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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 April 2014 (03.04.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/052038 A1

(51) International Patent Classification:
A61F 2/00 (2006.01) *A61B 17/02* (2006.01)
A61B 17/068 (2006.01)

(21) International Application Number:
PCT/US2013/059582

(22) International Filing Date:
13 September 2013 (13.09.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/628,500 27 September 2012 (27.09.2012) US

(71) Applicant: **ETHICON, INC.** [US/US]; P.O. Box 151, U.S. Route 22, Somerville, New Jersey 08876 (US).

(72) Inventors: **CARDINALE, Michael**; 7C Dorado Drive, Morristown, New Jersey 07960 (US). **WORTHINGTON, Anthony**; 337 Blacksmith Shop Road, East Falmouth, Massachusetts 02536 (US). **TANNHAUSER, Robert J.**; 265 Holland Court, Bridgewater, New Jersey 08807 (US). **SKULA, Emil Richard**; 48 Urban Club Road, Wayne, New Jersey 07470 (US).

(74) Agents: **JOHNSON, Philip S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 (US).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

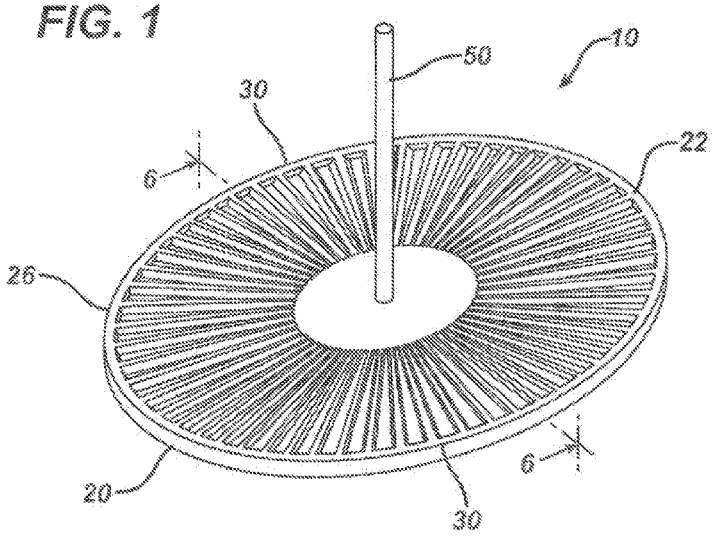
— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) Title: TEMPORARY AIDS FOR DEPLOYMENT AND FIXATION OF TISSUE REPAIR IMPLANTS

FIG. 1



(57) Abstract: Deployment device (10) for use as adjuncts with tissue repair implants (100). The devices are removeably mounted to mesh tissue repair implant devices to manipulate the devices into position and provide for secure fixation about the periphery (102) of such mesh implant devices by providing guide structures such as grooves (60) for directing and positioning a surgical tacking instrument.

WO 2014/052038 A1

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

TEMPORARY AIDS FOR DEPLOYMENT AND FIXATION OF TISSUE REPAIR IMPLANTS

Technical Field

The field of art to which this invention relates is medical devices, more particularly, medical devices useful as tissue repair implants.

Background of the Invention

Body wall defects such as hernias and trocar punctures are typically repaired by implanting surgical mesh patch implants at the site of the body wall defect. The mesh patch implants are secured to the surrounding tissue in a conventional manner including tacking, suturing, gluing, etc. A surgical mesh implant is typically constructed to have one or more layers of a porous surgical mesh shaped to conform to the body wall defect in order to provide for optimal securement. The mesh implants must also be designed to promote sufficient tissue ingrowth such that the body wall defect repair is incorporated into the body wall tissue to provide superior strength and durability. Another desired attribute of a tissue repair implant is that it have softness and flexibility, along with minimal mass in order to provide the patient with the requisite post-operative comfort.

Since tissue repair implants are typically made from surgical meshes or fabrics that are flexible, the implants may present deployment issues to the surgeon during the course of a surgical repair procedure, when it is necessary to insert the mesh into a patient's body cavity and then appropriately affix the mesh implant to secure it in place in order to effect the repair of the tissue defect. Typically, the mesh in its relaxed configuration will be significantly larger than the size of the defect and the size of the opening in the patient through which the mesh is introduced. The mesh implant is usually folded or rolled by the surgeon in order to introduce it to a location adjacent to the tissue defect. It must be then unfolded or unrolled to its at-rest planar configuration to allow for fixation. The mesh repair implant must then be moved into place adjacent to the body wall so that it can be fixated in a conventional manner using tacks, sutures, etc. Those skilled in this art will appreciate the difficulties in moving and fixating a soft, low

mass, flexible mesh implant during a surgical repair procedure. The difficulties are significantly enhanced in minimally invasive surgeries.

In order to improve the handling characteristics of mesh implants, devices have been developed that urge the mesh implant into a planar configuration after insertion into the patient's body. In the case of mesh implants for open procedures, elastic supports such as monofilament rings have been sewn into the mesh implants. However, it is known that these support structures may fail *in vivo* leading to life threatening complications and severe patient pain and discomfort. Instruments have also been developed to deliver tissue repair implants to a tissue defect site. The instruments typically have manipulatable fingers or members that maintain the mesh in a substantially planar position at the defect site; and, after the implant is affixed to the defect site the fingers or members are withdrawn into the delivery instrument and the instrument is removed. Such instruments also have disadvantages. The fingers or members may injure tissue or viscera causing a variety of complications, and the instruments may fail in use and not properly function to maintain the mesh implant in a planar position, or may fail to release the implant. In addition, the instruments are typically disposable, and, are expensive, thereby adding to the cost of the procedure.

In many open tissue defect procedures, it is necessary to utilize a skirted mesh device or a device having a pocket in order to provide an accessible structure for affixing the device securely to the inner wall of the body cavity (e.g., the peritoneum and fascia), since the surgeon is not able to affix the mesh from the visceral side of the device. In an endoscopic procedure, the surgeon can view the visceral side of the tissue repair patch remotely via an endoscopic camera system, and precisely guide a fixation instrument to fixate the device about the periphery and interior to the periphery in a multiple crown fixation pattern. In an open procedure this is typically not possible and the surgeon must guide the end of a fixation device by estimating the position of the periphery of the mesh device and by palpating the patient's skin to determine the location. This technique may have several deficiencies associated with it. As mentioned previously, in order to have an adequate repair with the best prospects for proper healing it is necessary to secure the mesh implant such that the mesh is placed as close and flush to the surface of the interior body wall as possible. If the mesh is not secured uniformly to body tissue about its periphery, the mesh may wrinkle or otherwise deform leaving sections of the mesh elevated above the surface

of the body wall. This type of installation will not provide an optimal surgical or patient outcome, and revision surgery may be required. In addition, the spaces between the raised section of the mesh and the body cavity wall may be prone to surgical adhesions, infections, poor tissue integration, bowel entrapment, etc., further complicating the outcome for the patient.

There is a need in this art for novel adjunct devices that may be combined with a surgical tissue repair implant such that the device urges a tissue repair implant into a planar configuration for optimal surgical affixation, but is removable after the affixation is completed. There is a further need for such a device that has features which enable the surgeon to guide the end of an affixation instrument to properly locate fasteners about the periphery of the device.

Summary of the Invention

Therefore a novel deployment device for a tissue repair implant is disclosed. The deployment device has a flexible planar member. The planar member has a top surface and a bottom surface and an outer periphery. The planar member being capable of moving between a first at rest position to a second deformed position. A plurality of guide structures extend radially outward along the top of the planar member. The guide structures have inward proximal ends and outward distal ends. An optional peripheral rim about the outer periphery of the planar member acts as a stop at the distal ends of the channels. The deployment device optionally has a grasping element extending up from the planar member.

Another aspect of the present invention is the combination of a surgical mesh tissue repair implant and the novel deployment device of the present invention.

Still yet another aspect of the present invention is a method of repairing a tissue defect using the novel deployment device of the present invention.

These and other aspects and advantages of the present invention will become more apparent from the following description and accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a perspective view of an embodiment of a deployment device of the present invention.

FIG. 2 is a side view of the deployment device of FIG. 2.

FIG. 3 is top or plan view of the deployment device of FIG. 1.

FIG. 4 is a partial magnified perspective view of a section of the deployment device of FIG. 1.

FIG. 5 is a cross-sectional view taken along ViewLine 5-5 of device of FIG. 3.

FIG. 6 is a cross-sectional perspective view taken along ViewLine 6-6 of the device of FIG. 1.

FIG. 7 is a perspective view of a dual layer mesh tissue repair device having a pocket and a tissue affixation skirt.

FIG. 8 is a side view of the mesh tissue repair device of FIG. 7.

FIG. 9 is a side view of a deployment device of the present invention having the planar grooved member contained within the interior pocket of the mesh of FIG. 7; a surgical tacking instrument is illustrated having a shaft, with a distal section of the shaft being partially contained in a groove on the deployment device, and wherein the distal end of the shaft is adjacent to the end of the groove and the rim of the device.

FIG. 10 is a top view of the deployment device and mesh repair device of FIG. 9.

FIGS. 11 and 12 are perspective views of the deployment device, mesh repair device and tacking instrument of FIG. 9.

FIG. 13 is a cross-sectional view of the deployment device and mesh repair device of FIG. 9 showing the shaft of the surgical tacking instrument engaged in a groove with the distal end of the shaft proximal to the peripheries of the deployment device and the mesh repair device.

FIG. 14 is a magnified cross-sectional view of the periphery of the deployment device and mesh device of FIG. 13, illustrating the distal end of the shaft adjacent to the periphery of the skirt of the mesh device and in a position to apply tacks through the skirt into tissue.

FIG. 15 is a partial magnified top view of the deployment device of FIG. 14, showing the distal end of the shaft of the fastening device in a groove adjacent to the inner wall of the rim.

FIG. 16 is a perspective view of a deployment device of the present invention wherein the planar member is moved from the at rest position to a deployment position for insertion of the planar member though the top opening and into the pocket of a mesh repair device.

FIG. 17 is a perspective view illustrating a deployment device of the present invention engaged in the pocket of a surgical mesh inserted into a patient's body cavity; the shaft of a surgical tacking instrument is seen to be extending up through the opening in the patient's body wall.

