and fastening said screen in a tubular configuration either receiving or received by said tissue portions, or both.
52. The method according to claim 50, which includes the additional steps of: preforming said screen in a tubular configuration; and inserting one or both of said tissue portions into said screen and/or inserting said screen into one or both of said tissue portions.
53. The method according to claim 50, which includes the additional steps of: stabilizing and compressing the tissue portions and the device with an externally-applied vacuum dressing to maintain the embedded prong position against increasing distraction load on the prongs and to improve the efficiency of the system.
54. The method according to claim 50, which includes the additional step of attaching said screen to at least one of said tissue portions.

55. The method according to claim 50, which includes the additional steps of:
forming said screen in a tubular configuration with a double helix of strands;
forming said prongs on said strands; and constricting said screen in response
to tension on said tissue portions.
56. The method according to claim 50, which includes the additional steps of:
providing each said strand with generally parallel, adjacent primary and
auxiliary lines; connecting said prongs to said primary lines; sliding said
primary and auxiliary lines relative to each other; engaging said prongs with
said auxiliary lines; and reorienting said prongs relative to said primary lines.

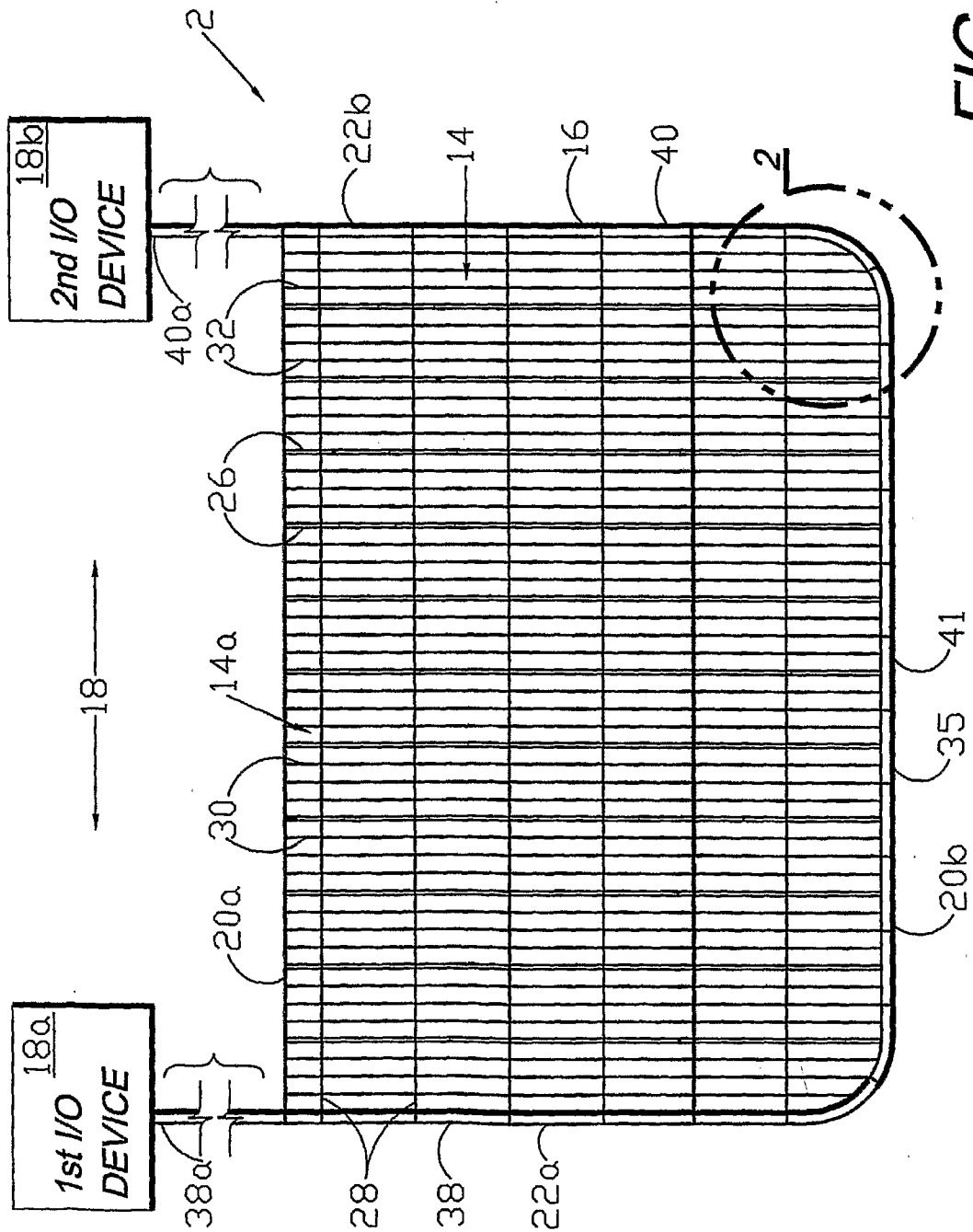


FIG. 1

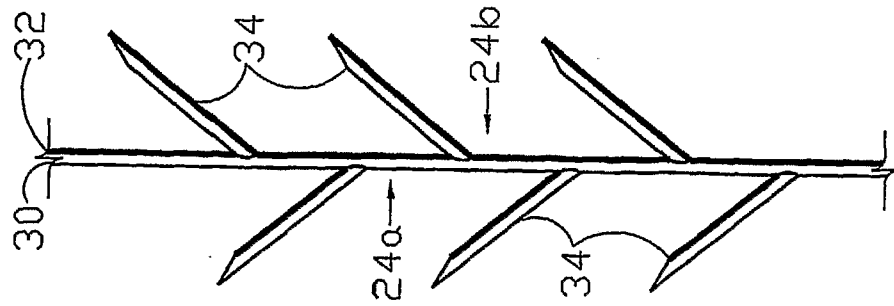


FIG. 3

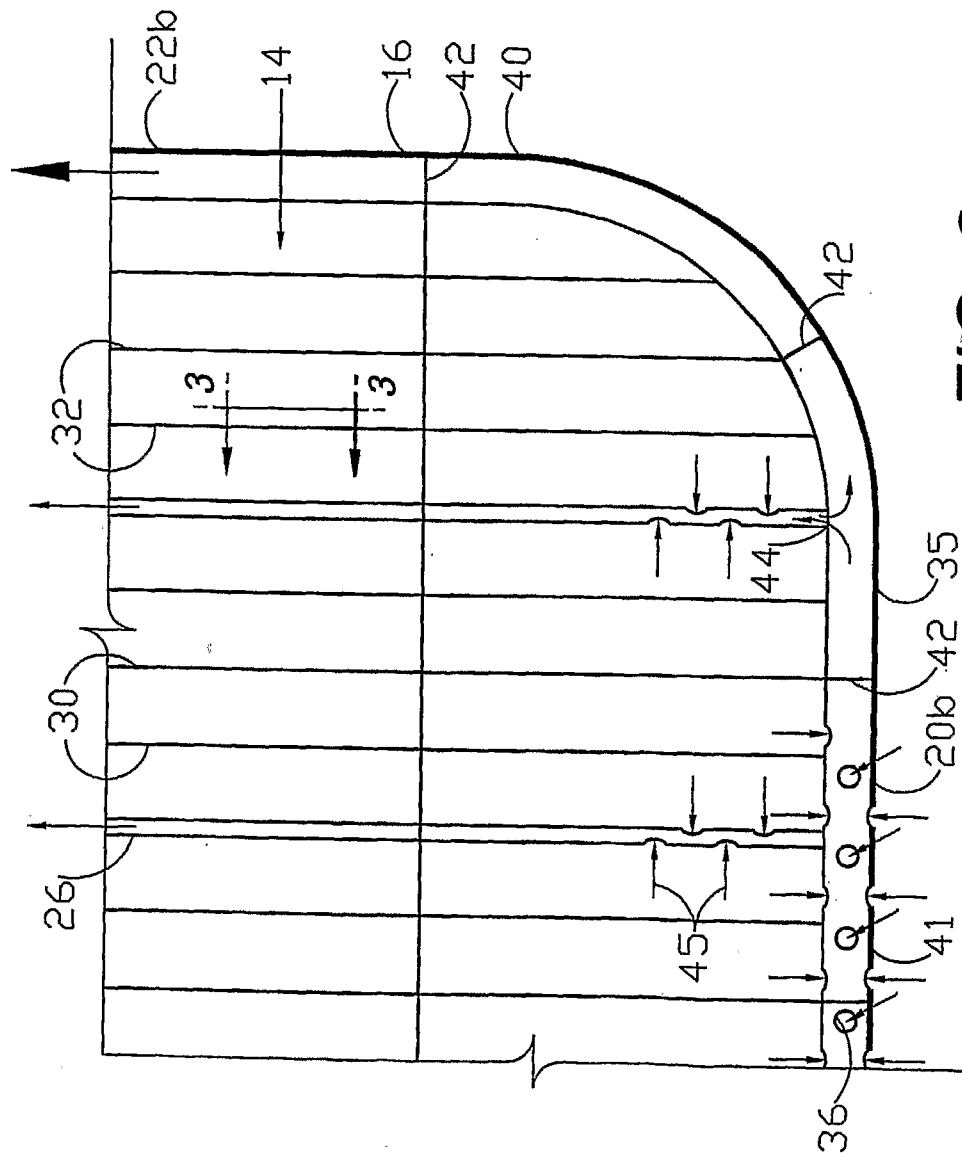


FIG. 2

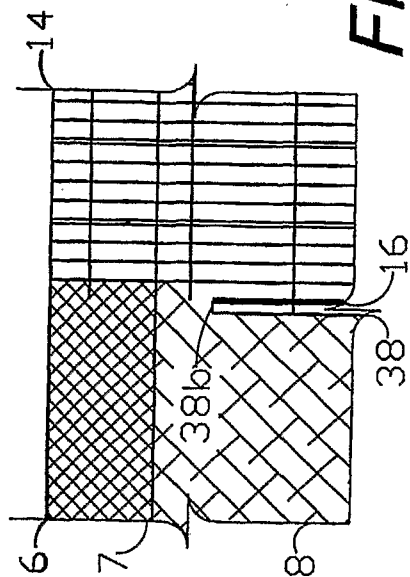


FIG. 4a

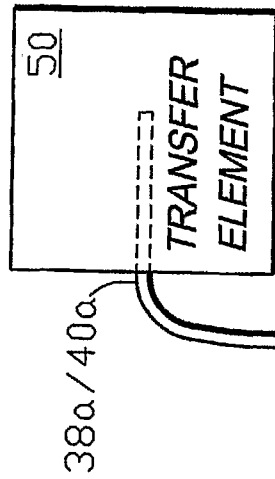


FIG. 4d

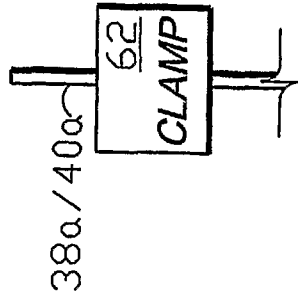


FIG. 4f

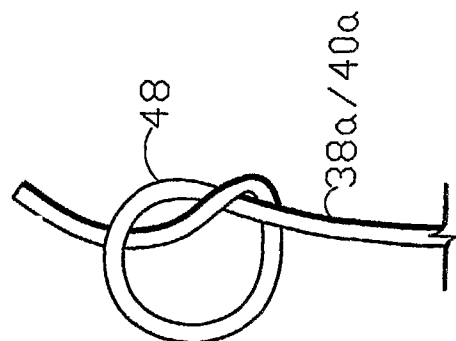


