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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 October 2013 (17.10.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/155174 A1

(51) International Patent Classification:
A61F 2/00 (2006.01)

(21) International Application Number:
PCT/US2013/035961

(22) International Filing Date:
10 April 2013 (10.04.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/443,347 10 April 2012 (10.04.2012) US

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

(72) Inventors: **CARDINALE, Michael**; 140 Madison Avenue, Morristown, New Jersey 07960 (US). **TANNHAUSER, Robert, J.**; 265 Holland Court, Bridgewater, New Jersey 08807 (US). **CHOMIAK, Harry, Martin**; 48 Urban Club Road, Wayne, New Jersey 07470 (US). **MCROY, Lynn**; 527 Horizon Way, Neshanic Station, New Jersey 08853 (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).

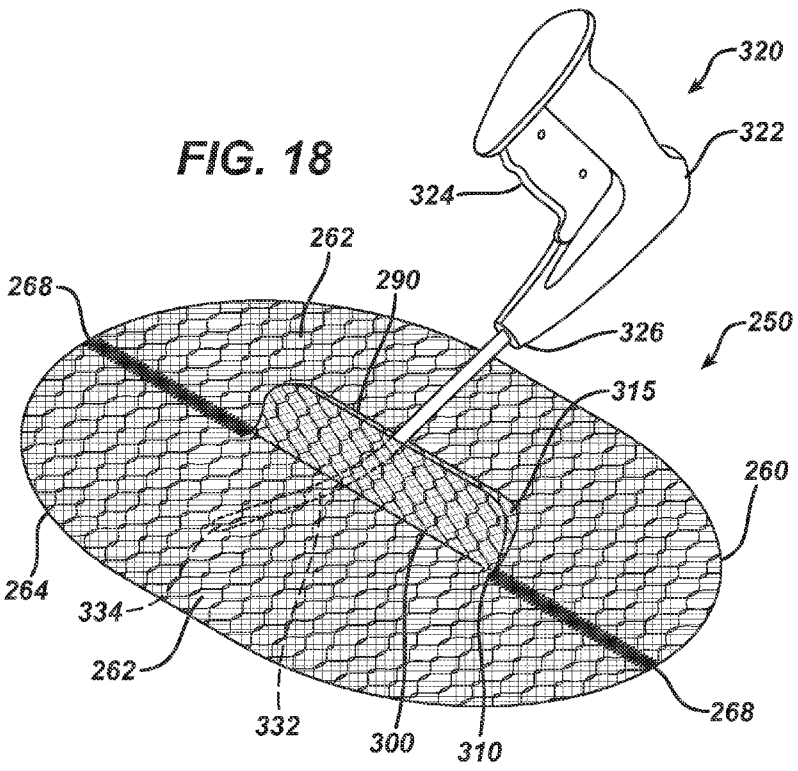
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, 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, 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,

[Continued on next page]

(54) Title: SINGLE PLANE TISSUE REPAIR PATCH

FIG. 18



(57) Abstract: A novel single plane tissue repair patch is disclosed. The patch (10) has a base member with an opening therethrough, and a closure member (30) associated with the opening. The mesh may be used in open surgical procedures for hernia repairs and other repairs of body wall defects.

WO 2013/155174 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, 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))*

— *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))*

SINGLE PLANE TISSUE REPAIR PATCH

Technical Field

The field of art to which this invention pertains is implantable surgical tissue repair patches, more particularly implantable surgical mesh hernia patches for use in hernia repair procedures.

Background of the Invention

Hernia repair is a relatively straightforward surgical procedure, the ultimate goal of which is to restore the mechanical integrity of the abdominal wall by repairing a muscle wall defect through which the peritoneum and possibly a section of the underlying viscera has protruded. There are various types of hernias, each with its own specific surgical repair procedure, including ventral hernias, umbilical hernias, incisional hernias, sports hernias, femoral hernias, and inguinal hernias. It is believed that most hernias are attributable to a weakness in sections of the tissues of the abdominal wall.

Precipitating events, such as unusual movements or lifting extremely heavy weights, may cause the weak spots in the abdominal wall tissue to be excessively stressed, resulting in tissue separation or rupture and protrusion of a section of peritoneum and underlying viscera, e.g., intestine, through the separated or ruptured tissue section. This weakness may be attributable to several factors. Weakness in the abdominal wall may be congenital or may be associated with a prior incision from a surgical procedure or a trocar wound. Other factors may include trauma, genetic predisposition, and aging.

Even though the commonly used, conventional surgical procedures for correcting or repairing the various types of hernias are somewhat specific, there is a commonality with respect to the mechanical repair. Typically, the protrusion of the peritoneum through a muscle or abdominal wall defect results in a hernia sack containing the underlying and protruding viscera. The hernia sack is dissected and the viscera are pushed back into the abdominal cavity. Then, a tissue reinforcing or repair implant such a mesh patch device is typically implanted and secured at the site of the abdominal wall

defect. Autologous tissue quickly grows into the mesh implant, providing the patient with a secure and strong repair. In certain patient presentations, it may be desirable to suture or otherwise close the defect without an implant, although this is typically much less desirable for the optimal outcome.

One common type of hernia is a ventral hernia. This type of hernia typically occurs in the abdominal wall and may be caused by a prior incision or puncture, or by an area of tissue weakness that is stressed. There are several repair procedures that can be employed by the surgeon to treat such hernias, depending upon the individual characteristics of the patient and the nature of the hernia. In one technique, an onlay mesh is implanted on the dorsal surface of the anterior fascia of the abdominal wall. Another technique provides for an inlay mesh, where the prosthetic material is sutured to the abdominal wall and acts as a "bridge" to close the abdominal defect. Placement of a prosthetic mesh posterior to the rectus muscle of the abdominal wall is known as the Reeves Stoppa or retromuscular technique. In this technique, a mesh implant is located beneath the muscle of the abdominal wall but above the peritoneum. Implantation of the mesh in the intra-peritoneal location can be done via an open or laparoscopic approach. The mesh is inserted into the patient's abdominal cavity through an open anterior incision or via a trocar and positioned to cover the defect. The surgeon then fixates the mesh implant to the abdominal wall with conventional mechanical fixation or with sutures placed through the full thickness of the abdominal wall. There are a variety of such mechanical fixation devices that can be used in laparoscopic or open surgery, e.g., tacking instruments. Intraperitoneal placement of mesh via an open approach may be the desired technique of repair where the layers of the abdominal wall are attenuated and a laparoscopic approach is not desired. Placement of mesh via this technique presents several unique challenges including poor visibility during mesh handling and fixation, poor handling, and deficient ergonomics of the currently available products. Mesh repair patch implants designed for intraperitoneal placement typically requires an additional treatment or layer to function as a tissue separating component to separate the viscera from the prosthetic abdominal wall repair layer, and thereby prevent or substantially

inhibit the formation of post-operative adhesions. The addition of this layer may add to the complexity of wound healing due to the presence and mass of an additional layer.

Although hernia repair patch implants exist for open ventral hernia repairs, there are deficiencies known to be associated with their use. The deficiencies include difficulty in handling the mesh, poor visibility during mesh handling, implantation and fixation, poor usability and ergonomics when using a laparoscopic instrument, and the use of dual or multiple layers of mesh. The commercially available meshes repair patch implants for this application typically have at least dual layers of mesh or fabric with pockets or skirts to provide for affixation to the parietal wall via the top layer or skirt. It can also be appreciated that multiple layer meshes introduce more foreign body mass and tend to be more expensive and complicated to manufacture than a single layer mesh implant

Accordingly, there is a need in this art for novel tissue repair implants, such as ventral hernia repair patch implants, that can be used in an open surgical procedure, and which do not require a mesh anchoring or affixation layer, and which may be secured to tissue using a single or multiple crown technique.

Summary of the Invention

Accordingly, novel tissue repair patches are disclosed. The tissue repair patches have a substantially flat or planar base member. The base member is preferably a mesh. There is an opening located in the base member, and, there is a closure member associated with the opening. The base member has a top side and a bottom side. The patch may have a polymeric layer on at least part of at least one side of the base member. It is preferred that the side of the mesh that faces the viscera have a polymeric layer covering substantially all of that side. The tissue repair patches of the present invention are especially useful in an open hernia repair procedure, such as a ventral hernia repair, and are also useful in other types of body wall tissue repairs.

Another aspect of the present invention is a method of repairing a body wall defect, such as a hernia defect, in an open surgical procedure using the above-described tissue repair patch implants.

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 plan view of an embodiment of a single plane tissue repair mesh patch of the present invention; the patch has a base member having an opening, and a closure patch member mounted to the top side of the base member over the opening.

FIG. 2 is an exploded perspective view of the repair mesh patch of FIG. 1.

FIG. 3 is an illustration showing a surgical tacking instrument having an elongated shaft partially inserted underneath the flap member and through the opening of the base member of the repair patch of FIG.1; the instrument shaft is seen as having access to the bottom side of the base member.

FIG. 4 is a plan view of a tissue repair patch of the present invention that is similar to the repair patch shown in FIG.1, but which has a rectangular closure patch member connected along its opposed minor sides; the closure patch member is seen to contain a direction guide for use by the surgeon in orienting the patch during implantation.

FIG. 5 is an exploded perspective view illustrating two halves of another embodiment of a tissue repair patch of the present invention; the two halves are connected to form a repair mesh patch having closure flaps.

FIG. 6 is a plan view of a tissue repair patch of the present invention made by joining the two halves seen in FIG. 5; the flaps are in the at rest position.

FIG. 7 is a perspective view of the tissue repair patch of FIG. 6; the flaps are in the at rest position.

FIG. 8 is a perspective view of the tissue repair patch of FIG. 7 showing both of the flaps in the up position, uncovering the opening in the base member, thereby providing access through the base member.

FIG. 9 illustrates the tissue repair patch of FIG. 8 with a curved shaft of a surgical tacking instrument inserted partially through the opening of the base member.

FIG. 10 is a plan view of another embodiment of a tissue repair patch of the present invention; the mesh patch is seen to have an opening with a surgical suture and surgical needle mounted about the opening in a continuous mattress suture configuration.

FIG. 11 illustrates the tissue repair patch of FIG. 10, wherein the opening has been closed by applying tension to the suture after the patch has been affixed to the parietal wall of the patient over the hernia defect.

FIG. 12 is an exploded perspective view of another preferred embodiment of a tissue repair patch of the present invention; the patch is seen to have an upper closure flap and a lower closure flap mounted about an opening in the base member.

FIG. 13 is a plan view of the tissue repair mesh of FIG. 13, showing the closure flaps mounted about the opening in the base member with one closure flap adjacent to the bottom side of the base member and one closure flap adjacent to the top side of the base member; the flaps are in an at rest position.

FIG. 14 is a plan view of a preferred embodiment of a tissue repair patch of the present invention; the patch is seen to have a pair of closure flap members.

FIG. 14a is a cross-sectional view of the repair patch of FIG. 12 along View Line 14a-14a.

FIG. 14b is a magnified partial view of the cross-section of FIG. 12a.illustrating the flaps positioned about the opening in the base member of the patch.

FIG. 15 is an exploded perspective view of two base member halves of the tissue repair patch of FIG.14; both halves have a closure flap member extending from the base member sections.

FIG. 16 is a perspective view of the tissue repair patch made by joining together the two halves seen in FIG.15; one closure flap is positioned below the base member and one closure flap is positioned above the base member.

FIG. 17 is a perspective view of the tissue repair mesh patch of FIG. 16; both closure flaps are in the up position such that the opening in the base member is accessible between the flaps.

FIG. 18 is a perspective view of the mesh repair patch of FIG. 17, illustrating the distal end of a curved elongated shaft of a surgical tacking instrument partially inserted through the opening of the base member in a position below the patch to secure the mesh repair patch to tissue.

FIG. 19 is a perspective view of the tissue repair patch of FIG. 18, with both flaps optionally sutured together in an upward extending position to close the opening in the base member after the patch has been affixed to tissue.

FIG. 20 is a cross-sectional side view of the tissue repair patch of FIG. 16 inserted into the abdominal cavity of a patient and positioned adjacent to the patient's peritoneum; a curved shaft of a surgical tacking instrument is seen inserted thorough an access opening such as a hernia defect in the patient's body wall and through the opening in the base member of the repair patch, such that the distal end of the shaft is in position below the patch to secure a section of the base member of the patch with a tack to the body wall.

FIG. 21 is a perspective view of the mesh repair patch of FIG. 17, illustrating the distal end of a straight elongated shaft of a surgical tacking instrument partially inserted through the opening of the base member in a position to secure the tissue repair patch to tissue.

FIG. 22 is a side view of the tissue repair patch of FIG. 21 inserted into the abdominal cavity of a patient and positioned adjacent to the patient's peritoneum; a distal section of a straight shaft of a surgical tacking instrument is seen inserted thorough an access opening in the patient's body wall and through the opening in the base member of the repair patch, such that the distal end of the shaft is in position below the patch to secure a section of the base member of the patch with a tack to the body wall.

FIG. 23 is an illustration of a hernia repair procedure wherein a surgeon is securing the tissue repair patch of FIG. 17 in position over a hernia defect using a surgical tacking instrument having a curved elongated shaft; the distal section of the shaft is inserted through an access opening in the patient's body wall and through an opening in the tissue repair patch in order to secure the tissue patch to the peritoneum; the surgeon's hand is seen palpating the abdomen above the distal end of the shaft of the instrument to place a tack in a desired position on the patch.

FIG. 24 is a cross-sectional side view illustrating a preferred embodiment of a tissue repair patch of the present invention in place over a hernia defect adjacent to a patient's peritoneum; a curved elongated shaft of a surgical tacking instrument has been positioned through an access opening in the patient's body wall and through an opening in the patch to attach a section of the base member of the patch to the peritoneum; the patient's visceral organs are seen positioned adjacent to the bottom side of the patch and the peritoneum, and the closure flaps are seen to extend upwardly through the opening in the body wall.

FIG. 25 is an exploded perspective view of an alternate embodiment of a mesh tissue repair patch of the present invention; the base member is seen to have an opening in the base member surrounded by a closure ring, and a closure patch having a mating closure ring is also shown.

FIG. 26 is a perspective view of the tissue repair patch of FIG. 25 showing the patch secured to the base member.

FIG. 27 illustrates a peritoneal view of the bottom side of a preferred embodiment of a tissue repair patch of the present invention secured to the peritoneum with a double row of surgical tacks referred to as a double crown technique; the opening in the base member is seen to be closed, and both flaps have been positioned upwardly away from the top of the base member; the flaps are secured to close the opening in the base member.

FIG. 28 is a perspective view of an alternate embodiment of a mesh tissue repair patch of the present invention; the patch is seen to have a slit in the base member providing a central opening.

FIG. 29 is a perspective view of the patch of FIG. 28 having a surgical suture mounted about the slit in a shoe lace type configuration to close the opening in the slit.

FIG. 30 is a perspective view of the tissue repair patch of FIG. 29, after the suture ends have been tensioned, thereby closing the opening and slit after the patch is secured to the patient's body wall.

Detailed Description of the Invention

The novel tissue repair patches or devices of the present invention are particularly useful in open ventral or incisional hernia repair surgical procedures. The tissue repair patch devices consist of a base member having an opening. The base member has a closure member or device associated with the opening for securing the opening after implantation. The repair patch devices of the present invention have utility in other conventional tissue repair procedures including inguinal hernia repair procedures, trocar puncture wounds, trocar incisional hernias, etc.

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 tissue repair patches of the present invention may be made from any conventional biocompatible materials. 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.

Although it is preferred to use surgical meshes to construct the hernia repair patches of the present invention, other conventional woven or nonwoven surgical repair fabrics or thermally formed implants may also be used. In addition, the tissue repair patches may be made from other conventional implantable materials such as PTFE (polytetrafluoroethylene), e.g., ePTFE films and laminates. The patches may consist of composites of polymeric films and meshes, and/or fabrics.

The meshes useful in the hernia repair patch devices of the present invention will be manufactured in a conventional manner using conventional manufacturing equipment and methods including knitting, weaving, non-woven techniques, and the like. The meshes will typically have a pore size sufficient to effectively provide for tissue ingrowth; for example, they may have pore sizes in the range of about 0.3mm to about 5mm, and other conventional size ranges. Examples of commercially available nonabsorbable and bioabsorbable polymeric meshes that may be used to construct the hernia repair patches of the present invention include ETHICON PHYSIOMESH™ and ETHICON PROCEED™ Surgical Mesh, available from Ethicon, Inc., Route 22 West, Somerville, NJ 08876.

When constructing the novel tissue repair patches of the present invention from surgical fabrics other than meshes, the fabrics will have open pores with a pore size sufficient to effectively provide for tissue ingrowth; for example, with a typical size of about 0.3 mm to about 3mm. By "open pores" is meant openings that extend from one side of the fabric to the opposed side, providing a pathway through the fabric. The fabric repair members may be constructed from monofilaments, multifilaments, or combinations thereof. Examples of commercially available non-mesh fabrics that can be used to manufacture the hernia repair patches of the present invention include woven fabrics, textiles and tapes for surgical applications. Other fabrics or materials include perforated condensed ePTFE films and nonwoven fabrics having pore sizes of at least one millimeter. The non-mesh fabrics may be constructed of conventional biocompatible materials.

The fabric or mesh may contain, in addition to a long-term stable polymer, a resorbable polymer (i.e., bioabsorbable or biodegradable). The resorbable and the long-term stable polymer preferably contain monofilaments and/or multifilaments. The terms resorbable polymers and bioabsorbable polymers are used interchangeably herein. The term bioabsorbable is defined to have its conventional meaning. Although not preferred, the fabric or mesh tissue repair member may be manufactured from a bioabsorbable polymer or bioabsorbable polymers without any long-term stable polymers.