FIG. 18 is a cross-sectional view of the body wall of the patient of FIG. 16 showing the mesh positioned such that it is adjacent to the interior surface of the body wall with the distal end of the tacking instrument in position to tack the periphery of the skirt of the mesh to the tissue of the interior of the body wall.

Detailed Description of the Invention

The deployment devices of the present invention may be constructed from any conventional biocompatible materials that provide sufficiently effective rigidity and flexibility, as well as ease of manufacture. The materials include conventional absorbable and nonabsorbable polymeric materials. The nonabsorbable polymeric materials include polyolefins, polytetrafluoroethylene, nylon, silk, thermoplastics, elastomers, and other polymeric materials that are sufficiently thin to promote flexibility, and the like. The absorbable polymeric materials include polylactides (PLA), polyglycolides (PGA), polydioxanones (PDO, PDS), copolymers of PGA/trimethylene carbonate (TMC), polycaprolactones, copolymers of any forementioned polymers, and the like. If desired the deployment materials may be made from conventional metals and alloys including surgical stainless steel, shape memory metals such as nitinol, copper-aluminum-nickel, nickel-titanium and the like. The deployment devices may also be constructed from biocompatible composite materials including polycarbonates, polymethylmethacrylate , and the like.

The deployment devices of the present invention may be made using conventional manufacturing equipment and processes including injection molding, solvent casting, machining, cutting, cast molding, thermoforming, and the like.

Tissue repair implants and surgical instruments for applying tacks to fixate tissue repair implants are disclosed in the following commonly assigned, co-pending patent applications, which are incorporated by reference: US Serial Nos. 12/464,151; 12/464,165; 12/464,177; 12/464,143; 12/944,651; and 12/815,275.

The mesh tissue repair devices that can be utilized with the novel deployment devices of the present invention include conventional tissue repair meshes having skirts or pockets that are useful in open surgical procedures to repair a tissue defect in a body wall. The meshes will typically have a bottom layer and a top layer of a conventional tissue repair materials with an access opening in the top layer. The bottom layer of the mesh may have a conventional adhesion barrier material affixed to at least part of its bottom or outer surface. The mesh materials may be conventional knitted or crocheted meshes, e-PTFE materials, woven and non-woven surgical fabrics, etc. The mesh materials may be constructed of conventional polymeric materials including polypropylene, Nylon, e-PTFE, polyester, ultra high molecular weight polyethylene, and the like. The polymeric materials may be bioabsorbable or nonabsorbable, or may consist of combinations of bioabsorbable and nonabsorbable materials. Examples of commercially available mesh implants include: ETHICON PHYSIOMESH™ and ETHICON PROCEED™ Surgical Mesh, available from Ethicon, Inc., Route 22 West, Somerville, NJ 08876; Ventrio™ ST Hernia Patch and Ventrio™ Hernia Patch available from BARD Davol; the Parietex™ Composite Open Skirt (PCO OS) Mesh from Covidien plc; and the C-QUR TacShield™ available from Atrium Medical Corporation.

The patches and their components are preferably made from conventional biocompatible polymers that may be nonabsorbable or bioabsorbable. The term bioabsorbable is defined to have its conventional meaning and includes both biodegradable and bioresorbable. Examples of such nonabsorbable polymers include polypropylene, polyester, nylon, ultra high molecular weight polyethylene, and the like and combinations thereof. Examples of suitable bioabsorbable polymers include polylactides (PLA), polyglycolides (PGA), polydioxanones (PDO, PDS), copolymers of PGA/trimethylene carbonate (TMC), copolymers of PLA/TMC, and the like. If

desired, combinations of biocompatible nonabsorbable polymers and bioabsorbable polymers may be utilized to construct the tissue repair implant patch devices of the present invention.

Referring now to FIGS. 1-14, an embodiment of a deployment device of the present invention is seen. The device 10 is seen to have planar member 20. Planar member 20 has top surface 22 and bottom surface 24. Planar member 20 is illustrated as having a substantially oval configuration, but may have other geometric configurations including circular, elliptical, square, rectangular, diamond shaped, hexagonal, polygonal, curved, combinations thereof, etc. Member 20 is seen to have optional circumferential rim member 30 extending about the periphery 26 of the planar member 20. Rim member 30 may be continuous or segmented. The rim member 30 is seen to have top 32, inner stop wall 34 and outer wall 36. If desired, the top 32 of rim member 30 may be at the same level of the surface 22, or may be higher or lower. The top surface 20 is also seen to have optional flat inner section 23. Extending from the planar member 20 is the optional manipulation member 50. Member 50 is seen to have a cylindrical rod-like configuration having proximal end 52 and free distal end 54. Member 50 may have a variety of shapes and configurations, and may be flexible or rigid. Examples include rods, finger grips, tapes, ropes, loops, handles, finger holes, straps, etc. In one embodiment, the member 20 may have an optional opening (not shown) extending through the member.

The planar member 20 is seen to have a plurality of grooves 60. The grooves 60 are seen to extend into top surface 22 and extend radially outward from the center of member 20 out to the rim member 30. The grooves 60 are seen to have bottoms 61, inner ends 62, outer ends 63, opposed sides 65, and open tops 64. Each groove contains a passage 64 for receiving at least part of a distal section of a surgical fastening instrument. The grooves are seen to have opposed radial wall members 70, having inner ends 71, side walls 75, tops 77 and distal ends 72 that abut or intersect the inner stop wall 34 of rim member 30. The grooves or guide structures 60 are seen to be contained in member 20, but may alternatively extend up from the top surface 22. The grooves 60 may also be formed from spaced apart rib members extending up from top surface 22 of planar member 20. Although not illustrated, the grooves 60 may take the form of radially extending hollow tubular members having passages for receiving a shaft of a surgical fastening instrument. The grooves are aligned at some consistent spacing, e.g., 1 cm, to ensure that the tacking instrument delivers fixation points consistently and evenly about the perimeter of the

device. Optionally, the grooves 60 may have one or more circumferential guide elements or indicators. These indicators may be located radially outwardly at one or more locations within each groove to provide consistent positioning of rows of fasteners (crowns) inwardly from the outer ends 63 of the grooves 60. These tactile indicators may be raised sections, ribs, depressions, frictional irregularities, etc., which provide tactile feedback to the surgeon as the tip of the applicator is moved along the groove along the groove or guide. The indicators may extend from the bottom 61 and/or sides 65.

The planar member 20 is moveable between a first at-rest position and a second deployment position. In the second deployment position, the planar member 20 may be folded or otherwise manipulated such that it is insertable into the pocket of a mesh tissue repair device, such as mesh tissue repair device 100 as seen in FIG. 16. In another embodiment, not shown, a plurality of collapsible members may be affixed to the planar member 20 to collapse and move the member 20 from a first at rest position to the second deployment position, and vice versa.

A pocketed mesh tissue repair device 100 that may be utilized with the novel deployment devices of the present invention is seen in FIGS. 7 and 8. The mesh device 100 is seen to have a first or bottom layer 110 and a second or top layer 120. The mesh layer 110 is seen to have bottom 112, top 114 and outer periphery 115. Mesh layer 120 is seen to have top 122, bottom 124, outer periphery 125, and central opening 127. Layers 110 and 120 are joined about their peripheries 115 and 125 to form the device 100. Mesh repair device 100 is seen to have outer periphery 102 and interior pocket 104. The pocket 104 is accessible through opening 127. The top layer 120 forms a skirt between opening 127 and outer periphery 125, which is used to affix the mesh device 100 to tissue.

Referring now to FIGS. 9-15, a deployment device 10 of the present invention mounted to a mesh repair device 100 is seen. A surgical tacking instrument 150 is seen. Tacking instrument 150 is seen to have a proximal handle 160 having an actuation trigger 165. Extending from the distal end 154 of instrument 150 is the shaft 170, having distal end 174 and proximal end 172. The shaft 170 is seen to be curved to facilitate affixation of the skirt of top layer 120 to the tissue of an adjacent body wall. Surgical tacks are discharged through discharge tip 177 on distal end 174. Although most conventional tacking instruments may be used in conjunction

with the novel deployment devices of the present invention, a particularly suitable surgical tacking instrument is disclosed in co-pending, commonly assigned U. S. Patent Application Serial Numbers 12/944651 and 13/470022, filed on November 11, 2010 and May 11, 2012 respectively which are incorporated by reference.

As seen in FIGS. 9-15, the planar member 20 of deployment device 10 has been inserted into pocket 104 of mesh tissue repair device 100 through opening 127. The shaft is partially contained in a groove 60 such that the shaft is guided toward the outer or distal end 63 of the groove 60 adjacent to the inner stop wall 34 of rim member 30. The discharge tip 177 of shaft 170 is proximate to the periphery 102 of mesh device 100. In this position a tack can be inserted from the instrument 150 through discharge tip 177 through mesh layer 120 into adjacent body tissue.

FIGS. 17-18 illustrate the device 10 of the present invention deployed in the pocket of a mesh device 100 in a body cavity 200 of a patient. The body cavity 200 is surrounded by body wall 210 having top outer surface 212 and bottom interior surface 214. Opening 216 in outer surface 212 is seen to be over tissue defect 220 in body wall 210. The top mesh layer 120 of mesh implant 100 is seen to be deployed adjacent to the interior surface 214 of body wall 200. Manipulation handle 50 of deployment device 10 is seen to extend through defect 220 and opening 216. A section of shaft 170 of tacking instrument 150 extends through opening 216 and defect 220 and is guided in a channel 60 of planar member 20 toward the periphery 102 of mesh device 100. The distal end 174 of shaft 170 is seen to be positioned in channel 60 such that the discharge tip 177 is adjacent to stop wall 34 and positioned to secure skirt or top mesh 120 adjacent to the periphery 102 of mesh device 100.