FIG. 4b

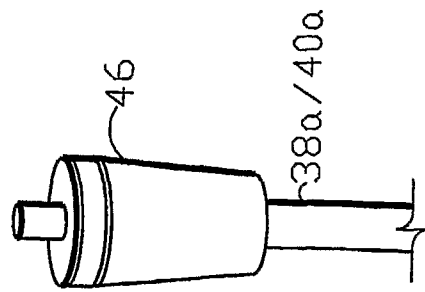


FIG. 4c

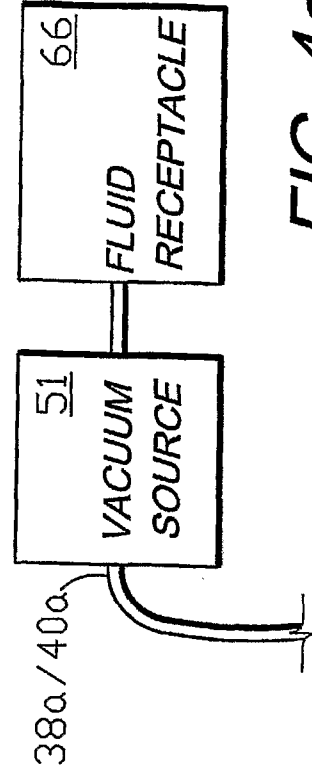


FIG. 4e

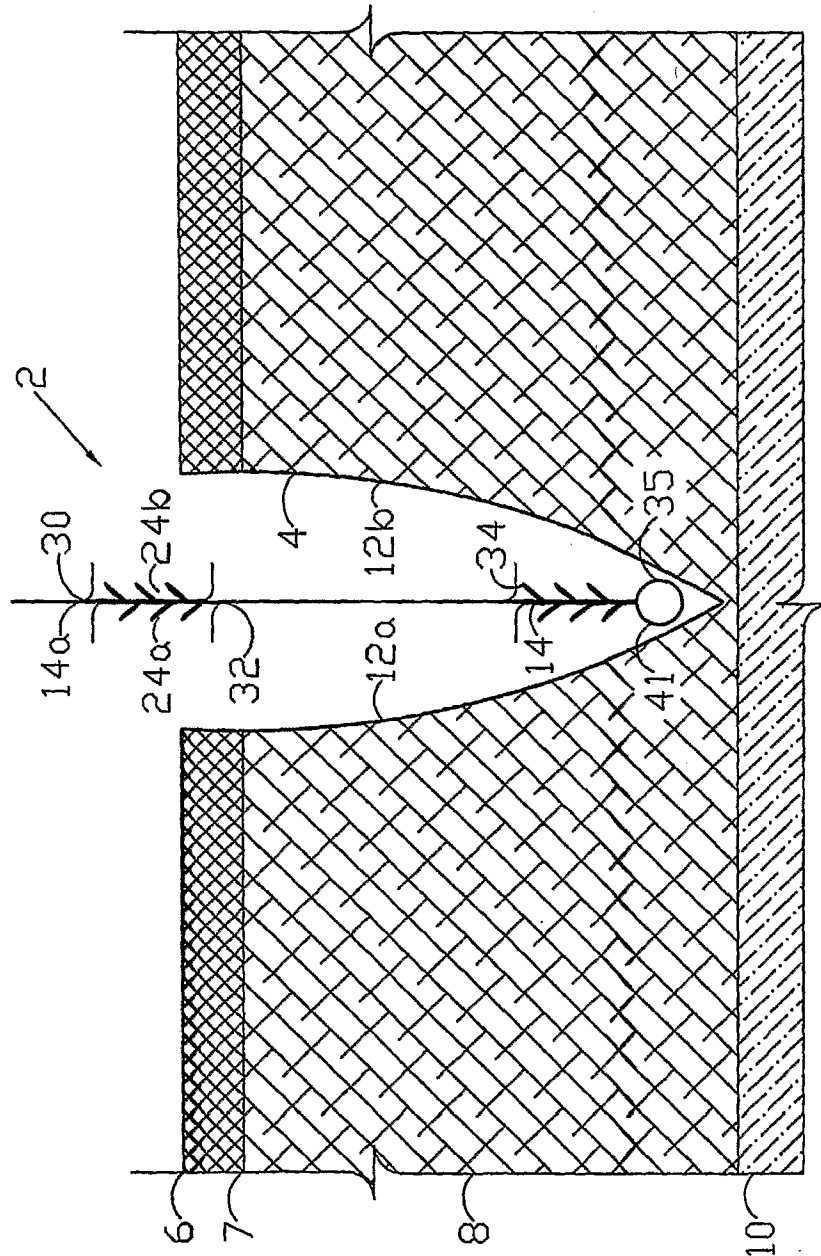


FIG. 5a

5/45

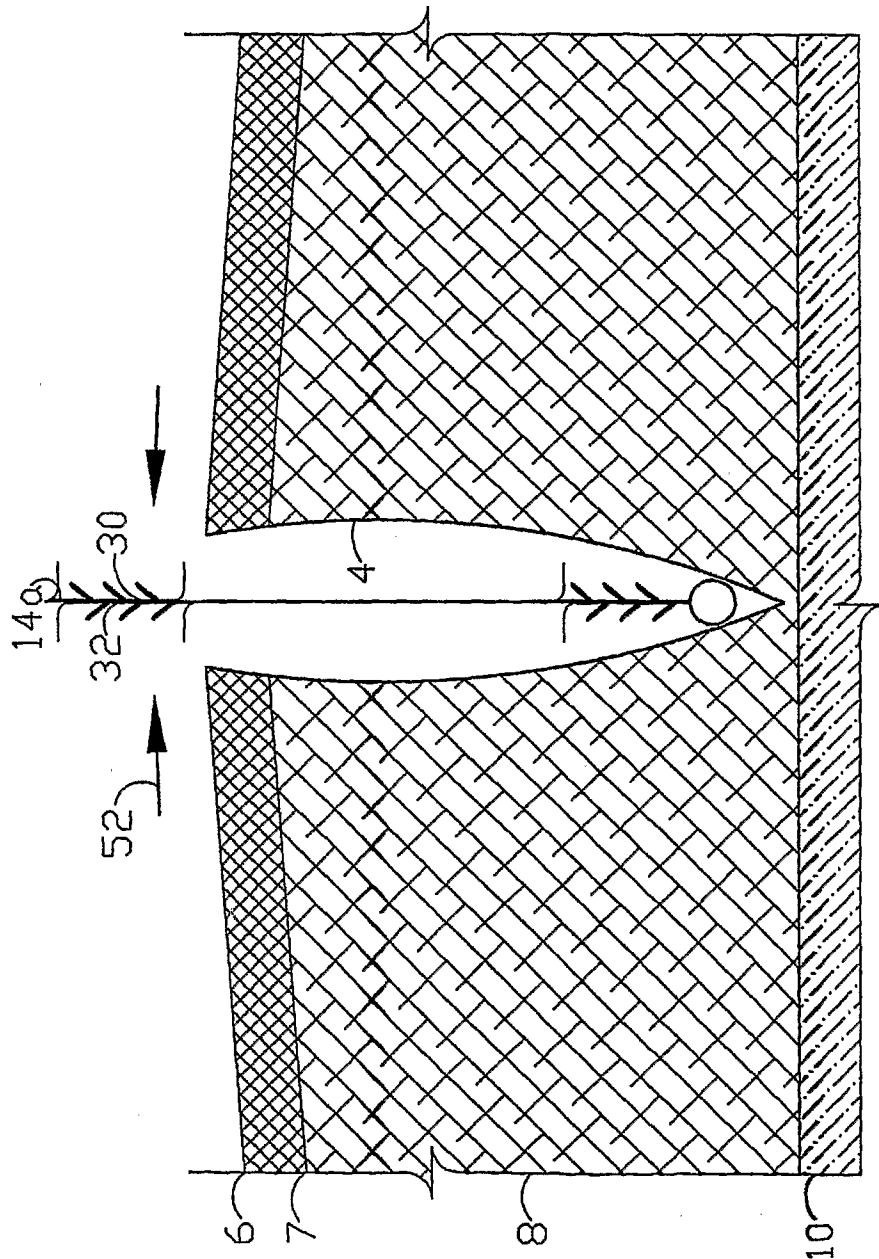


FIG. 5b

6/45

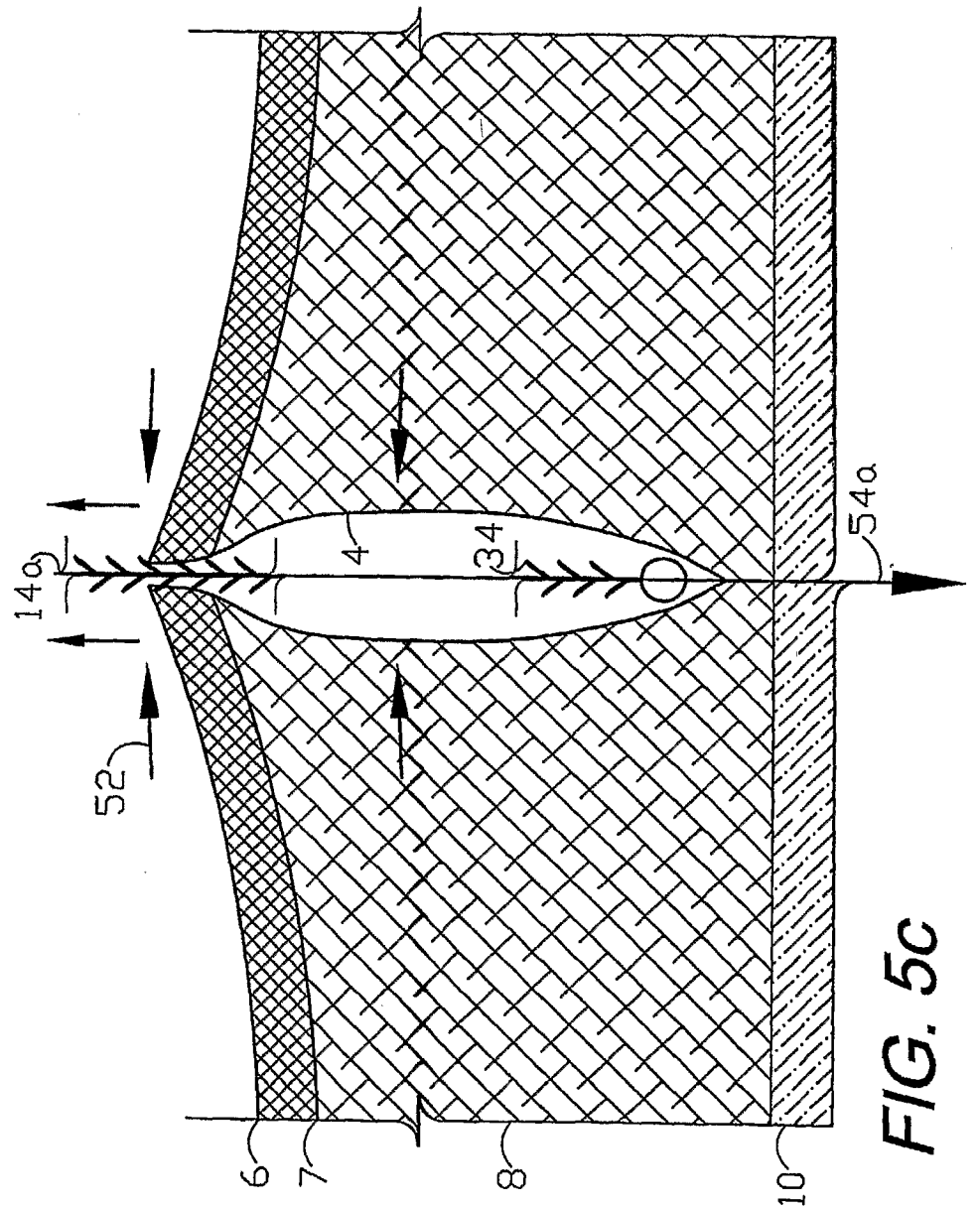


FIG. 5c

7/45

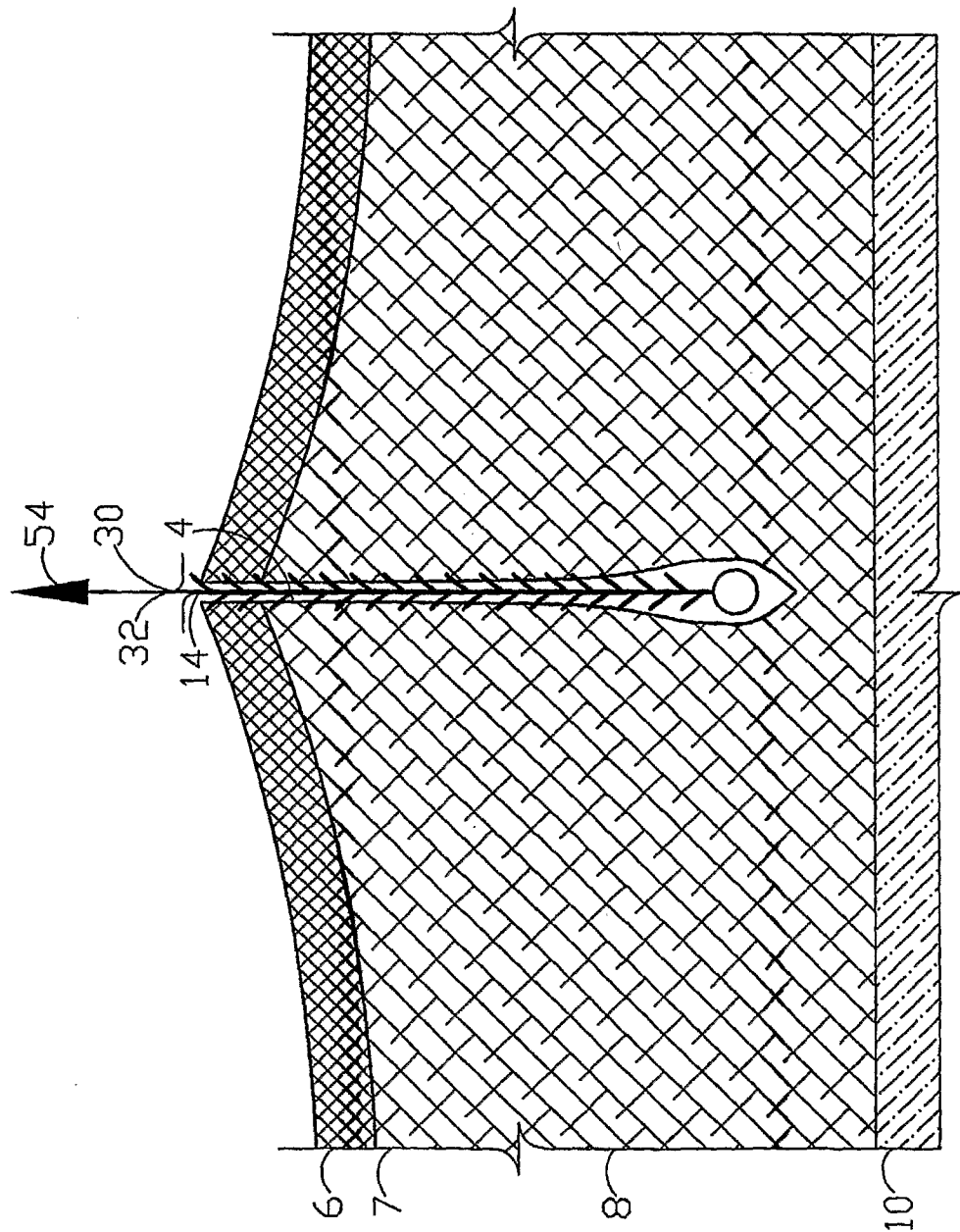


FIG. 5d

8/45

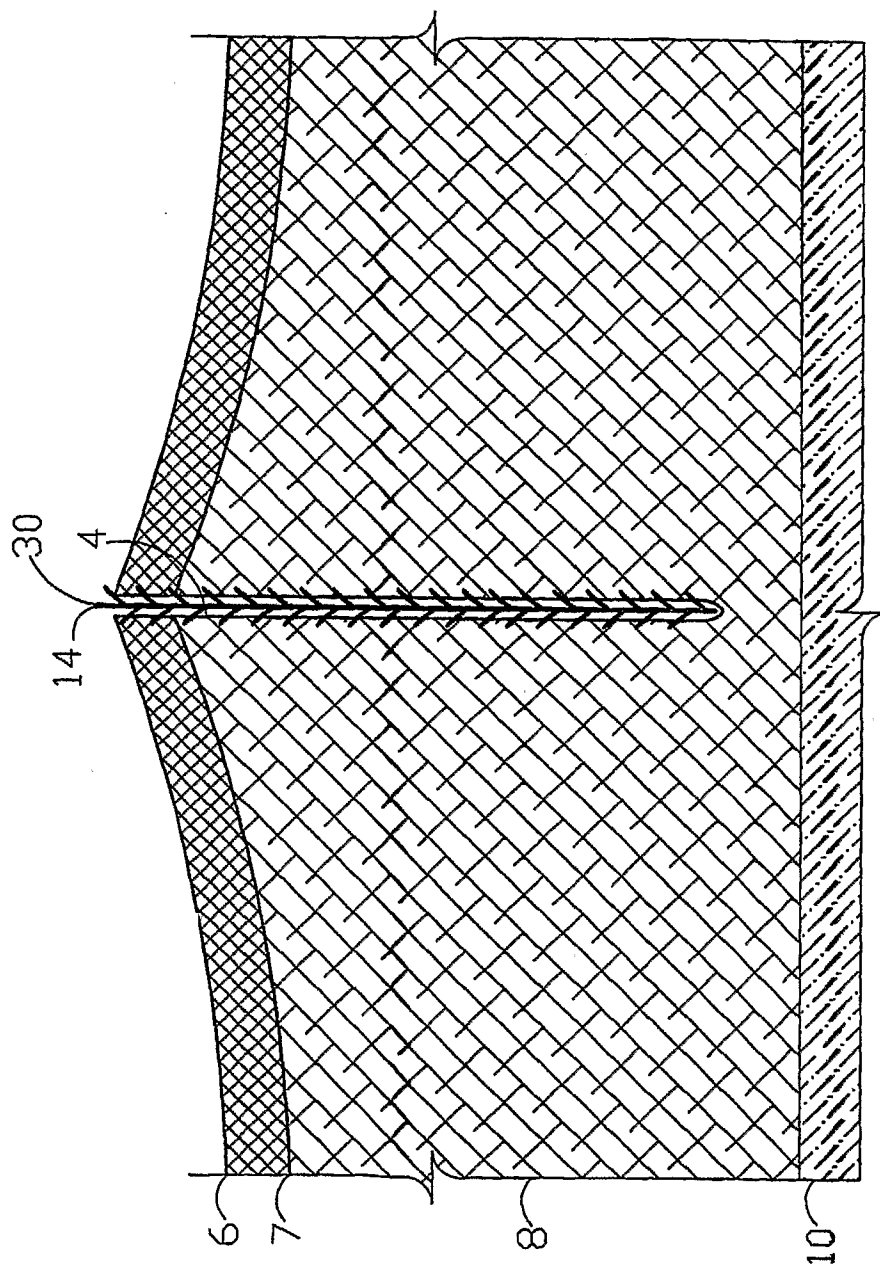


FIG. 5e

9/45

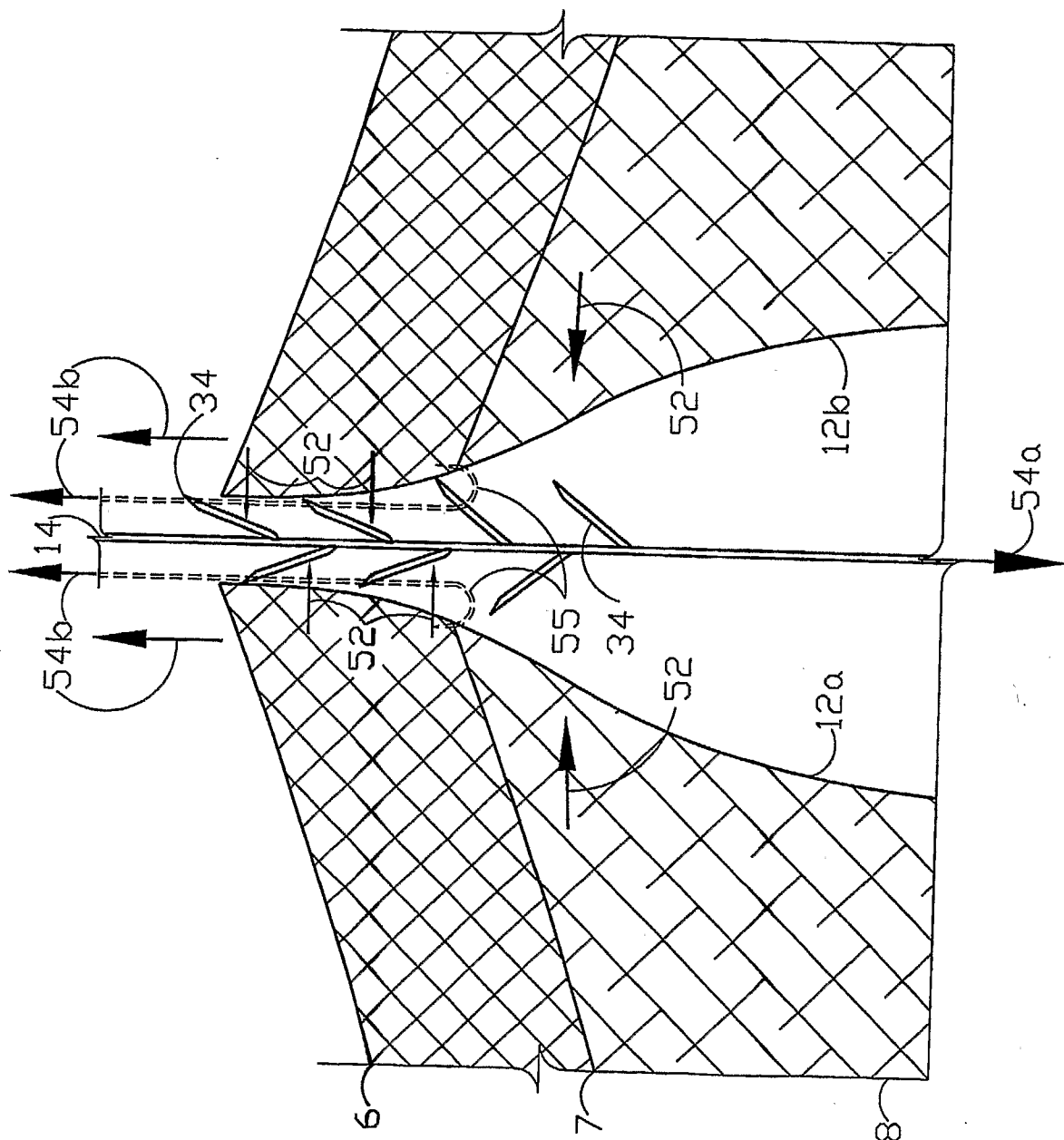


FIG. 6a

10/45

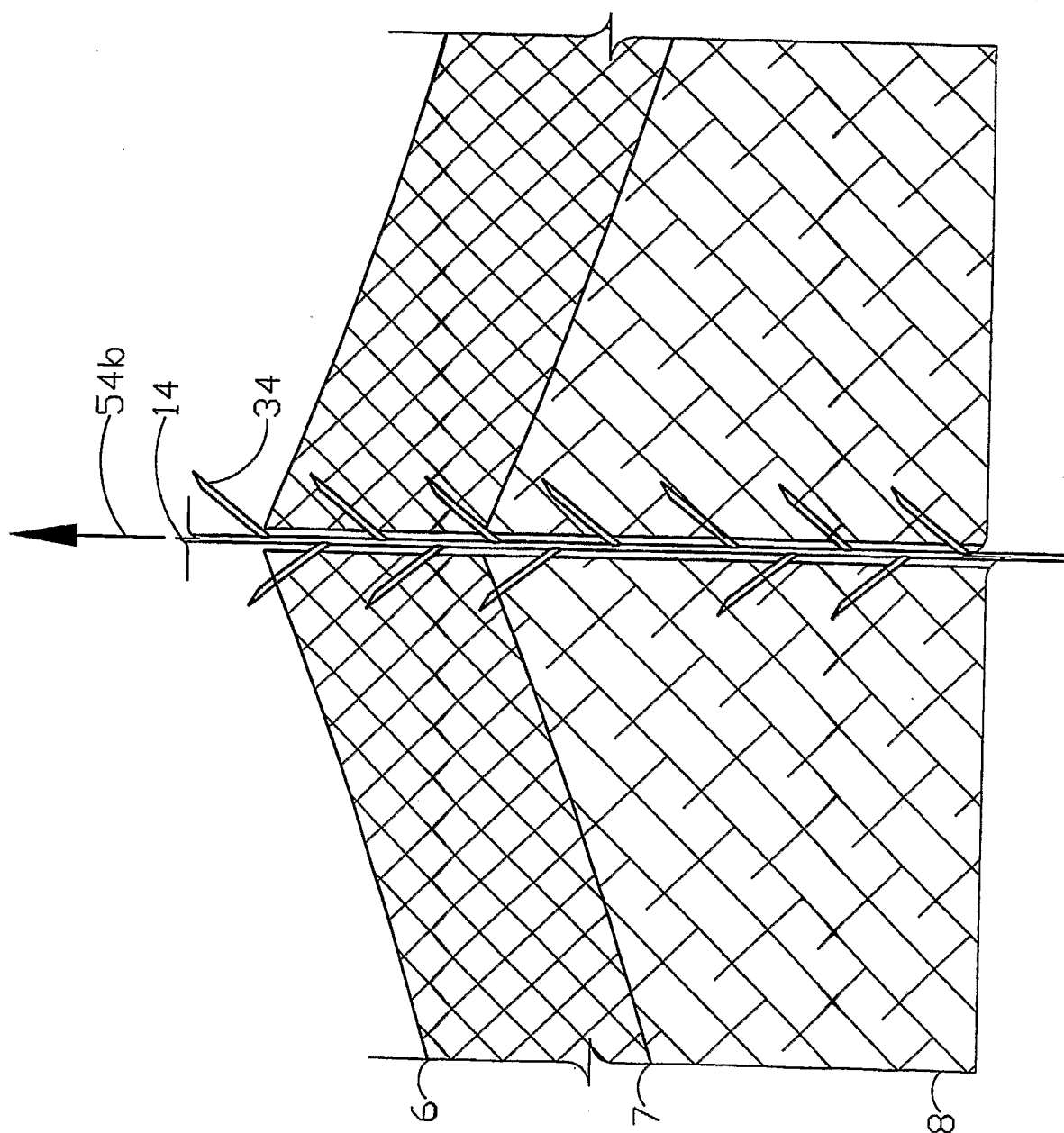


FIG. 6b

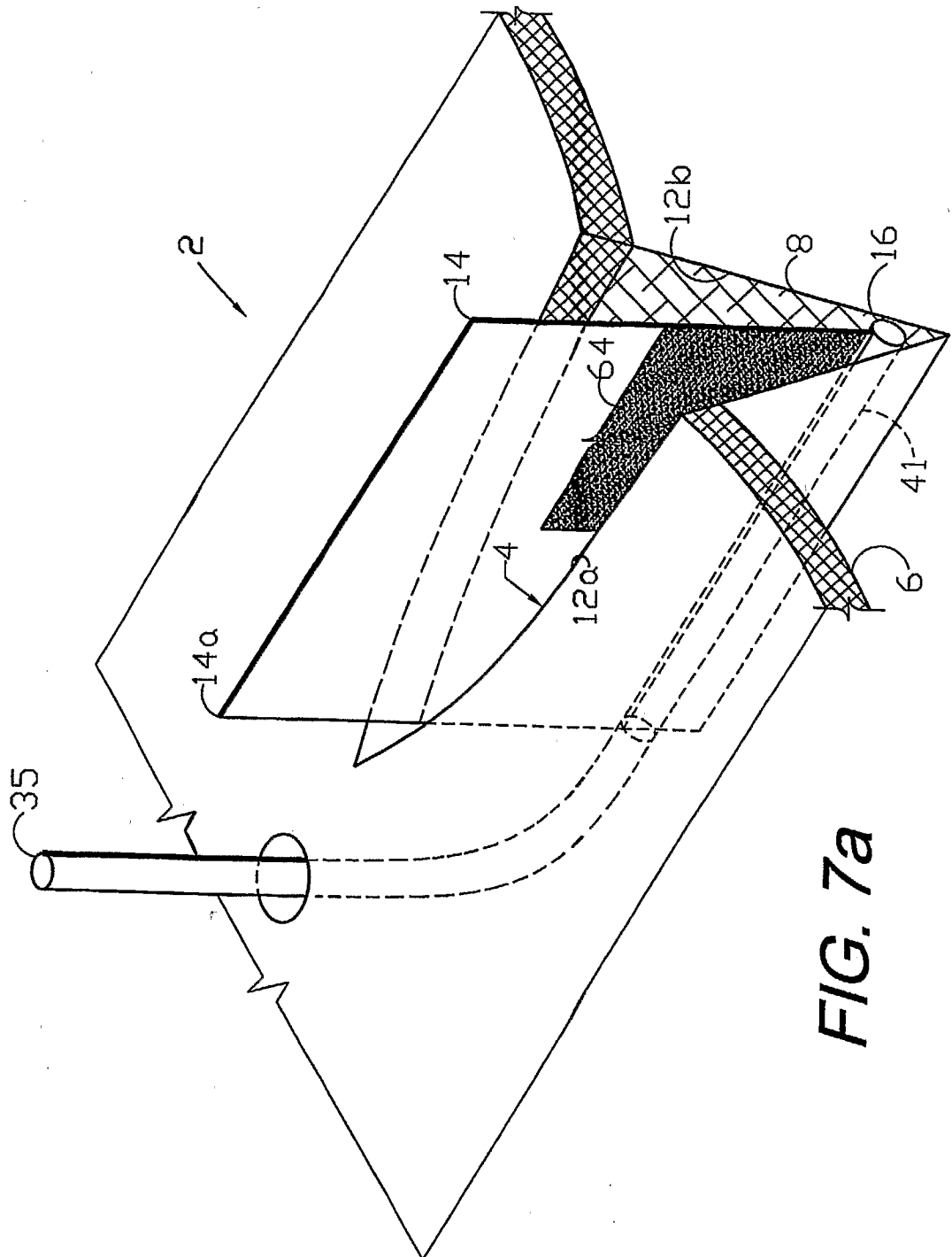


FIG. 7a

12/45

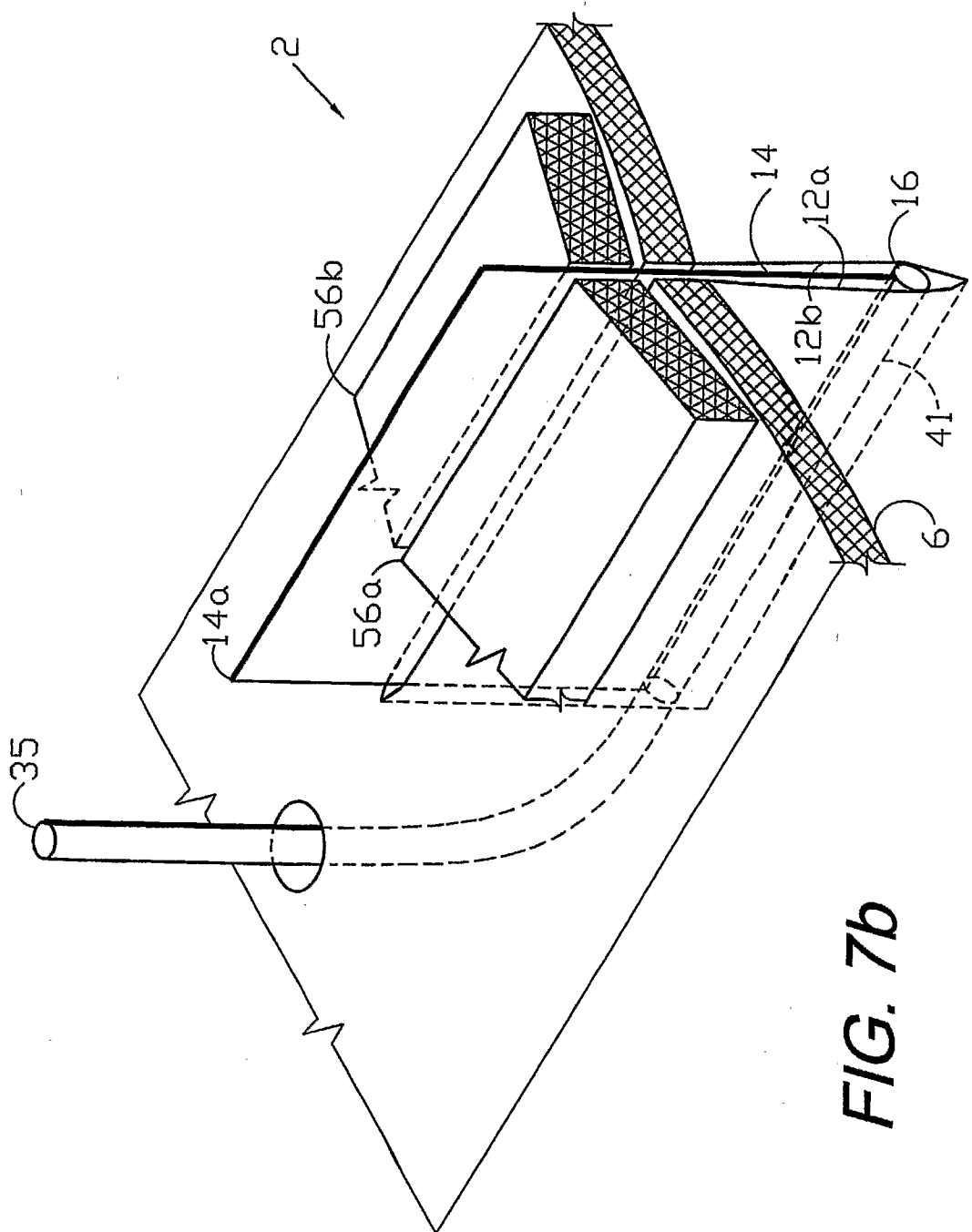


FIG. 7b

13/45

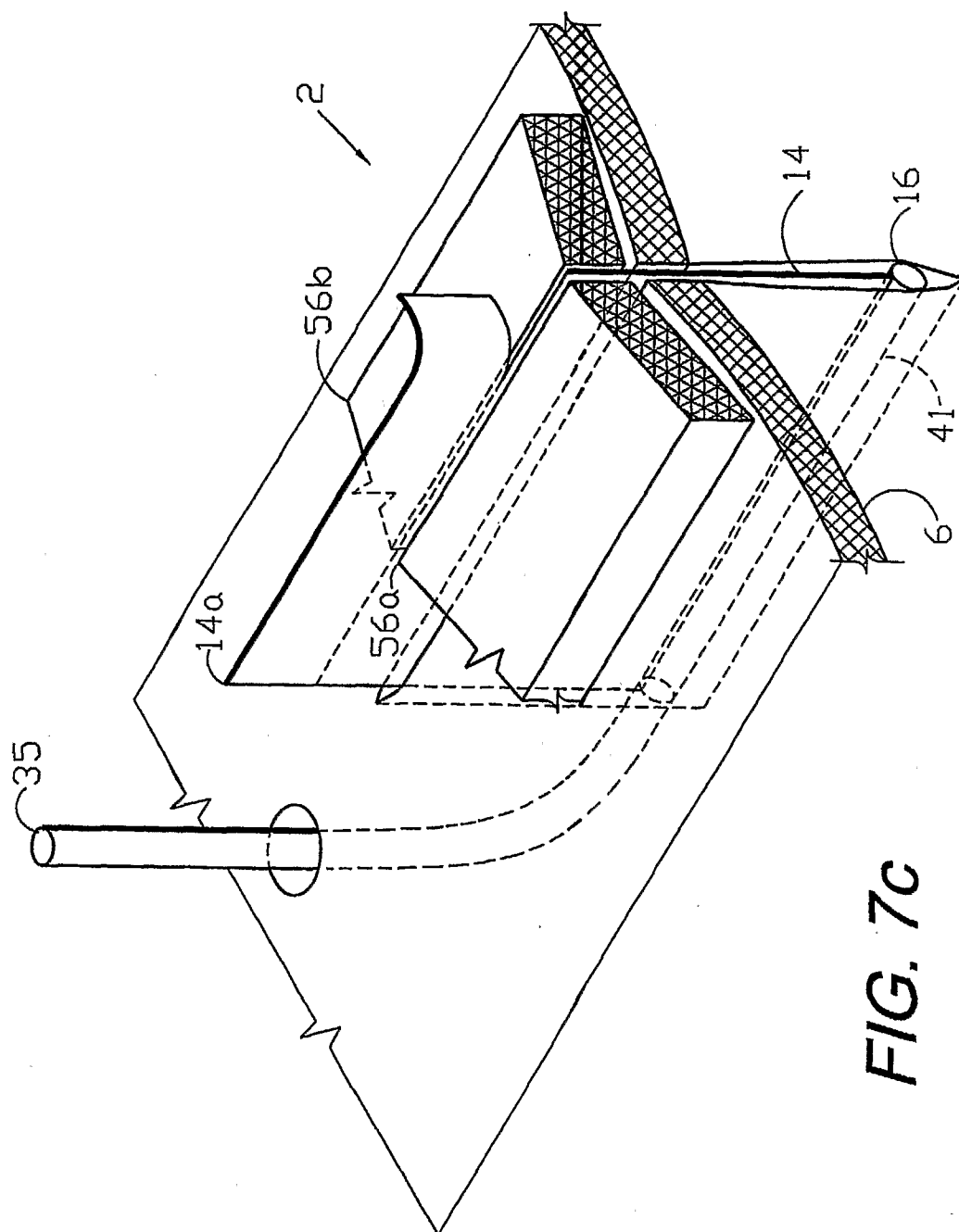


FIG. 7c

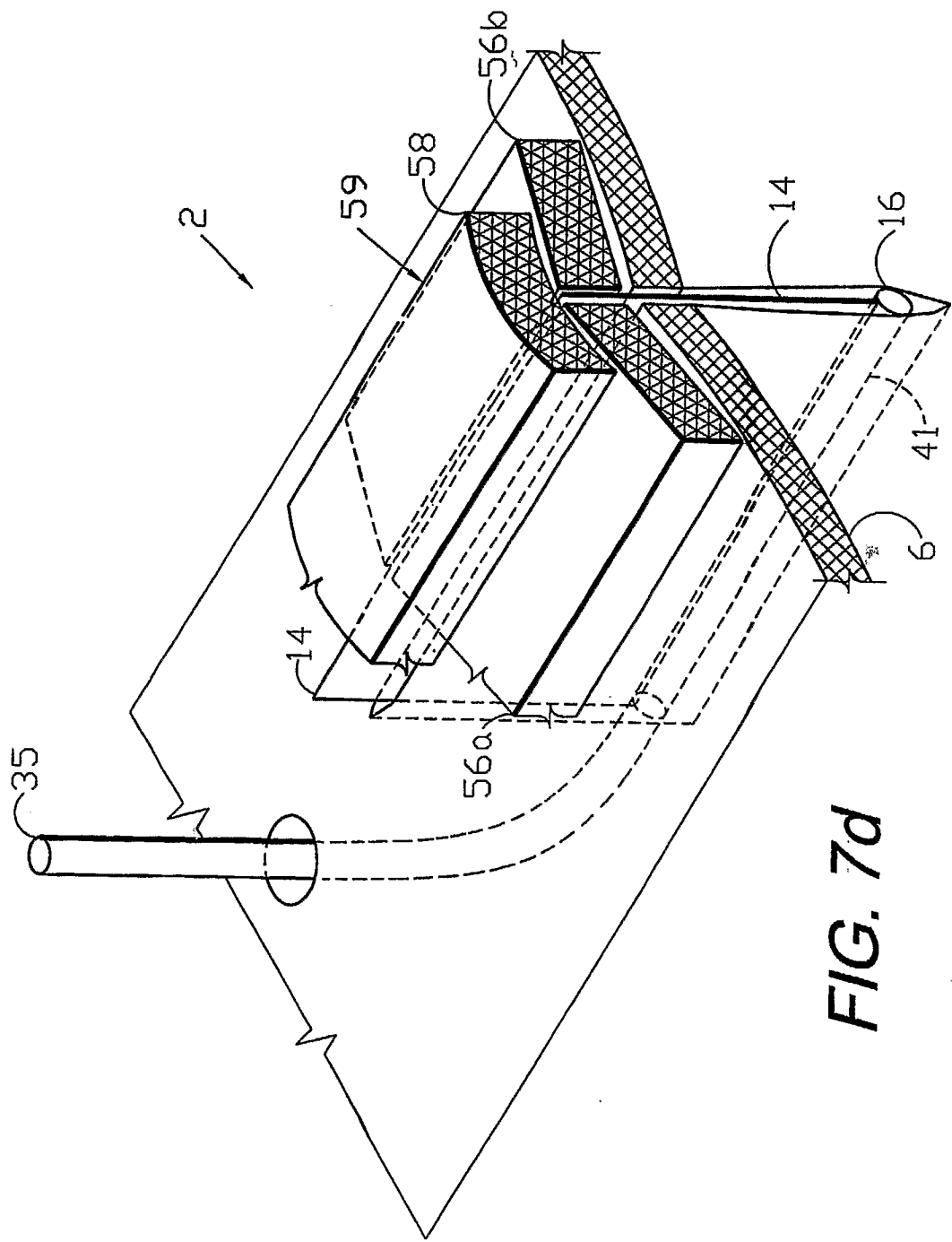


FIG. 7d

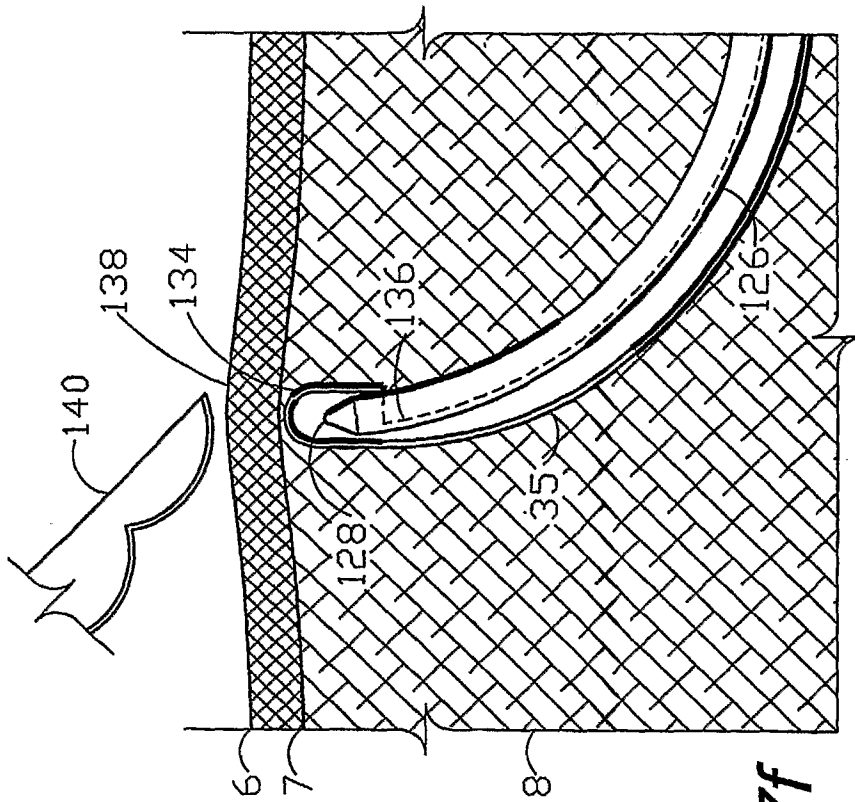


FIG. 7f

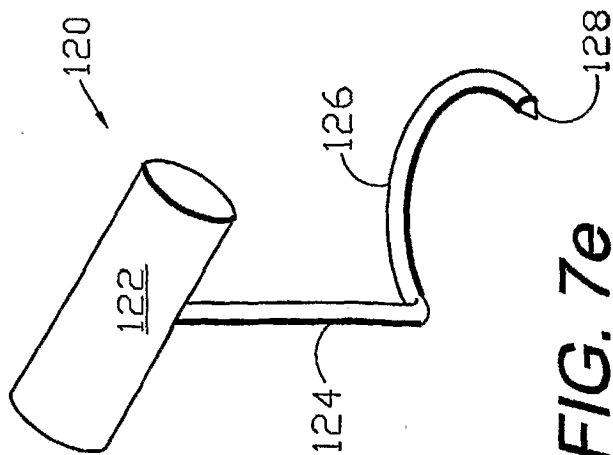


FIG. 7e

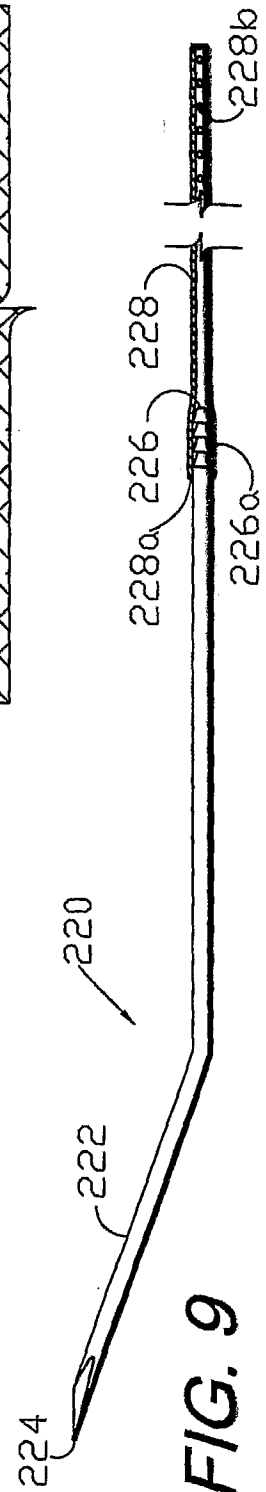
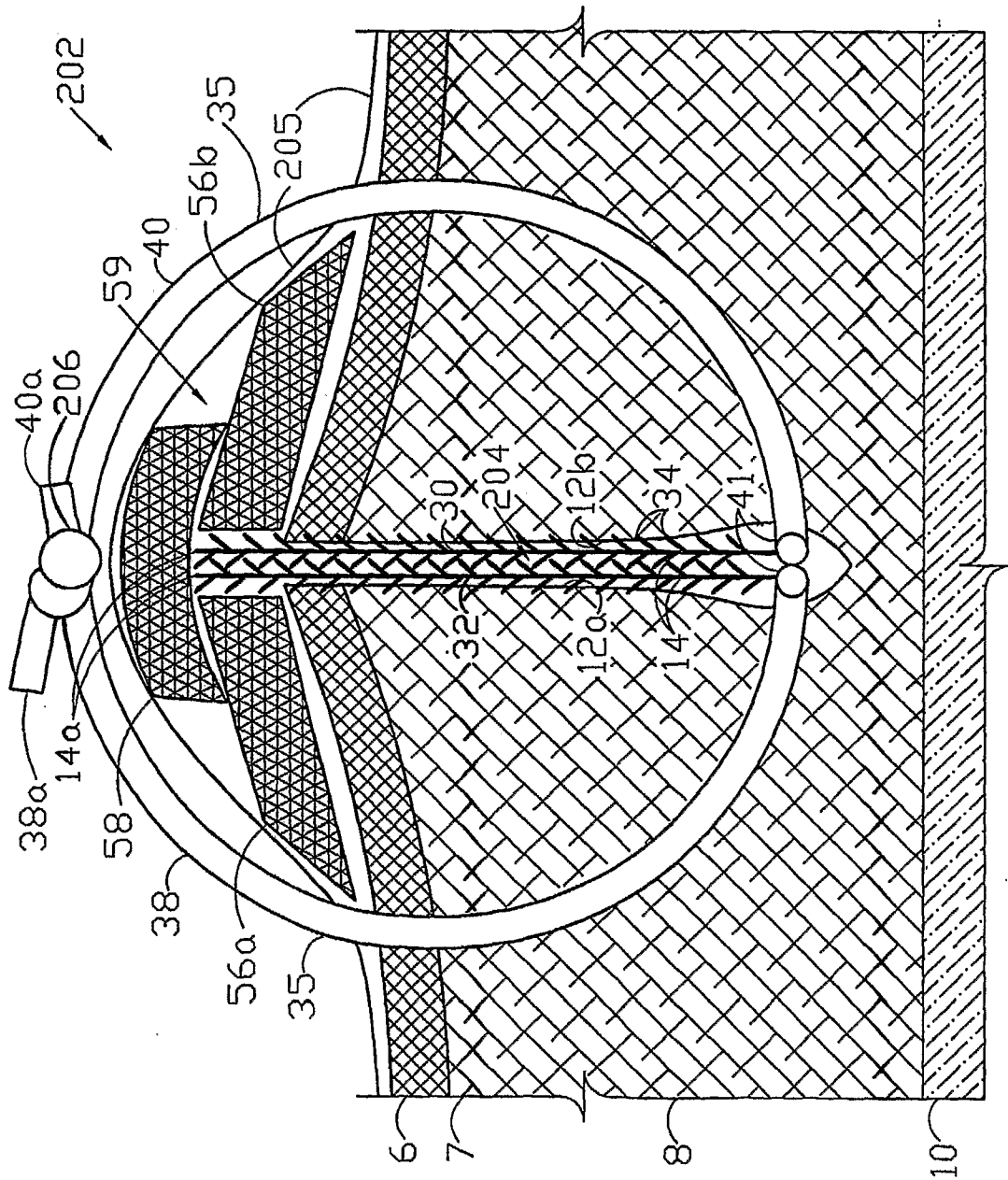