The tissue repair patches of the present invention may also include polymer films. The films may be attached to the top surface, the bottom surface or both surfaces and may also cover the peripheral edges of the repair patch devices or extend beyond the periphery of the repair patch devices. The films that are used to manufacture the tissue repair patch implant devices of the present invention will have a thickness that is sufficient to effectively prevent adhesions from forming, or otherwise function as a tissue barrier or tissue separating structure or membrane. For example, the thickness may typically range from about 1μm to about 500μm, and preferably from about 5μm to about 50μm, however this will depend upon the individual characteristics of the selected polymeric films. The films suitable for use with the repair patches of the present

invention include both bioabsorbable and nonabsorbable films. The films are preferably polymer-based and may be made from various conventional biocompatible polymers,including bioabsorbable and nonabsorbable polymers. Non-resorbable or very slowly resorbable substances include polyalkenes (e.g., polypropylene or polyethylene), fluorinated polyolefins (e.g., polytetrafluoroethylene or polyvinylidene fluoride), polyamides, polyurethanes, polyisoprenes, polystyrenes, polysilicones, polycarbonates, polyarylether ketones (PEEKs), polymethacrylic acid esters, polyacrylic acid esters, aromatic polyesters, polyimides as well as mixtures and/or co-polymers of these substances. Also useful are synthetic bioabsorbable polymer materials for example, polyhydroxy acids (e.g., polylactides, polyglycolides, polyhydroxybutyrates, polyhydroxyvaleriates), polycaprolactones, polydioxanones, synthetic and natural oligo- and polyamino acids, polyphosphazenes, polyanhydrides, polyorthoesters, polyphosphates, polyphosphonates, polyalcohols, polysaccharides, and polyethers. However, naturally occurring materials such as collagen, gelantin or natural-derived materials such as bioabsorbable Omega 3 fatty acid cross-linked gel films or oxygenated regenerated cellulose (ORC) can also be used.

The films used in the tissue repair patch devices of the present invention may cover the entire outer surfaces of the hernia patch member or a part thereof. In some cases, it is beneficial to have films overlapping the borders and/or peripheries of the repair patches. The repair patches of the present invention may also have adhesion barrier layers attached to one or both sides. The adhesion barriers will typically consist of conventional biocompatible polymeric materials including but not limited to absorbable and nonabsorbable polymers. Examples of conventional nonabsorbable polymeric materials useful for adhesion barriers include expanded polytetrafluoroethylene, polytetrafluoroethylene, silicone, and the like. Examples of conventional absorbable polymeric materials useful for adhesion barriers include oxidized regenerated cellulose, poliglecaprone 25 (copolymer of glycolide and epsilon-caprolactone), and the like.

It is particularly preferred that the tissue repair patches of the present invention have a mesh construction, and the embodiments illustrated in the Figures have such a mesh construction. The tissue repair implants of the present invention have particular utility for hernia repair procedures, but may be used in other tissue repair surgical procedures as well.

Referring now to FIGS. 1-3, a tissue repair patch 10 of the present invention is seen. The patch 10 has a mesh construction. The repair patch 10 is seen to have substantially flat or planar base member 20 and closure patch member 30. The base member 20 is illustrated having a substantially oval shape or configuration, but may have other configurations including square, rectangular, circular, polygonal, etc, combinations thereof and the like. The base member 20 is seen to have top side 22, bottom side 24, and periphery 26. Extending through the base member 20 is the slot 40 having opening 42 bounded by opposed sides 44 and opposed ends 43. The closure patch member 30 is seen to be a substantially flat or planar member having a substantially oval configuration. The closure patch member 30 is seen to have top side 32, bottom side 34, and periphery 35. Closure patch member 30 is seen to have opposed curved ends 37 and opposed sides 38. Patch member 30 is mounted to the top of base member 20 via connections 39 along the ends 37 such that the bottom side 34 of closure patch 30 is adjacent to the top side 22 of base member 20. The closure patch is mounted using any conventional affixation method to create the connections 39, including but not limited to sewing, welding, tacking, riveting, stapling, gluing, etc., and the like. The closure patch 30 is mounted to the base member 20 to cover the slot 40 and opening 42. Openings 48 adjacent to sides 38 provide access passages for surgical instruments to and through opening 42 of slot 40. A partial schematic of a surgical tacking instrument 60 which can be used to tack the base member 20 of patch 10 to tissue is seen in FIG. 3. The instrument 60 has proximal handle 62 and distally extending elongated shaft 70 having distal end 78. A distal section 76 of the shaft 70 is seen to extend through opening 48, underneath the bottom side 34 of closure flap 30 and through opening 42 of slot 40 such that it is positioned below the bottom side 24 of base member 20. The distal end 78 is seen to be positioned in proximity to the periphery 26 of the base member 20 adjacent to bottom side 24 so that

surgical tacks may be fired to secure the patch to tissue adjacent to the top side 22 of base member 20 and the top side 32 of closure patch member 30. The repair patch 10 is fixated around its perimeter 26 to tissue with fixation points placed, for example, about every 1 to 2 cm, i.e., the fixation devices or tacks are separated by about 1 cm to 2 cm distances. Although in many embodiments of the tissue or hernia repair patches of the present invention it is preferred to have a slot in the base member to provide an opening through the base member, the opening may be a slit or other types of openings having different geometric configurations may be utilized including circular, oval, rectangular, polygonal, etc., combinations thereof and the like. Although not preferred, it is possible to form the tissue repair patches of the present invention such that the base member and/or closure member are curved or otherwise in more than one plane.

Once the tissue repair patch 10 of the present invention has been implanted and secured to tissue by tacking or other conventional methods (e.g., stapling, suturing, etc.), the shaft section 76 of surgical affixation instrument 60 is removed from the body through the slot 40. The closure patch member 30 prevents underlying tissue or viscera from moving through the slot 40 and opening 42.

An alternative embodiment of the tissue repair patch 10 is seen in FIG. 4. The patch 10 is seen to have similarly shaped base member 20, however the closure member 50 is seen to have a substantially rectangular shape with opposed minor end sides 56 and opposed major sides 57. Closure member 50 has top side 52 and bottom side 54 adjacent to top side 22 of base member 20. The patch member 50 is mounted to base member 20 over slot 40 by connections 59 along minor sides 56. The connections may be made as described previously. Openings 48 beneath sides 57 provide access to slot 40 and opening 42. As seen in FIG. 4, the tissue repair patch 10 is seen to have a directional indicator 80 contained on or in the closure member 50. Indicator 50 may be conventionally sewn, molded or formed, printed, dyed or laminated into or onto the member 50. The indicator 80 is seen to have central section 81, having opposed transverse sections 82 extending therefrom. Extending longitudinally in an opposed manner are the longitudinal sections 85 and 87. Section 87 is seen to be thicker than

section 85. The indicator 80 allows the surgeon to determine the location of the patch with respect to the patient after insertion by aligning the respective axes of the tissue repair patch 10 with respect to the patient and the incision, allowing for more precise fixation, either using a tacking instrument or using surgical sutures for affixation. Such directional indicators may be used with other embodiments of the tissue repair patches of the present invention.

Referring now to FIGS. 5-9, an alternative embodiment of a tissue repair patch 100 of the present invention is seen. The patch 100 is seen to have substantially flat or planar base member 110 formed from substantially flat or planar base sections 120 and 140. The base member 110 has bottom side 112, top side 114 and periphery 116. Base section 120 is seen to have straight side 122 having ends 124. Base section 120 is also seen to have curved side 126 having ends 128 that connect to ends 124. Extending out from straight side 122 is the closure flap member 130 having hinged side 132 and free end 134 separated from side 122 by slot 136. Slot 136 has closed end 137 and open end 138. The closure flap member 130 is seen to have a generally rectangular configuration, but may have other geometric configurations including circular, oval, polygonal, etc., combinations thereof and the like. Base section 140 is seen to have straight side 142 having ends 144. Base section 140 is also seen to have curved side 146 having ends 148 that connect to ends 144. Extending out from straight side 142 is the closure flap member 150 having hinged side 152 and free end 154 separated from side 142 by slot 156. Slot 156 has closed end 157 and open end 158. The closure flap member 150 is seen to have a generally rectangular configuration, but may have other geometric configurations including circular, oval, polygonal, etc., combinations thereof and the like. The base member 110 and the tissue repair patch 100 are formed from the base sections 120 and 140 by connecting the base sections along straight sides 122 and 142 along seams 118. This can be done in any conventional manner including sewing, welding, tacking, stapling, gluing, etc., and combinations and equivalents thereof. It can be seen that only the straight sides 122 and 142 are connected on either side of the closure flap members 130 and 150. The closure flaps members 130 and 150 are mounted together such that hinged side 132 of closure flap 130 is contained in slot 156 of flap member 150

and hinged side 152 of closure flap 140 is contained in slot 136 of closure member 130. This creates the slit 160 in base member 110 having through opening 165 bounded by interior portions of straight sides 122 and 142 of the base sections 120 and 142, respectively, and also bounded by the hinged sides 132 and 152 of the flap members 130 and 150, respectively. In the at rest position as seen in FIG. 6, the flap member 130 rests upon the top side 145 of the base section 140 of base member 110, while the flap member 150 rest upon the top side 125 of base section 120. In this at rest configuration the slit 160 and opening 165 are covered. The tissue repair patch 100 is seen in the ready position in FIG. 8, with the closure flap members 130 and 150 in the upright position exposing the slit 160 and opening so that a fixation instrument can be inserted through the opening 165. A tacking instrument 170 is illustrated in FIG. 9 with tissue repair patch 100 of the present invention. The tacking instrument 170 is seen to have proximal handle 172 and actuation trigger 174. Extending from the distal end 176 of handle 170 is the curved shaft 180 having distal section 182 and distal end 184. The distal section 182 is seen to be inserted through slit 160 and opening 165 between upwardly extending flaps 130 and 150 such that the distal end 184 may be moved about the bottom side 112 of the base member 110 in order to secure the base member to tissue with surgical tacks. Once tacks are placed through the base member 110 of patch 100 to secure the patch 100 to tissue, the tacking instrument 170 may be removed from the slit 160 and the two flap members 130 and 150 can be interlocked by folding or rotating the flap members downwardly onto the top 114 of the base member 110. One or both of the flap members may be optionally bonded or affixed to the base member 110 using various conventional closure methods including adhesives, sutures, surgical fasteners, etc.

An alternate embodiment 400 of a single plane tissue repair patch of the present invention is seen in FIGS. 10 and 11. The repair patch 400 has a base member 410 having a top side 412 and a bottom side 414. The patch has a periphery 416. Located in the base member 410 is a slit 420 having an opening 424 bounded by sides 422. The slit 420 has ends 428. Mounted about the slit 420 is a surgical suture 430 having ends 432 and 434 and surgical needle 436 mounted to end 432, and optionally, although not

shown, to end 434. The suture 430 is mounted about the opening 424 in a conventional mattress suture (continuous) configuration. As seen in FIG. 11, the opening 424 is closed by tensioning the suture ends 432 and 434, causing the sides 422 to approximate. If desired, the suture needles 436 can be used to engage tissue with the suture 430. Referring to FIGS. 28 and 29, a variation of suture mounting is illustrated. The repair patch 450 is similar to repair patch 400, but has a rectangularly shaped base member 451 having opposed major sides 454 and opposed minor sides 456 connected by rounded corners 457. The base member 451 has bottom side 458 and top side 459, and outer periphery 452. The base member 451 has centrally located slit 460 having an opening 464 bounded by sides 462. The slit 460 has ends 468. Mounted about the slit 460 is a surgical suture 470 having ends 472 and 474. The suture 470 is mounted in a "shoe lace" type configuration. The suture 470 is seen to be mounted to slit 460 by engaging opposed sides 462 of slit 460 about the opening 464. Suture 470 is seen to have ends 472 and 474 located adjacent to one another along one end 468 of slit 460. The slit 460 is secured after placement of the patch 450 by pulling on ends 472 and 474 thereby closing opening 464. The suture 460 may optionally have surgical needles mounted to one or both of the ends 472 and 474. The base members 410 and 451 may have any suitable geometric configuration.

A preferred embodiment of a tissue repair patch 200 of the present invention is seen in FIGS. 12 and 13. The patch 200 is seen to have a substantially flat or planar base member 210 having a top 212, bottom 214 and periphery 216. The base member 210 is seen to have an oval shape, but may have other geometric shapes including rectangular, circular, square, polygonal, combinations thereof and the like. Located in the base member 210 is the slot 220 having opening 222 therethrough. Slot 220 is bounded by opposed sides 224 and 225 and curved ends 226. The patch 200 is seen to have upper closure flap 230 and lower closure flap 240. Upper closure flap 230 is seen to have a substantially rectangular shape, although it may have other geometric configurations including circular, oval, rectangular, polygonal, etc., and the like. Flap 230 is seen to have top side 231 and bottom side 232. The flap 230 also has opposed sides 235 and 236 connected by opposed end sides 237. The flap 230 is mounted to the top side 212 of base

member 210 adjacent to side 224 of slot 220 by connecting the flap 230 along its side 235 in a conventional manner such as sewing, gluing, stapling, welding, riveting and the like to create a seam 239. In this manner, the flap 230 has its bottom side 232 facing the top side 212 of base member 210, and is positioned to cover slot 220 and opening 222 in the at rest position. The closure flap may be rotated upwardly about seam 239 to uncover slot 220 and opening 222. Mounted to the bottom side 214 of base member 210 is the other closure flap 240. Flap 240 is seen to have top side 241 and bottom side 242. The flap 240 also has opposed sides 245 and 246 connected by opposed end sides 247. The flap 240 is mounted to the bottom side 214 of base member 210 adjacent to side 225 of slot 220 by connecting the flap 240 along its side 245 in a conventional manner such as sewing, gluing, stapling, welding, riveting and the like to create a seam 249. In this manner, the flap 240 has its top side 241 facing the bottom side 214 of base member 210, and is positioned to cover slot 220 and opening 222 in the at rest position. The closure flap may be rotated downwardly about seam 249 to uncover slot 220 and opening 222. The flap 240 may also be rotated upwardly about seam 249 through slot 220 and opening 222.

Referring now to FIGS. 14, 14a, 14b, and 15-17, a preferred tissue repair patch 250 of the present invention is seen. The patch 250 is similar to patch 200, but is constructed in a different manner from two separate base section members. The patch 250 is seen to have substantially flat or planar base member 260 formed from substantially flat or planar base sections 270 and 280. The base member 260 has bottom side 264, top side 262 and periphery 266. Base section 270 is seen to have straight side 272 having ends 274. Base section 270 is also seen to have side 276 having curved ends 278 that connect to ends 274. Extending out from straight side 272 is the closure flap member 290 having hinged side 292 and free side 294. The closure flap member 290 is seen to have a generally rectangular configuration, but may have other geometric configurations including, circular, oval, rectangular, polygonal, etc. and the like. Base section 280 is seen to have straight side 282 having ends 284. Base section 280 is also seen to have side 286 having curved ends 288 that connect to ends 284. Extending out from straight side 282 is the closure flap member 300 having hinged side 302 and free

side 304. The closure flap member 300 is seen to have a generally rectangular configuration, but may have other geometric configurations including circular, oval, rectangular, polygonal, etc., and the like. The base member 260 and the hernia closure patch 250 are formed from the base sections 270 and 280 by connecting the base sections along straight sides 272 and 282 along seams 268. This can be done in any conventional manner including sewing, welding, tacking, stapling, gluing, etc., and combinations and equivalents thereof. It can be seen that the straight sides 272 and 282 are connected on either side of the closure flap members 290 and 300, thereby creating a slit 310 between the members 290 and 300 having an opening 315. The slit 310 is bounded by the hinged sides 292 and 302 of the closure flap members 290 and 300 and has opposed ends 312. When assembling the patch 250 and base member 260, closure flap 290 is inserted through opening 315 in slit 310. In the at rest position as seen in FIGS. 12 and 16, the flap member 300 rests upon the top side of the base section 270 of base member 260, while the flap member 290 rests upon the bottom side of base section 280. In the at rest state, closure flaps 290 and 300 each cover the slit 310 and opening 315. It will be appreciated that either closure flap may be rotated through the slit 310 and opening 315, although patch 250 as illustrated shows closure flap member 290 rotated though the slit and resting adjacent to the bottom side 264 of base member 260. In addition slit 310 may have other geometric configurations and shapes including a slot, etc.

Referring now to FIGS. 17-22, the repair patch 250 is seen in a ready position for securement to tissue in a tissue repair procedure such as a hernia repair procedure. As seen in FIG. 17, the patch has been placed in a ready position by rotating flap 300 upwardly away from the top 262 of base member 260. Flap 290 is also seen to be rotated upwardly through slit 310 and opening 315. By rotating closure flaps 290 and 300 in this manner, the slit 310 and opening 315 are uncovered providing access to a surgical instrument, such as a tacking instrument, or the surgeon's fingers. A surgical tacking instrument 320 is seen in FIG. 18 along with tissue repair patch 250 of the present invention. The tacking instrument 320 is seen to have proximal handle 322 and actuation trigger 324. Extending from the distal end 326 of handle 322 is the curved shaft 330 having distal section 332 and distal end 334. The distal end section 332 is seen to be

inserted through slit 310 and opening 315 between upwardly extending closure flaps 290 and 300 such that the distal end 334 may be moved about the bottom side 264 of the base member 260 in order to secure the base member 260 to tissue with surgical tacks. The hernia patch 250 is seen implanted in a patient in FIG. 20. A cross-section of a body wall 370 having a surgically created opening 372 is seen. The body wall 370 is seen to have an inner peritoneal layer 374, a next upper fascia layer 375, a next muscle layer 376, a fat layer 377, and finally a top dermal layer 378. The top side 262 of base member 260 is seen to be mounted adjacent to the peritoneal layer 334, with the closure flap members 290 and 300 extending out and through the opening 332. Shaft 330 of tacking instrument 320 is seen inserted through surgical opening 332, through slit 310 and opening 315 and into the patient's underlying body cavity. The distal end section 332 and distal end 334 are seen to be positioned adjacent to bottom side 264 of base member 260 in order to attach a section of the base member 260 to the peritoneal layer 374. Referring to FIG. 19, the patch 250 is seen with the flap members 290 and 300 optionally secured along their bottom sides 302 and 292 respectfully by surgical suture 380 having ends 381 and 382. Surgical needle 388 is attached to suture end 281. The sutured flap members close the opening 315 in slit 310. Alternatively, the flap members may be joined or secured together to close the slit 310 by conventional adhesives, surgical fasteners, etc. The flap members 290 and 300 may alternatively be utilized in their at rest position during implantation. The shaft of a tacking instrument would be inserted beneath flap 300 through slit 310 and opening 315 without rotating the flaps upwardly. After securement, the flaps may be left in the at rest position without additional securement of the flaps. The flap 290 would prevent tissue or visceral from moving into slot 310 and opening 315; any pressure against flap 290 would cause it to seal against the bottom side 264 of base member 260, closing off slit 310.