The deployment devices 10 of the present invention may be utilized in surgical repair procedures to correct body wall defects in the following manner. A patient having a ventral hernia defect is prepared for surgery in a convention manner. The surgeon then initiates the surgical procedure by making an incision in the skin and subcutaneous tissue overlying the hernia. In the case of planned intra-peritoneal mesh placement, the hernia sac is opened. A suitably sized conventional ventral hernia mesh repair device is selected as the mesh tissue repair implant. An appropriately sized deployment device of the present invention is manipulated from

an at-rest position to a deployment position by folding the planar member about its longitudinal axis. The planar member is then inserted through the top opening of the mesh device into the interior pocket, and moved to the at rest planar position, such that the rim of the deployment device is adjacent to the periphery of the mesh tissue repair implant. The mesh and deployment device are then handled as a system, folded along their respective axes, and inserted into the open space developed inside of the abdominal wall. The manipulation member can be used to position the mesh repair device about the hernia defect from the exterior of the patient. The manipulation member can also be pulled taut through the central opening to hold the mesh against the bottom interior surface of the abdominal wall by grasping and manipulating the manipulation member. A tacking instrument is then inserted into the mesh pocket through the top opening of the mesh device. The tip and shaft of the tacking instrument is guided into a groove in the top surface of the deployment device. Once the tip of the tacking instrument reaches the inner stop wall, the device is in the appropriate position relative to the periphery of the mesh. Manual counter pressure is applied to the top outer surface of the body wall and the tacking instrument is fired to deliver a fixation point through the mesh and into the interior layer of the abdominal wall (i.e. peritoneum and fascia). The tacking instrument is moved to an adjacent groove on the deployment device in order to ensure a second fixation point is applied a fixed distance away from the first fixation point, along the periphery of the mesh. Once the entire mesh is fixated about the periphery of the mesh device, the tacking instrument is removed. With the mesh fixated, the deployment aide is removed by bending it to remove the aide from the mesh. The skin incision is closed using appropriate suturing or closure techniques.

If desired, the deployment device may be left in the pocket of the mesh device after implantation and affixation, particularly if the deployment device is constructed of biodegradable polymers.

The following example is illustrative of the principles and practice of the present invention, although not limited thereto.

Example

A patient with a ventral hernia defect is prepared for an open hernia repair procedure in the following manner. The skin area surrounding the hernia is scrubbed with a conventional

antimicrobial solution such as betadine. The patient is administered conventional general anesthesia in a conventional manner by induction and inhalation. An open surgical procedure is selected to repair the defect. The surgeon then initiates the surgical procedure by making an incision in the skin and subcutaneous tissue overlying the hernia. In the case of planned intra-peritoneal mesh placement, the hernia sac is opened. The edges of the healthy fascia around the defect are examined and any attachments of the viscera to the abdominal wall are divided to create a free space for fixation of the mesh.

The surgeon selects a suitably sized conventional hernia mesh patch device useful in an open ventral hernia repair procedure, wherein the mesh has an opening, a top layer forming a skirt and a pocket. An appropriately sized deployment device of the present invention is removed from its sterile packaging. The planar member of the device is manipulated from an at rest position to a deployment position by folding the planar member about its longitudinal axis. The planar member is then inserted through the top opening of the mesh device into the interior pocket, and moved to the at-rest planar position, such that the rim of the deployment device is adjacent to the periphery of the mesh implant device. The manipulation member of the deployment device projects through the opening to the exterior or the mesh and out through the opening in the abdominal wall.

The mesh and deployment device are then handled as a system, simultaneously folded along their respective axes, and inserted through the opening in the abdominal wall and into the open space developed inside of the abdominal wall. The central opening of the mesh is aligned with the incision made through the skin and abdominal wall using the manipulation member from the exterior of the patient. Stay sutures may optionally be placed through the mesh into the abdominal tissue as desired, i.e. at the four compass points of the mesh (North, South, East, and West). The mesh/deployment device system is aligned such that the manipulation member can be accessed through the central opening of the mesh, tissue defect, and skin incision. The manipulation member can be pulled taut to hold the mesh against the bottom interior surface of the abdominal wall.

A tacking instrument is then inserted into the mesh pocket. The tip and shaft of the tacking instrument are guided into a groove in the top surface of the deployment device. The tip follows the groove until it contacts the inner stop wall of the deployment device. Once the tip of

the tacking instrument reaches this wall, the device is in the appropriate position relative to the periphery of the mesh. Manual counter pressure is applied to the top outer surface of the body wall and the tacking instrument is fired to deliver a fixation point through the mesh and into the interior layer of the abdominal wall (i.e. peritoneum and fascia). The tacking instrument is moved to an adjacent groove on the deployment aide in order to ensure a second fixation point is applied a fixed distance away from the first fixation point, along the periphery of the mesh. Once the entire mesh is fixated uniformly about its periphery, the tacking instrument is removed.

The deployment aide is then removed. With the mesh fixated, the deployment aide is removed by bending it to remove the aide from the mesh. The hernia defect may be primarily closed if desired. The skin incision is closed using appropriate suturing or closure techniques, and the incision is appropriately bandaged and the patient is moved to a recovery room.

The novel hernia repair devices and methods of the present invention have numerous advantages. The advantages include providing an adjunct device that allows a mesh tissue repair device to be manipulated from the exterior of the patient and fixated in a uniform manner about the periphery of the device using fasteners applied in a uniform manner about the periphery of the mesh implant device. By placing tacks with consistent spacing, the usage of tacks is optimized. Excessive tacks are avoided while ensuring that there are no excessive gaps between fixation points. Gaps can pose a risk to bowel entrapment. Another advantage is that the deployment aide is pliable and does not pose a risk of damaging the mesh repair device or the contents of the abdomen. The deployment aide also serves as a barrier to guide the tacking device upward toward the targeted tissue. The base of the deployment aide also serves as a barrier to shield viscera and abdominal contents from a tack or fixation point that may be accidentally delivered in the incorrect direction towards the viscera. This last point is important as a fixation point delivered toward the viscera may result in bowel perforation and a contaminated field.

Although this invention has been shown and described with respect to detailed embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail thereof may be made without departing from the spirit and scope of the claimed invention.

We claim:

1. A deployment device for a tissue repair implant, comprising:

a planar member, the planar member having a top surface, a bottom surface, and an outer periphery, and being capable of moving between a first at-rest position to a second deployment position; and,

a plurality of guide structures on at least a part of at least one surface of the planar member and extending radially outward.

2. The device of claim 1, wherein the planar member additionally comprises a central opening.

3. The device of claim 1, wherein the guide structures comprise ribs separated by spaces to form channels extending radially outwardly along the top surface.

4. The device of claim 1, additionally comprising a rim about the outer periphery of the planar member.

5 The device of claim 1, wherein the guide structures comprise grooves in the top surface of the planar member

6. The device of claim 1, wherein the guide structures comprise tubes.

7. The device of claim 4, wherein the rim has an inner stop wall.

8. The device of claim 1, wherein the planar member is foldable to place it in the deployment position.

9. The device of claim 1, additionally comprising a plurality of moveable elements attached to the planar member for moving it from the first at rest position to the second deployment position.

10. The device of claim 1, additionally comprising a manipulation member extending up from the top surface of the planar member.

11. The device of claim 10, wherein the manipulation member is selected from the group consisting of rods, tapes, finger grips, ropes, loops, handles, finger holes, and straps.

12. A tissue repair implant, comprising the combination of:

a mesh tissue repair device comprising:

a first base layer of surgical mesh having a top surface, a bottom surface, and an outer periphery;

a second layer of mesh mounted to the base layer and secured to the base layer about the periphery of the base layer, the second layer having a top surface and a bottom surface, such that a pocket is formed between the top surface of the base layer and the bottom surface of the second layer; and,

an opening in the second layer providing access to the pocket; and,

a deployment device contained at least partially within the pocket, the device comprising:

a flexible planar member, the planar member having a top surface, a bottom surface and an outer periphery, and being capable of moving between a first at-rest position to a second deployment position; and,

a plurality of guide structures on at least a part of at least one surface of the planar member and extending radially outward,

wherein the deployment device is removable from the pocket after deployment and fixation of the tissue repair implant.

13. The implant of claim 12, wherein the guide structures comprise ribs separated by spaces to form channels extending radially outwardly along the top surface.

14. The implant of claim 14, additionally comprising a rim about the outer periphery of the planar member.

15. The implant of claim 12, wherein the guide structures comprise grooves in the top surface of the planar member

16. The implant of claim 12, wherein the guide member comprised tubes.

17. The implant of claim 14, wherein the rim has an inner stop wall.

18. The implant of claim 12, wherein the planar member is foldable to place it in the deployment position.

19. The implant of claim 12, additionally comprising a plurality of moveable elements attached to the planar member for moving it from the first at-rest position to the second deployment position.

20. The implant of claim 12, wherein the planar member additionally comprises a central opening.

21. The implant of claim 12, additionally comprising a manipulation member extending up from the top surface of the planar member.

22. The implant device of claim 21, wherein the manipulation member is selected from the group consisting of rods, tapes, finger grips, ropes, loops, handles, finger holes, and straps.