FIG. 9

16/45



17/45

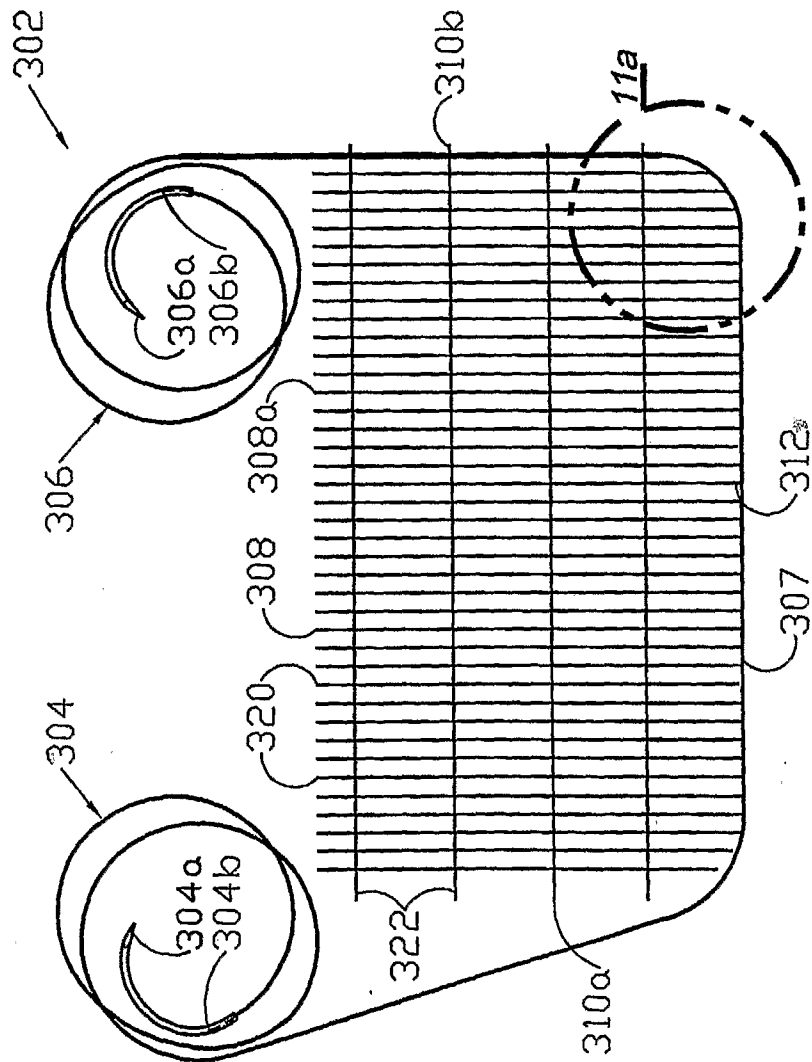


FIG. 10

18/45

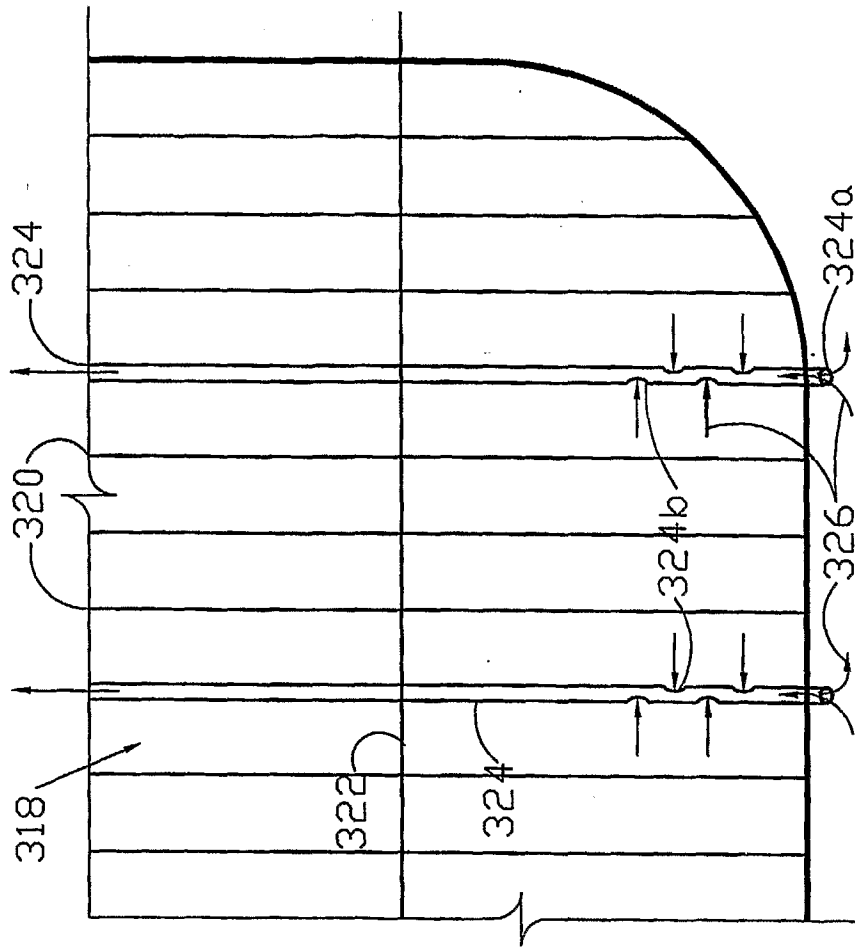


FIG. 11a

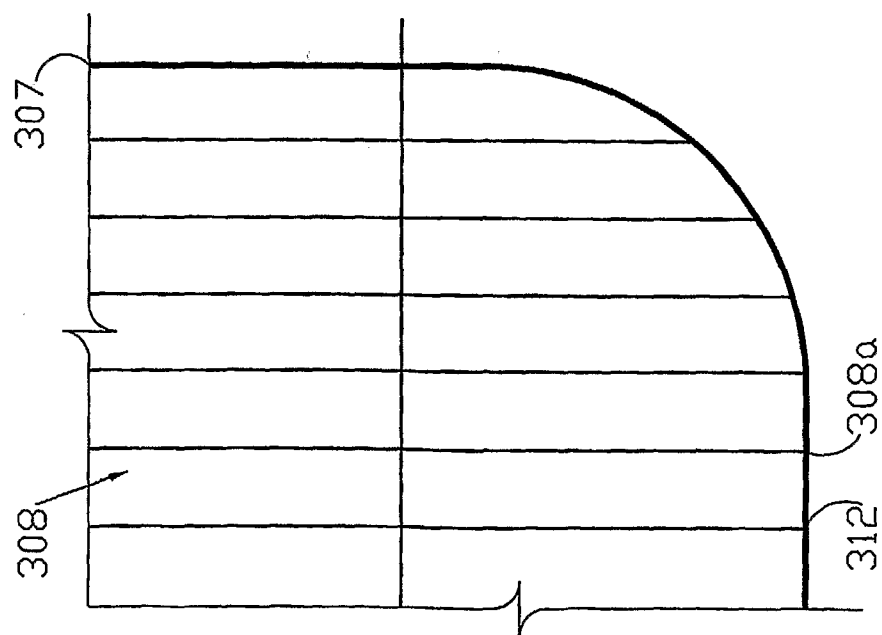


FIG. 11b

19/45

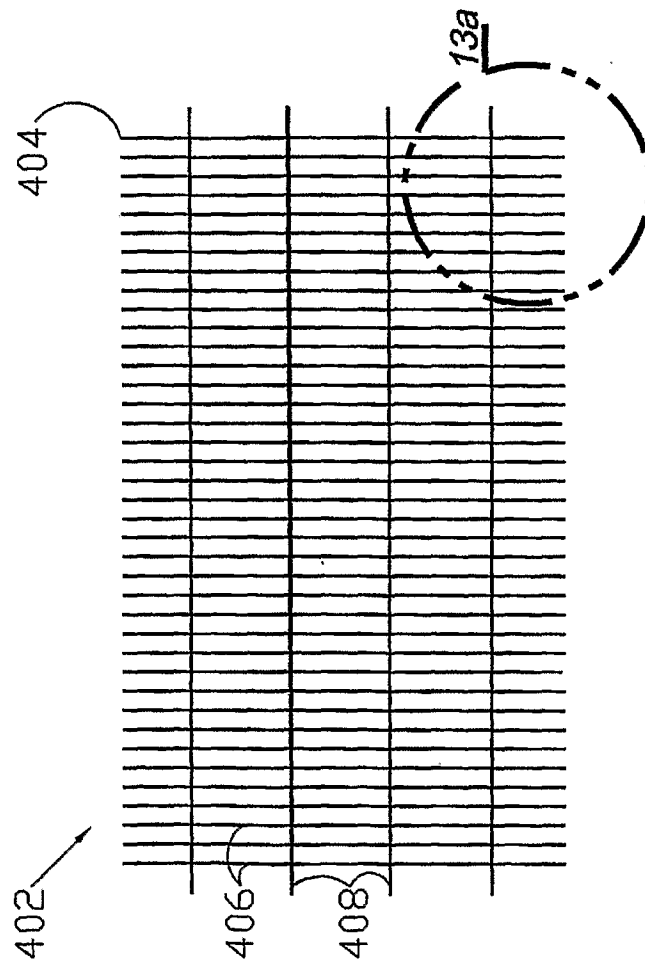


FIG. 12

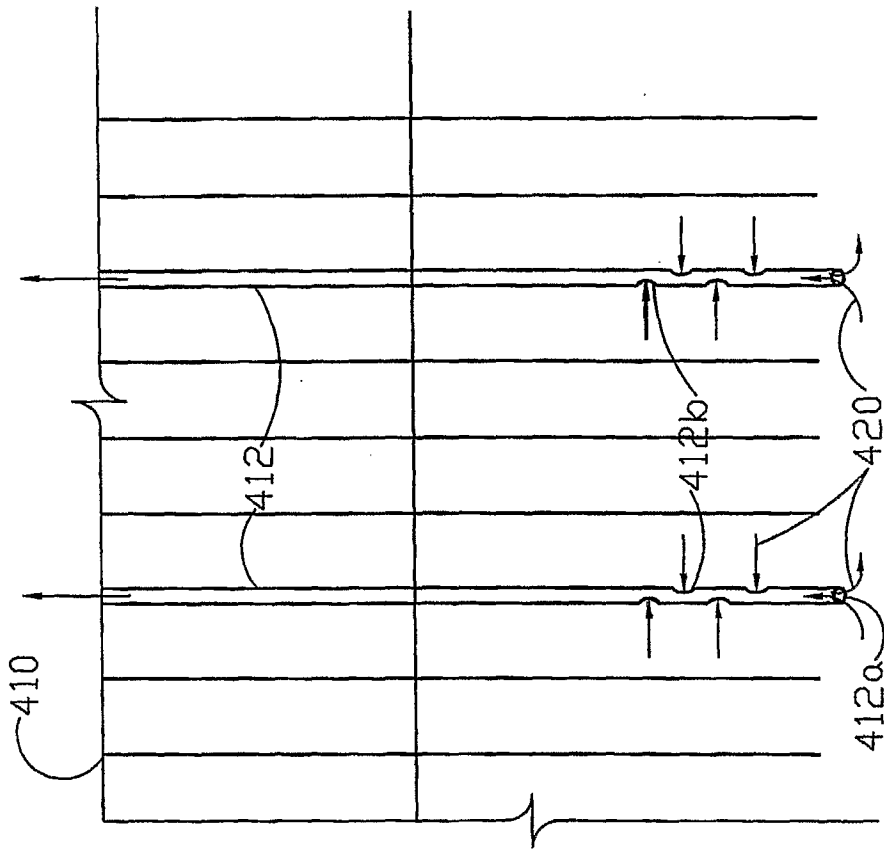


FIG. 13b

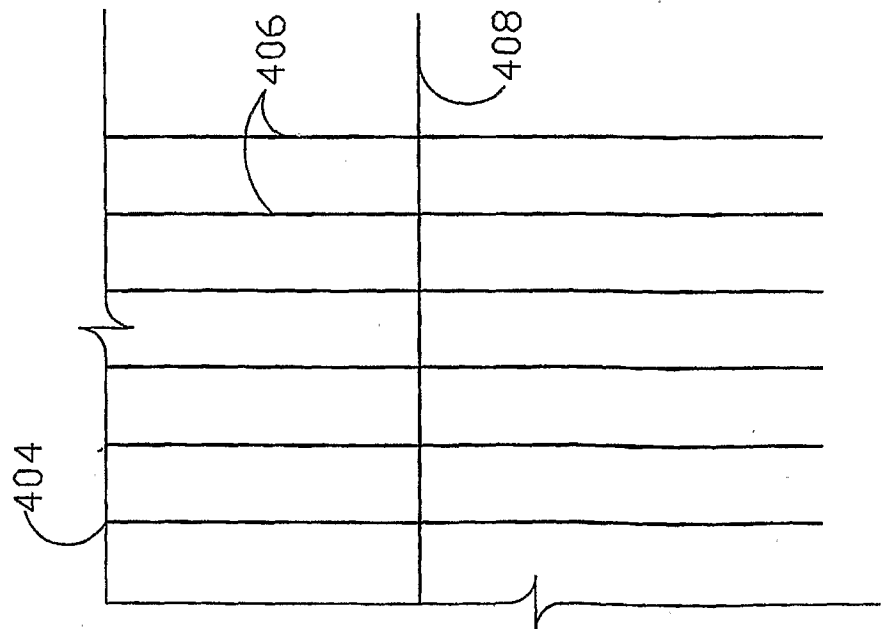


FIG. 13a