A surgical tacking instrument 340 having a straight shaft 350 that can be used to secure a tissue repair patch of the present invention is seen in FIGS. 21 and 22. The instrument 340 has a proximal handle 342 with an actuation trigger 344. Extending from the distal end 346 of handle 340 is the straight shaft 350 having distal section 352 and distal end 354. The distal end section 352 is seen to be inserted through slit 310 and

opening 315 between upwardly extending closure flaps 290 and 300 such that the distal end 354 may be moved about the bottom side 264 of the base member 260 in order to secure the base member 260 to tissue with surgical tacks. The tissue repair patch 250 is seen implanted in a patient in FIG. 22. A cross-section of a body wall 370 having a surgically created opening 372 is seen. The body wall 370 is seen to have an inner peritoneal layer 374, a next upper fascia layer 375, a next muscle layer 376, a fat layer 377, and finally a top dermal layer 378. The top side 262 of base member 260 is seen to be mounted adjacent to the peritoneal layer 374, with the closure flap members 290 and 300 extending out and through the opening 332. Shaft 350 of tacking instrument 350 is seen inserted through surgical opening 372, through slit 310 and opening 315 and into the patient's underlying body cavity. The distal end section 352 and distal end 354 are seen to be positioned adjacent to bottom side 264 of base member 260 in order to attach a section of the base member 260 to the peritoneal layer 374.

FIGS. 23 and 24 illustrate the implantation of a tissue repair patch 250 of the present invention in a patient during a surgical procedure to repair a hernia defect. The surgeon is seen to be holding the handle 322 of a surgical tacking instrument 320 with one hand while engaging the trigger 324. The instrument has a curved shaft 330, and the proximal section 332 of shaft 330 has been placed through opening 372 of body wall 370, and through slit 315 and opening 350 of hernia repair patch 250. Repair patch 250 has been implanted in the patient's body cavity such that the upper side 262 of base member 260 is adjacent to the peritoneal layer 374. The closure flaps 290 and 300 have been rotated upwardly to expose slit 310 and opening 315 and extend out through opening 372 of body wall 370 so that they extend partially above dermal layer 378. The patient's viscera 379 are seen to be adjacent to the bottom side 264 of base member 260. Shaft 330 of tacking instrument 320 is seen inserted through surgical opening 372, through slit 310 and opening 315 and into the patient's underlying body cavity. The distal end section 332 and distal end 334 are seen to be positioned adjacent to bottom side 264 of base member 260 in order to attach a section of the base member 260 to the peritoneal layer 374. The surgeon's other hand is seen to be palpating the patient's body wall 370 above the distal end 334 in order to locate the position of a tack prior to delivering it by

actuating trigger 324. Referring to FIG. 26, after implantation of the patch 250 and securement with tacks 380, the bottom side 264 of base member 260 may have two concentric crowns of tacks 382 and 384 to secure the patch 250 to the peritoneal layer 374.

Another embodiment of a tissue repair patch of the present invention is seen in FIGS. 25 and 26. The repair patch 500 is seen to have substantially flat base member 510 having top side 512 and bottom side 514. Base member 510 is seen to have circular opening 520 bounded by periphery 522. Closure ring 530 is seen to be mounted about periphery 522 of circular opening 520. The patch 500 also has closure patch 540 having top side 542 and bottom side 544. Mounted to the bottom side 544 of patch 540 is mating closure ring 548. Mating closure ring 548 is removeably engageable with closure ring 530. When used in a surgical procedure, the surgeon removes the closure patch 540 from base member 510 thereby exposing opening 520. The base member 510 is then implanted in a body cavity of a patient such that the top side 512 of base member 510 is adjacent to the inner layer of the body cavity such as the peritoneum. The surgeon then inserts a distal section of the shaft of an attachment instrument such as a surgical tacker through opening 520 into the body cavity below bottom side 514 of the base member 510. After the base member 510 has been secured to the inner layer of tissue and the shaft of the securement instrument has been removed, the surgeon mounts the closure patch 540 to the top side 512 of the base member 510 such that the mating closure ring 548 and the closure ring 530 are engaged.

The repair patches of the present invention may optionally contain or be coated with sufficiently effective amounts of an active agent such as a therapeutic agent. Substances which are suitable as active agents include conventional agents that may be naturally occurring or synthetic and may include but are not limited to, for example, antibiotics, antimicrobials, antibacterials, antiseptics, chemotherapeutics, cytostatics, metastasis inhibitors, antideabetics, antimycotics, gynaecological agents, urological agents, anti-allergic agents, sexual hormones, sexual hormone inhibitors, haemostyptics, hormones, peptide-hormones, antidepressants, vitamins such as Vitamin C,

antihistamines, naked DNA, plasmid DNA, cationic DNA complexes, RNA, cell constituents, vaccines, and cells occurring naturally in the body or genetically modified cells.

In one embodiment, the active agents may be antibiotics including such agents as gentamicin or ZEVTERA™ (ceftobiprole medocaril) brand antibiotic (available from Basilea Pharmaceutica Ltd., Basel Switzerland). In one embodiment, an implant may include broadband antimicrobials used against different bacteria and yeast (even in the presence of bodily liquids) such as octenidine, octenidine dihydrochloride (available as active ingredient Octenisept® disinfectant from Schulke & Mayr, Norderstedt, Germany as), polyhexamethylene biguanide (PHMB) (available as active ingredient in Lavasept® from Braun, Switzerland), triclosan, copper (Cu), silver (Ag), nanosilver, gold (Au), selenium (Se), gallium (Ga), taurolidine, N-chlorotaurine, alcohol based antiseptics such as Listerine® mouthwash, N a-lauryl-L-arginine ethyl ester (LAE), myristamidopropyl dimethylamine (MAPD, available as an active ingredient in SCHERCODINE™ M), oleamidopropyl dimethylamine (OAPD, available as an active ingredient in SCHERCODINE™ O), and stearamidopropyl dimethylamine (SAPD, available as an active ingredient in SCHERCODINE™ S). In one embodiment, the agent may be octenidine dihydrochloride (hereinafter referred to as octenidine) and/or PHMB.

Although it is preferred to have a single, centrally located opening in the hernia repair patch devices of the present invention, the opening and associated closure member may be offset from the center. Additionally, more than one opening and closure member may be utilized in the hernia repair devices of the present invention.

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

Example 1

A patient with a ventral or incisional hernia 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. 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.

At this point in the procedure, the surgeon then prepares a mesh tissue repair hernia patch of the present invention having closure flaps and a base member for insertion through the abdominal wall defect and into the abdominal cavity such that the top side of the mesh is adjacent to the peritoneum surrounding the defect, and the bottom side of the mesh device is facing down toward the patient's viscera. Stay sutures may be placed through the mesh into the abdominal tissue as desired, i.e. at the four compass points of the mesh (North, South, East, West). The flaps are rotated upwardly after placement to expose the opening in the base member of the mesh. The mesh is fixated with a conventional surgical tacker or other means of fixation. A tacker is inserted through the opening such that the distal end of the tacker is between the mesh and the viscera. The perimeter of the mesh is then fixated using a plurality of tacks in a crown configuration. The tacker is removed and the opening in the mesh is closed by folding the flaps as appropriate for the present invention. The flaps may be optionally secured using adhesive, suture, rivets, or other closure means, or may be returned to their at rest position without securement to each other. 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 of the present invention have numerous advantages. The novel repair patch devices provide a single layer mesh repair device that

can be affixed via tacking in an open intraperitoneal hernia repair procedure. The repair patch devices have additional advantages including less foreign material (i.e., lower mass of foreign material) and the ability to implant a single layer tissue repair mesh in open procedures. The tissue repair devices of the present invention, preferably made from mesh, may potentially accelerate the rate of tissue integration, provide less area for biofilm formation, have a lower cost of manufacture, and are easier to package, sterilize, and use with improved ergonomics.

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.

Claims

We claim:

1. A tissue repair patch, comprising:

a substantially flat base member having a top side and a bottom side;

an opening located in said base member; and,

a closure member associated with said opening.

2. The tissue repair patch of claim 1, additionally comprising a polymeric layer on at least one side of the base member.

3. The tissue repair patch of claim 1, additionally comprising an adhesion barrier on at least one side of the base member.

4. The patch of claim 1, wherein the base member comprises a mesh.

5. The patch of claim 1, wherein the base member comprises a fabric.

6. The patch of claim 5 wherein the fabric is woven.

7. The patch of claim 5 wherein the fabric is nonwoven.

8. The patch of claim 1, wherein the base member comprises an expanded polymeric film.

9. The patch of claim 1, wherein the base member comprises a biocompatible, nondegradable polymer.

10. The patch of claim 1, wherein the base member comprises a bioabsorbable polymer.

11. The patch of claim 7 wherein the nondegradable polymer is selected from the group consisting of polypropylene, polyester, nylon, and ultra high molecular weight polyethylene.

12. The patch of claim 10, wherein the bioabsorbable polymer is selected from the group consisting of polylactides, polyglycolides, polydioxanones, polycaprolactones, copolymers of glycolides and trimethylene carbonate, and copolymers of lactides and trimethylene carbonate, and copolymers and blends thereof.

13. The patch of claim 1, wherein the base member comprises a biocompatible nondegradable polymer and a bioabsorbable polymer.

14. The patch of claim 1, wherein the opening is a slit.

15. The patch of claim 1 wherein the opening is circular.

16. The patch of claim 1, wherein the opening is slot shaped.

17. The tissue repair patch of claim 1, wherein the closure member comprises opposed closure flap members hingingly mounted about the opening.

18. The tissue repair patch of claim 1, wherein the closure member comprises a patch having an outer periphery, wherein a section of the periphery is mounted to the top side of the base member about the opening.

19. The tissue repair patch of claim 1, wherein the closure member comprises a surgical suture mounted about the opening.

20. The tissue repair patch of claim 1, wherein the closure member comprises a patch having a top side and a bottom side with an engagement member extending from the bottom side, and wherein the base member has a mating engagement member mounted to the top side about the opening, such that the closure patch may be engaged and disengaged from the base member.

21. The tissue repair patch of claim 1, wherein the opening comprises a slit having opposed sides and the closure member comprises a surgical suture threaded about the slit adjacent to the sides.

22. The tissue repair patch of claim 17, wherein the flaps have free end sections separated from the base member by slots, such that each closure flap member may be engaged in the slot of an opposed flap member.

23. The patch of claim 1, wherein the opening is centrally located.

24. The patch of claim 1, comprising at least two openings and closure members.

25. The patch of claim 2, wherein the polymer film comprises a nonabsorbable polymer.

26. The patch of claim 2, wherein the polymer film comprises a bioabsorbable polymer.

27. The patch of claim 25, wherein the polymer is selected from the group consisting of silicone, PTFE, polyester, and polypropylene.

28. The patch of claim 26, wherein the bioabsorbable polymer is selected from the group consisting of oxidized regenerated cellulose, polydioxanone, poliglecaprone 25 (copolymer of glycolide and epsilon-caprolactone) and combinations thereof.

29. The patch of claim 2, wherein the polymer film is an adhesion barrier.

30. The patch of claim 3, wherein the adhesion barrier comprises a polymer selected from the group consisting of group consisting of oxidized regenerated cellulose, polydioxanone, poliglecaprone 25 (copolymer of glycolide and epsilon-caprolactone) and combinations thereof.

31. The patch of claim 3, wherein the adhesion barrier comprises a polymer selected from the group consisting of silicone, PTFE, and ePTFE.

32. A method of performing a body wall defect repair, comprising the steps of:

A. inserting a tissue repair patch on an inside layer of a body wall having a tissue defect, wherein the repair patch comprises:

a substantially flat base member having a top side and a bottom side;

an opening located in said base member; and,

a closure member associated with said opening;

B. positioning the patch about the defect such that the top side of the base member is adjacent to the inside layer of the body wall;

C. inserting the end of a surgical fixation instrument through the opening to access the bottom side of the base member and fixating the base member to the inside layer of the body wall; and,

D. manipulating the closure member to close off the opening.

33. The method of claim 32, wherein the tissue repair patch additionally comprises a polymeric layer on at least one side of said base member.