23. A method of repairing a tissue defect in a body wall, comprising:

A. providing a mesh repair device, the device comprising:

a first base layer of surgical mesh having a top surface, a bottom surface, and an outer periphery;

a second layer of mesh mounted to the base layer and secured to the base layer about the periphery of the base layer, the second layer having a top surface and a bottom surface,

such that a pocket is formed between the top surface of the base layer and the bottom surface of the second layer; and,

an opening in the second layer providing access to the pocket;

B. providing deployment device for a tissue repair implant, comprising:

a planar member, the planar member having a top surface, a bottom surface, and an outer periphery, and being capable of moving between a first at rest position to a second deployment position; and,

a plurality of guide structures on at least a part of at least one surface of the planar member and extending radially outward;

C. manipulating the planar member of the deployment device from the first at-rest position to the second deployment position;

D. inserting the planar member into the pocket of the mesh repair device;

E. moving the planar member and the mesh repair device into a body cavity adjacent to a tissue defect in a body wall such that the planar device moves to the at-rest position;

F. manipulating the mesh repair device into a position suitable for repairing the tissue defect;

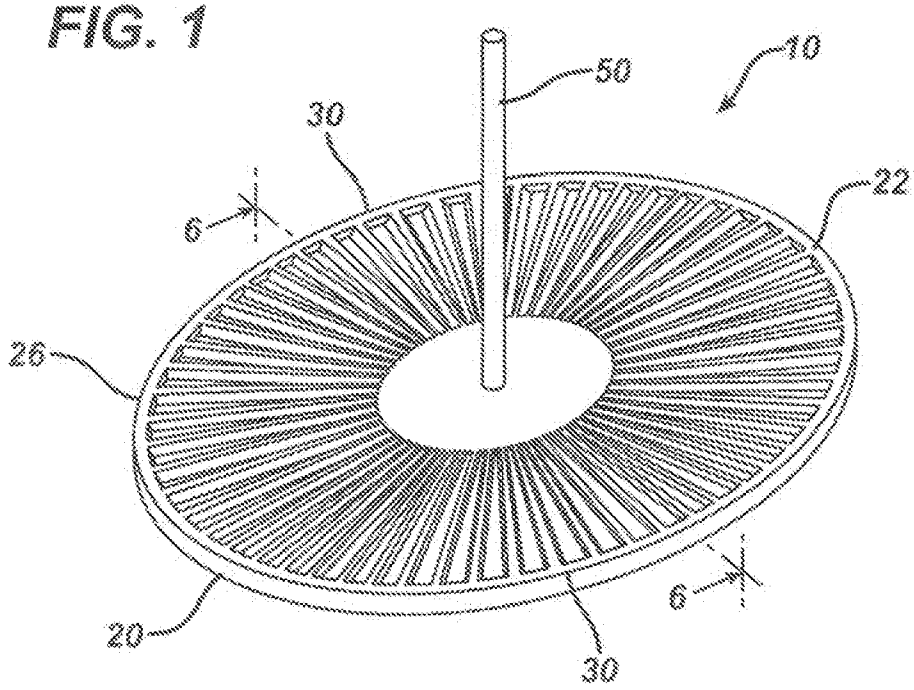
G. inserting the distal end of a surgical fastening device into the pocket of the mesh such that the guide structures direct the distal end of the device to the periphery of the mesh repair device and applying a surgical fastener through the second layer of mesh and into adjacent tissue of the body wall; and,