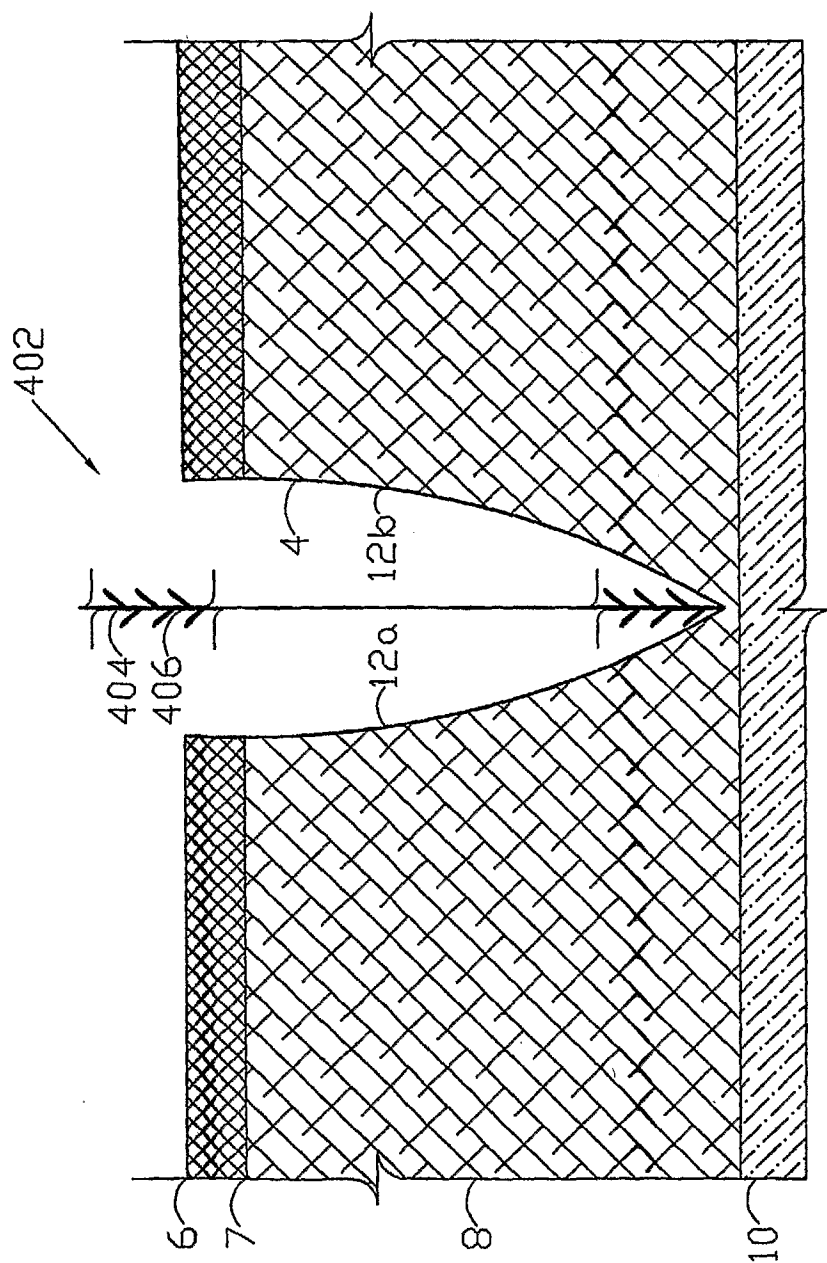


FIG. 14a

22/45

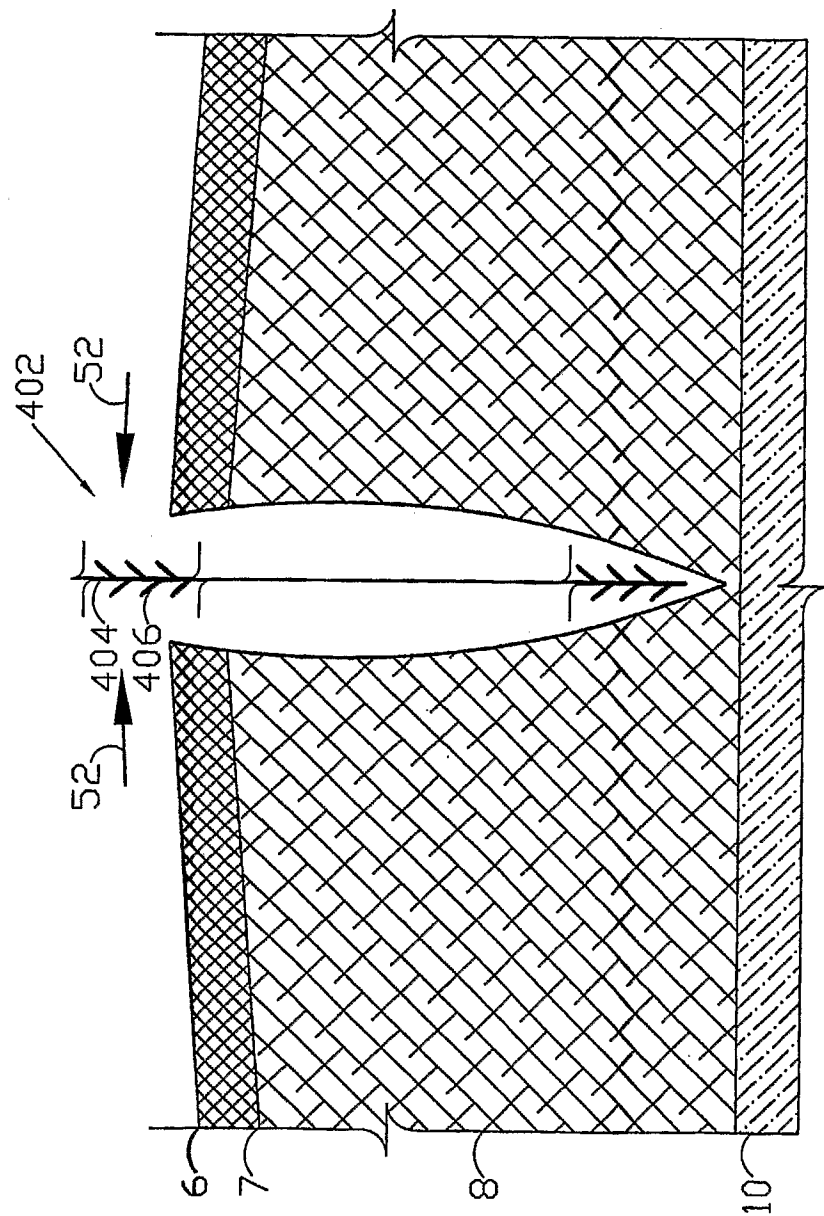


FIG. 14b

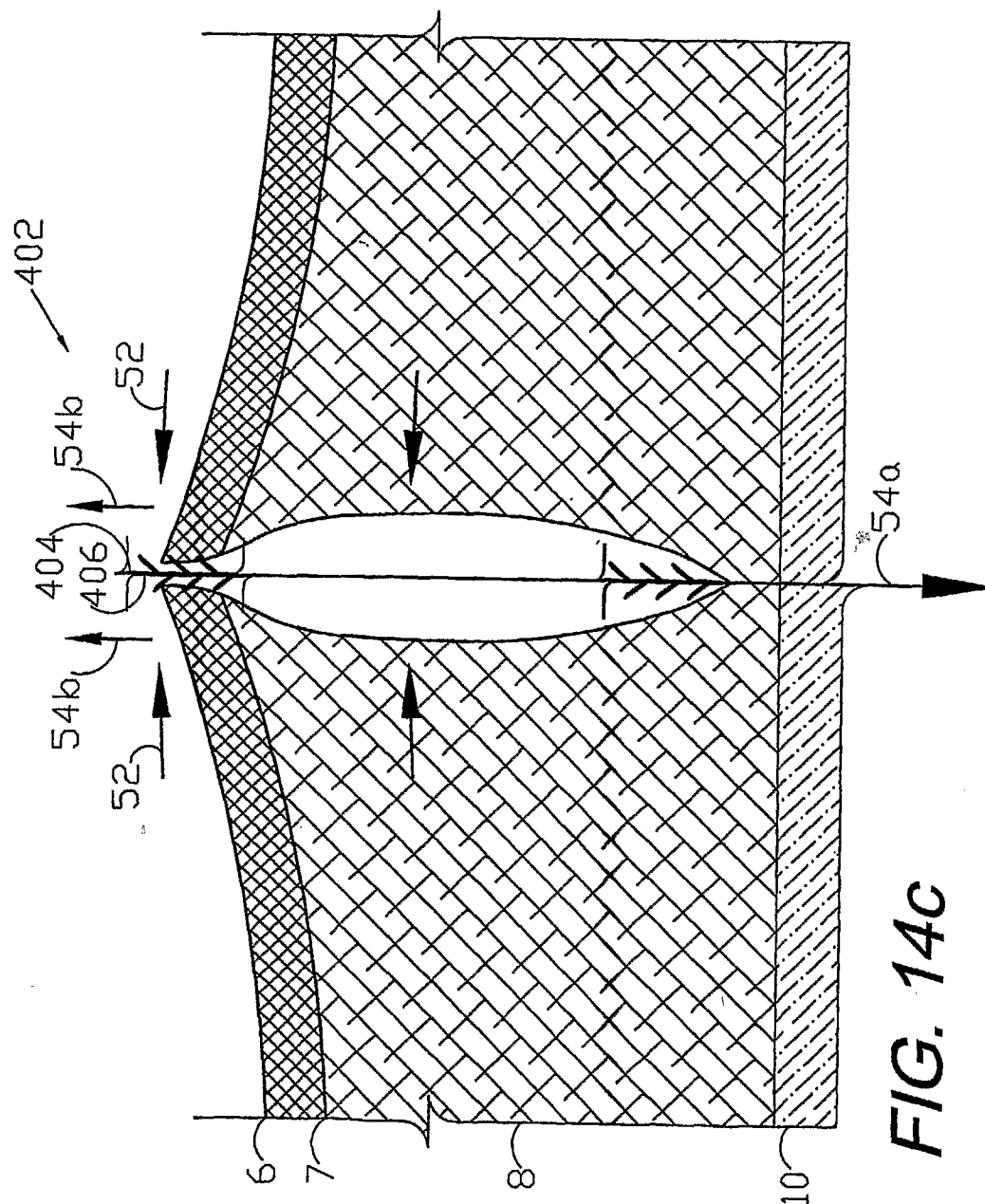


FIG. 14c

24/45

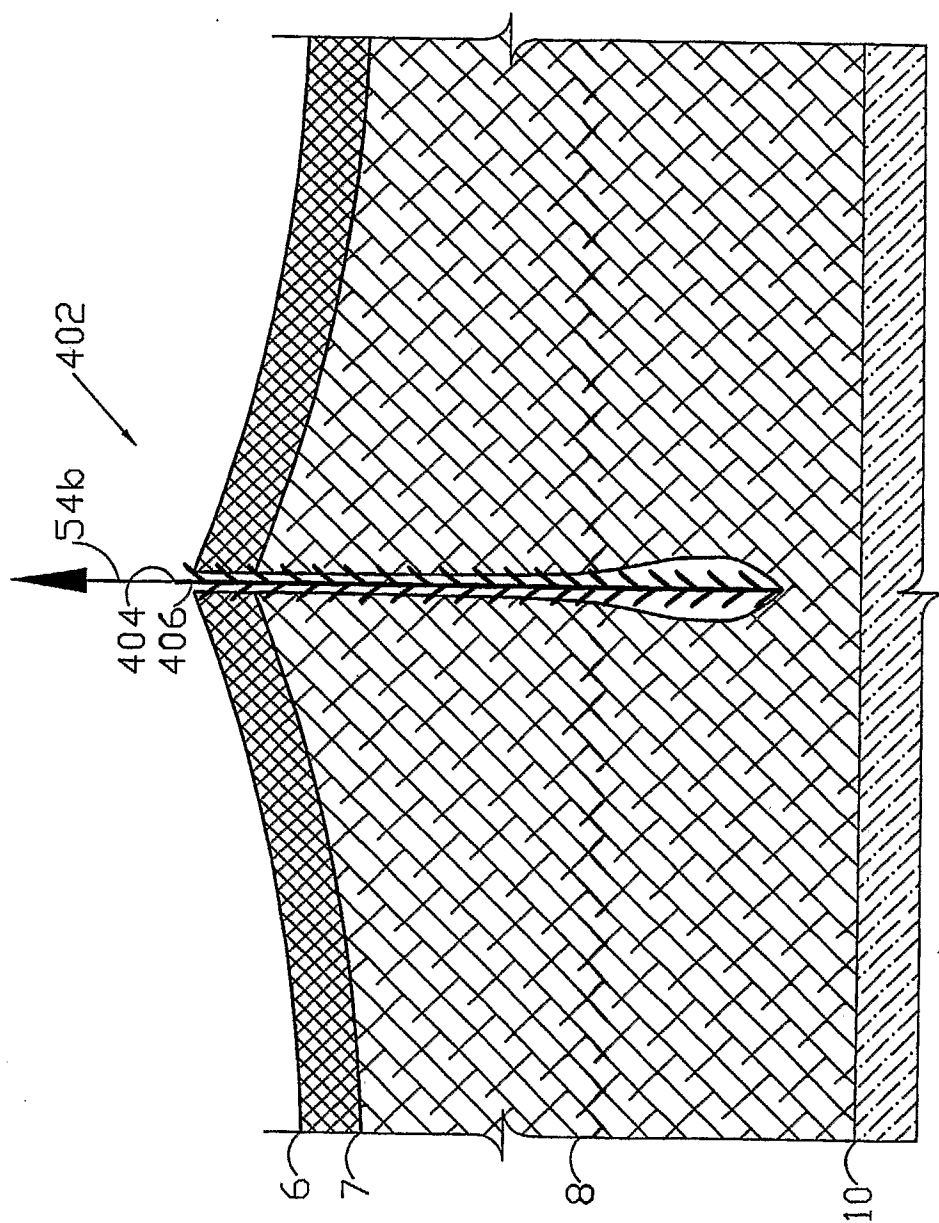


FIG. 14d

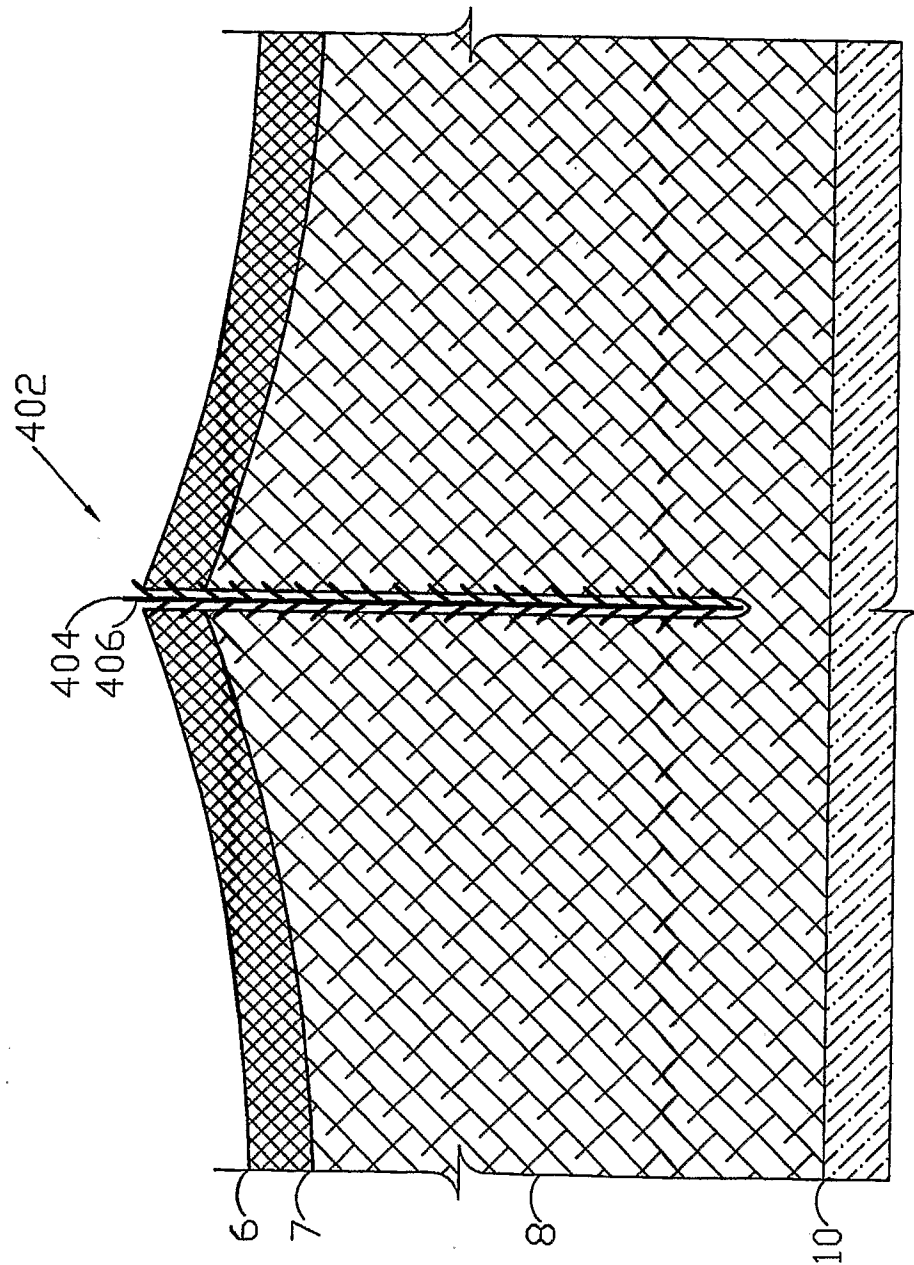


FIG. 14e

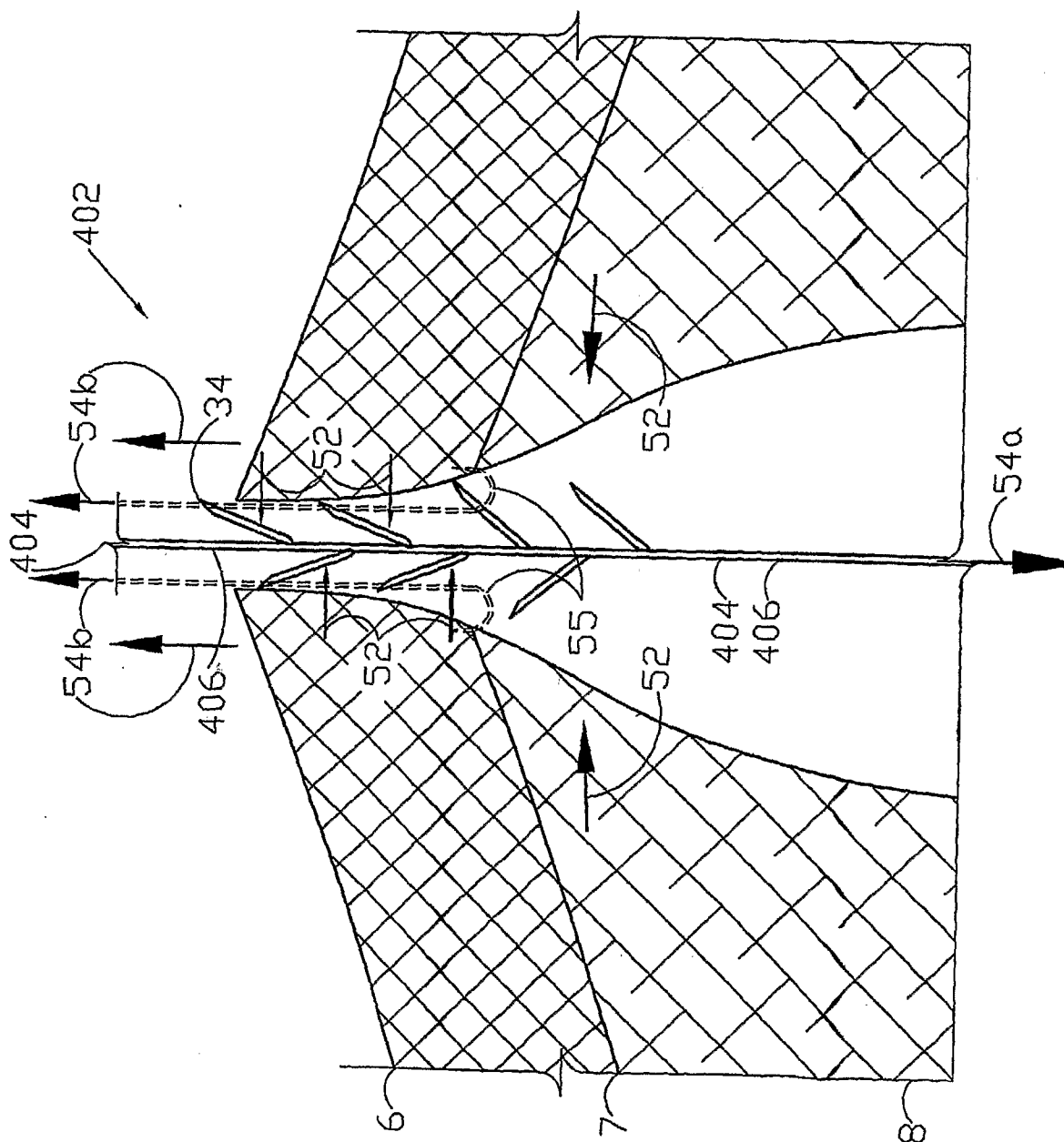
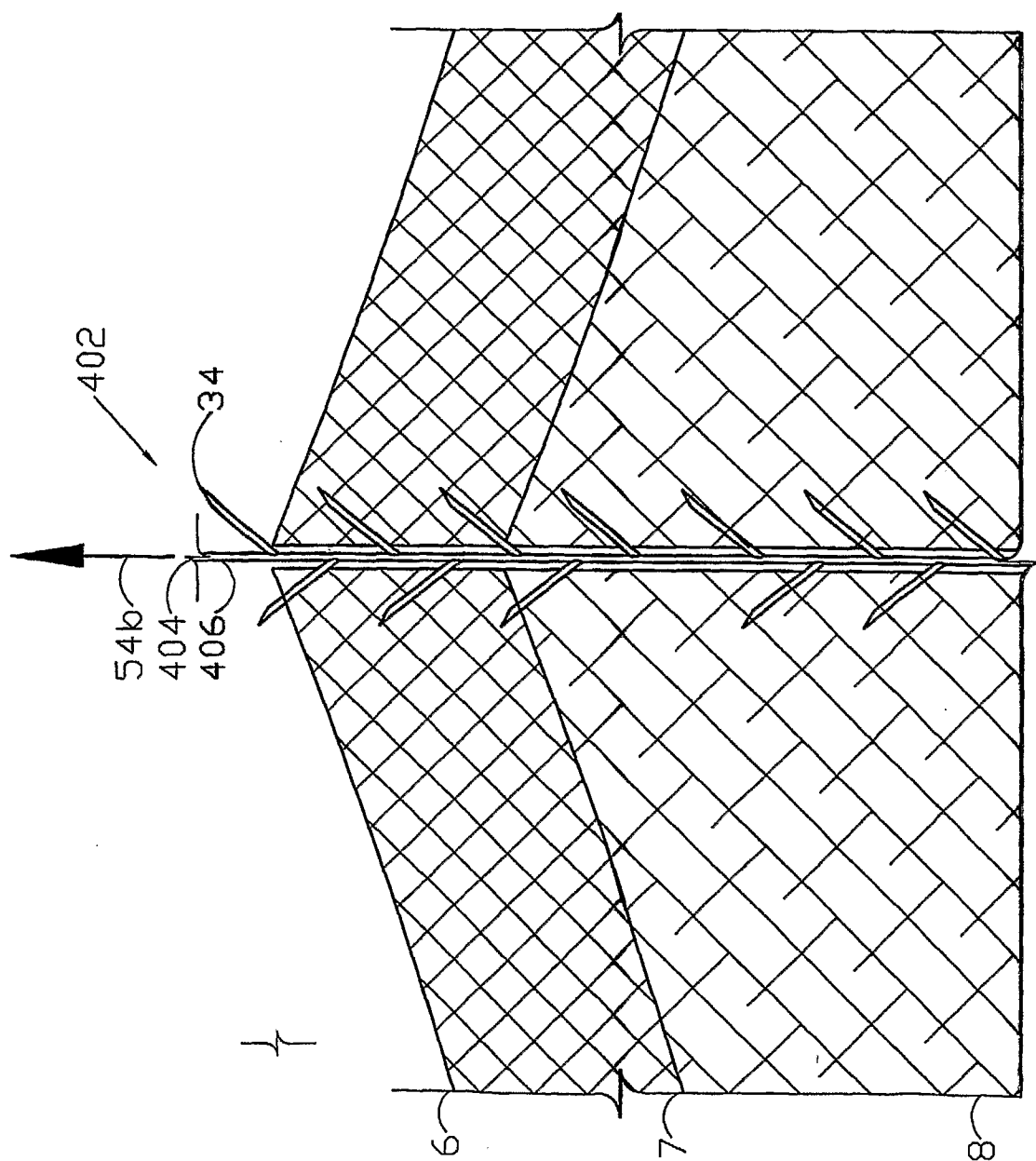