34. The method of claim 33, wherein the tissue defect is a hernia.

FIG. 1

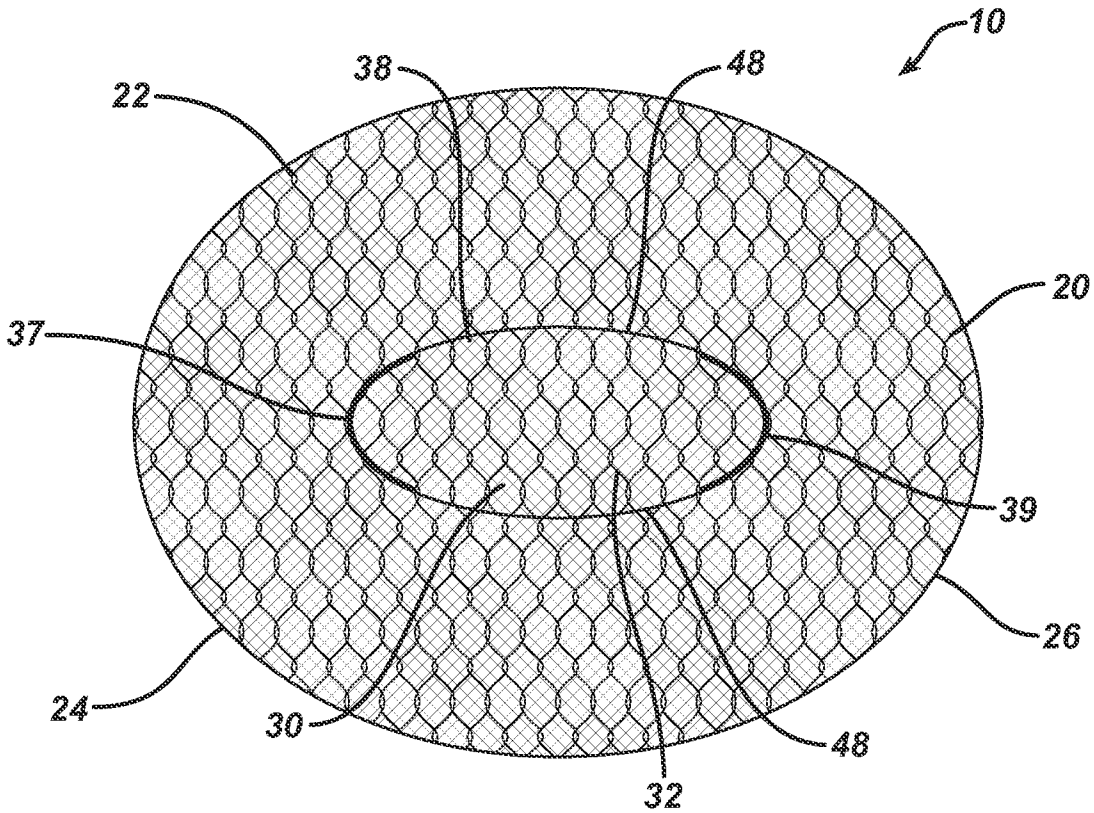


FIG. 2

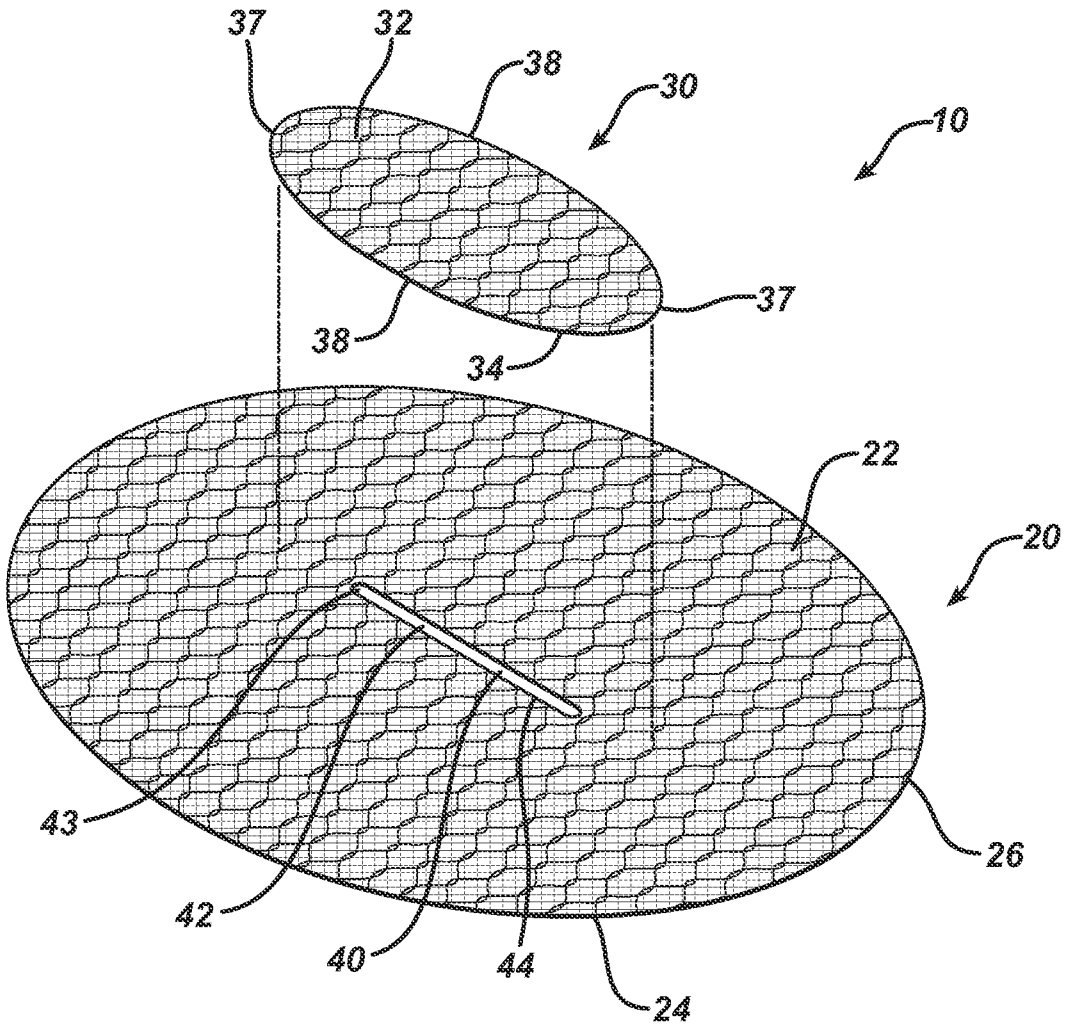


FIG. 3

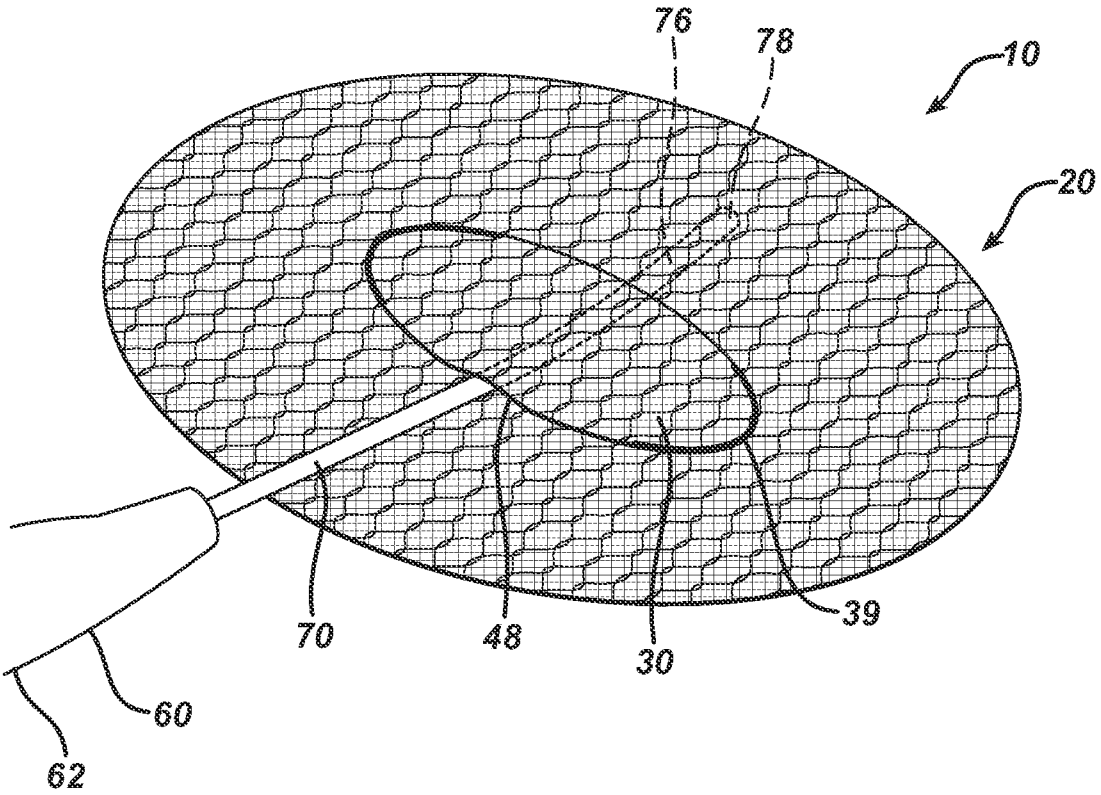


FIG. 4

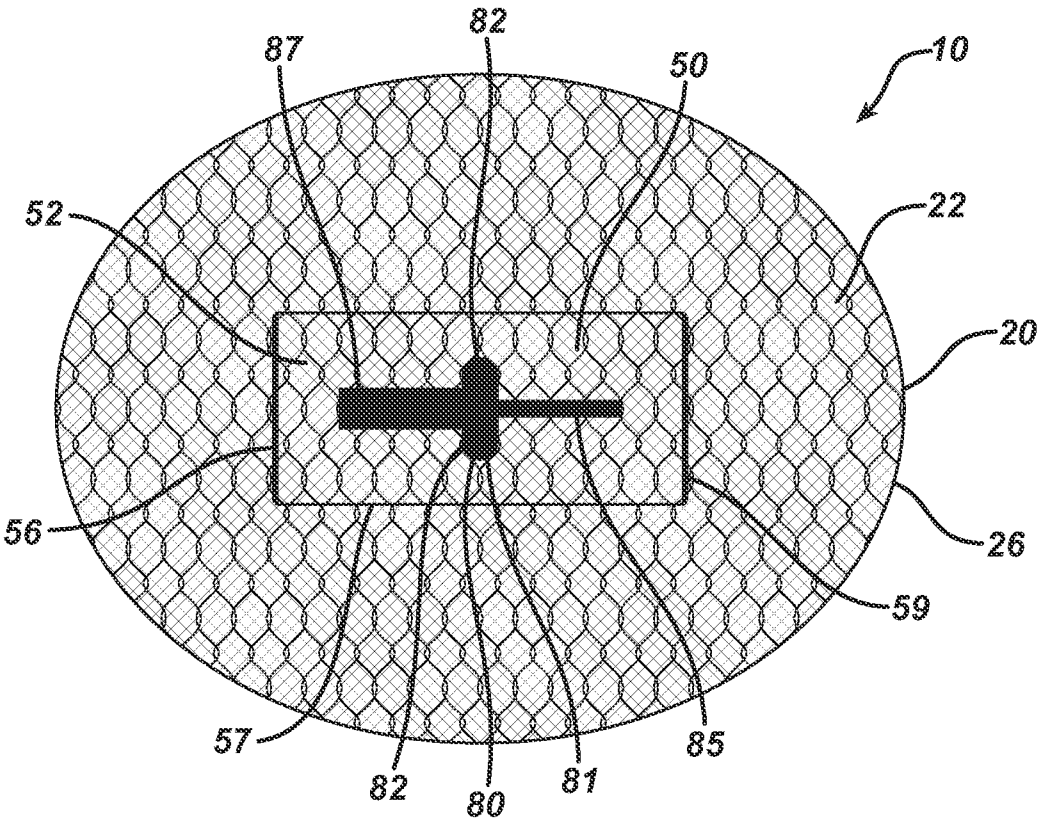


FIG. 5

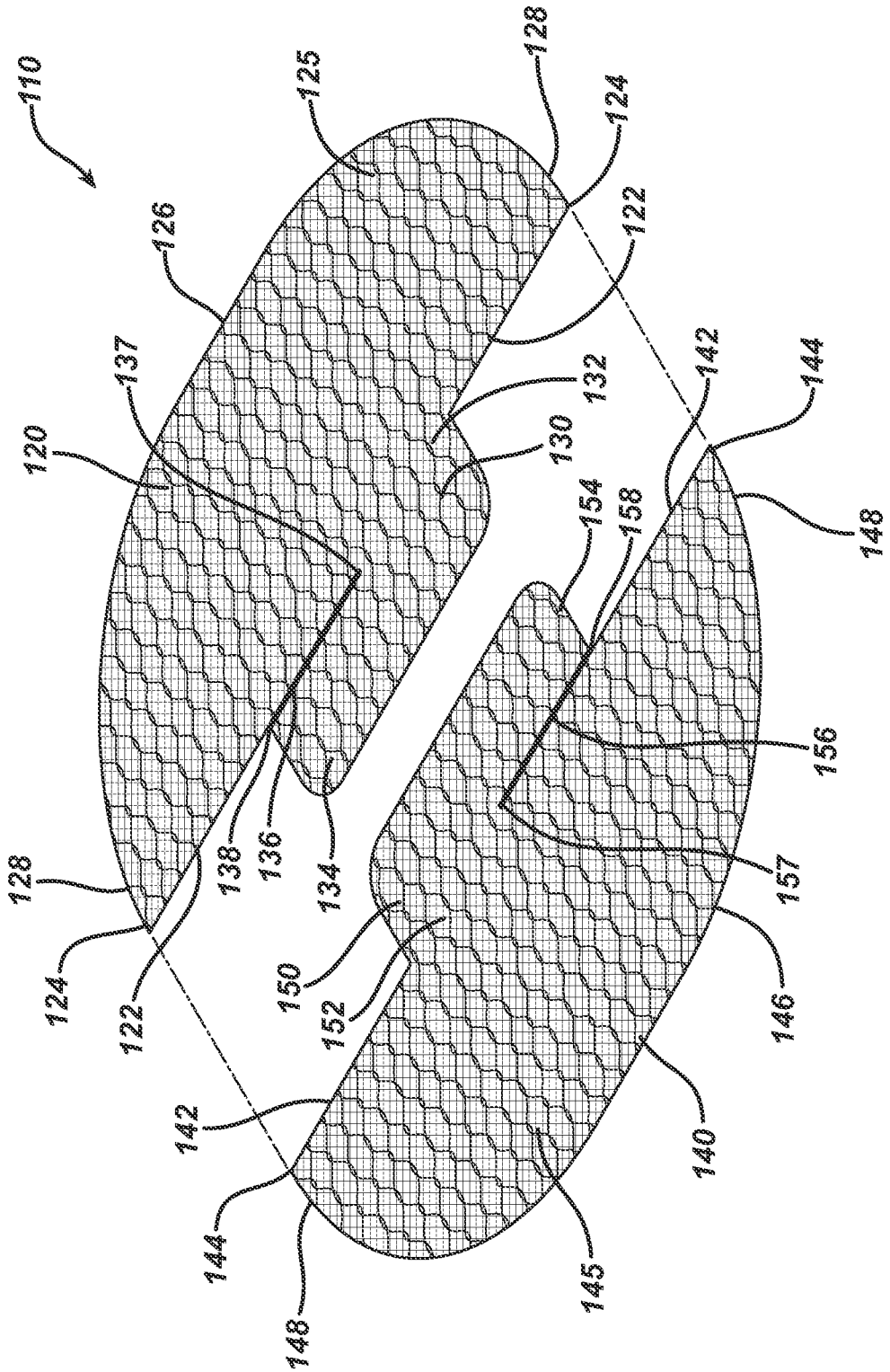

110
125
128
124
126
122
137
132
142
144
120
130
154
158
148
156
138
136
134
157
128
150
152
146
124
122
142
140
144
145
148