H. removing the deployment device from the mesh repair device.

24. The method of claim 23, wherein the deployment device can be temporarily attached to the mesh repair device.

25. The implant of claim 1, wherein the guide members are evenly spaced along the periphery of the deployment aide.

FIG. 1



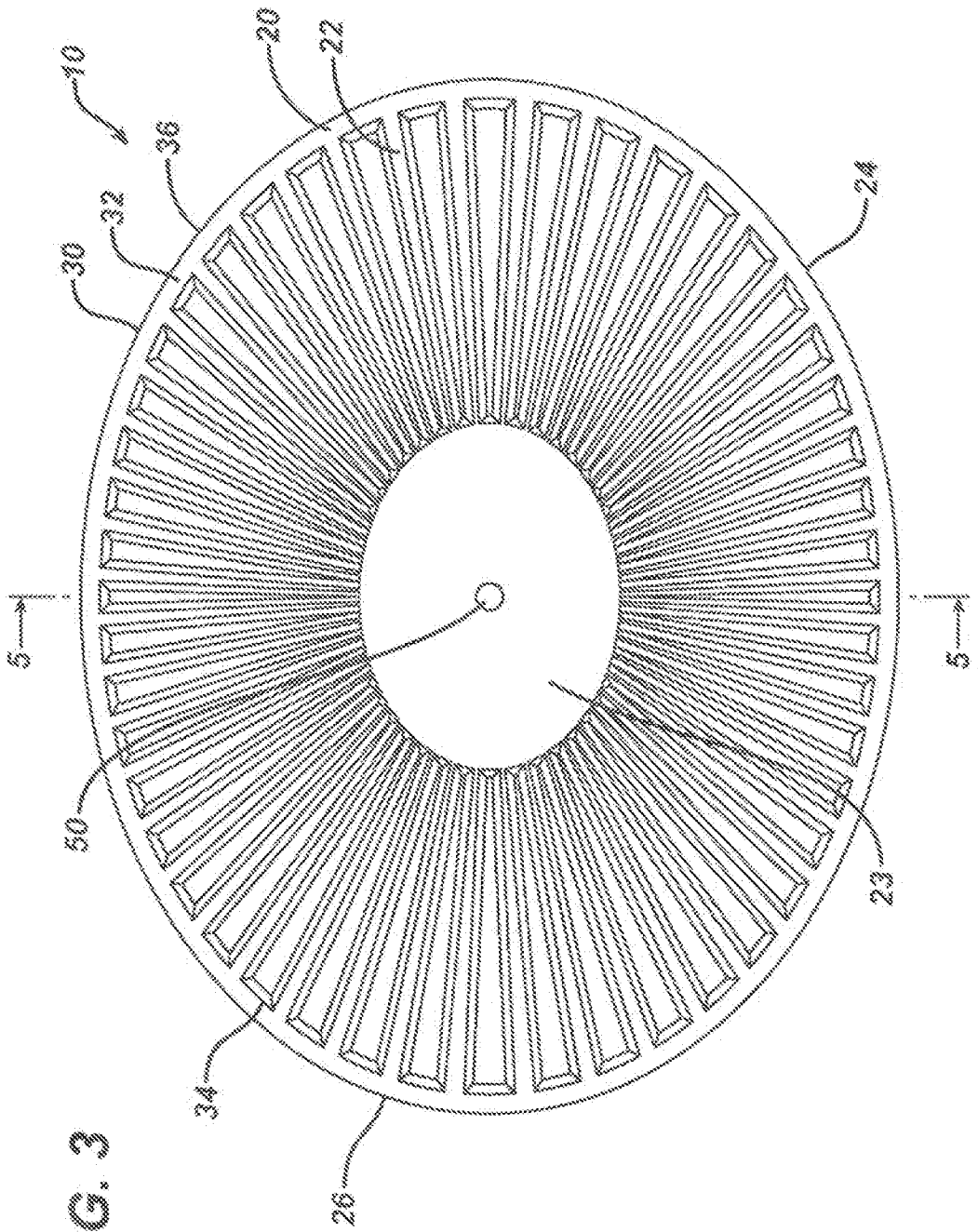


FIG. 3

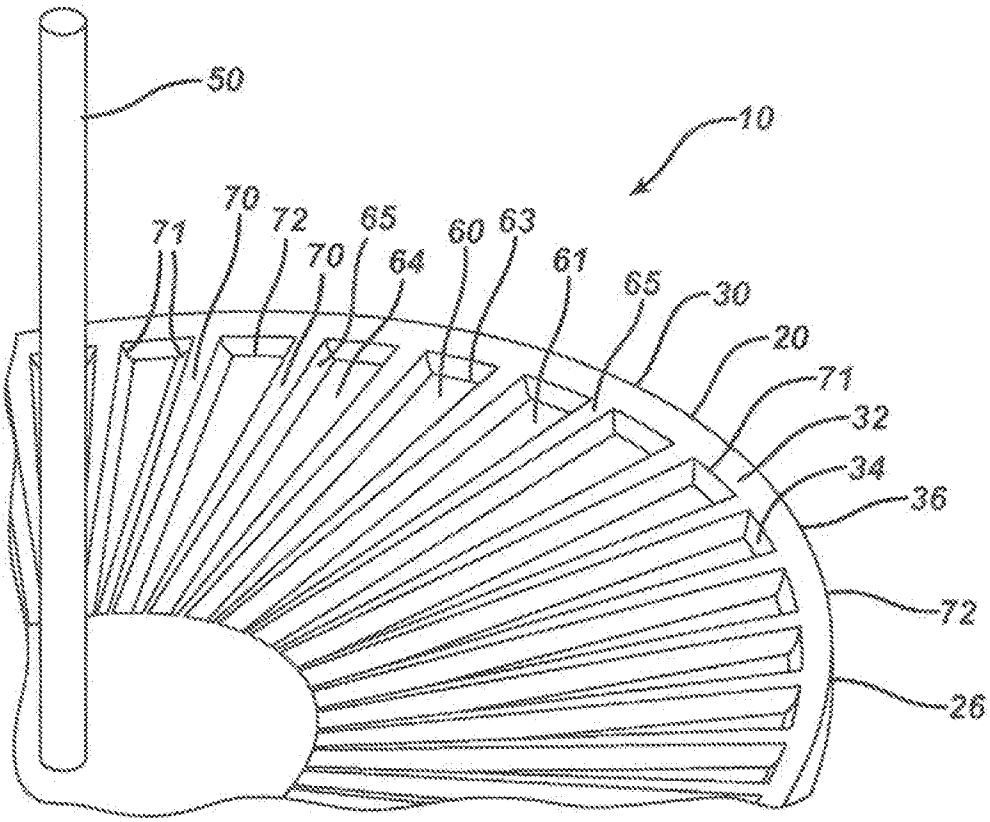


FIG. 4

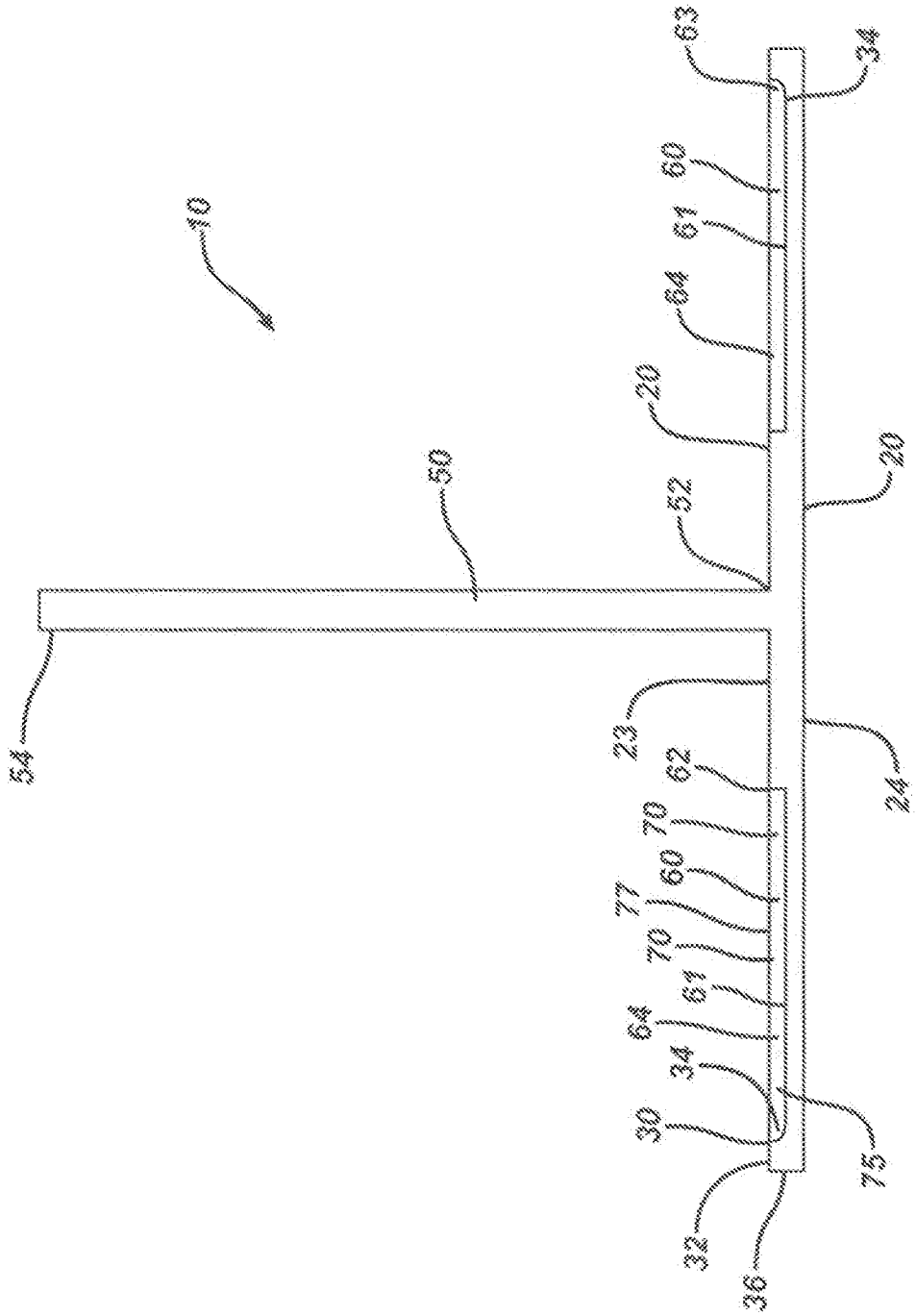

10
50
54
52
20
64
61
60
63
34
20
23
24
62
70
60
77
70
61
64
34
30
75
32
36

FIG. 5

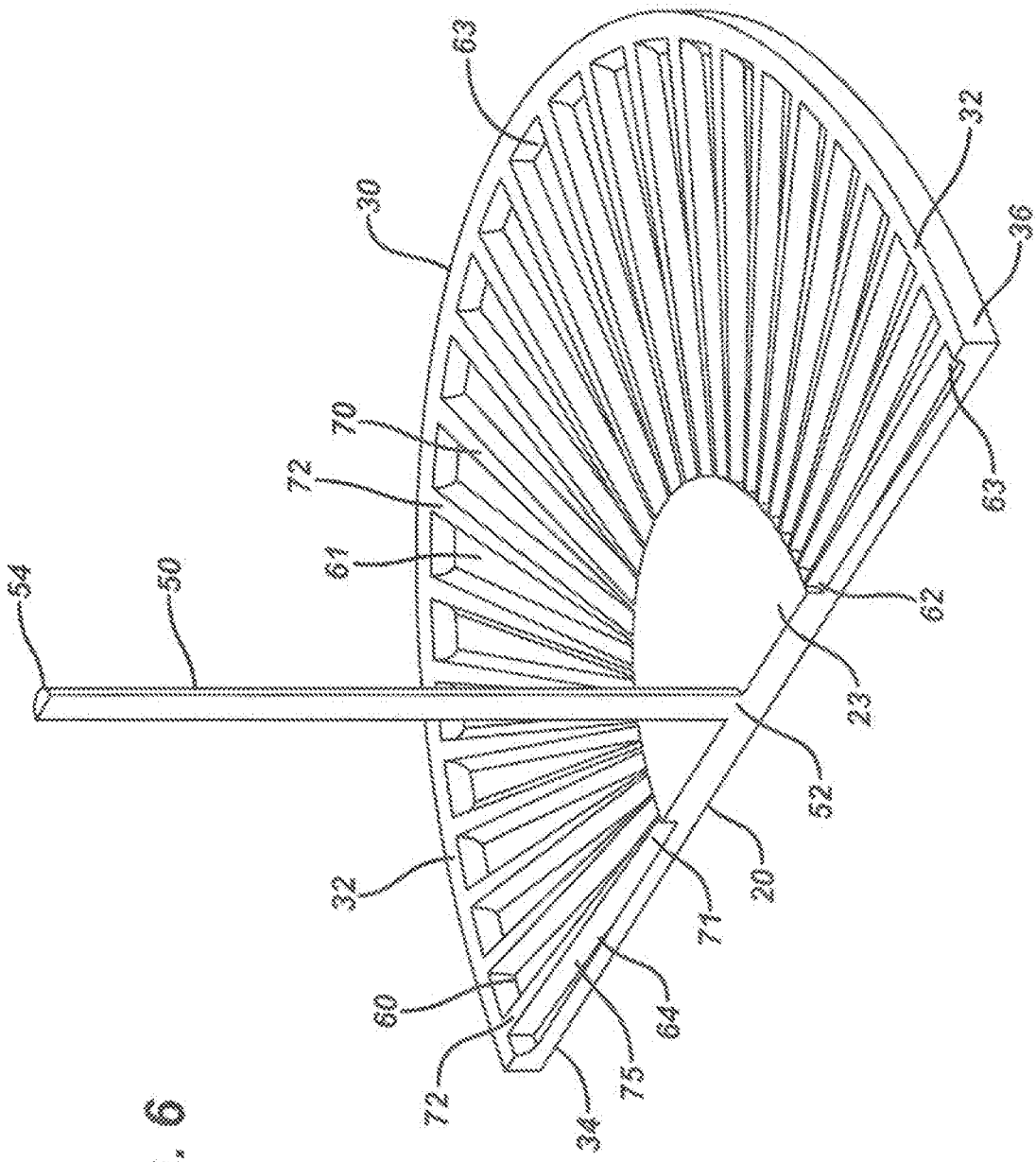


FIG. 6

FIG. 7

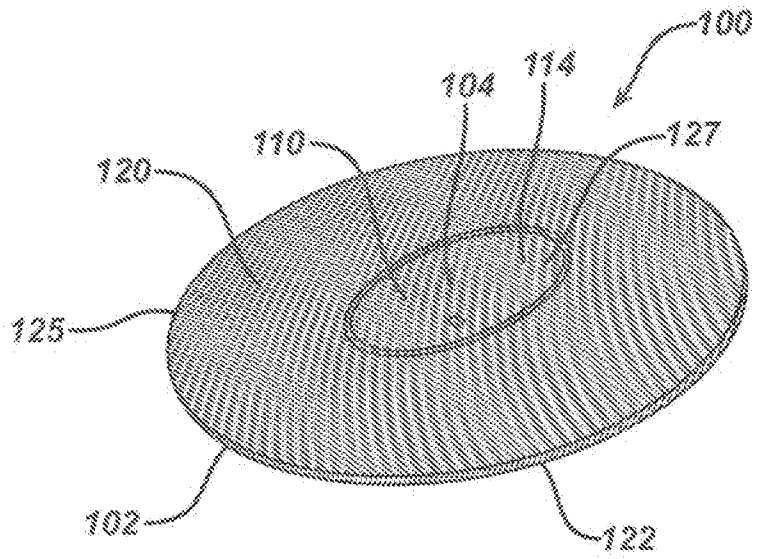

100
104
