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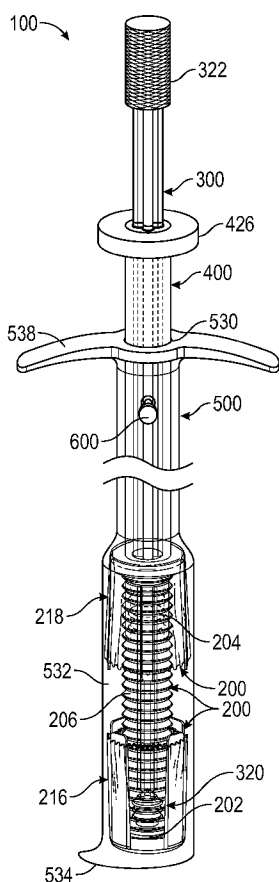


FIG. 1A

(57) Abstract: A wound closure apparatus can be a self-contained device for delivery and deployment of a tissue engineered wound plug that can secure fascial closure of laparoscopic port-site wounds. The wound plug can include a subfascial rivet head, a suprafascial rivet head, and a compressible column. Once in the wound, the wound plug may be deployed with the subfascial rivet head below the fascia of the wound and the suprafascial rivet head above the fascia of the wound. As this occurs, the column of the wound plug can be stationed within the opening of the wound. Once the wound plug is secured above, below, and within the fascial defect, the rivet heads may be interlocked within an inner channel of the column and remaining elements of the apparatus may be removed and discarded.





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WOUND CLOSURE APPARATUS AND METHOD

Field of the Disclosure

[0001] The present disclosure relates generally to a wound closure apparatus and method.

Background of the Disclosure

[0002] Minimally invasive surgery (MIS), also referred to as laparoscopic or endoscopic surgery, has experienced spectacular growth worldwide over the past few decades for the diagnosis and treatment of a variety of acute and chronic pathologies. Endoscopic procedures are economical, safer, and promote a more rapid recovery in contrast to conventional surgical approaches. Technological advancements in MIS are expected to have robust growth in the future. As endoscopic technologies develop and become the standard of care for most types of surgical interventions, the continued development of innovative quality tools to address the unique problems associated with this type of surgery must be vigorously pursued.

[0003] A laparoscopic surgery is performed by inserting a cannula (a hollow plastic or metal tube) through the abdominal wall, either by scalpel dissection or by blunt penetration with a piercing instrument (a trocar) occupying the central lumen of the cannula. When the cannula is placed through the skin and into the abdomen, the surgical blade or central trocar is withdrawn, leaving a cannula that is designed to inflate the abdominal cavity with carbon dioxide gas in order to distend the anterior abdominal wall away from the internal organs. The presence of this gas in the abdominal cavity is known as a pneumoperitoneum.

[0004] Once the pneumoperitoneum is established, a fiber optic endoscope (which may either be attached to a high-definition video camera or guided by direct vision) is inserted safely into the abdomen allowing visualization of the abdominal viscera. When complete visualization of the abdomen is accomplished, a number of secondary cannulae are placed via the previously described technique. The surgery is then performed through these cannulated passageways, referred to as ports. The ports function as conduits for the insertion and exchange of various specialized hand-held

or robotic-assisted instruments and devices to accomplish the laparoscopic procedure, which would otherwise be performed by an open surgical incision.

[0005] The observed benefits of MIS include reduced blood loss, lower risk of infection, more rapid recovery rates, and reduced postoperative pain. These benefits have caused laparoscopy to become the preferred method for an ever-increasing number of surgical procedures. As with any other surgery, however, MIS is not without its share of complications. Two common complications relevant to MIS surgeries are the formation of abdominal adhesions and/or hernia development.

[0006] While laparoscopic adhesion formation occurs less frequently than those related to open surgeries, the risk remains omnipresent as a result of the cumulative effect of the fibrin-forming inflammatory process. Factors that predispose the development of adhesions include: ischemia (poor blood supply), obesity, malnutrition, diabetes, or the devascularization of the peritoneum caused by the surgery itself. The development of adhesions generally occurs between the fifth and seventh postoperative day, resulting in scar-like bands. These adhesive bands may surround the intestine and adhere them either together, or to the peritoneum of the interior abdominal wall. However, months to years later after the initial surgery, these constrictive bands may form a thickened fibrous web which, when fully compact, are capable of inflicting severe pain or causing an intermittent-to-complete bowel obstruction. These two unfortunate scenarios will likely translate into higher medical costs related to emergency surgical procedures, lengthy hospital admissions, and prolonged recovery periods.