FIG. 6

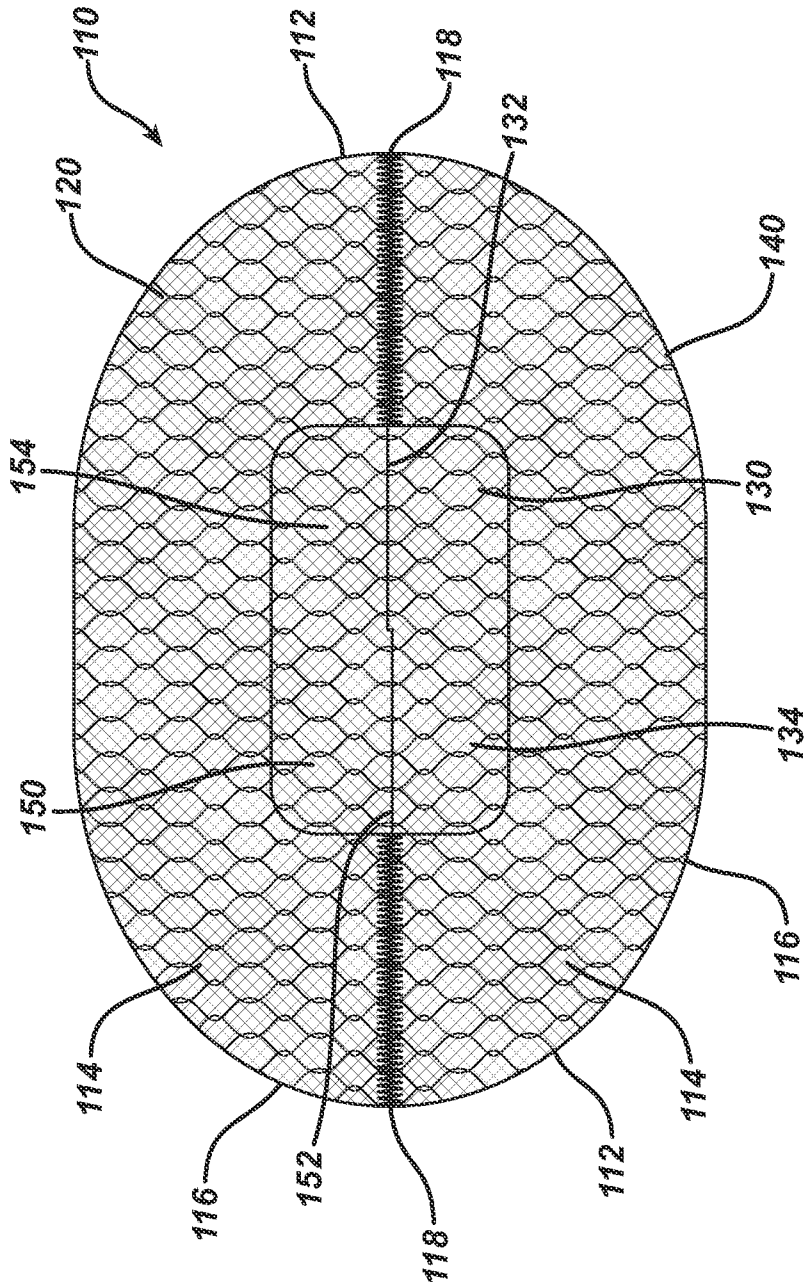

100
110
112
118
132
120
140
154
130
134
150
116
114
114
116
152
118
112

FIG. 7

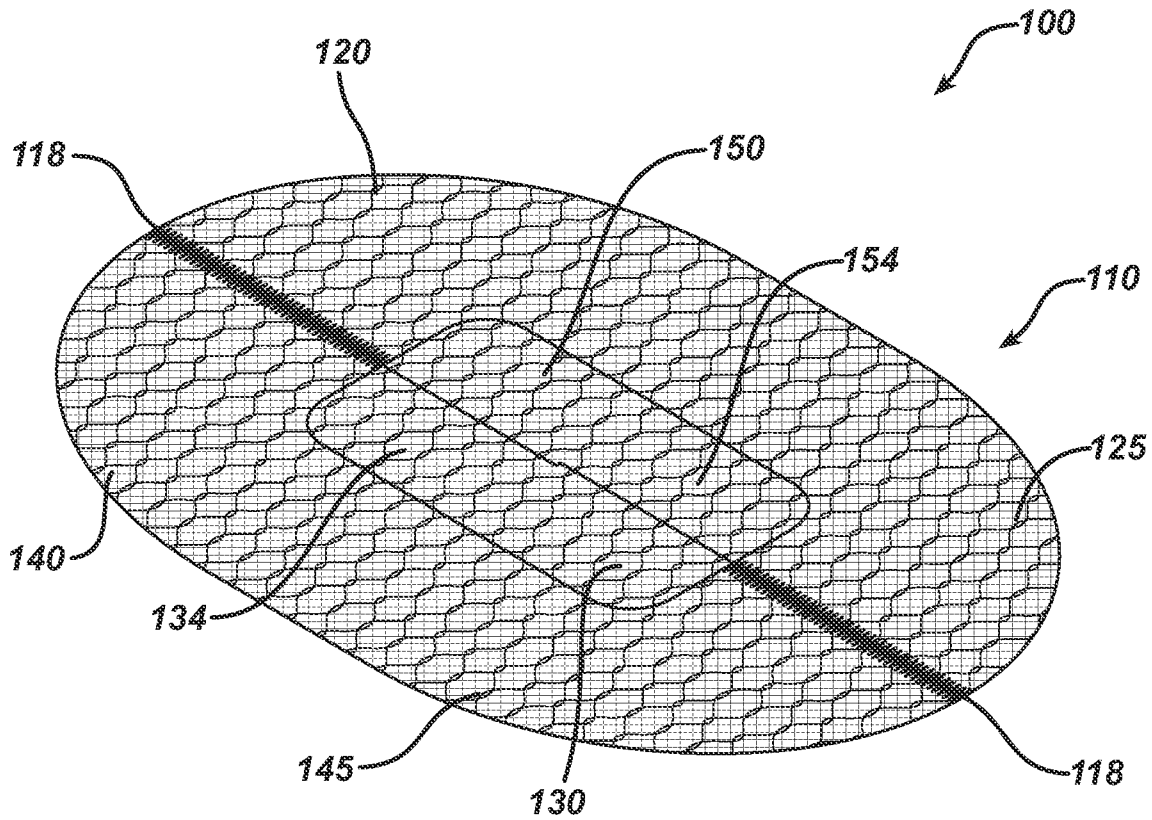


FIG. 8

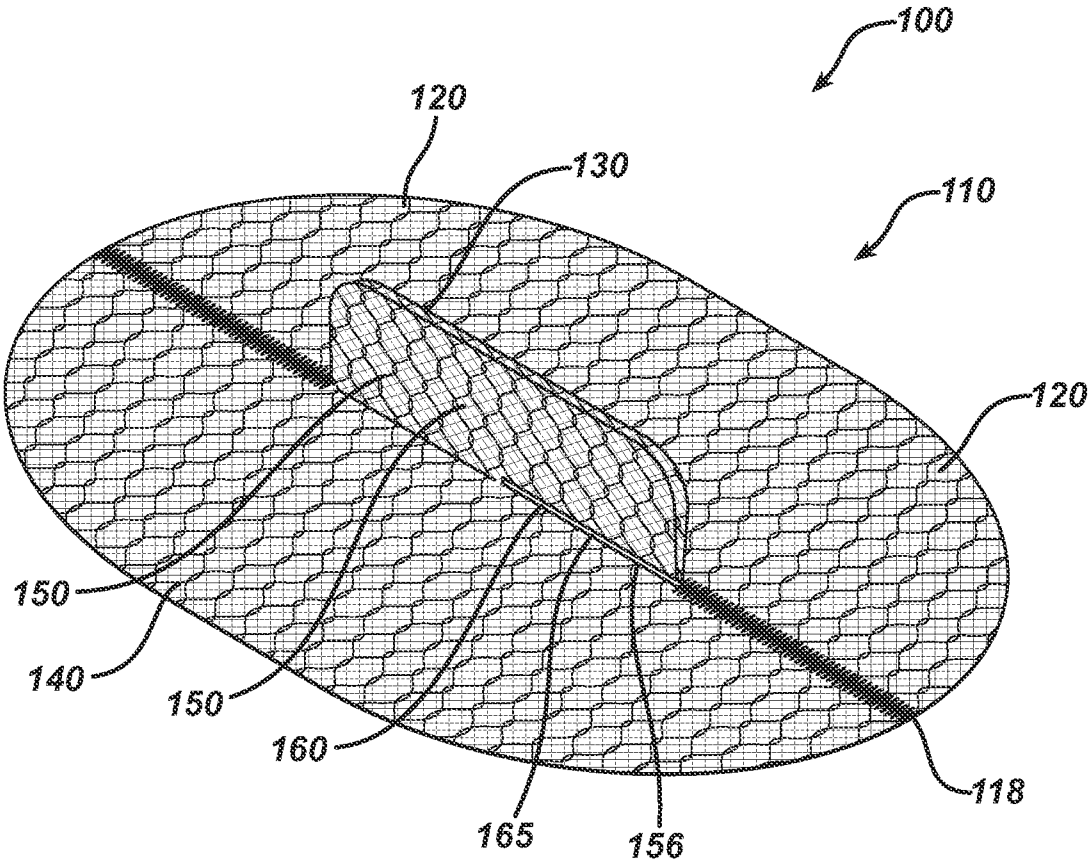


FIG. 9

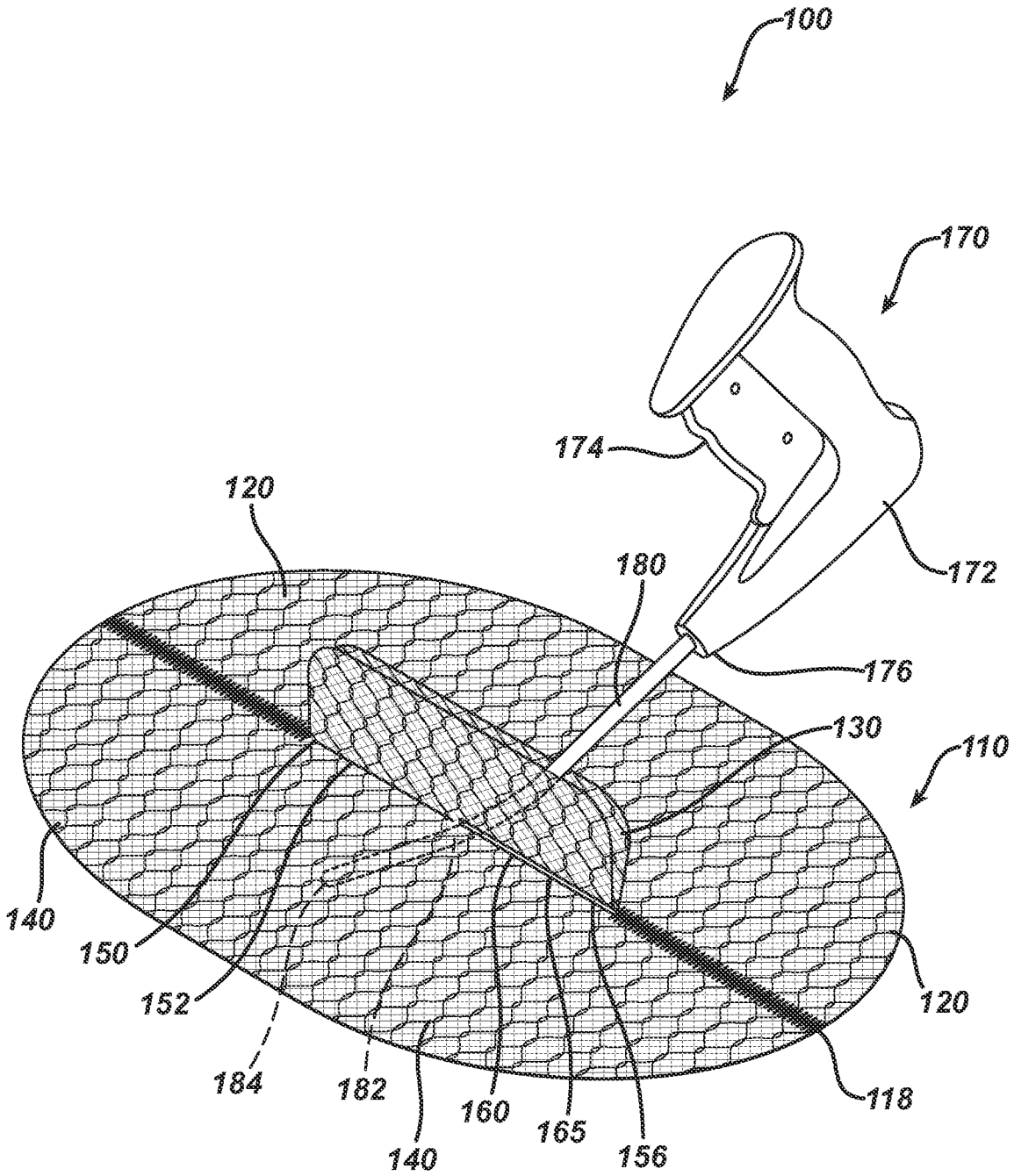

100
170
174
172
120
180
176
130
110
140
150
152
184
182
160
165
156
140