114
110
127
120
125
102
122

FIG. 8

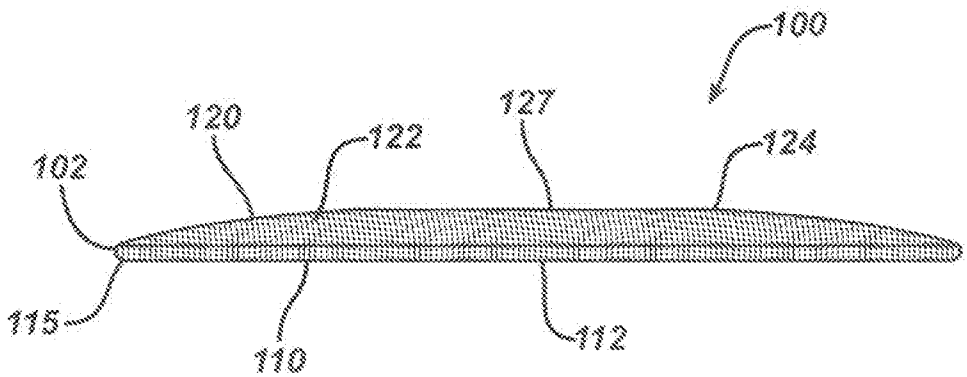

100
120
122
127
124
102
115
110
112

FIG. 9

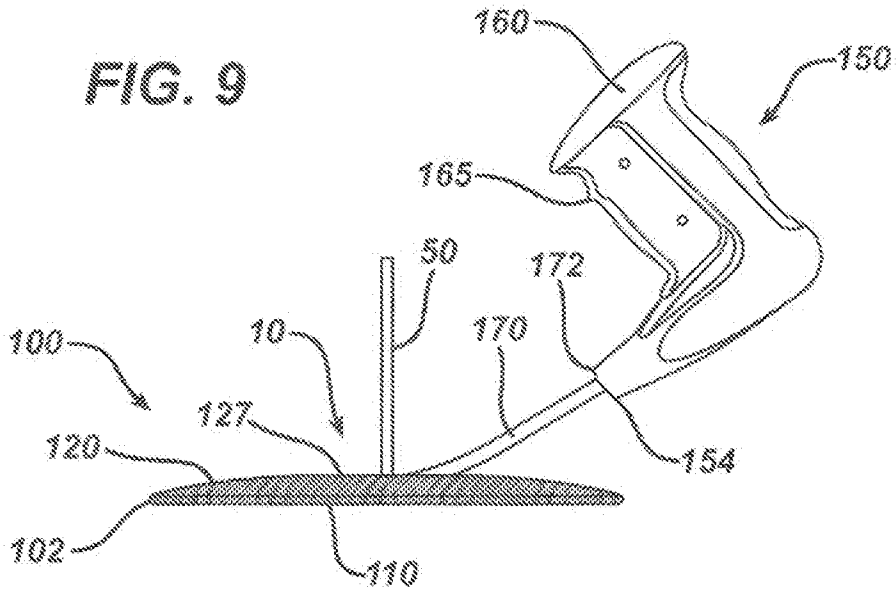

160
150
165
50
172
100
10
170
127
120
154
102
110

FIG. 10

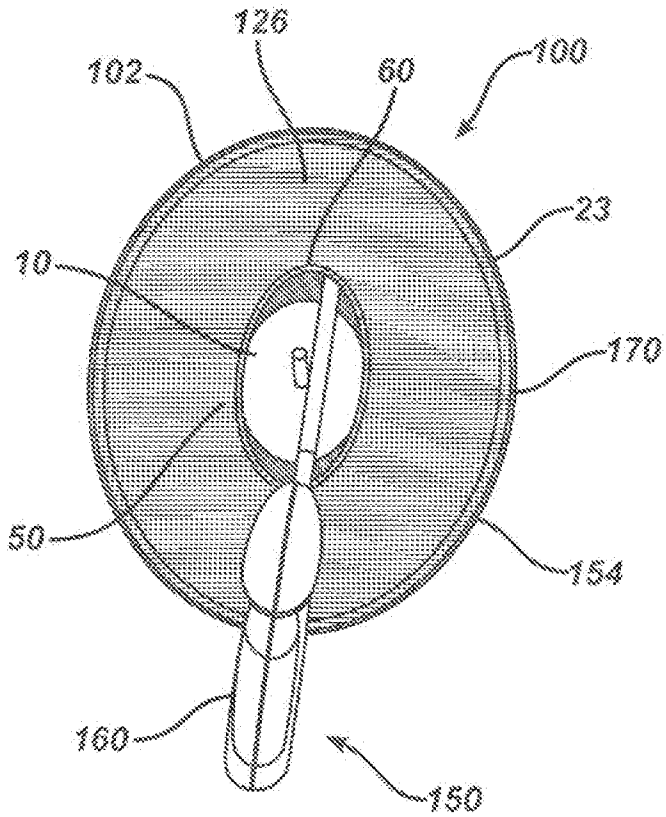

126
102
60
100
23
10
170
50
154
160
150

FIG. 11

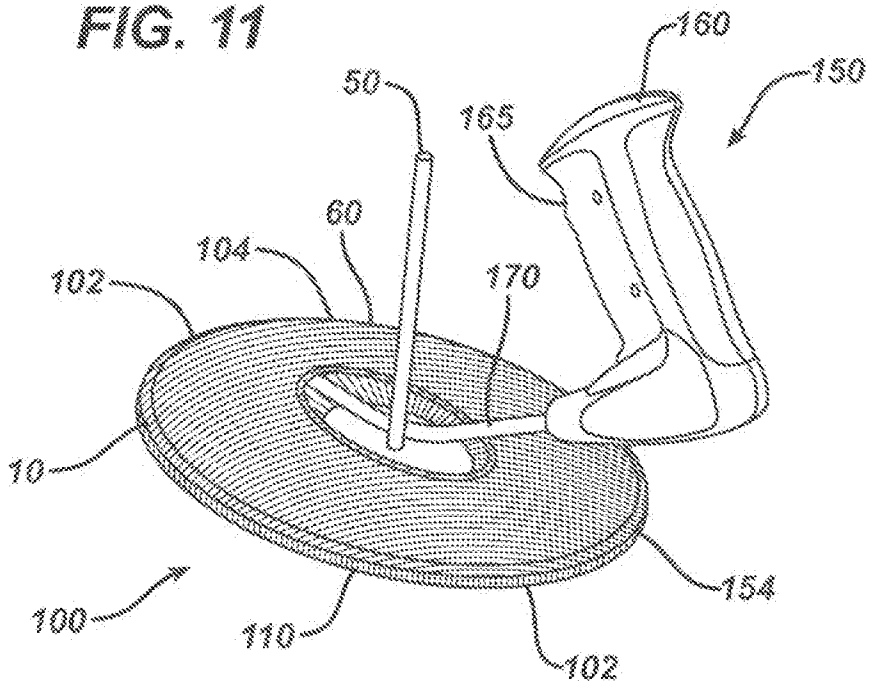
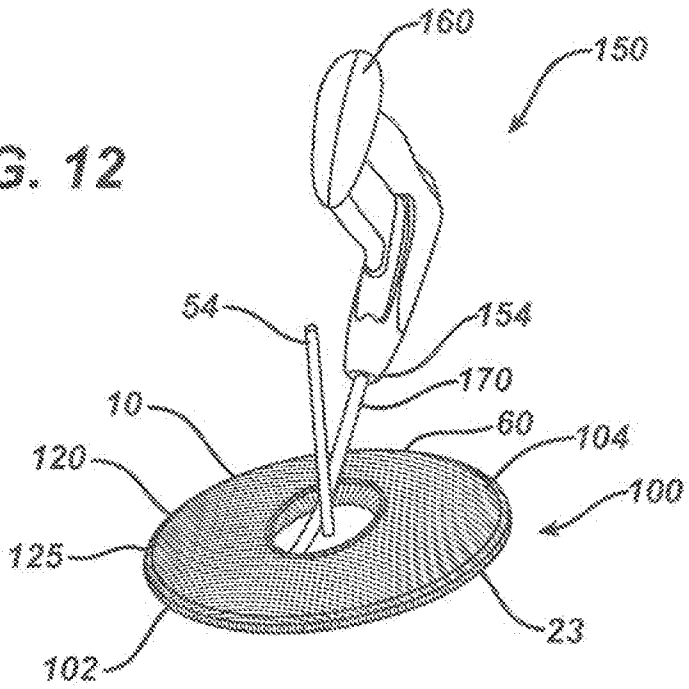

160
150
50
165
60
104
102
170
10
154
100
110
102

FIG. 12


160
150
54
154
170
10
60
104
120
100
125
23
102

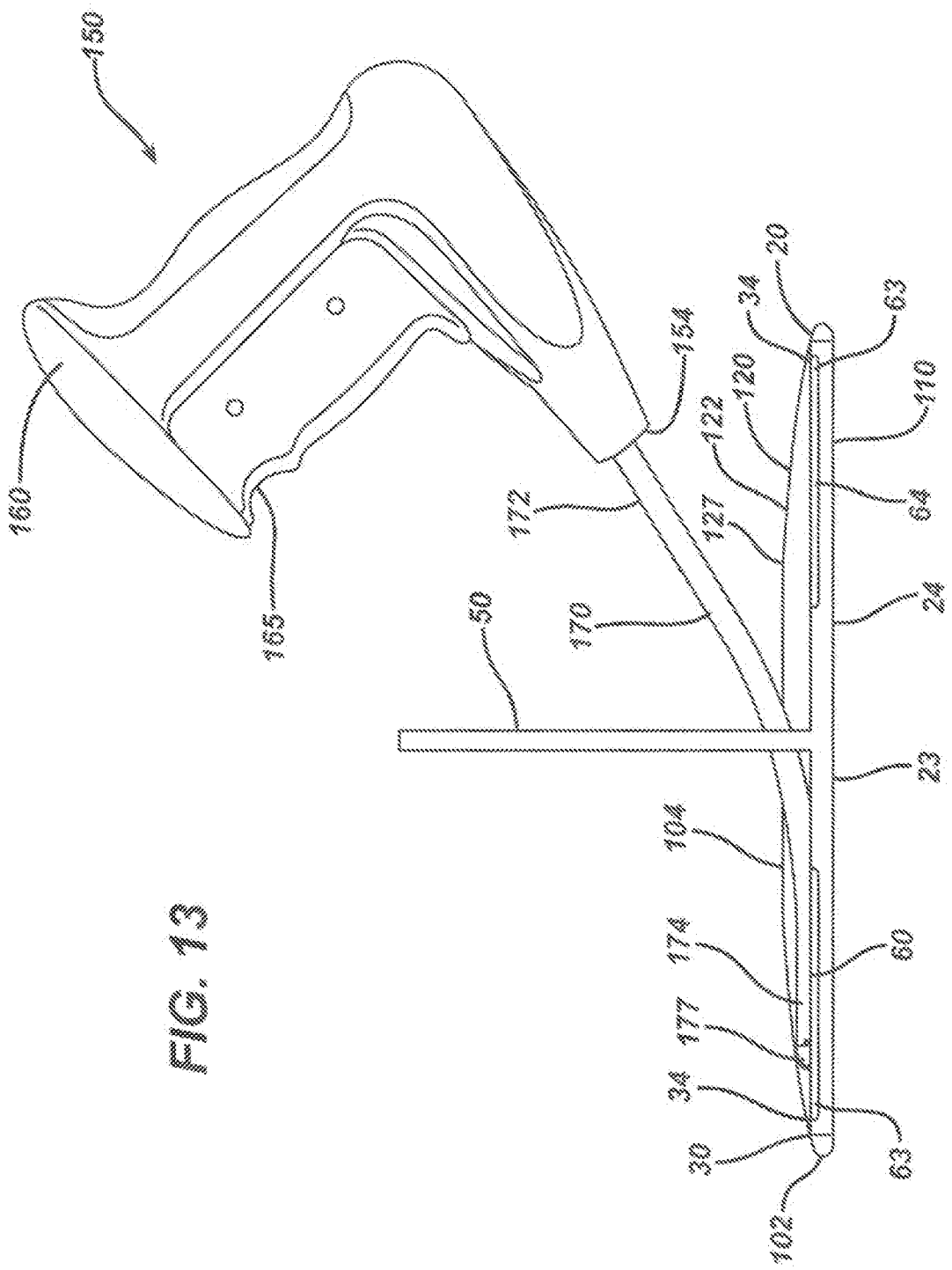

150
160
165
154
172
170
50
20
34
63
120
122
110
127
64
24
23
104
174
60
177
34
30
63
102