FIG. 14f

27/45

FIG. 14g



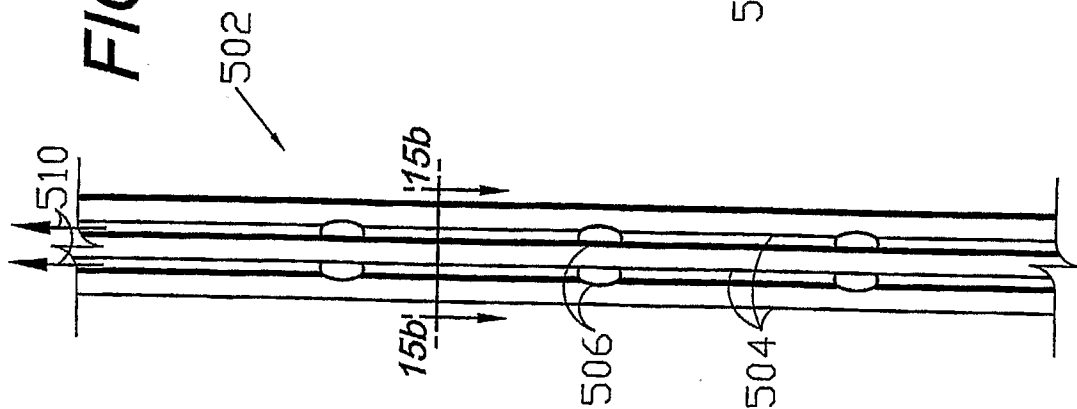


FIG. 15a

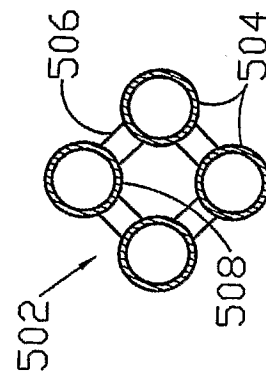


FIG. 15b

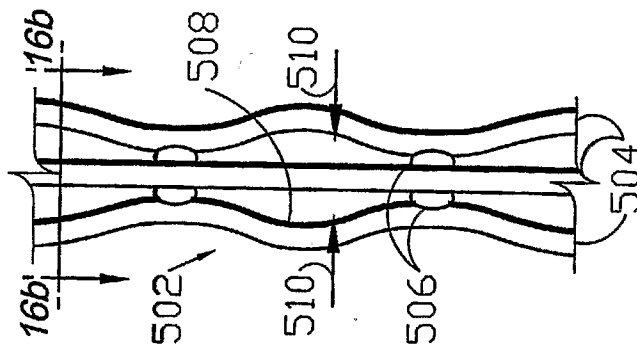


FIG. 16a

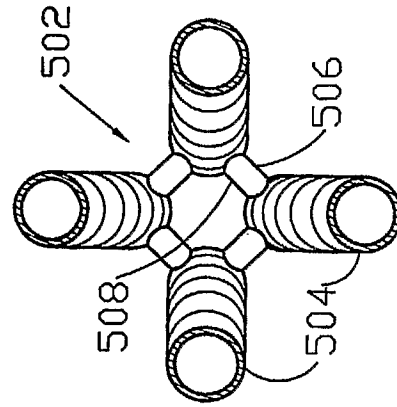


FIG. 16b

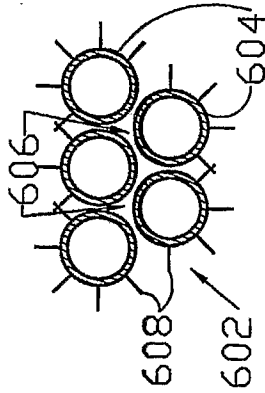


FIG. 17

29/45

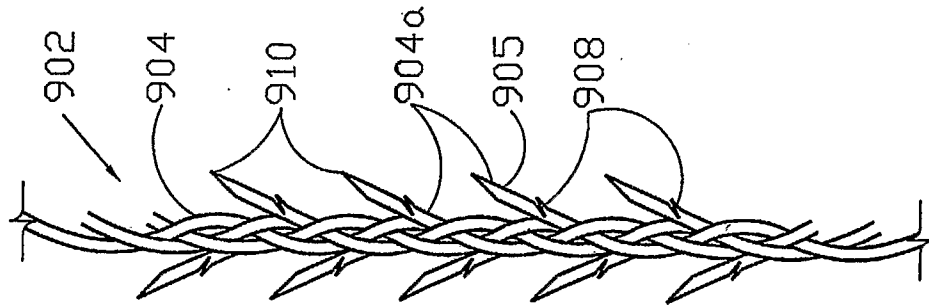


FIG. 20

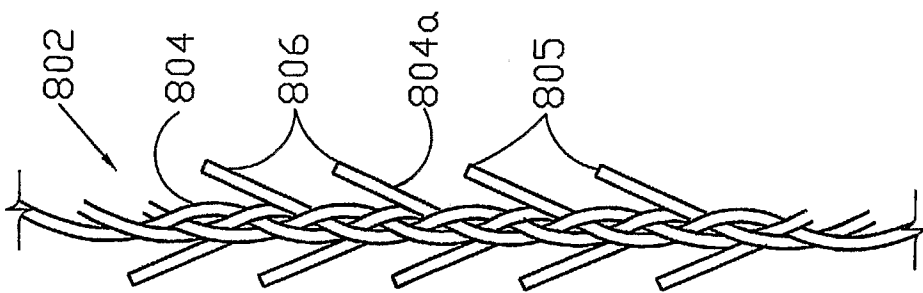


FIG. 19

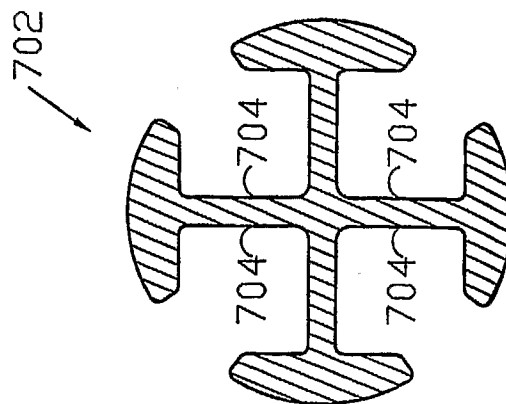


FIG. 18

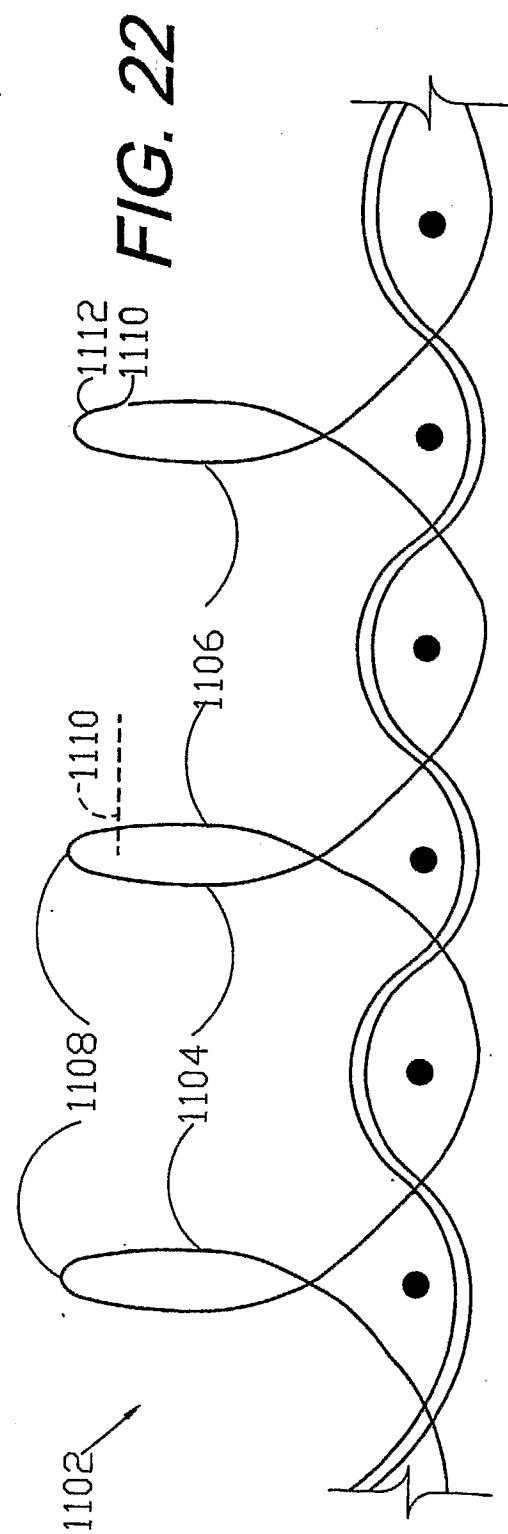
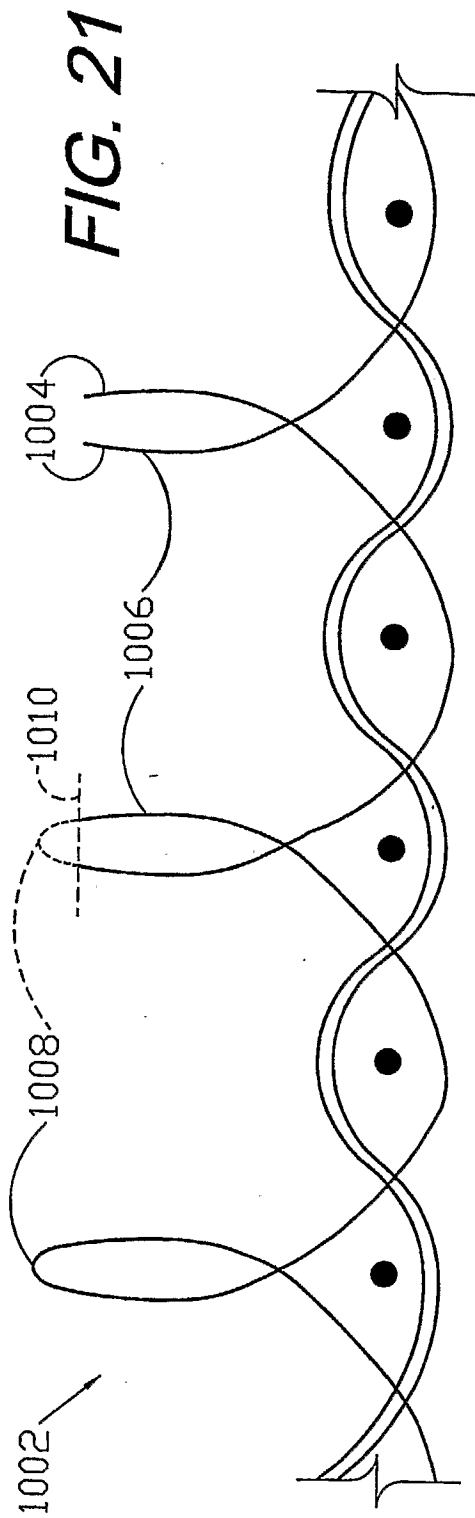


FIG. 23

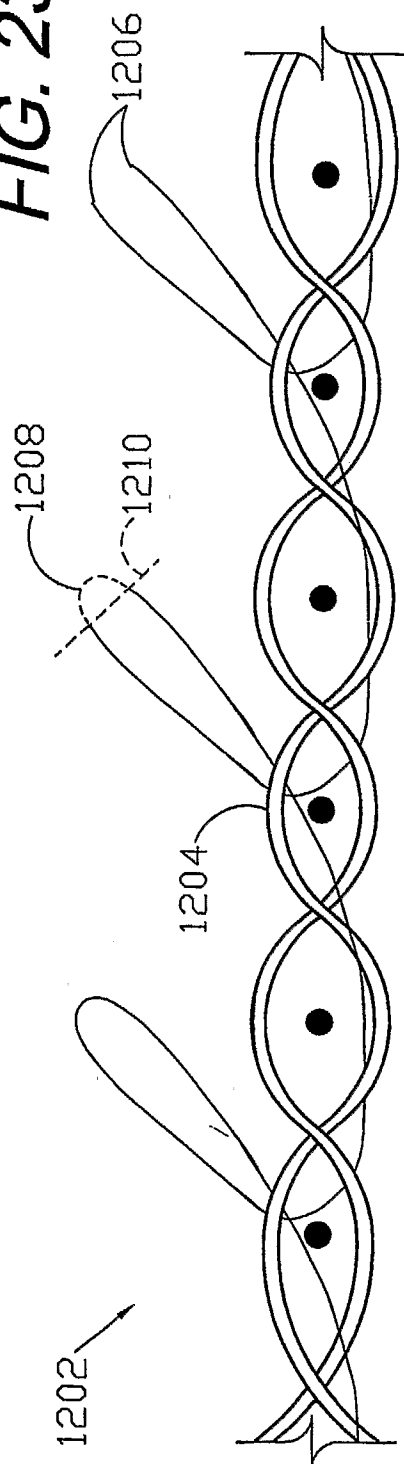
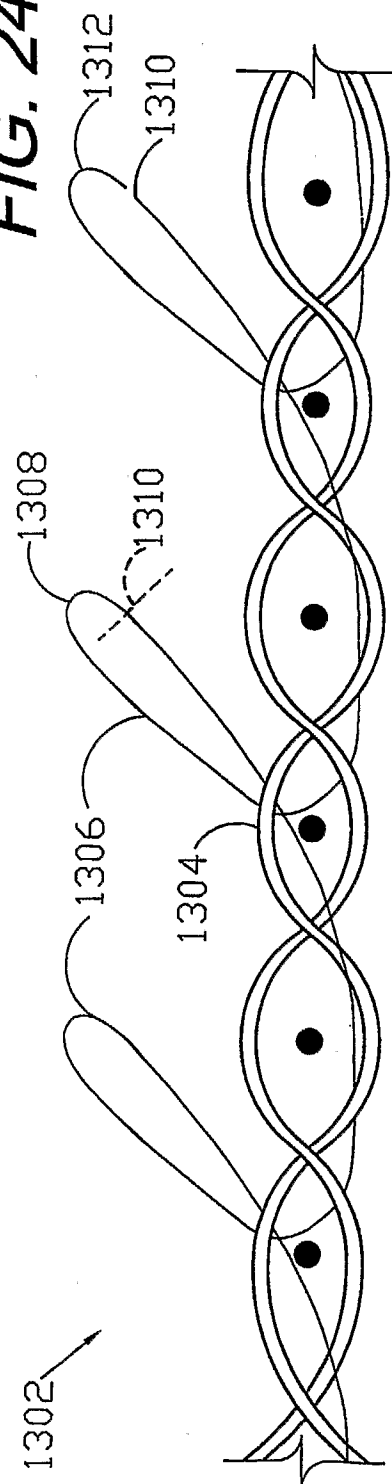


FIG. 24



32/45

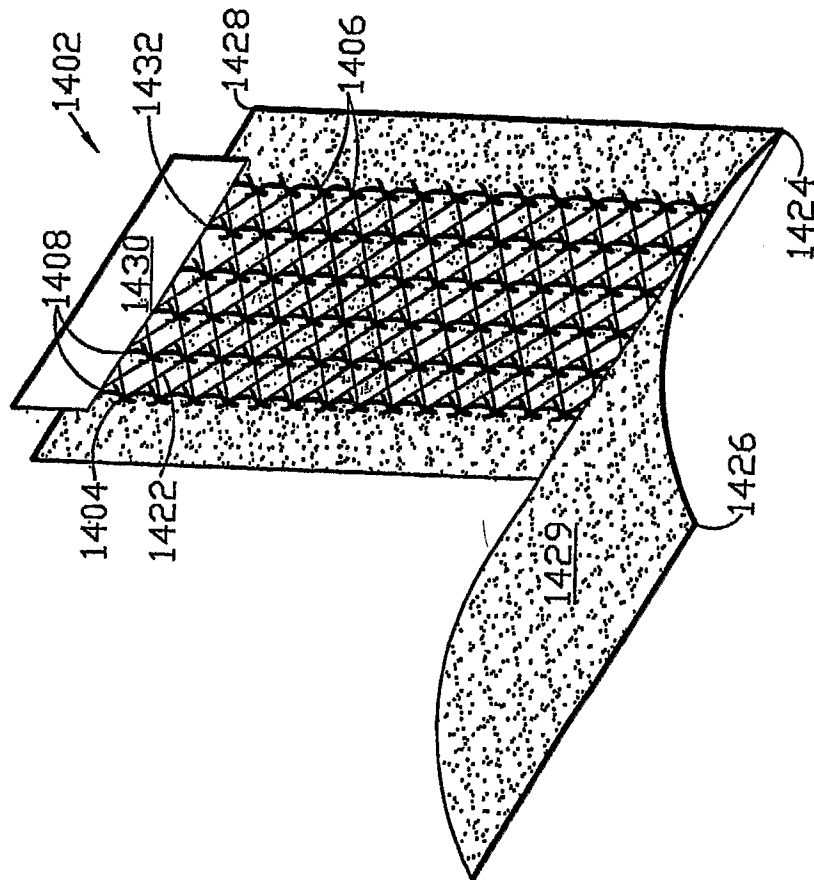


FIG. 25

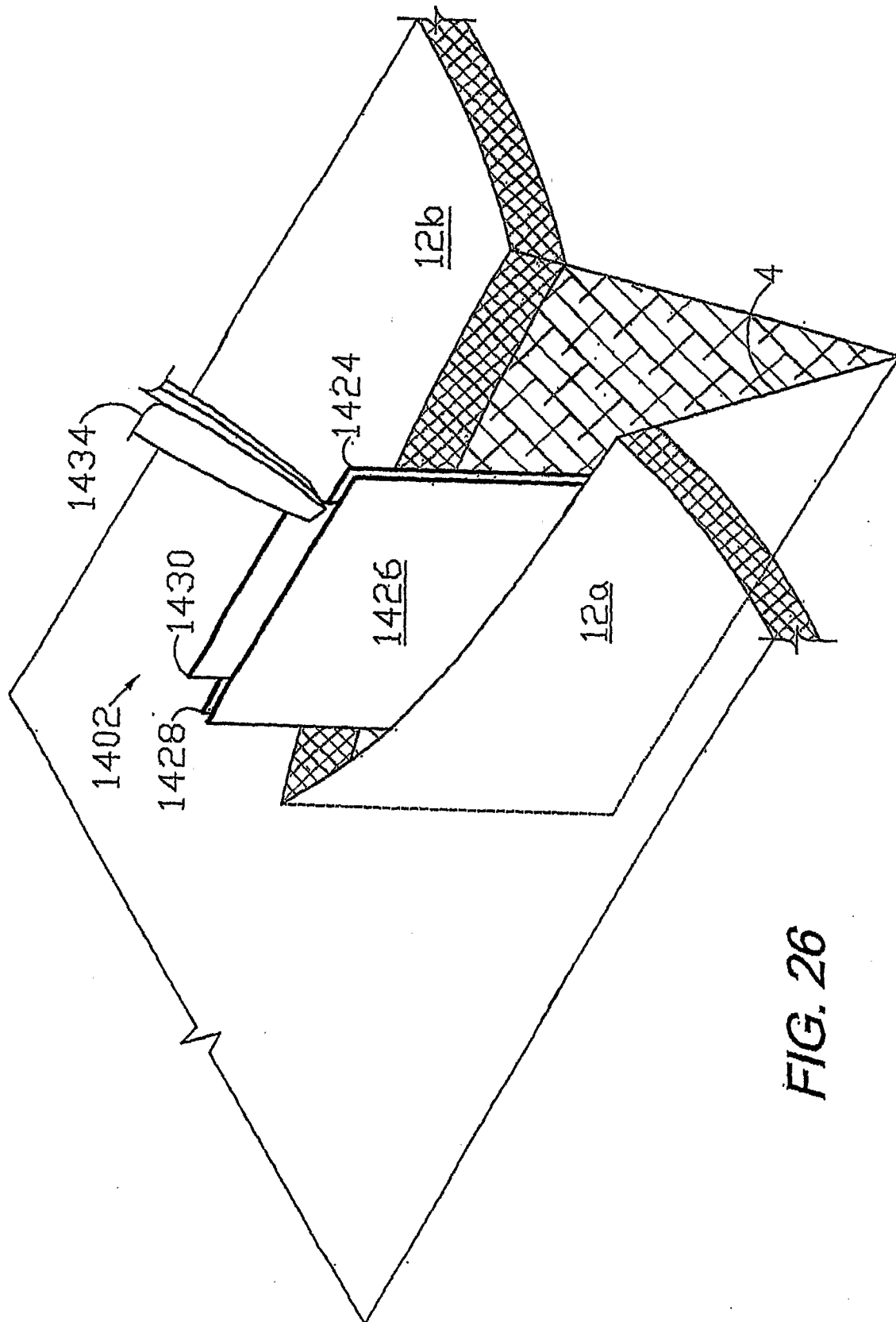


FIG. 26

34/45

FIG. 27

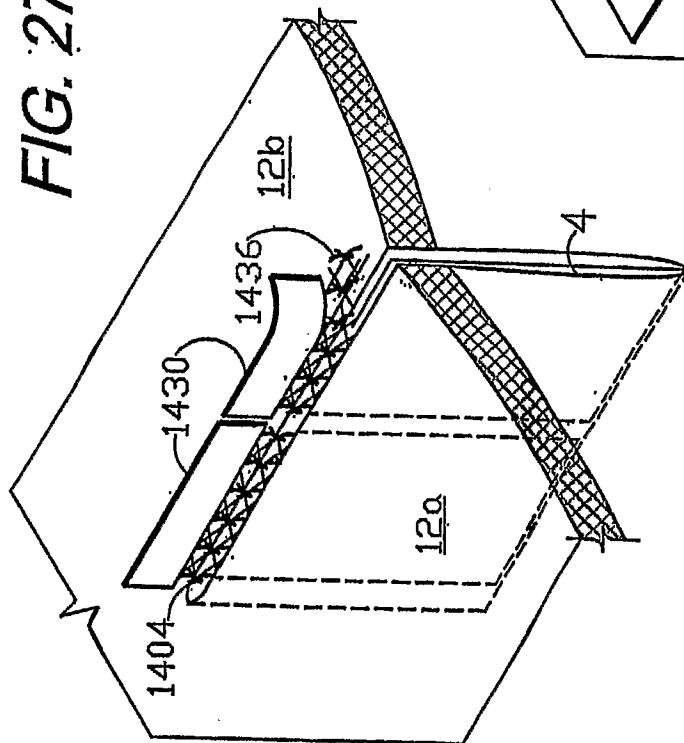
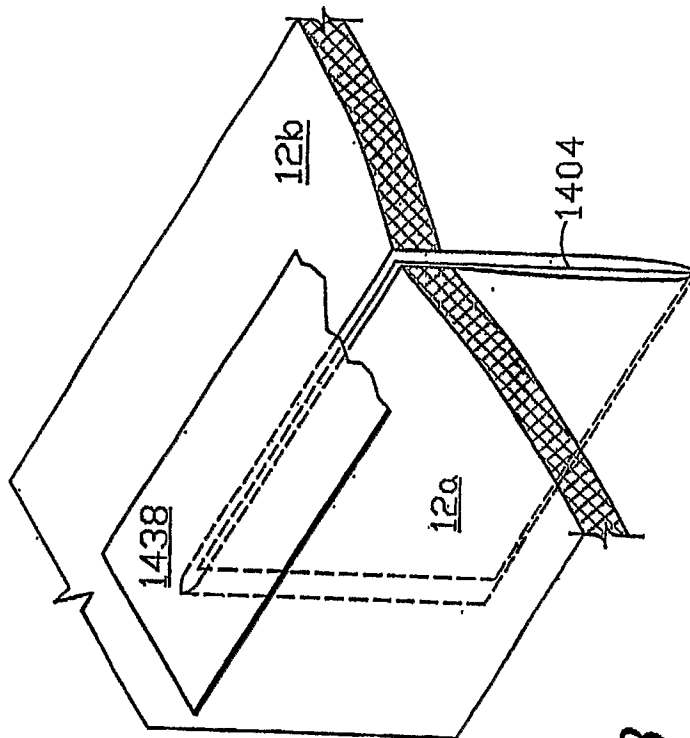