120
118

FIG. 10

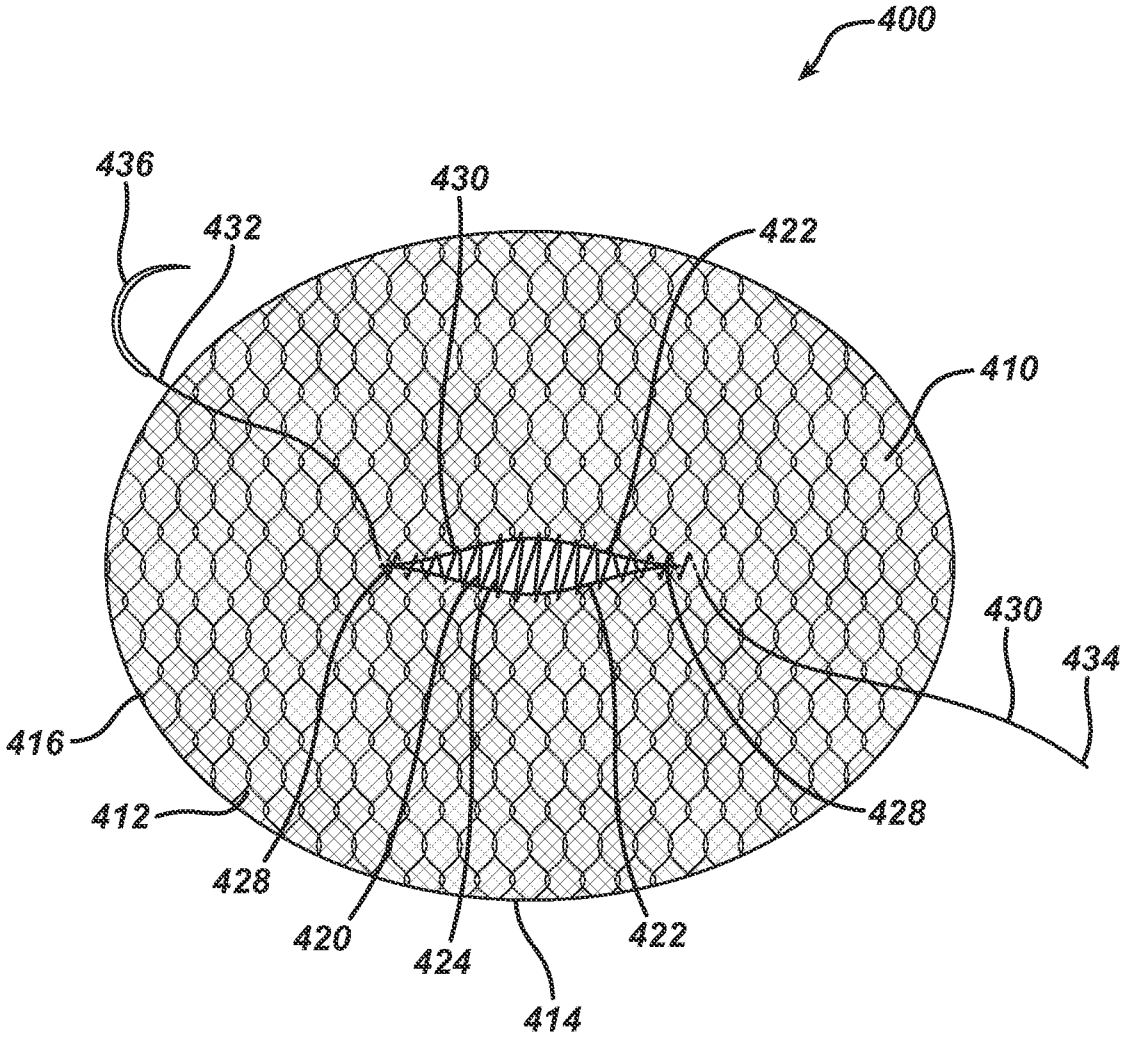


FIG. 11

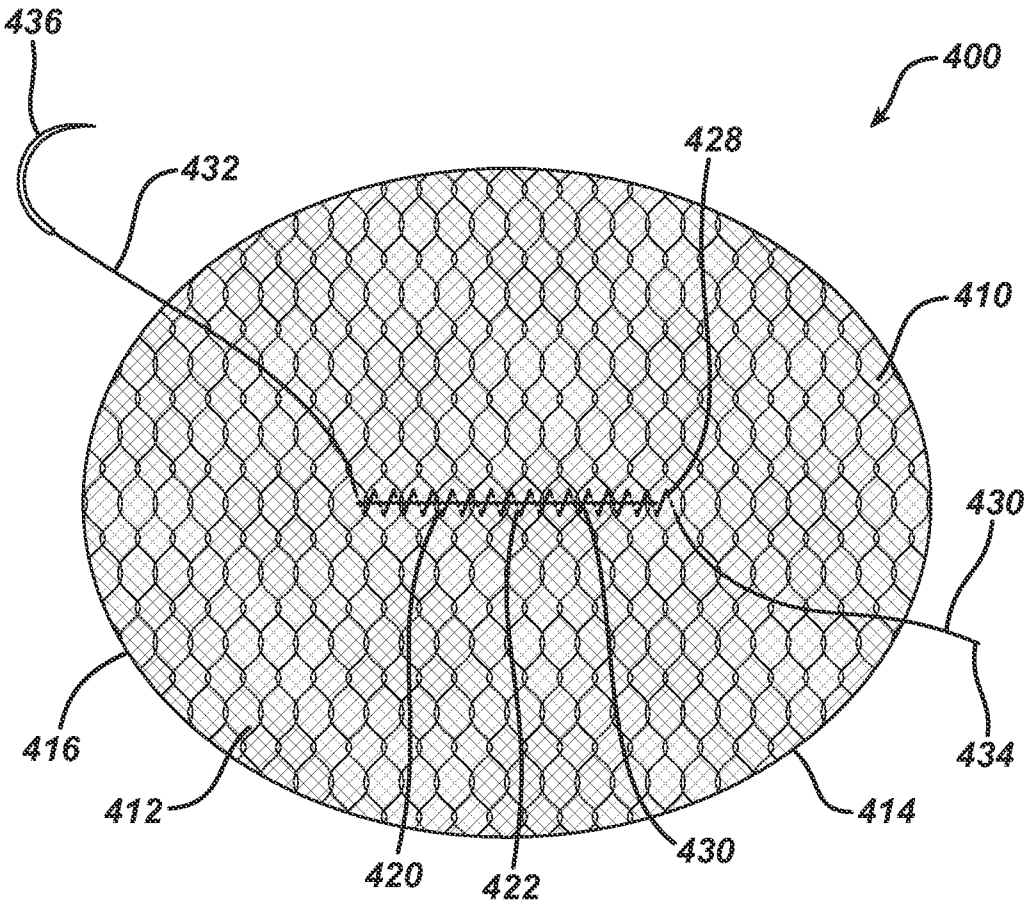


FIG. 12

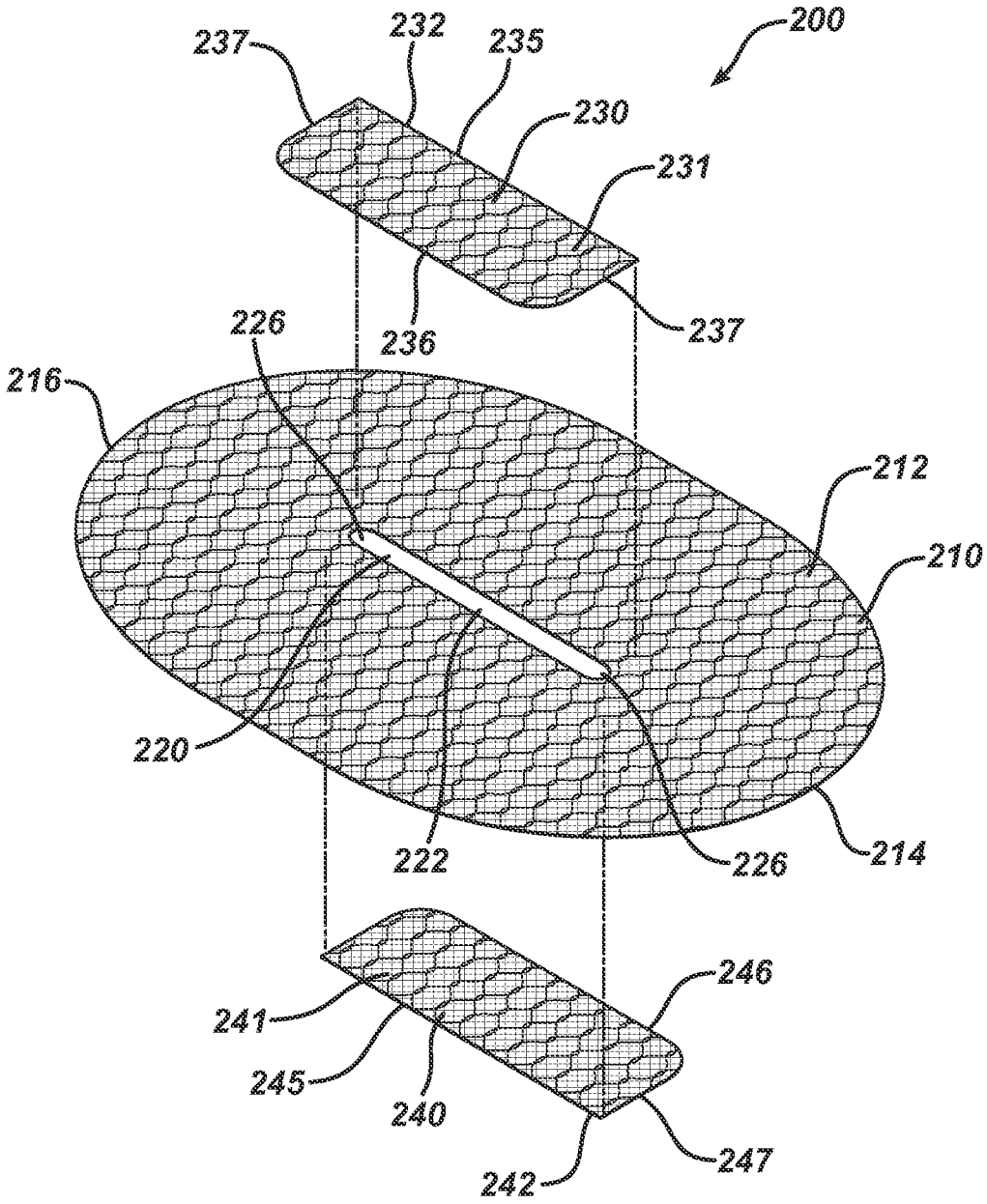

200
237
232
235
230
231
236
237
226
216
212
210
220
222
226
214
241
246
245
240
242
247

FIG. 13

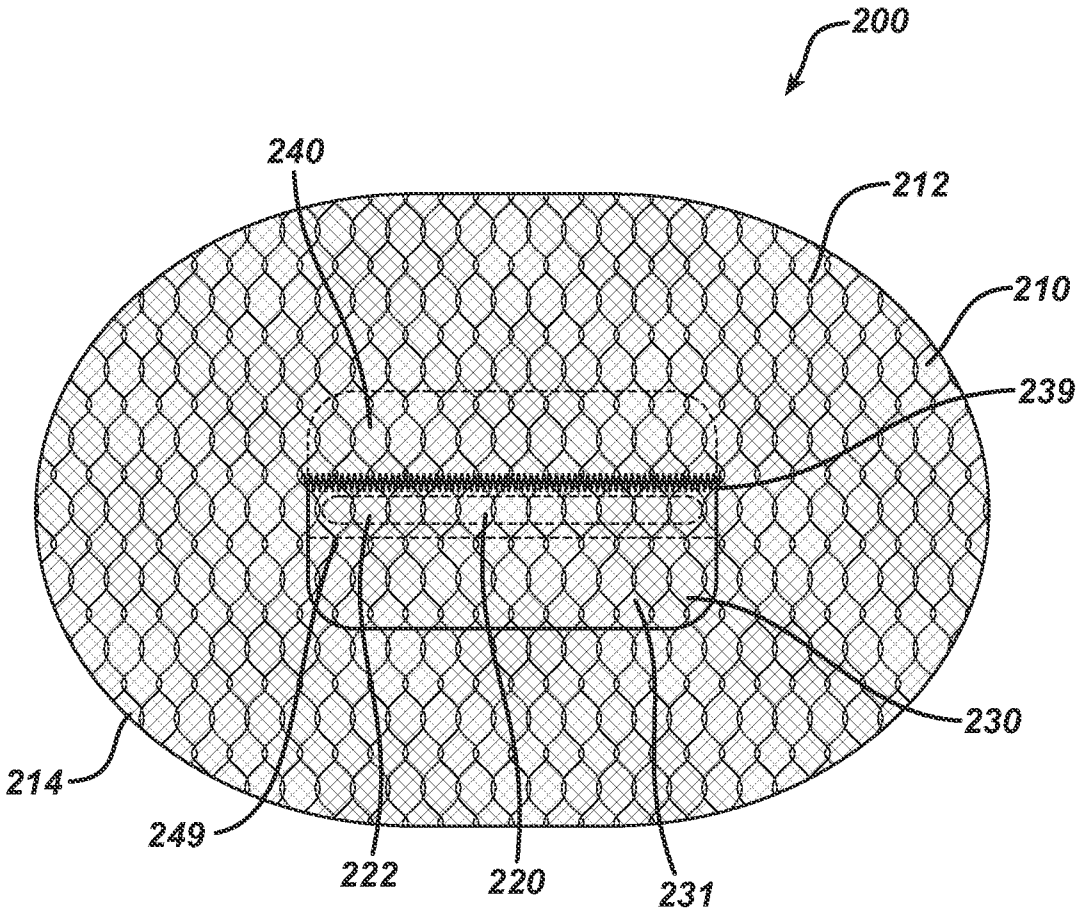
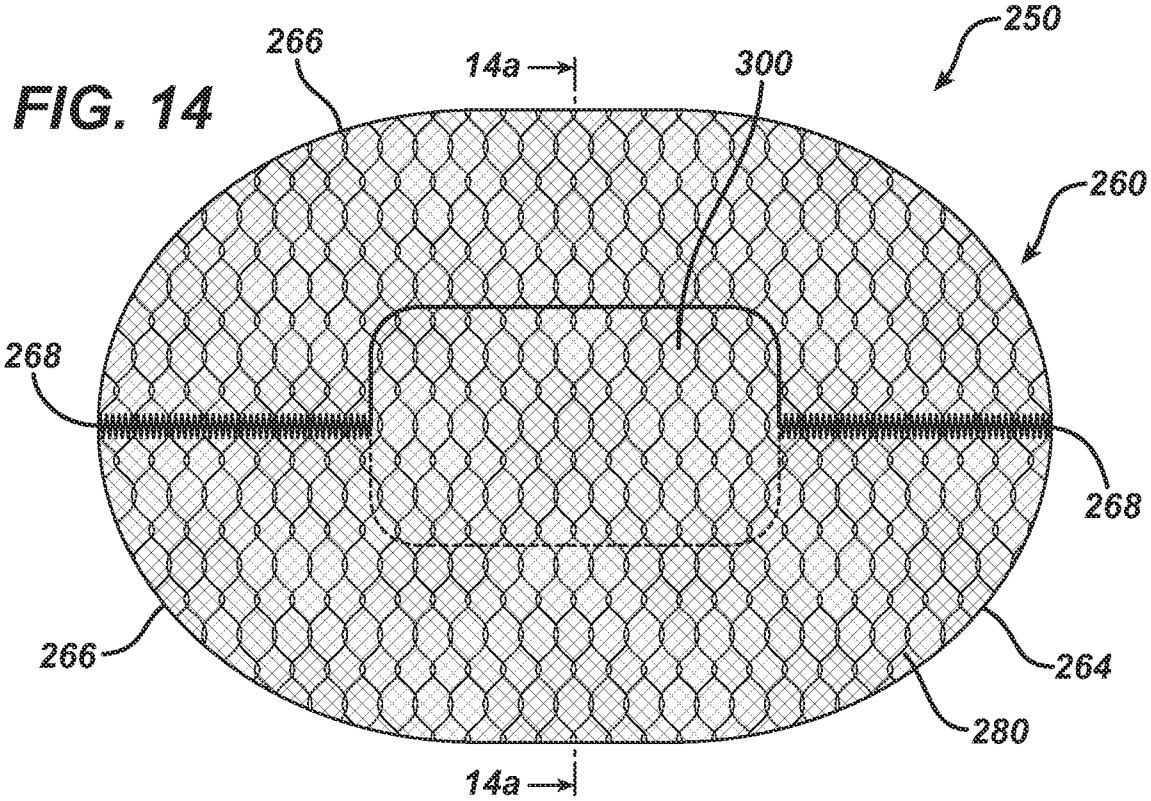