[0007] The other complication related to minimally invasive procedures is the port-site wound hernia, also referred to as an incisional or ventral hernia. The port-site wound hernia is defined as the abnormal protrusion of abdominal viscera through the wound's fascial defect. This type of hernia commonly develops in the first four years after the index surgery. At present, there is a problematic lack of long-term data on the incidence and natural history of port-site hernia development. Significant contributing factors for port-site wound herniation relate to the size and location of the fascial defect.

[0008] Obese patients, with a body mass index (BMI) of thirty or greater, are more susceptible to port-site wound herniation regardless of the fascial defect's size. This

may be attributed to the obese patient's enlarged pre-peritoneal space and/or tendency toward elevated intra-abdominal pressures. Extensive manipulation and stretching of the instrument port during the MIS procedure (i.e. retrieval of specimens, multiple re-insertions, or aggressive use of laparoscopic instruments or devices) may enlarge the size of the fascial defect beyond the wound's initial diameter thus rendering the fascial defect vulnerable to port-site wound herniation.

[0009] With regards to location, herniation occurs more frequently when the fascial defect is located in the midline of the abdomen, especially in the upper midline area or at the umbilicus, possibly due to the absence of supporting musculature in these areas. In contrast, port-site wound hernias occur less often when they are located below the umbilicus or more laterally on the abdomen.

[0010] Another contributing factor for the development of a port-site wound hernia is known as the Chimney Effect. This describes a partial vacuum that is created as the surgical cannula is withdrawn from the wound, much like a piston. As this negative pressure increases within the narrow perimeter of the wound, it is capable of drawing abdominal viscera through the fascial defect and in the subcutaneous tissue or out of the body, thus creating the port-site wound hernia.

[0011] There are two technical risk factors for port-site wound hernia: the surgical trocar design used for creating the wound, and/or the suture used for closing the fascial defect. With regards to the former, the bladed trocar presents a greater risk for port-site wound hernia development than non-bladed trocars. Port-site wound herniation may also be related to the repair of the fascial defect with suture, as exemplified by suture fractures, slipping of suture knots, excessive suture tension, or sutures that absorb too rapidly. Suture closure of these wounds can be time consuming and difficult whether the suturing method is performed by the traditional approach (a needle attached to a suture and operated by a needle holder held in the operator's hand), or by a contemporary method using wound closure devices. The latter generally incorporates a needle or sharp tool with a suture affixed to one end in order to approximate and close the fascial defect.

[0012] Regardless of the method, the application involves the same time-consuming and cumbersome approach for employing a needle (or sharp tool) with a suture affixed to one end in order to approximate and close the fascial defect within the

narrow recesses of the port-site wound. Moreover, these suture techniques have the predictable risk of injuring the underlying bowel, omentum, or other organs as the needle is swept through the fascial tissues.

[0013] In obese patients these suturing methods can be painstakingly difficult, since the fascia is obscured from view by adipose tissue. If the fascial defect is too deep and/or is located at a steep angled trajectory in relation to its small skin incision, a blind attempt (e.g., with no direct vision) is the only option for closing the fascial defect. This risky suturing effort generally fails to capture a sufficient margin of the wound's edge.

[0014] With regards to the contemporary devices, they may share the same vexing difficulties as the traditional method. However, a specific drawback with these devices relates to their requirement for a pneumoperitoneum and direct visualization during their surgical application. This time-consuming requirement proves problematic, since all of these devices are unable to close the port operating the telescopic lens.

[0015] These technical challenges can compromise the wound's integrity, resulting in complications such as poor wound healing, suture failure, and port-site wound herniation, all of which will inadvertently negate the advantages of the MIS procedure. Ultimately, these complications will lead to increased pain and loss of productivity for the patient, while at the same time reducing efficiency with increased costs to the health care system in general.

Summary of the Disclosure

[0016] Since the advent and proliferation of minimally invasive surgeries there has been a longstanding need for a rapid, safe and effective means of closing the strongest and most complete tissue layer of the port-site wound, specifically the anterior fascia of the abdominal wall. Embodiments of the disclosure are directed to an apparatus and method for the optimal closure of minimally invasive port-site wounds that, in contrast to traditional and contemporary approaches for closing the fascial defect, include enhancements to prevent complications while facilitating wound healing.