FIG. 28



35/45

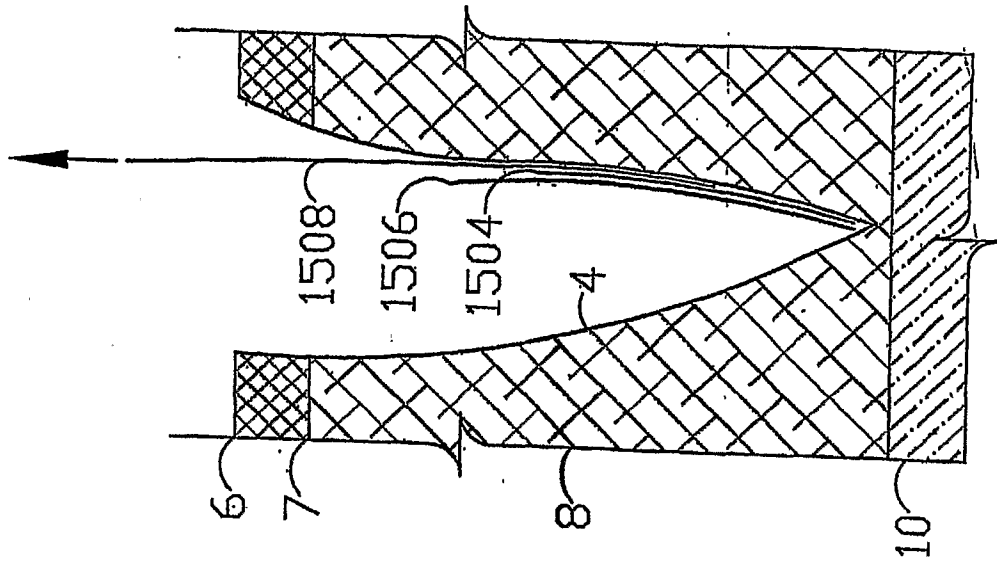


FIG. 30

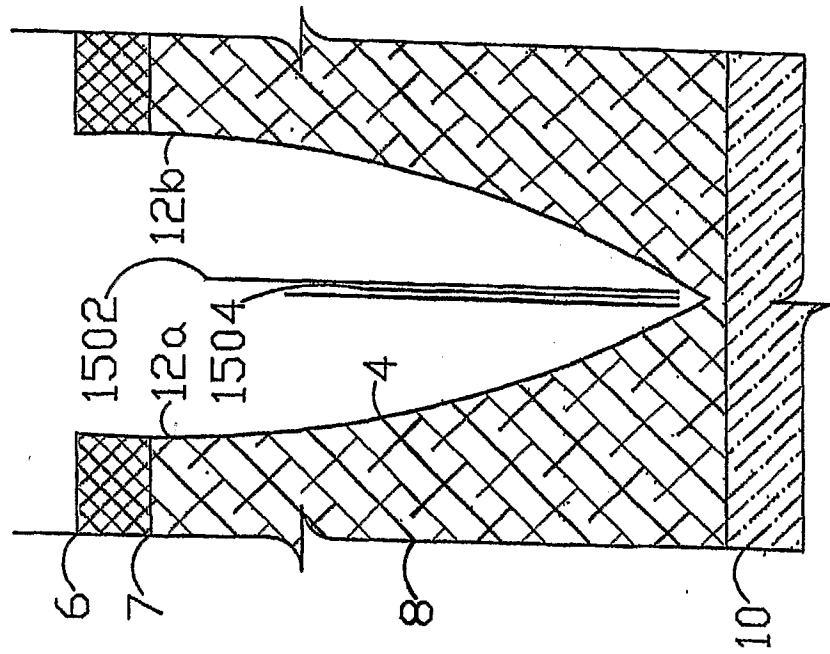
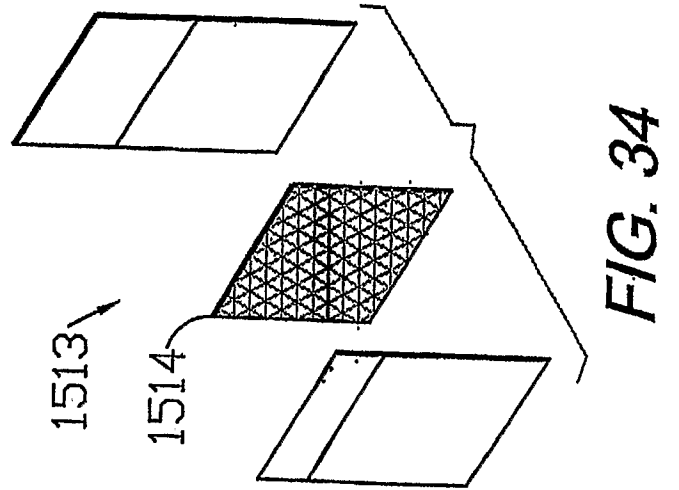
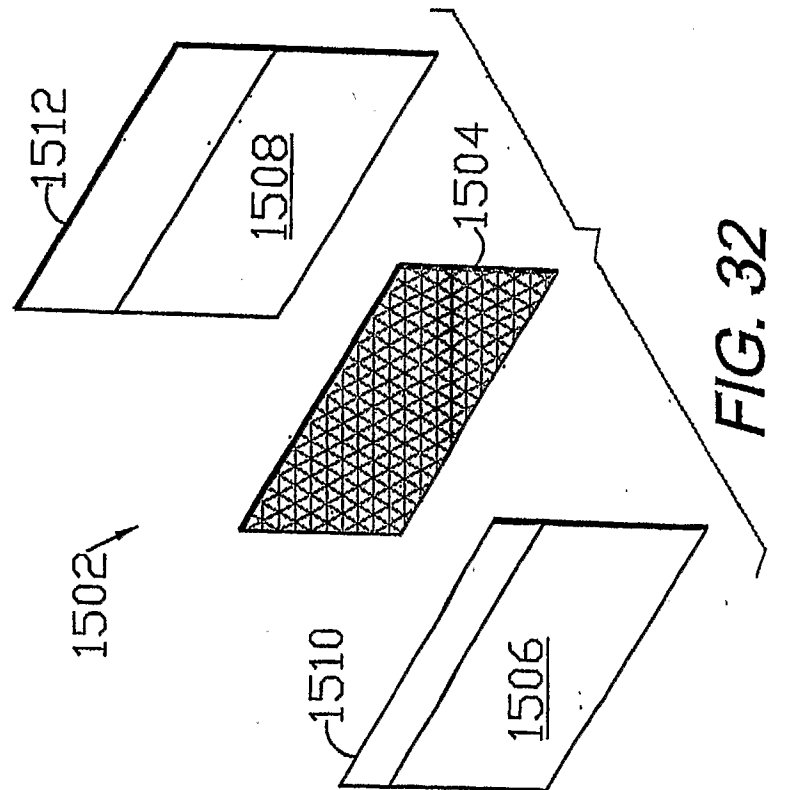
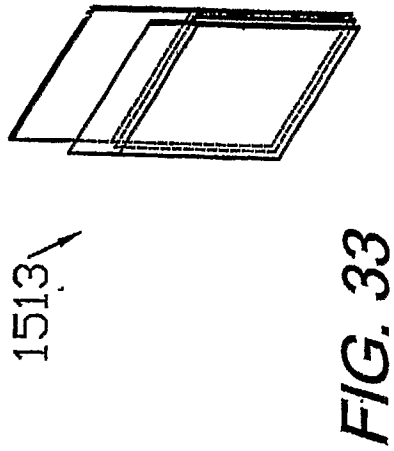
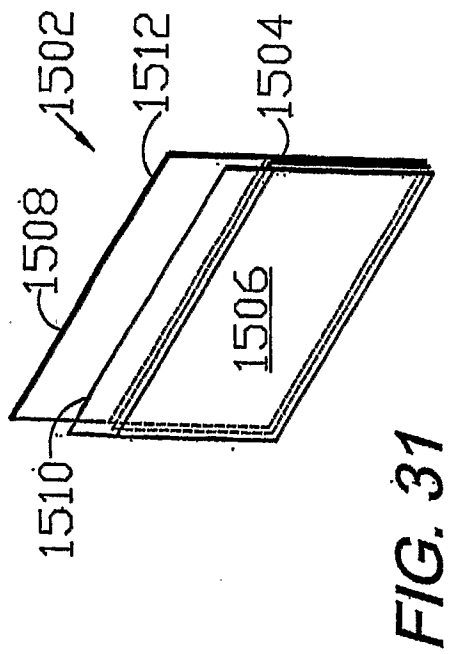


FIG. 29



37/45

FIG. 35

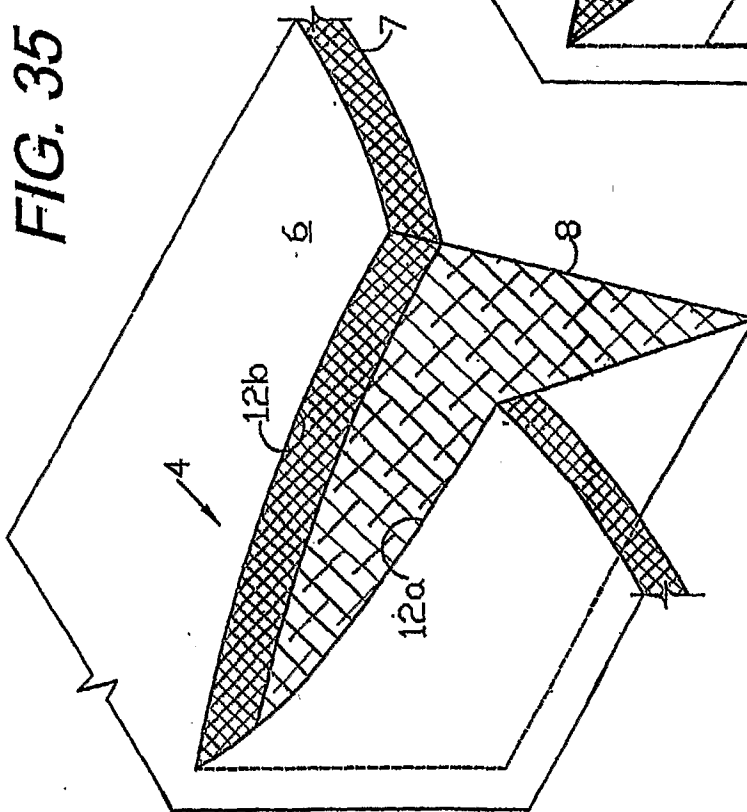
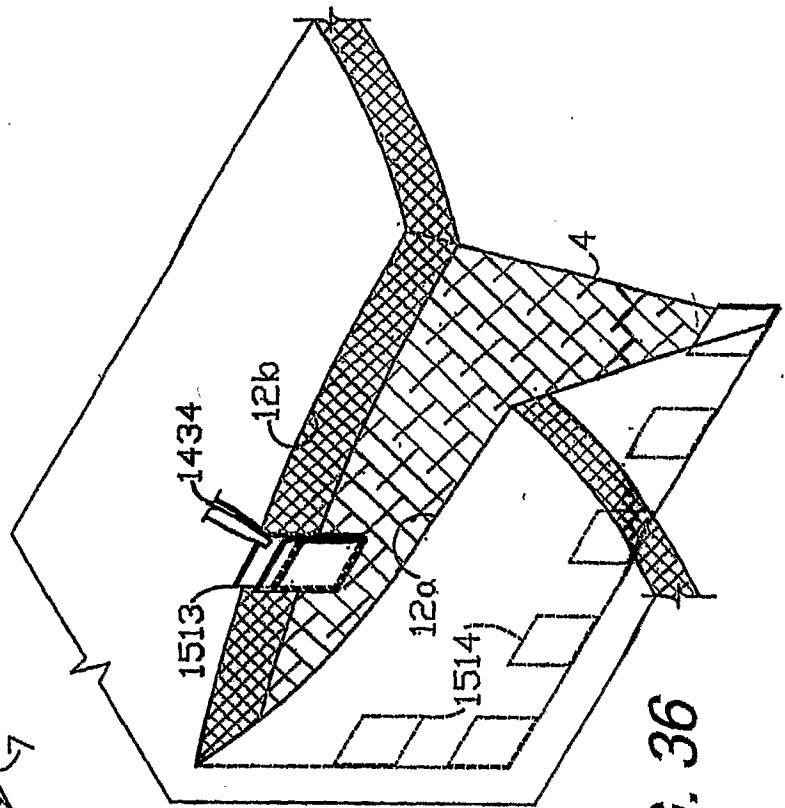