FIG. 14



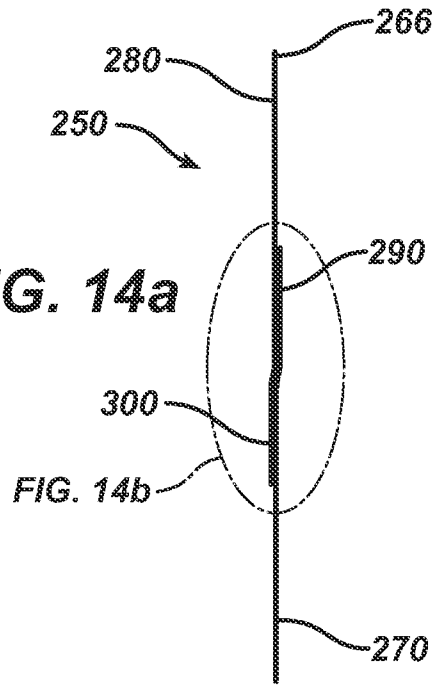


FIG. 14a

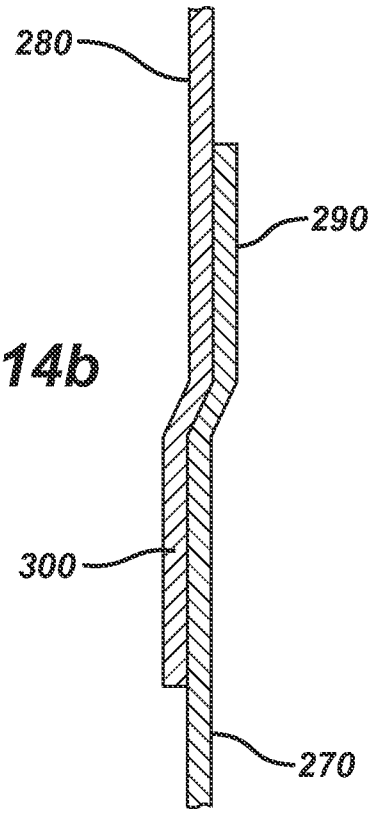


FIG. 14b

FIG. 15

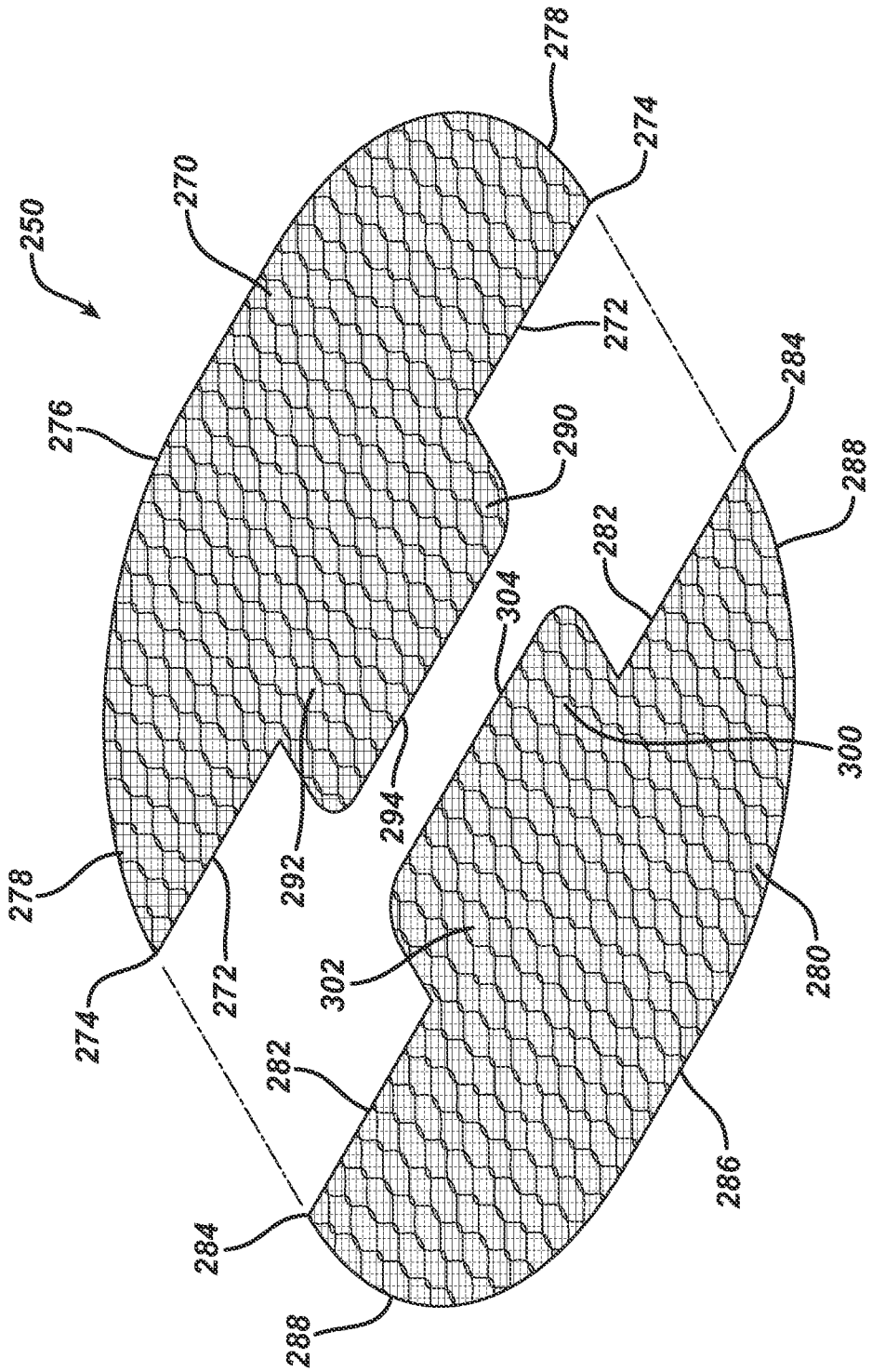

250
270
272
274
276
278
280
282
284
286
288
290
292
294
300
302
304

FIG. 16

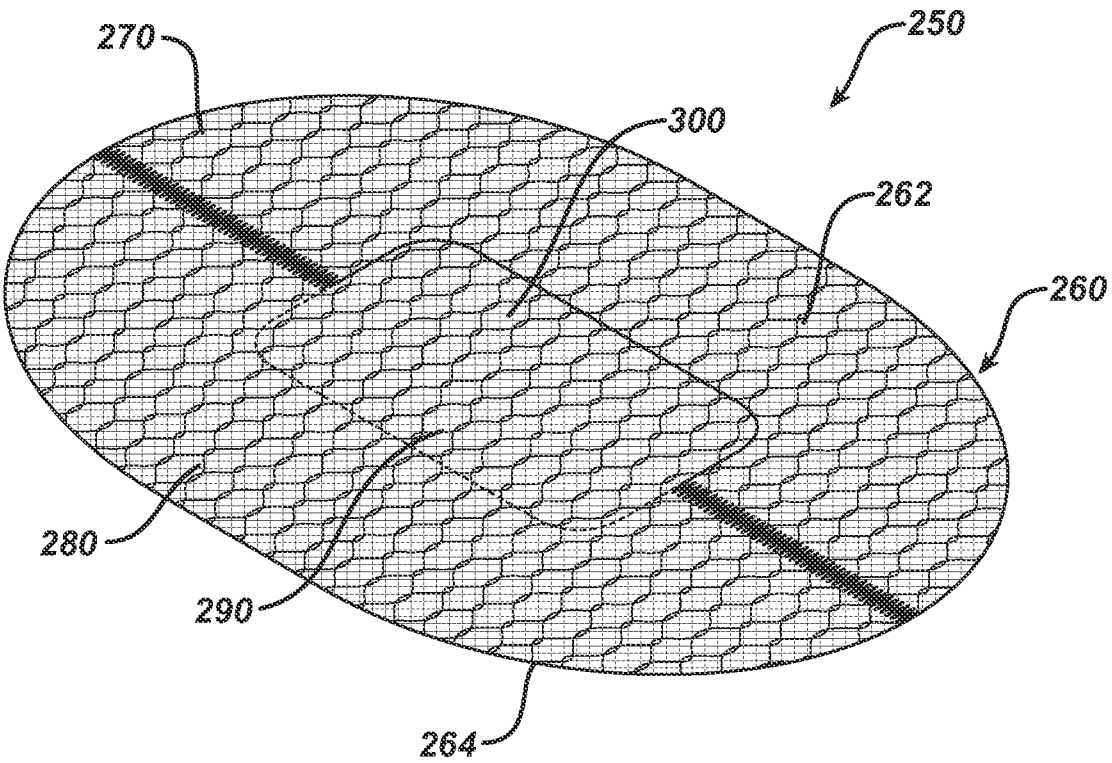


FIG. 17

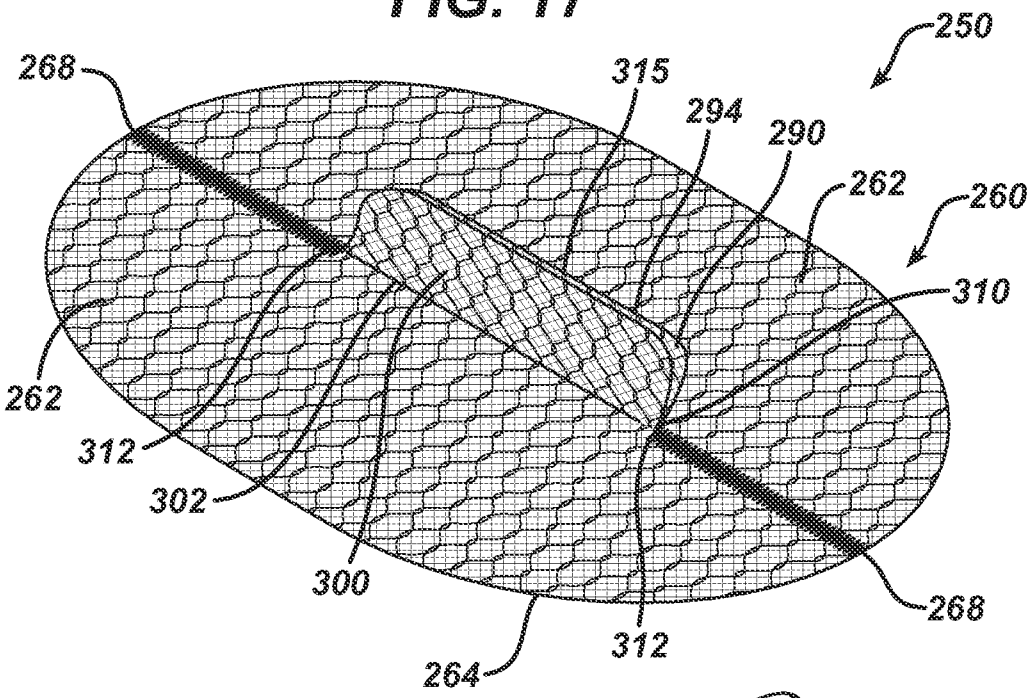

250
268
315
294
290
262
260
310
262
312
302
300
268
264
312

FIG. 18

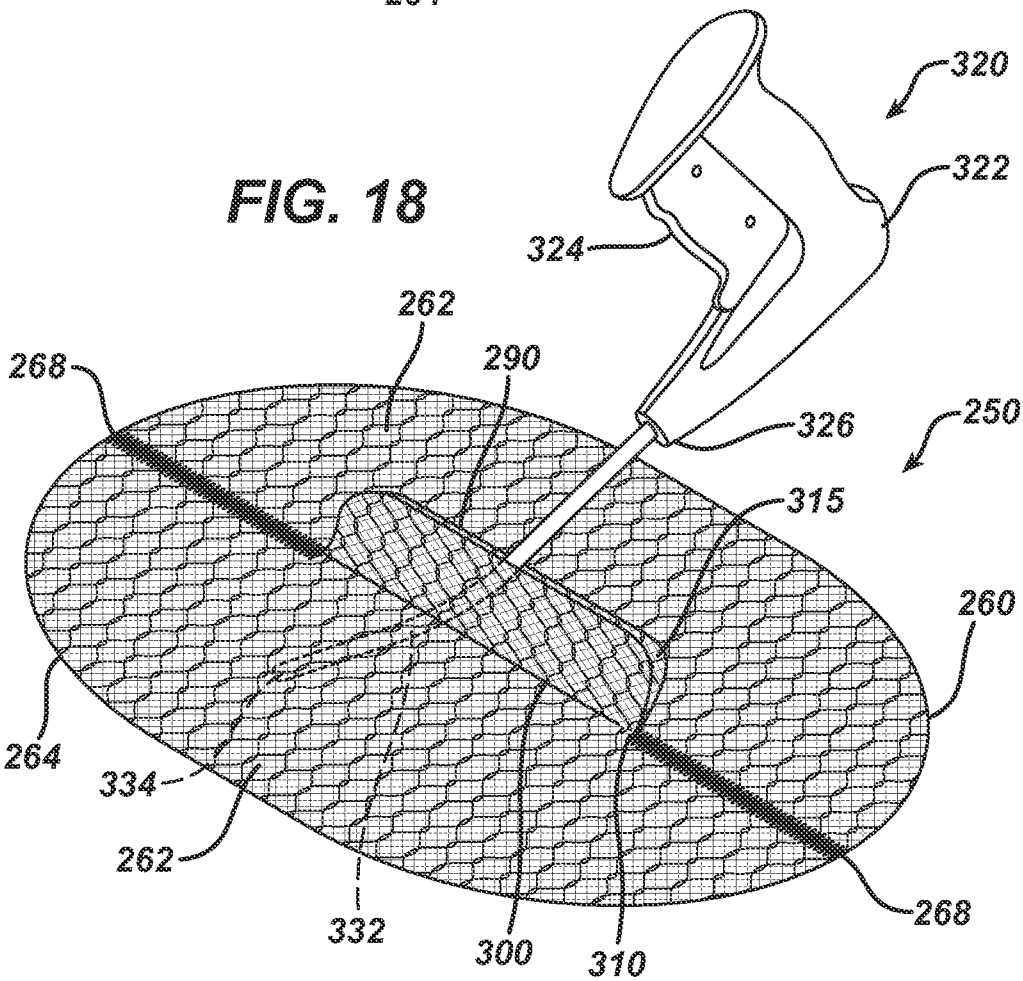

320
322
324
262
290
268
326
250
315
260
264
334
262
332
300
310
268

FIG. 19

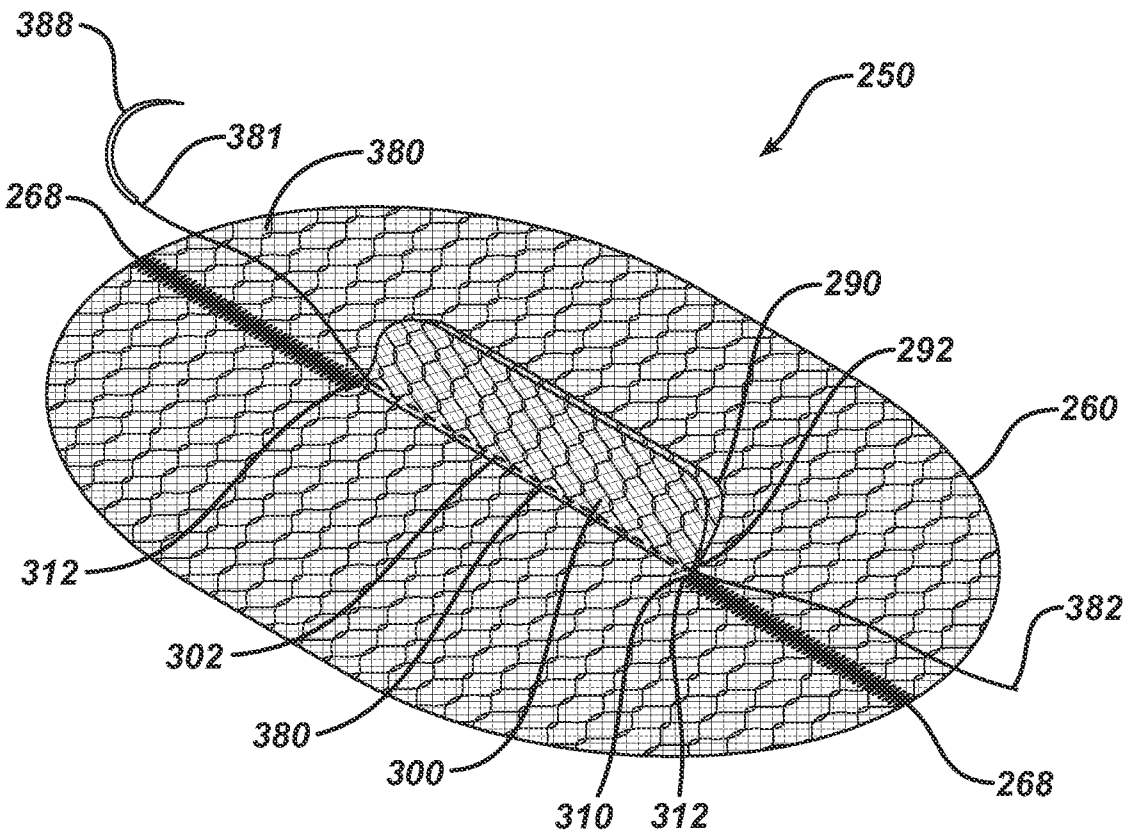


FIG. 20

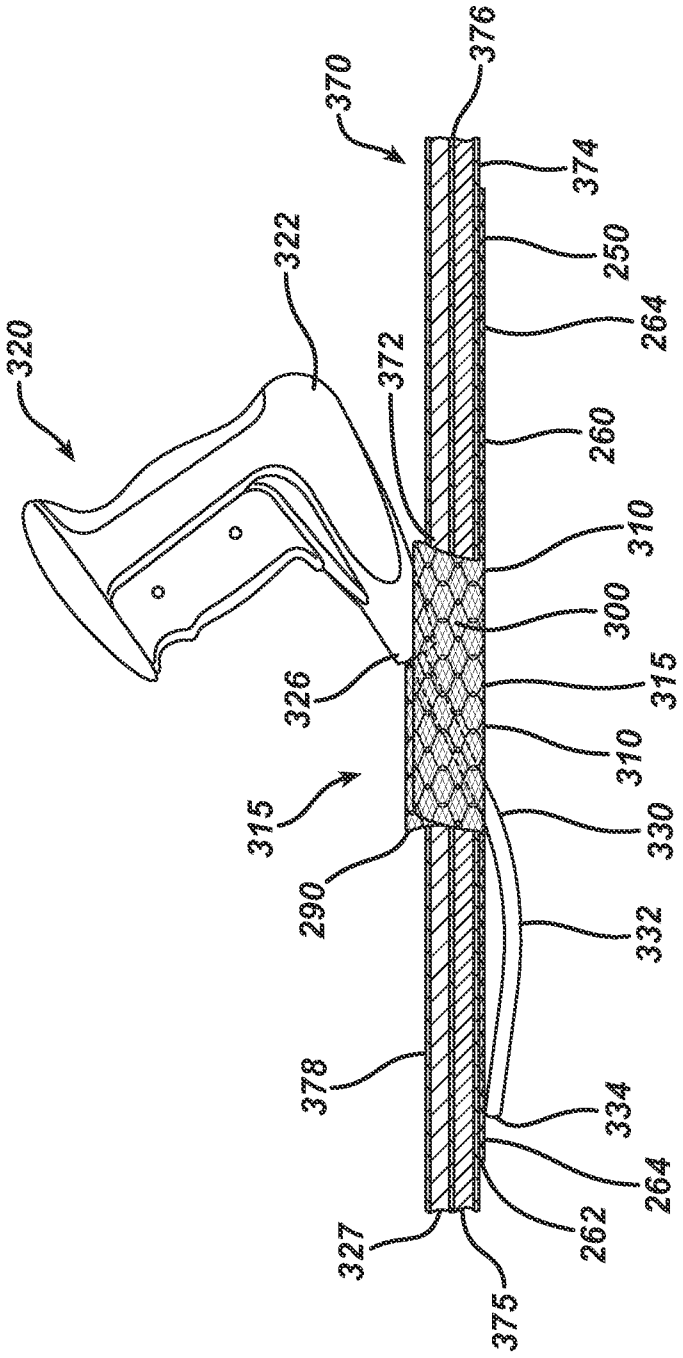
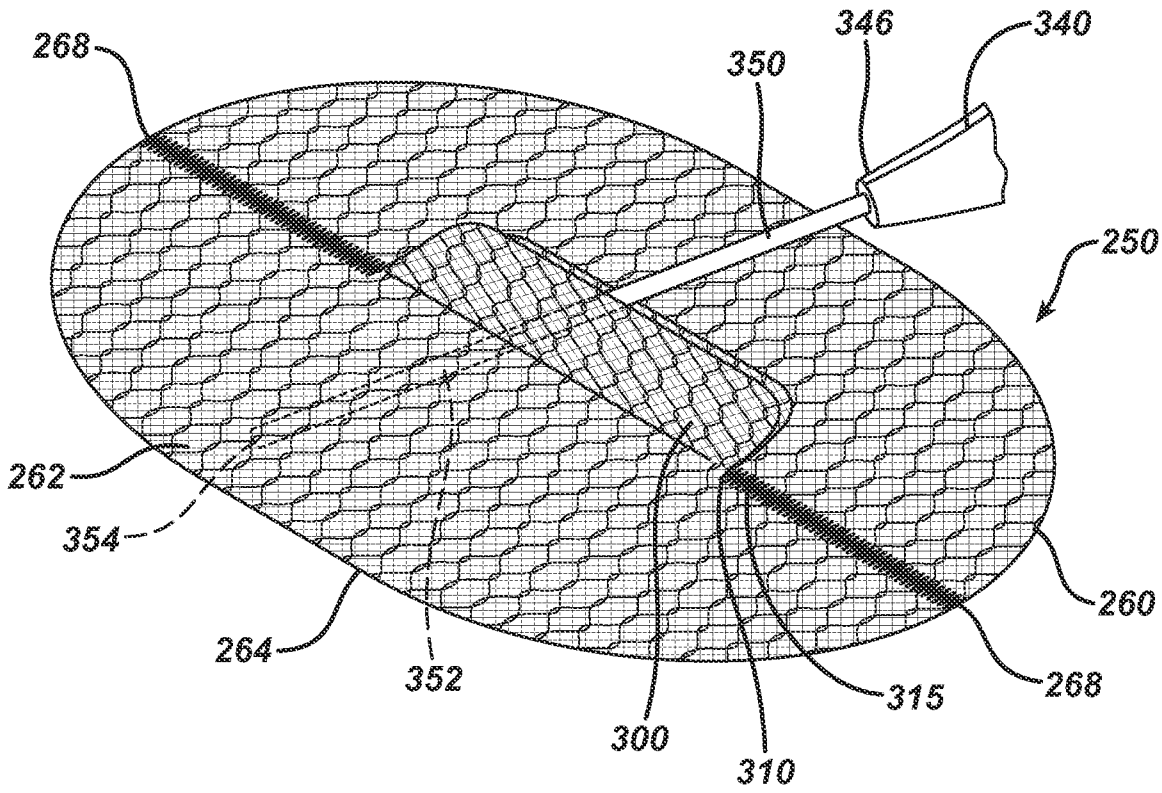

376
370
374
322
250
264
320
372
260
310
300
326
315
310
315
330
290
332
378
334
264
262
327
375

FIG. 21



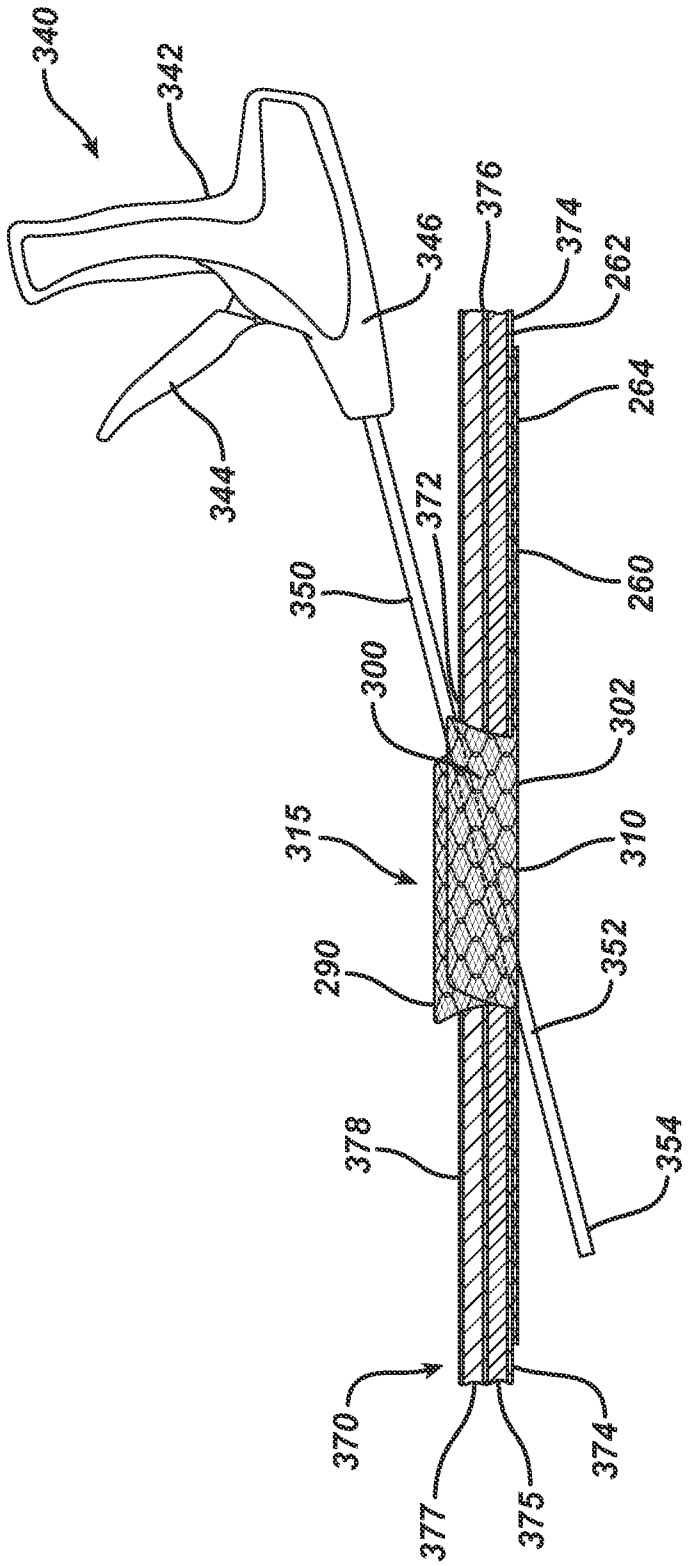

340
342
346
376
374
262
264
344
372
350
260
300
302
315
310
290
352
354
378
370
377
375
374