FIG. 13

FIG. 14

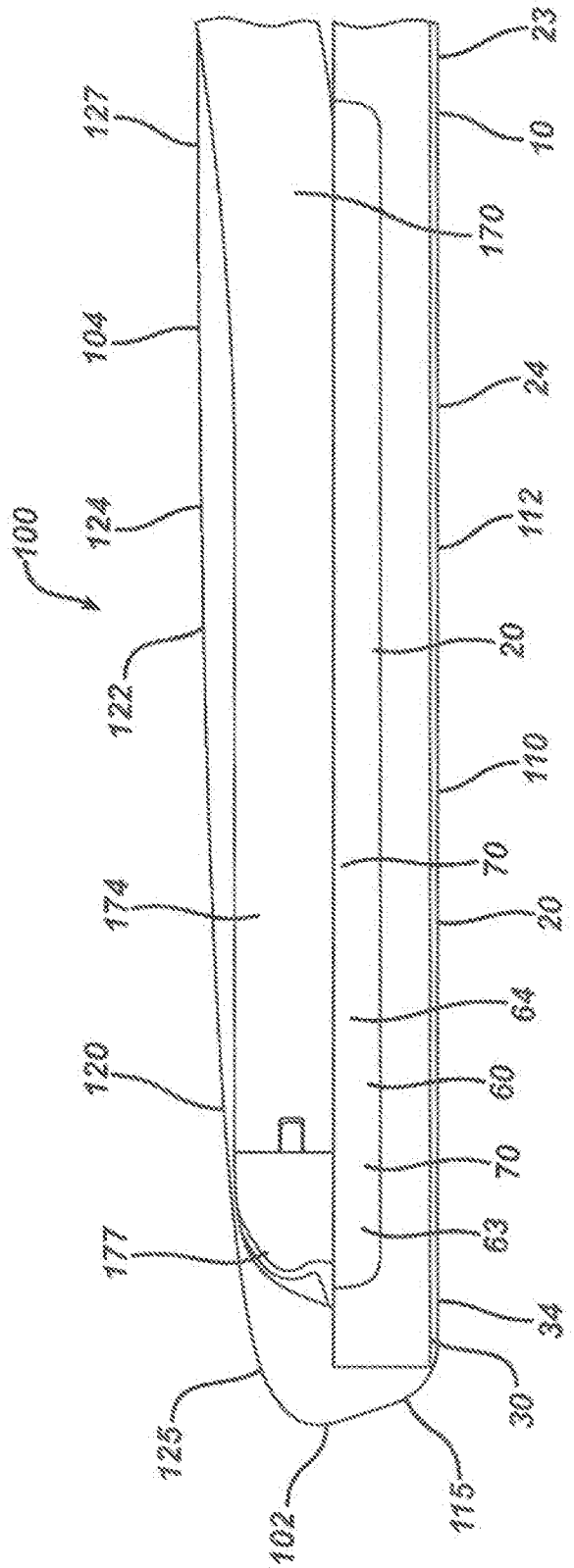

100
102
104
110
112
115
120
122
124
125
127
170
174
177
10
20
20
23
24
30
34
60
63
64
70
70
D

FIG. 15

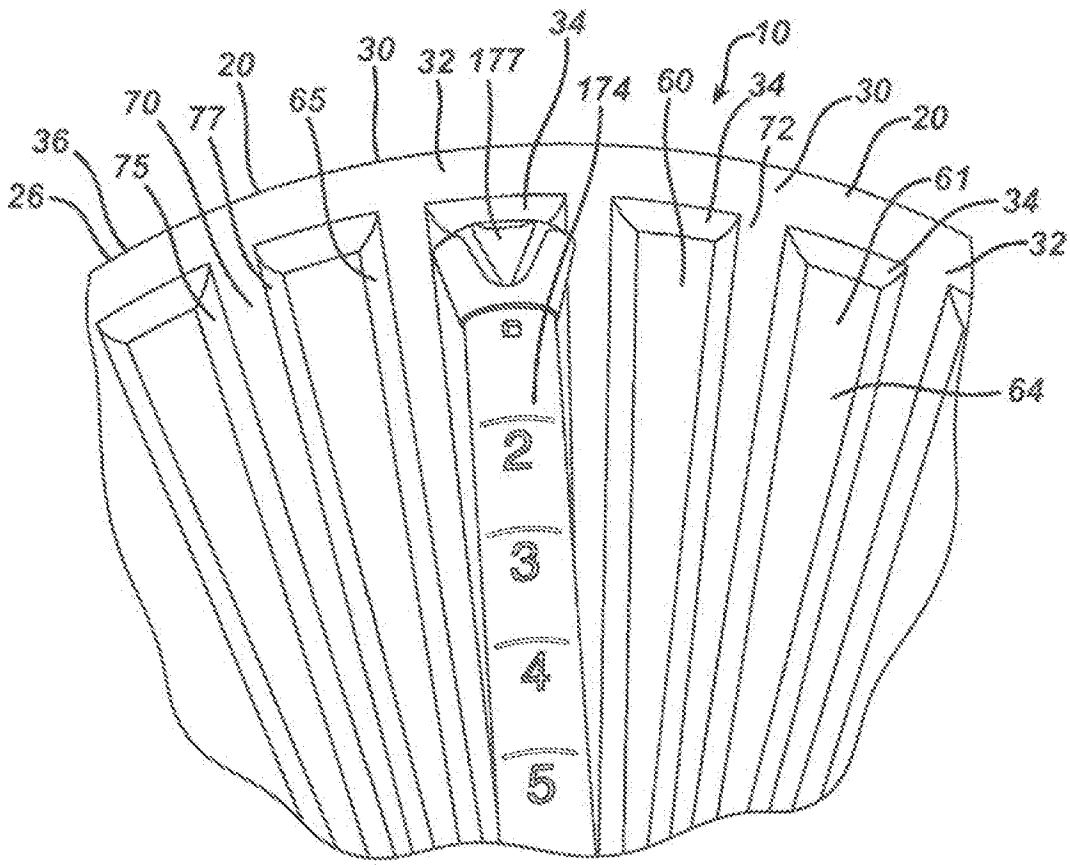

34
10
20
30
32
177
174
60
34
30
20
70
77
65
72
36
75
61
34
26
32
64
1
2
3
4
5

FIG. 16

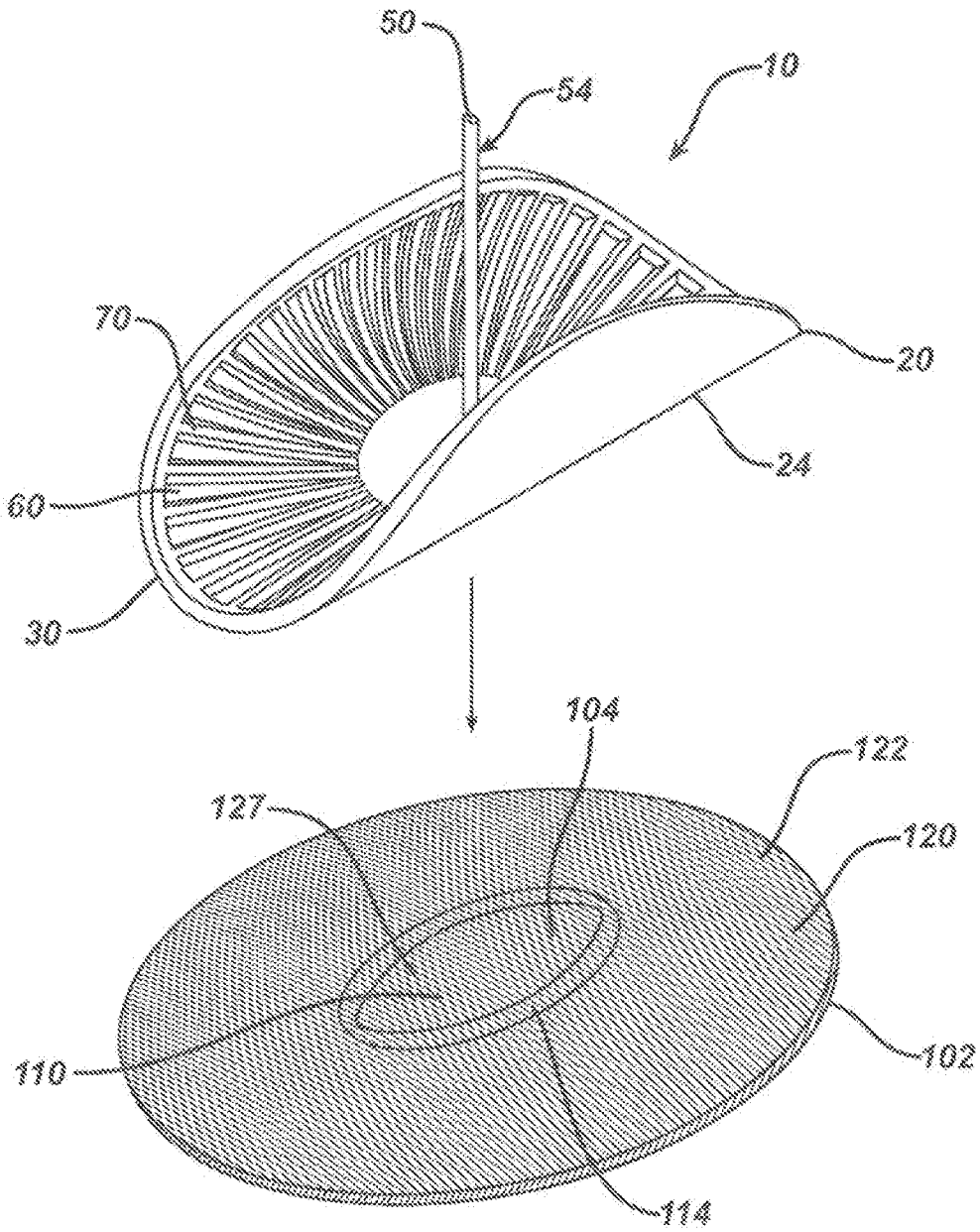
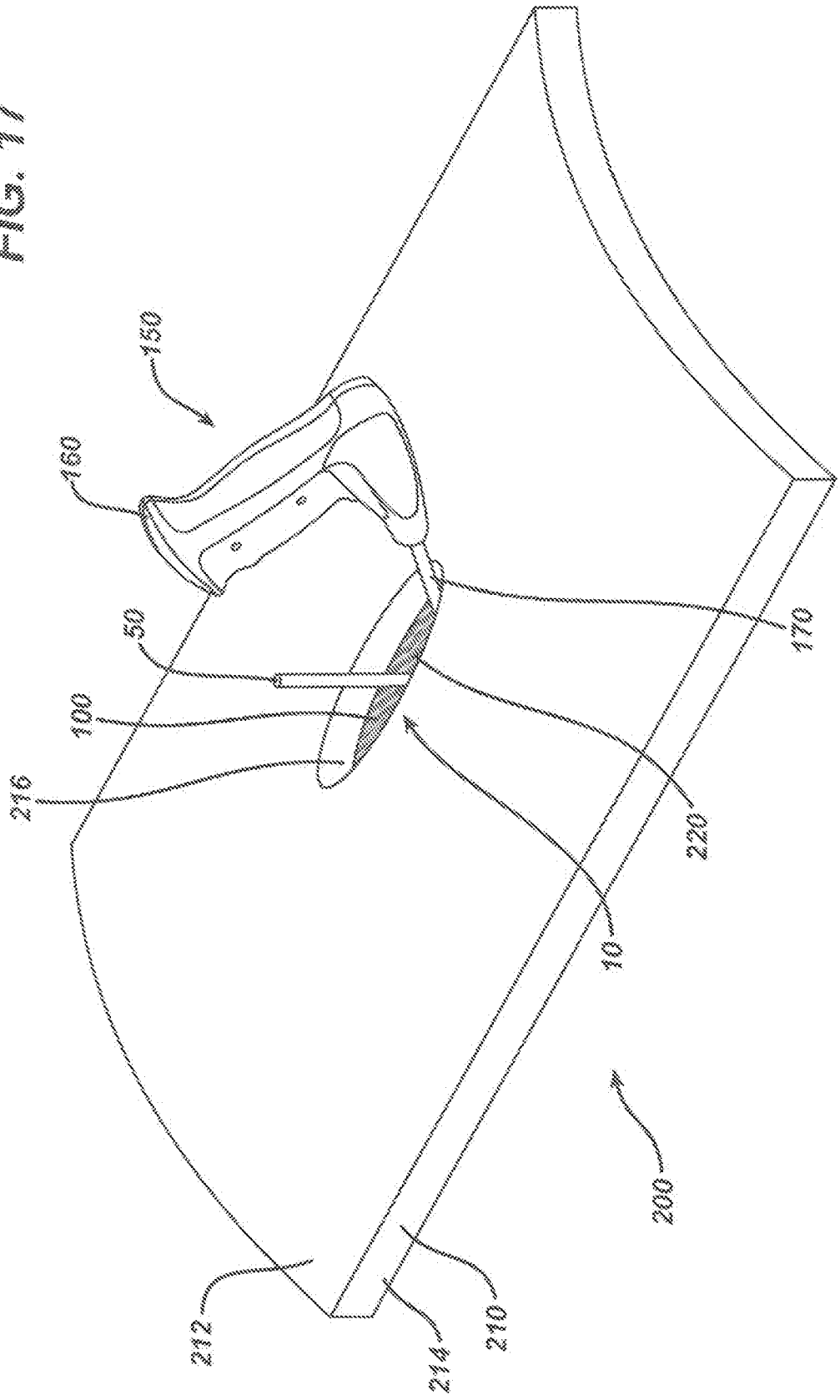