[0017] By virtue of its unique one-piece design, the apparatus can function as its own insertion device, deployment tool, and highly sophisticated tissue engineered implant.

Regenerative medicine may play a role in the development of the wound plug's biochemical properties by exhibiting characteristics that, when exposed to living tissues of the body, may not cause damage or adverse biological reactions (e.g., it may be biocompatible); may physiologically degrade and may be absorbed during a specific period of time (e.g., it may be bioabsorbable); and may be completely eliminated by the body's natural processes with no residual side effects (e.g., it may be bioresorbable). These essential characteristics may synergistically regenerate and heal the damaged tissues of the wound. The process can sustain the wound plug's durability and strength for the period of time deemed necessary for the wound plug to be absorbed by the body as the new tissues take its place. In this way, the apparatus can effectively, safely, and easily seal and close the fascial defect of the port-site wound.

[0018] The apparatus can be inserted and deployed within any size, depth or angle of port-site wound. Due to its highly versatile design, the apparatus can accurately locate the anterior abdominal fascia surrounding the fascial defect. The apparatus can ensure optimum application and deployment of its wound plug without necessitating the use of any surgical cannula, pneumoperitoneum, or telescopic lens to aid in its insertion, delivery, or deployment.

[0019] The apparatus can secure closure of the fascial defect by deployment of a unidirectional ratchet-rivet mechanism that engages the tissues of the fascial defect gently between two rivet heads. The apparatus can be deployed above, below, and within the anterior fascial defect, causing the defect to become gently sandwiched within the non-traumatic clamping force of the apparatus's wound plug. This three-dimensional approach for closing and sealing the defect echoes three basic tenets proposed in hernia mesh science. The first is the apparatus's suprafascial rivet head, which can secure the anterior fascial defect from above as an overlay. The second is the apparatus's subfascial rivet head, which can affix below the defect as an underlay. The third tenet can be achieved by the inlay position of the wound plug's shape memory column (stationed between the two rivet heads) that can fill and seal the void from within the fascial defect. The column can be compressible to fill any size wound and to keep body tissue from entering the wound. Further, it can fill in any gaps to prevent the other elements of the wound plug from shifting.

[0020] The tissues of the fascial defect may not be strictly fixed by the apparatus, which significantly reduces the detrimental effects of tissue ischemia (poor blood supply) or necrosis (tissue death) within the wound. The wound plug can spread over a wide surface area, beyond the circumference of the wound, to secure and promote tissue adherence and cellular growth. Another benefit of the wound plug's comprehensive overlay, underlay and inlay of the fascial defect and surrounding tissues is to prevent the plug from migrating or dislodging from its deployed position.

[0021] The straightforward and simple application of the apparatus may greatly reduce operating room expenditures in time, efficiency and labor; reduce risk of future adhesions and herniation; facilitate healing and regeneration of the tissues; reduce pain in the patient; and promote optimal patient outcomes with a rapid recovery rate. The apparatus may incorporate a wound plug that, by virtue of its varied chemical and biological composition, may be capable of providing structural and mechanical support for the ingrowth and regrowth of native tissues by interacting with the body's natural intra-cellular processes vital for wound healing.

Brief Description of the Drawings

[0022] For a better understanding of the various described embodiments, reference should be made to the Detailed Description below, in conjunction with the following drawings in which like reference numerals refer to corresponding parts throughout the figures.

[0023] Figure 1A-1B illustrate the wound closure apparatus according to embodiments of the disclosure.

[0024] Figures 2A-2N illustrate the wound plug according to embodiments of the disclosure.

[0025] Figures 3A-3B illustrate a post according to embodiments of the disclosure.

[0026] Figure 4 illustrates a rod according to embodiments of the disclosure.

[0027] Figures 5A-5C illustrate a shield according to embodiments of the disclosure.

[0028] Figures 6A-6D illustrate the apparatus during stages of deployment of the wound plug according to embodiments of the disclosure.

[0029] Figure 7 is a block diagram of a method for deploying a wound plug according to embodiments of the disclosure.

Detailed Description

[0030] In the following description of examples, reference is made to the accompanying drawings which form a part hereof, and in which it is shown by way of illustration specific examples that can be practiced. It is to be understood that other examples can be used and structural changes can be made without departing from the scope of the disclosed examples.