FIG. 22

FIG. 23

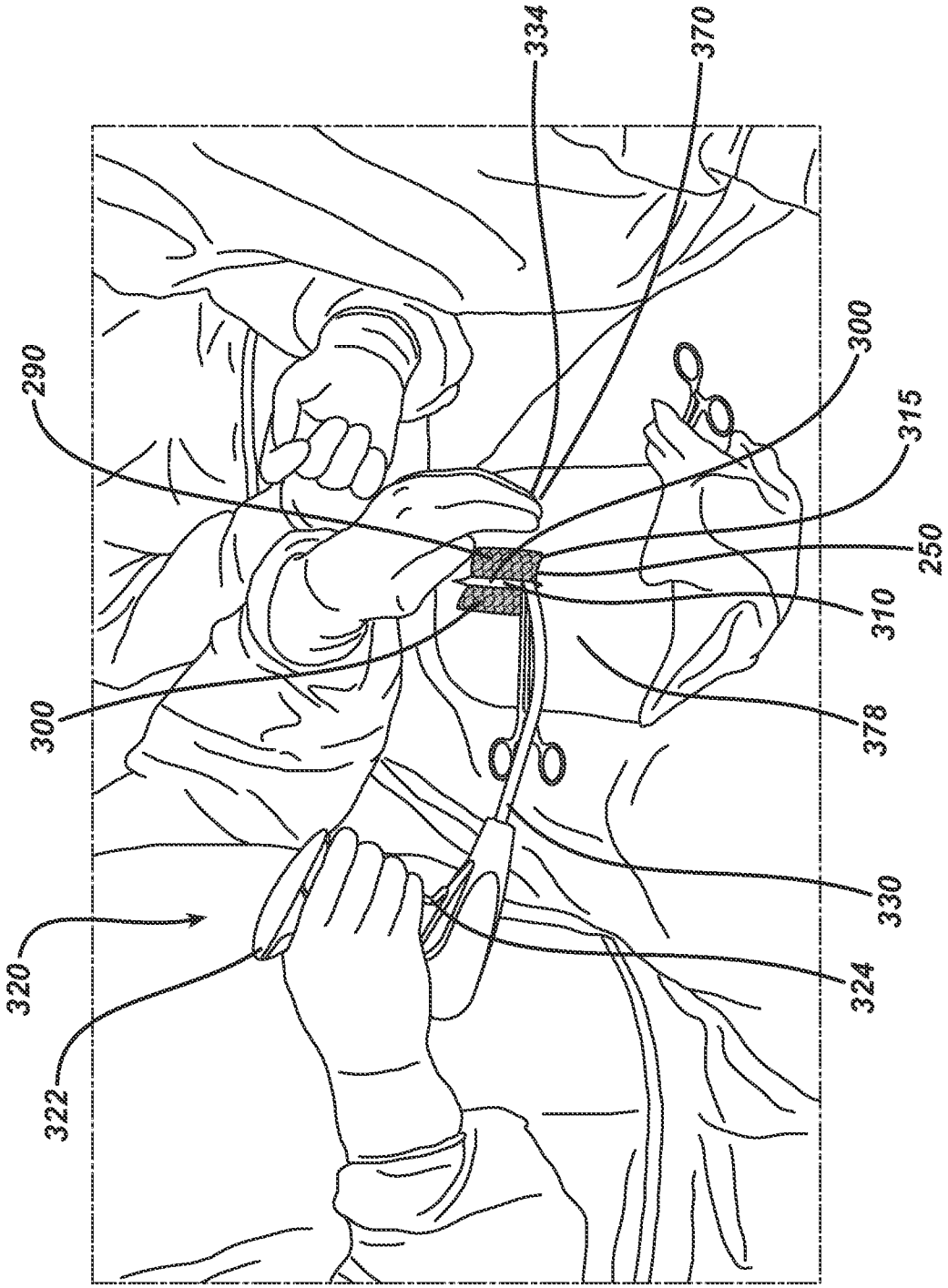


FIG. 24

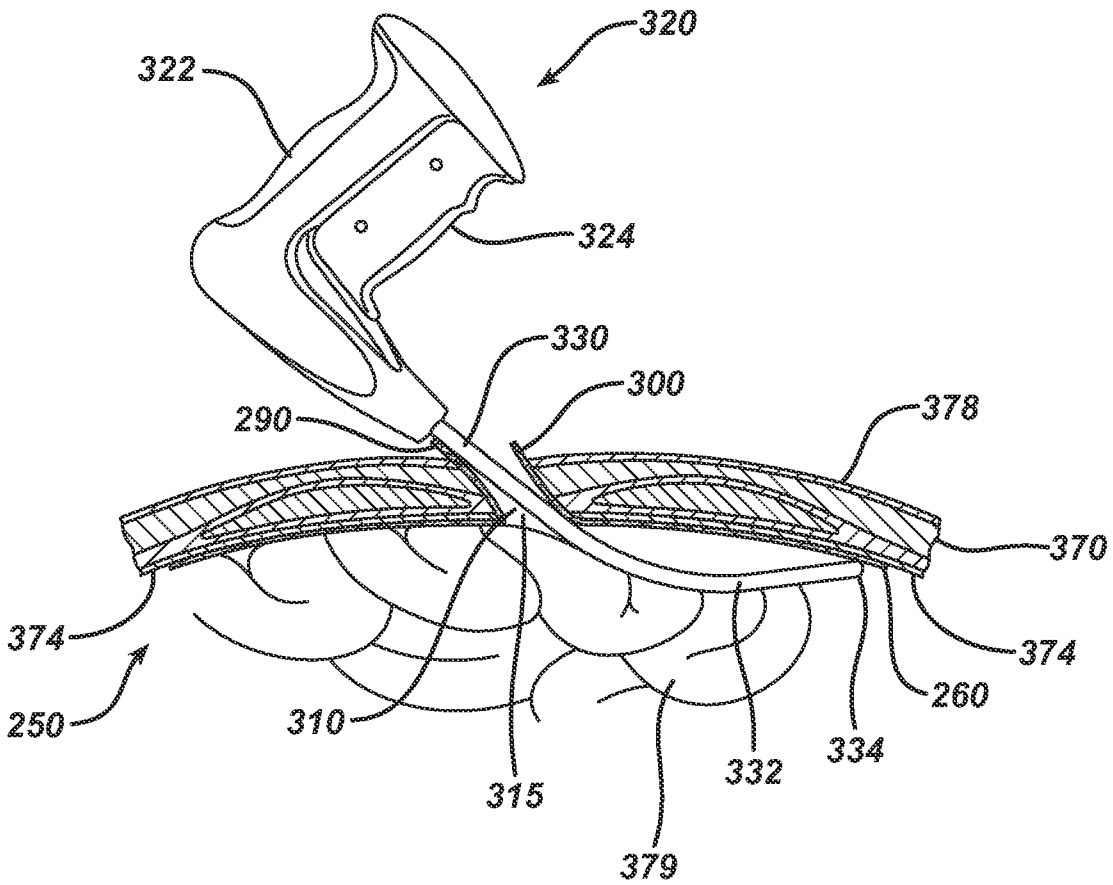

320
322
324
330
300
290
378
370
374
374
250
310
315
379
332
334
260

FIG.25

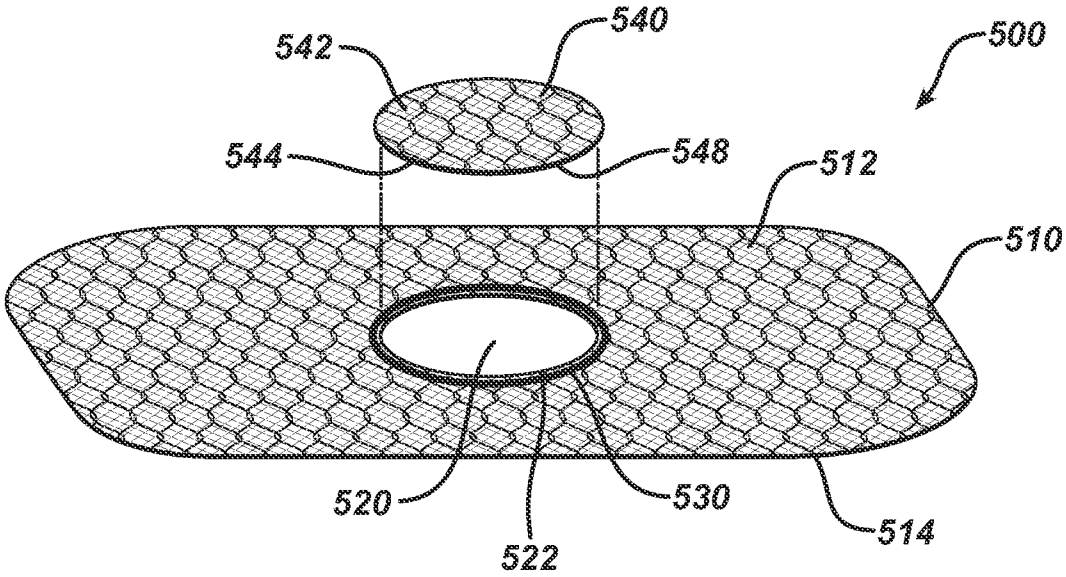

542
540
500
544
548
512
510
520
530
514
522

FIG. 26

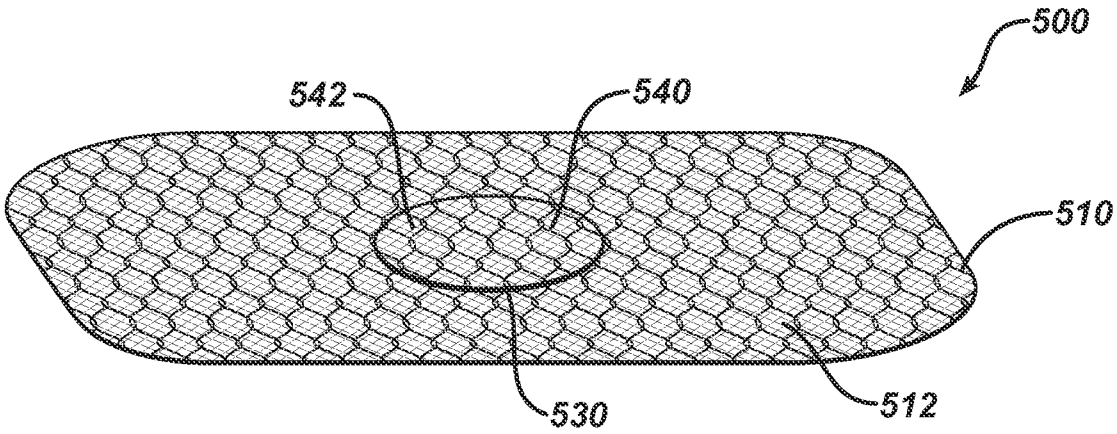

500
542
540
510
530
512

FIG. 27

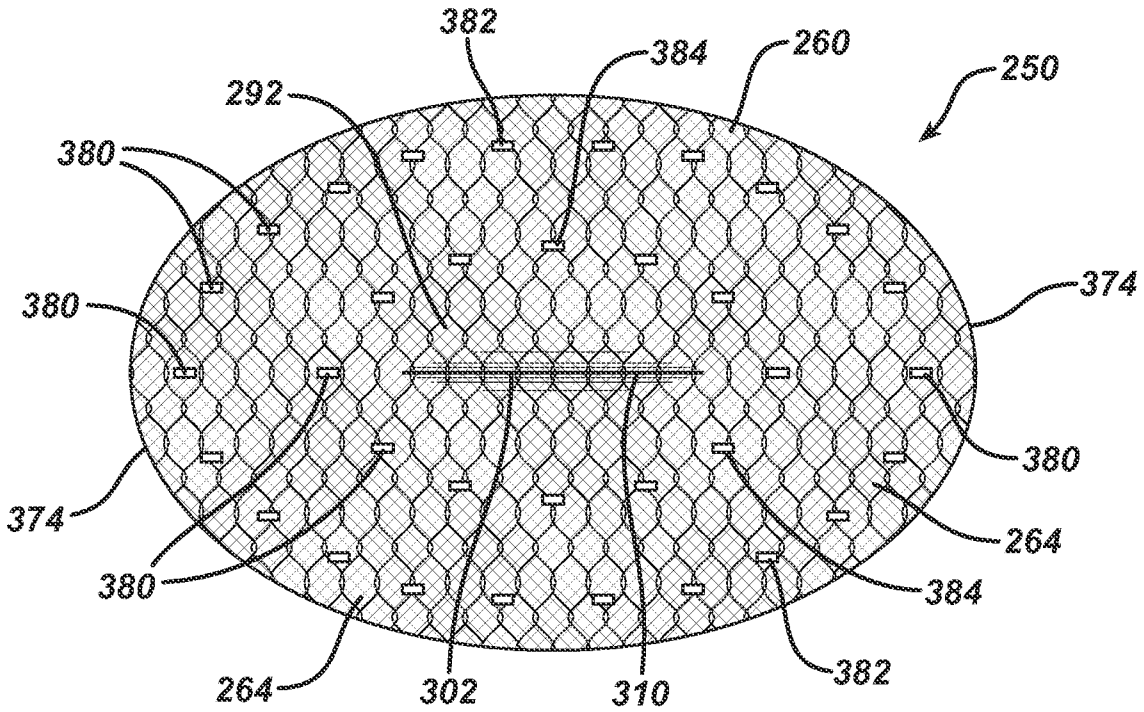


FIG. 28

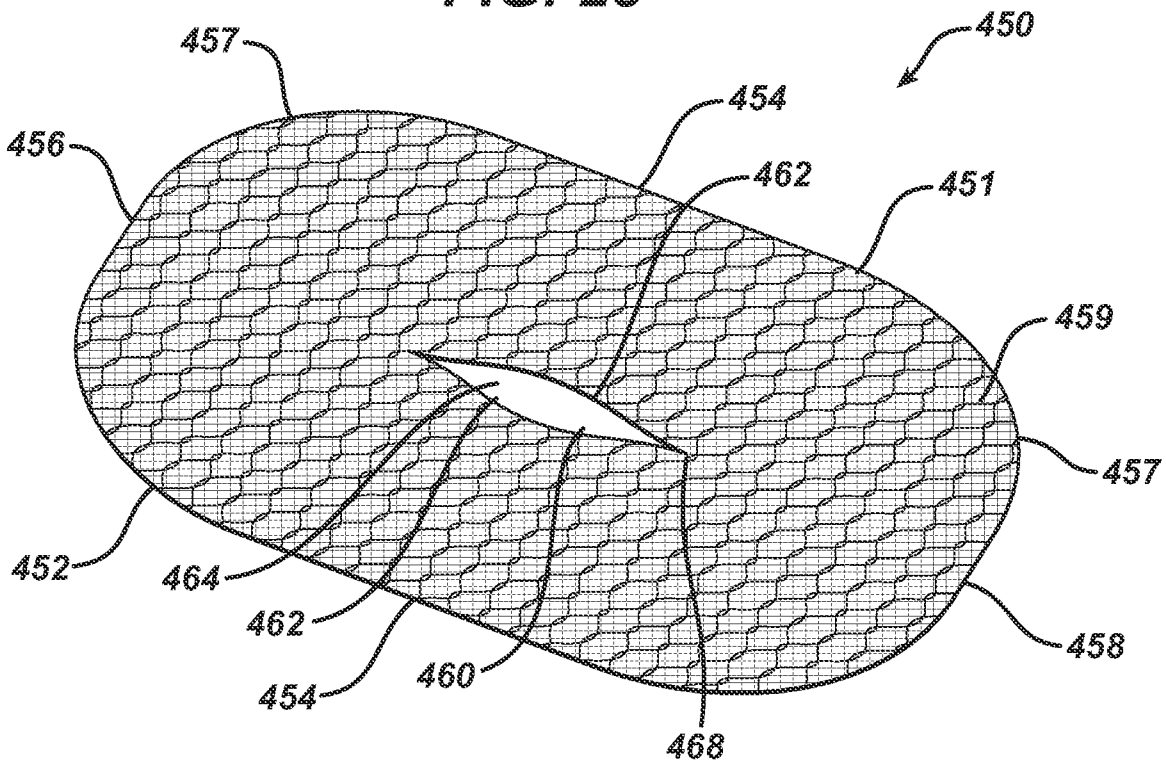

457
450
454
456
462
451
459
457
452
464
462
458
454
460
468

FIG. 29

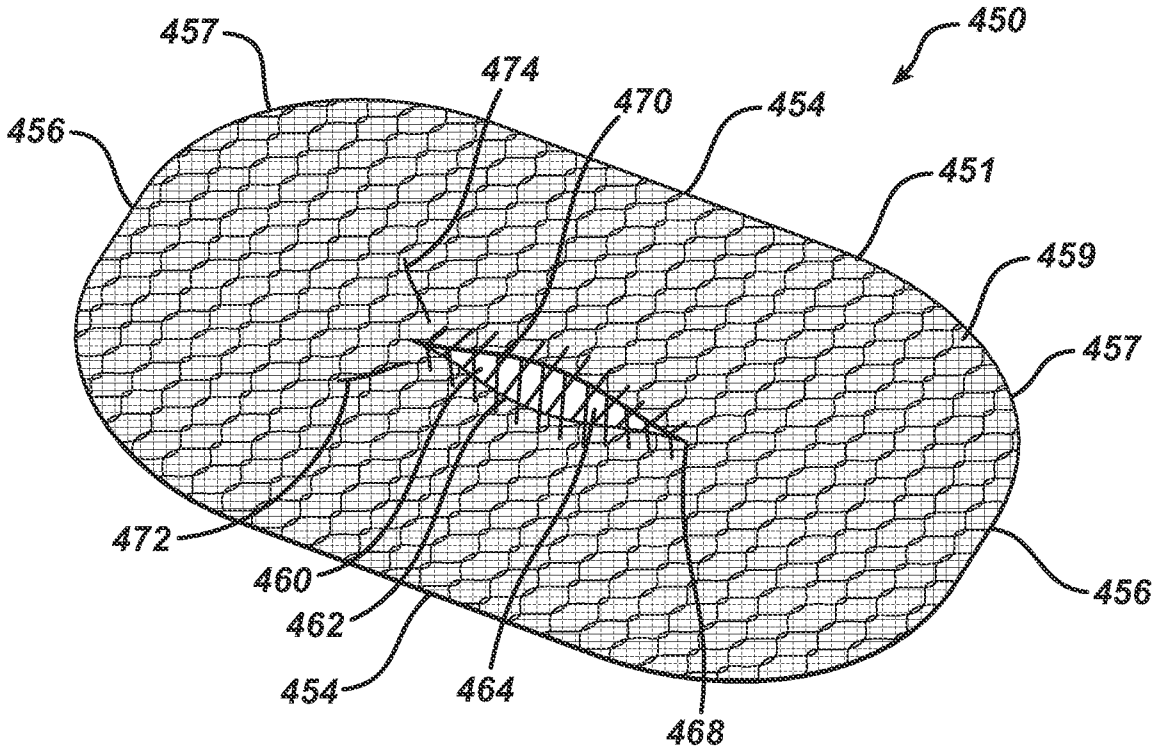
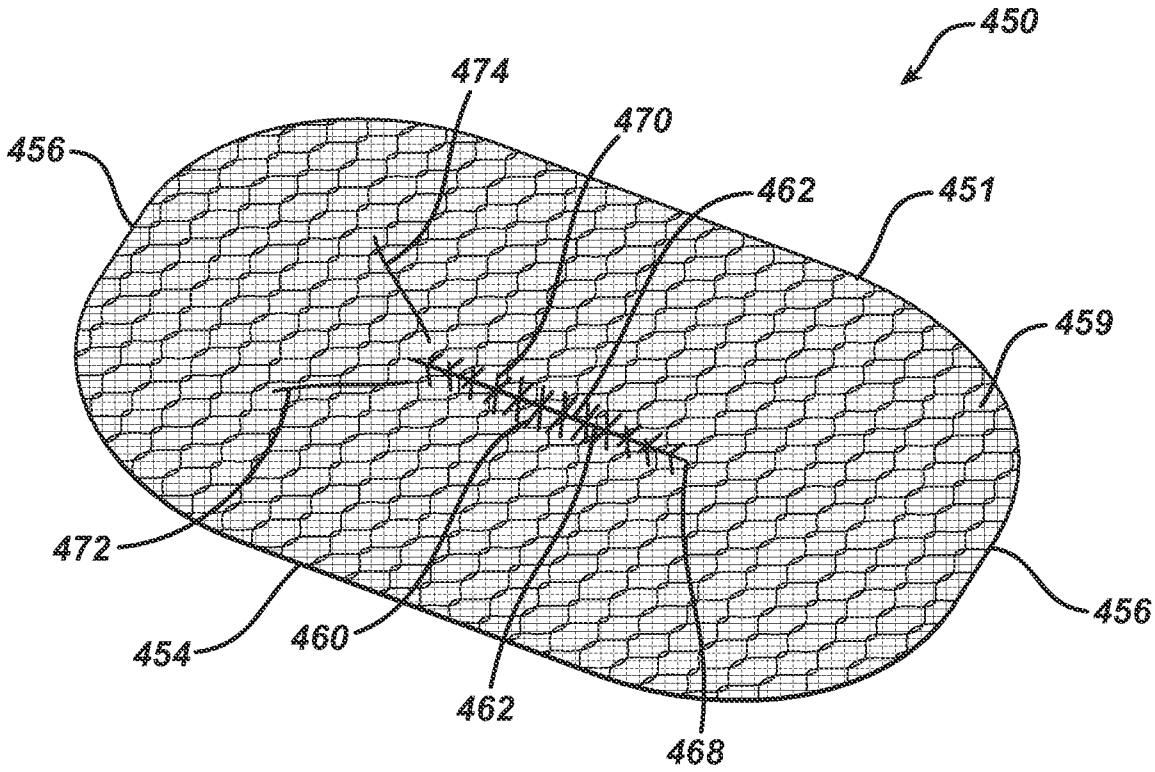

457
450
474
470
454
456
451
459
457
472
460
462
456
454
464
468

FIG. 30



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/035961

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/00
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

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,P	US 2012/316583 A1 (CHRISTOUDIAS GEORGE C [US]) 13 December 2012 (2012-12-13) the whole document	1-31

X	US 5 697 978 A (SGRO JEAN-CLAUDE [FR]) 16 December 1997 (1997-12-16)	1
Y	column 3 - column 5; figure 1	2-31

X	US 5 916 225 A (KUGEL ROBERT D [US]) 29 June 1999 (1999-06-29)	1
Y	the whole document	2-31

X	US 7 331 199 B2 (ORY FRANCOIS-REGIS [FR] ET AL) 19 February 2008 (2008-02-19)	1
Y	figures 5-9	2-31

	-/--	

[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
28 June 2013	04/07/2013

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	Serra i Verdaguer, J

4

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/035961

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.: 32-34
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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.

Continuation of Box II.1

Claims Nos.: 32-34

The subject-matter of claims 32 to 34, discloses a method of performing a body wall defect repair. The method comprises the step of inserting a tissue repair patch into a body. The International Searching Authority is not required to search methods for treatment of the human body by surgery or therapy (Rule 39.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/035961

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 693 720 A (SCHARNBERG LORNE C [US] ET AL) 15 September 1987 (1987-09-15)	1
Y	figure 2	2-31

X	US 5 425 740 A (HUTCHINSON JR WILLIAM B [US]) 20 June 1995 (1995-06-20)	1
Y	figure 5	2-31

X	WO 03/026530 A1 (NEGRO PAOLO [IT]; SOFRADIM PRODUCTION [FR]) 3 April 2003 (2003-04-03)	1
Y	figures 7,8	2-31

X	US 6 596 002 B2 (THERIN MICHEL [FR] ET AL) 22 July 2003 (2003-07-22)	1
Y	the whole document	2-31

4

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/035961

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012316583 A1	13-12-2012	US 8343231 B1	01-01-2013
		US 2012316583 A1	13-12-2012
US 5697978 A	16-12-1997	AT 204723 T	15-09-2001
		DE 69522425 D1	04-10-2001
		DE 69522425 T2	23-05-2002
		EP 0719527 A1	03-07-1996
		ES 2163485 T3	01-02-2002
		FR 2728776 A1	05-07-1996
		US 5697978 A	16-12-1997
US 5916225 A	29-06-1999	US 5916225 A	29-06-1999
		US 6224616 B1	01-05-2001
US 7331199 B2	19-02-2008	AT 447636 T	15-11-2009
		AU 5490101 A	07-11-2001
		EP 1274892 A1	15-01-2003
		EP 2143836 A1	13-01-2010
		ES 2334206 T3	08-03-2010
		FR 2807937 A1	26-10-2001
		JP 5049442 B2	17-10-2012
		JP 2003530981 A	21-10-2003
		US 2004054376 A1	18-03-2004
		US 2008195231 A1	14-08-2008
		WO 0181667 A1	01-11-2001
US 4693720 A	15-09-1987	NONE	
US 5425740 A	20-06-1995	AU 2477695 A	05-12-1995
		US 5425740 A	20-06-1995
		WO 9531140 A1	23-11-1995
WO 03026530 A1	03-04-2003	AT 347865 T	15-01-2007
		DE 60216781 T2	15-11-2007
		EP 1427350 A1	16-06-2004
		ES 2276962 T3	01-07-2007
		FR 2829922 A1	28-03-2003
		IT MI20020434 U1	22-03-2003
		JP 4243189 B2	25-03-2009
		JP 2005503236 A	03-02-2005
		US 2005021058 A1	27-01-2005
		WO 03026530 A1	03-04-2003
US 6596002 B2	22-07-2003	DE 10120942 A1	25-10-2001
		ES 2193834 A1	01-11-2003
		FR 2807936 A1	26-10-2001
		GB 2364648 A	06-02-2002
		IT MI20010841 A1	21-10-2002
		JP 4410959 B2	10-02-2010
		JP 2001353171 A	25-12-2001
		US 2002013590 A1	31-01-2002