FIG. 17



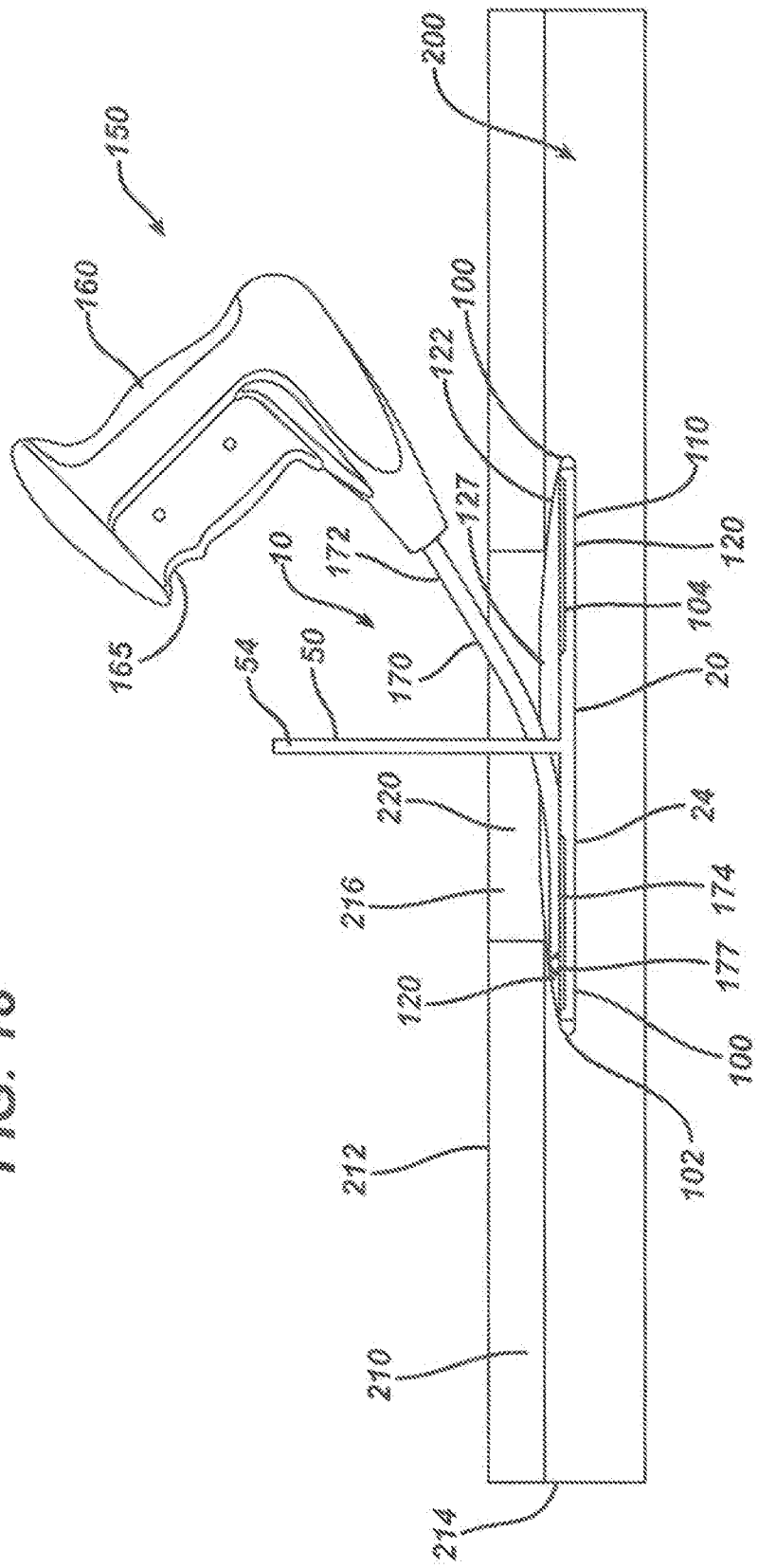

200
150
160
100
122
110
127
120
10
172
104
165
50
170
20
54
220
24
216
174
120
177
100
212
102
210
214

FIG. 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/059582

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/00 A61B17/068 A61B17/02
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 945 931 A1 (SGRO JEAN CLAUDE [FR]) 3 December 2010 (2010-12-03) page 14; figures 8,9	1-22,25
A	EP 0 557 964 A1 (UNITED STATES SURGICAL CORP [US]) 1 September 1993 (1993-09-01) figures 6,7	1-22,25
X	WO 2008/065653 A1 (HERNIA SOLUTIONS LTD [IL]; SHOLEV MORDEHAI [IL]; SZOLD AMIR [IL]; MATT) 5 June 2008 (2008-06-05) figure 9a page 18	1
X	US 2011/054500 A1 (LEVIN OFEK [IL] ET AL) 3 March 2011 (2011-03-03) figure 13a	1

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 November 2013	11/12/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Franz, Volker

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/059582

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/027542 A1 (PROXY BIOMEDICAL LTD [IE]; GINGRAS PETER [IE]; KING DEAN [IE]) 5 March 2009 (2009-03-05) figure 5a	1
A	US 2004/073257 A1 (SPITZ GREGORY A [US]) 15 April 2004 (2004-04-15) figures 4-6	1-22,25
A	US 2010/069930 A1 (ROSLIN MITCHELL [US] ET AL) 18 March 2010 (2010-03-18) figure 49a	1-22,25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/059582

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23, 24
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-matter of claims 23 and 24 relates to a method of treatment of the human body because the step of moving the mesh repair device into a body cavity involves a surgical step. Thus, according to Article 34.4(a)(i) and Rule 67.1(iv), no preliminary opinion will be established for those claims.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/059582

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2945931 A1	03-12-2010	NONE	
EP 0557964 A1	01-09-1993	CA 2090000 A1	25-08-1993
		EP 0557964 A1	01-09-1993
		US 5370650 A	06-12-1994
WO 2008065653 A1	05-06-2008	CA 2670673 A1	05-06-2008
		EP 2099385 A1	16-09-2009
		US 2010069947 A1	18-03-2010
		US 2013218179 A1	22-08-2013
		WO 2008065653 A1	05-06-2008
US 2011054500 A1	03-03-2011	NONE	
WO 2009027542 A1	05-03-2009	US 2011118706 A1	19-05-2011
		WO 2009027542 A1	05-03-2009
US 2004073257 A1	15-04-2004	US 2004073257 A1	15-04-2004
		US 2005159777 A1	21-07-2005
US 2010069930 A1	18-03-2010	EP 2344045 A1	20-07-2011
		US 2010069930 A1	18-03-2010
		WO 2010033189 A1	25-03-2010