FIG. 36



38/45

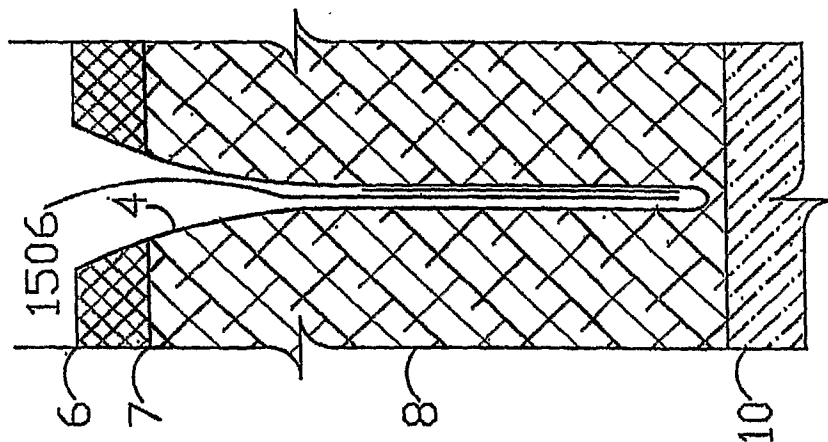


FIG. 37

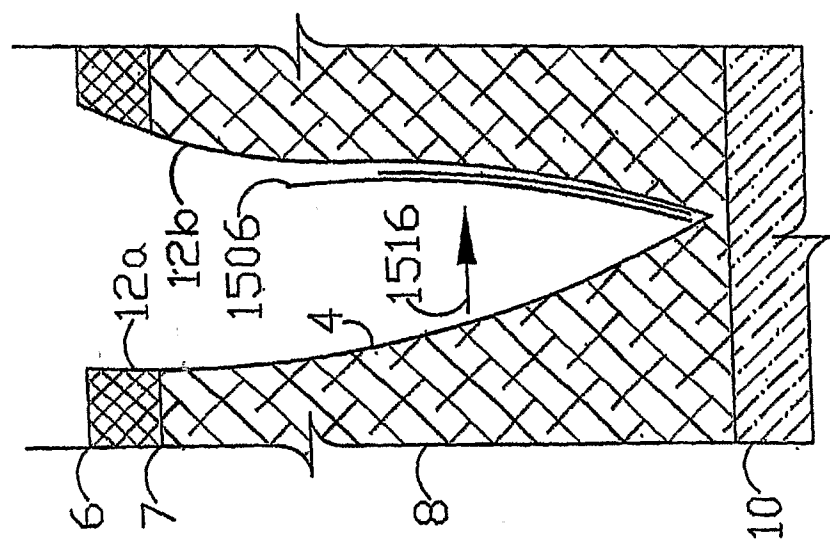


FIG. 38

39/45

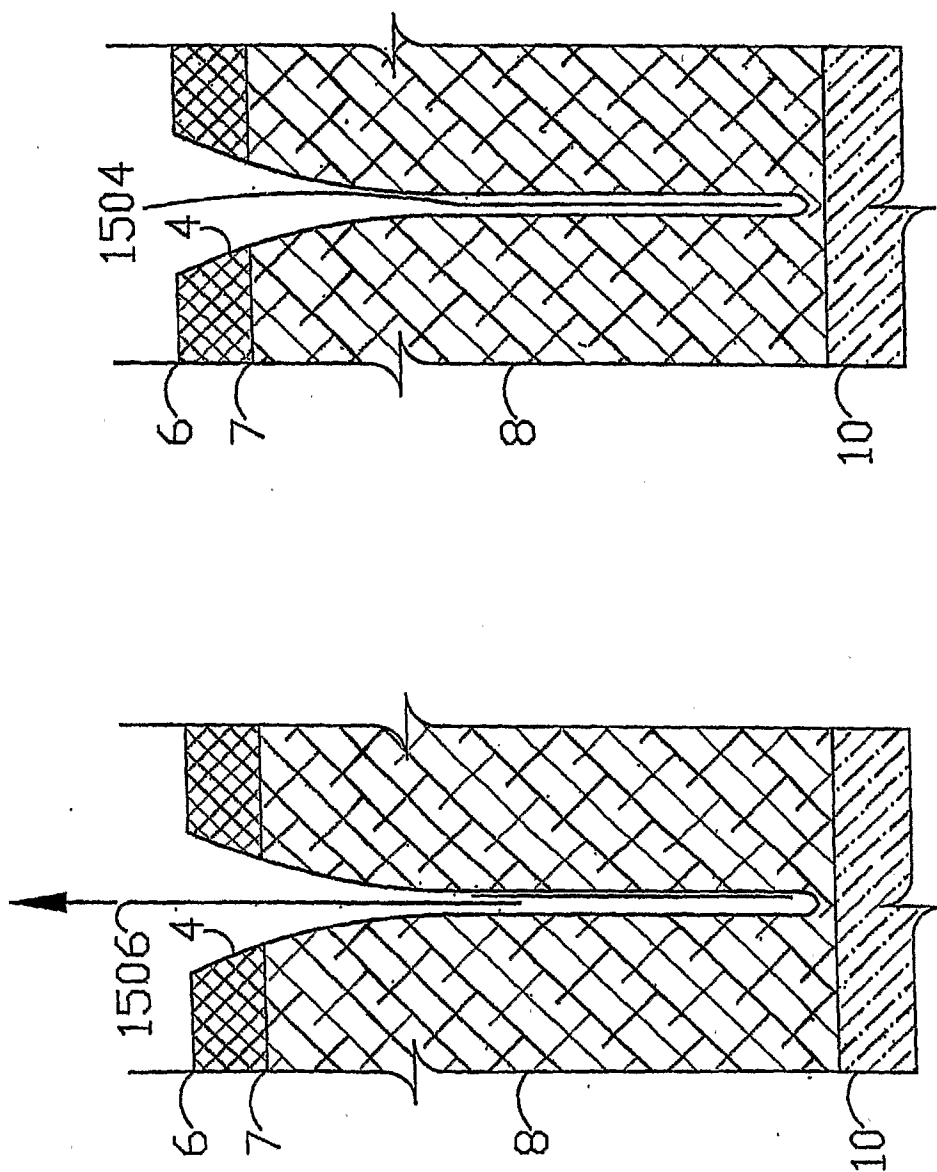
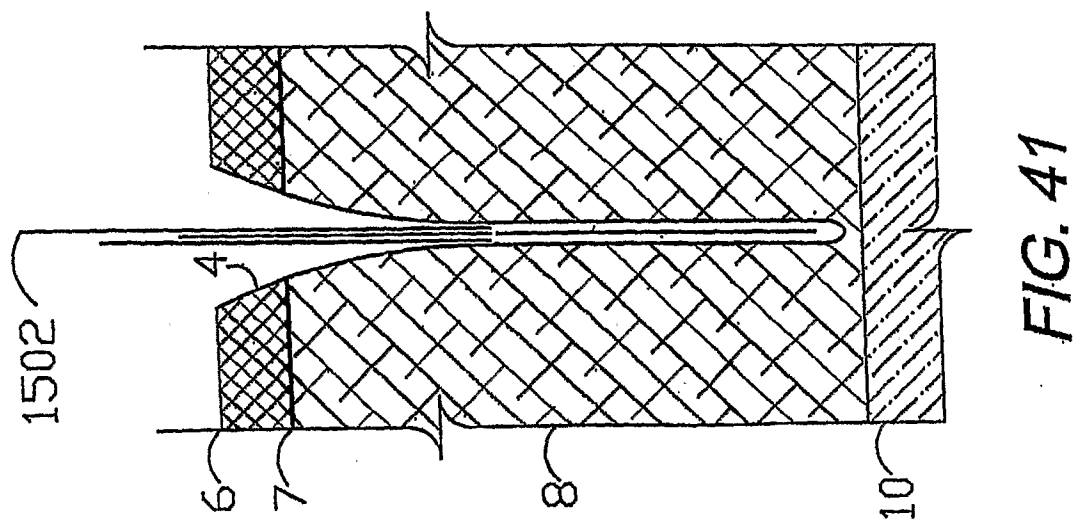
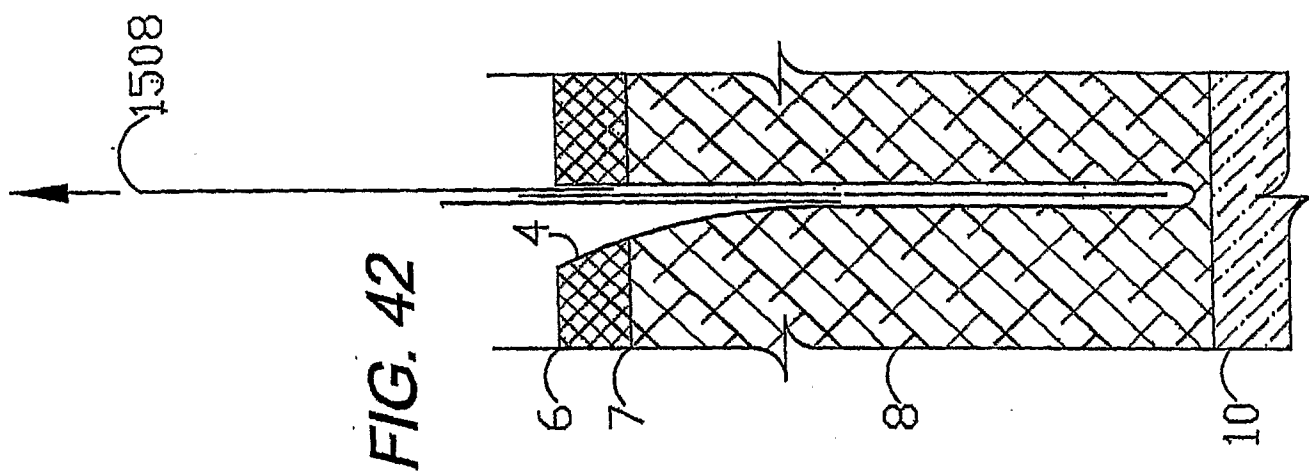


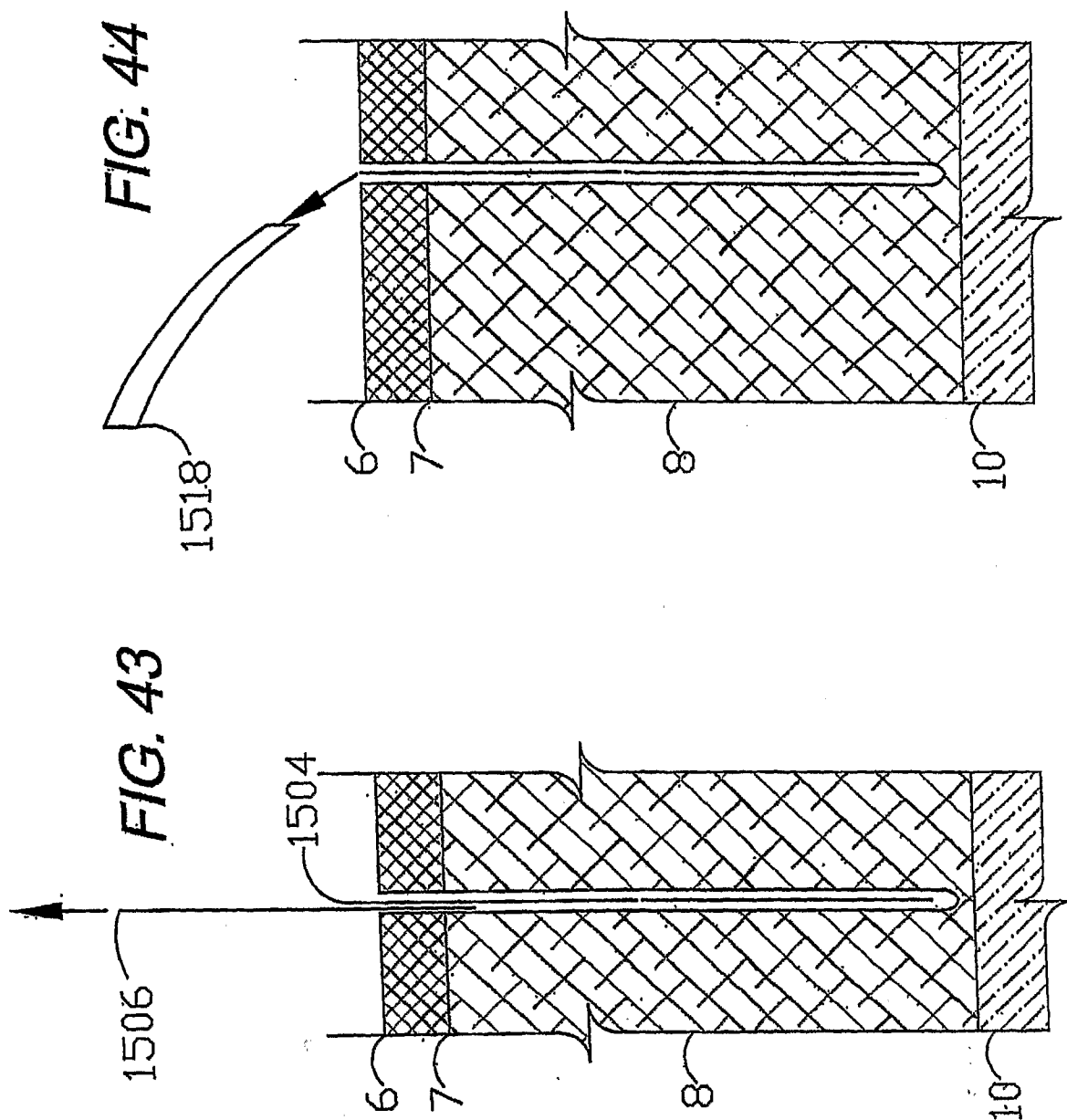
FIG. 40

FIG. 39

40/45



41/45.



42/45

FIG. 45

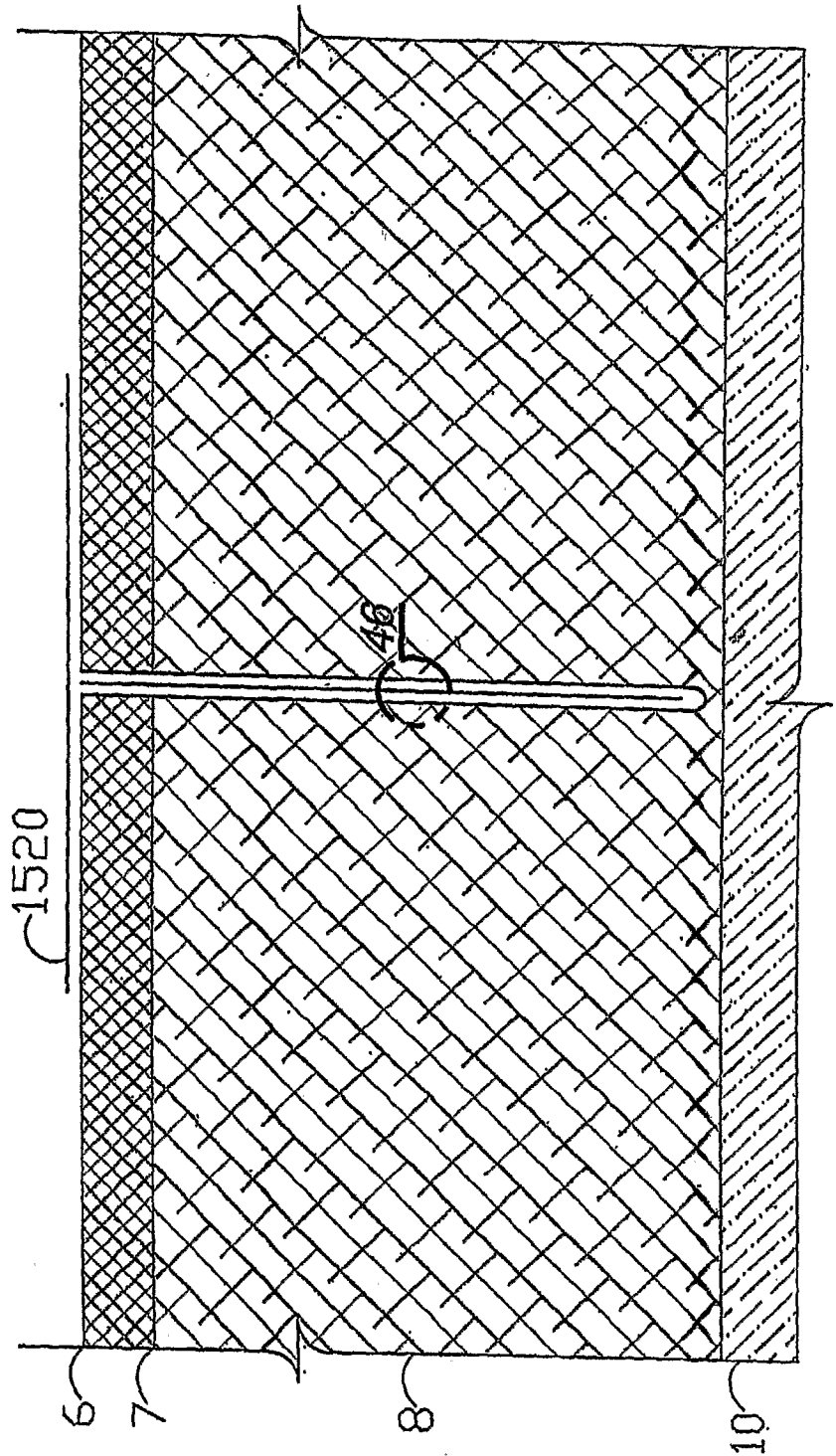
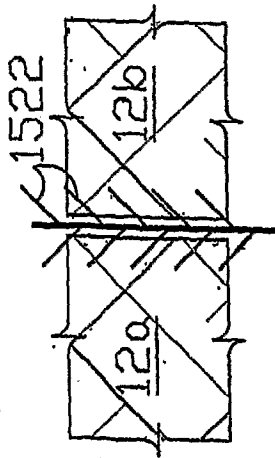


FIG. 46



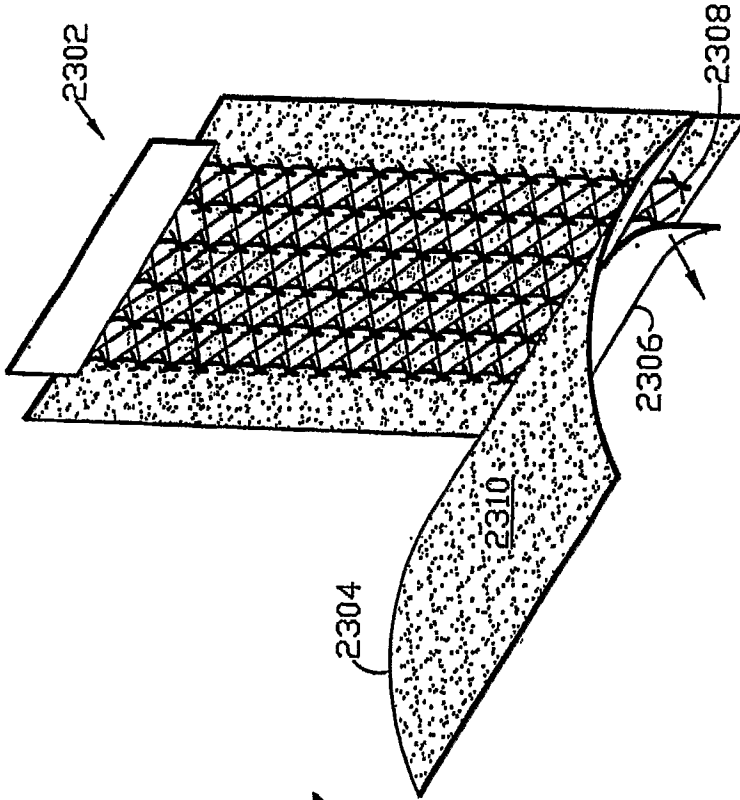


FIG. 47

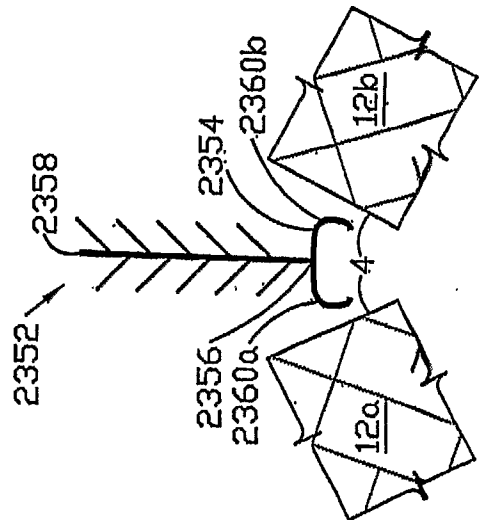


FIG. 48a

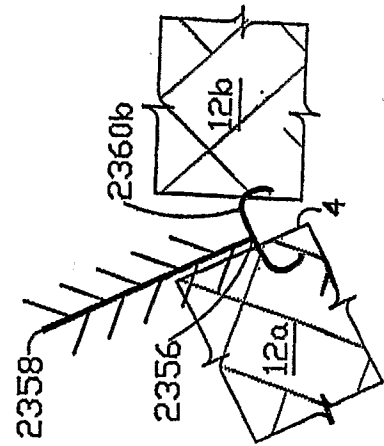


FIG. 48b

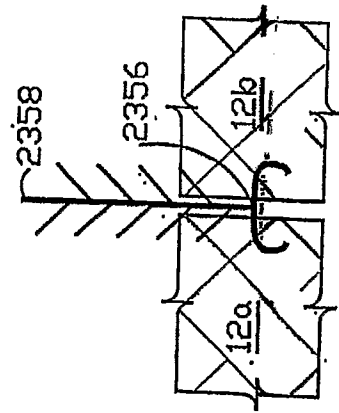


FIG. 48c

44/45

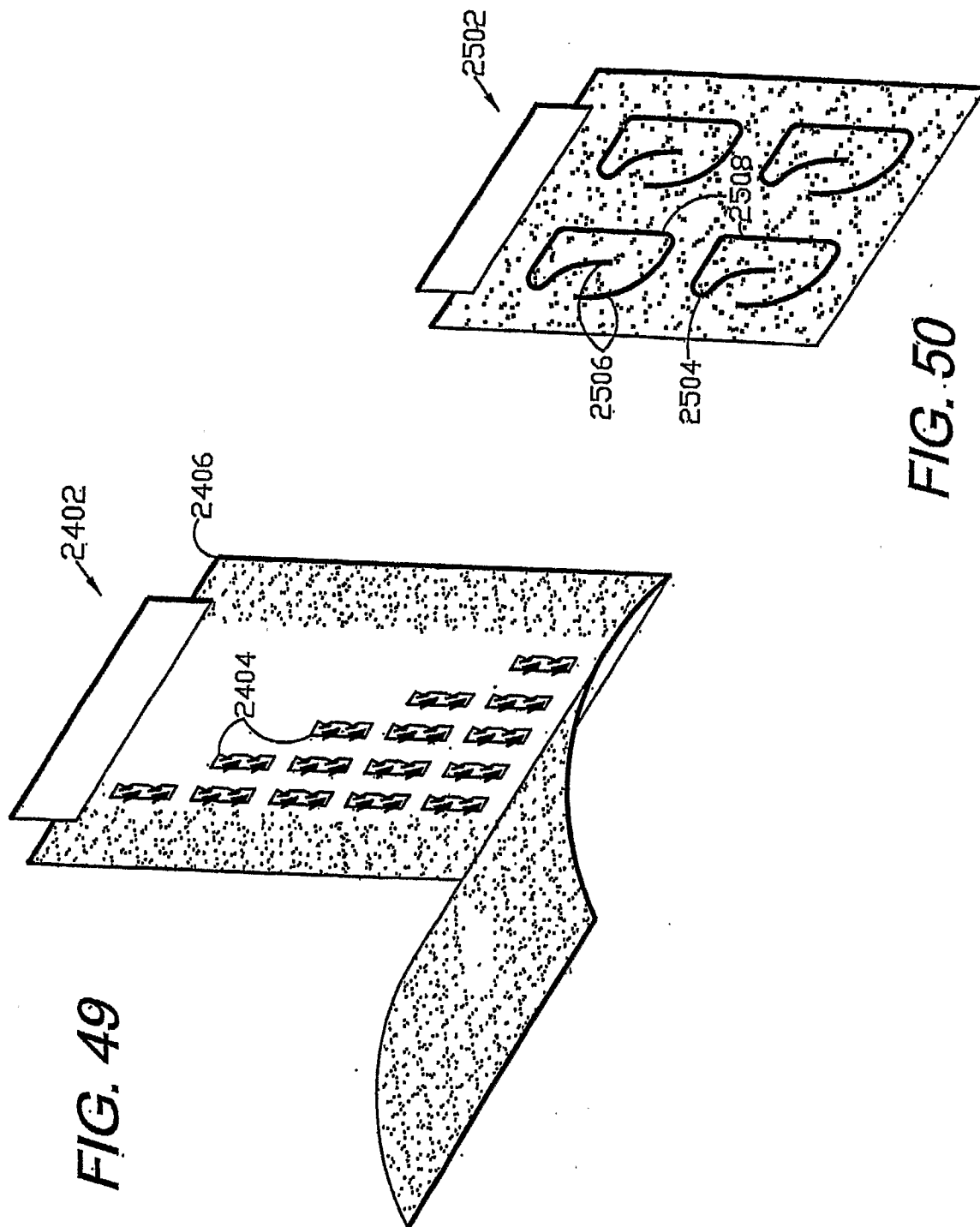


FIG. 50

FIG. 49

45/45