[0031] Since the advent and proliferation of minimally invasive surgeries there has been a longstanding need for a rapid, safe and effective means of closing the strongest and most complete tissue layer of the port-site wound, specifically the anterior fascia of the abdominal wall. Embodiments of the disclosure are directed to an apparatus and method for the optimal closure of minimally invasive port-site wounds that, in contrast to traditional and contemporary approaches for closing the fascial defect, include enhancements to prevent complications while facilitating wound healing.

[0032] By virtue of its unique one-piece design, the apparatus can function as its own insertion device, deployment tool, and highly sophisticated tissue engineered implant. Regenerative medicine may play a role in the development of the wound plug's biochemical properties by exhibiting characteristics that, when exposed to living tissues of the body, may not cause damage or adverse biological reactions (e.g., it may be biocompatible); may physiologically degrade and may be absorbed during a specific period of time (e.g., it may be bioabsorbable); and may be completely eliminated by the body's natural processes with no residual side effects (e.g., it may be bioresorbable). These essential characteristics may synergistically regenerate and heal the damaged tissues of the wound. The process can sustain the wound plug's durability and strength for the period of time deemed necessary for the wound plug to be absorbed by the body as the new tissues take its place. In this way, the apparatus can effectively, safely, and easily seal and close the fascial defect of the port-site wound.

[0033] The apparatus can be inserted and deployed within any size, depth or angle of port-site wound. Due to its highly versatile design, the apparatus can accurately

locate the anterior abdominal fascia surrounding the fascial defect. The apparatus can ensure optimum application and deployment of its wound plug without necessitating the use of any surgical cannula, pneumoperitoneum, or telescopic lens to aid in its insertion, delivery, or deployment.

[0034] The apparatus can secure closure of the fascial defect by deployment of a unidirectional ratchet-rivet mechanism that engages the tissues of the fascial defect gently between two rivet heads. The apparatus can be deployed above, below, and within the anterior fascial defect, causing the defect to become gently sandwiched within the non-traumatic clamping force of the apparatus's wound plug. This three-dimensional approach for closing and sealing the defect echoes three basic tenets proposed in hernia mesh science. The first is the apparatus's suprafascial rivet head, which can secure the anterior fascial defect from above as an overlay. The second is the apparatus's subfascial rivet head, which can affix below the defect as an underlay. The third tenet can be achieved by the inlay position of the wound plug's shape memory column (stationed between the two rivet heads) that can fill and seal the void from within the fascial defect. The column can be compressible to fill any size wound and to keep body tissue from entering the wound. Further, it can fill in any gaps to prevent the other elements of the wound plug from shifting.

[0035] The tissues of the fascial defect may not be strictly fixed by the apparatus, which significantly reduces the detrimental effects of tissue ischemia (poor blood supply) or necrosis (tissue death) within the wound. The wound plug can spread over a wide surface area, beyond the circumference of the wound, to secure and promote tissue adherence and cellular growth. Another benefit of the wound plug's comprehensive overlay, underlay and inlay of the fascial defect and surrounding tissues is to prevent the plug from migrating or dislodging from its deployed position.

[0036] The straightforward and simple application of the apparatus may greatly reduce operating room expenditures in time, efficiency and labor; reduce risk of future adhesions and herniation; facilitate healing and regeneration of the tissues; reduce pain in the patient; and promote optimal patient outcomes with a rapid recovery rate. The apparatus may incorporate a wound plug that, by virtue of its varied chemical and biological composition, may be capable of providing structural and mechanical support for the ingrowth and regrowth of native tissues by interacting with the body's natural intra-cellular processes vital for wound healing.

Apparatus

[0037] Figures 1A-1B illustrate a wound closure apparatus 100 according to embodiments of the disclosure. The apparatus can be a self-contained device for delivery and deployment of a tissue engineered wound plug 200 that can secure fascial closure of laparoscopic port-site wounds. The wound plug 200 can include a subfascial rivet head 202, a suprafascial rivet head 204, and a compressible column 206, wherein the compressible column surrounds and is coupled to each of the subfascial rivet head and the suprafascial rivet head.

[0038] The apparatus may include a post 300, a rod 400, and a shield 500 for delivery and deployment of the wound plug 200. The post 300 can include the subfascial rivet head 202 at a first end of the post and a handle 322 at a second end of the post. The rod 400 can have a rod cavity 466 through which the post 300 is positioned. A first end of the rod 400 can be in contact with the suprafascial rivet head 204 of the wound plug 200, and the rod can include a plate 426 at a second end of the rod. The shield 500 can contain portions of the wound plug 200, the post 300, and the rod 400 in a shield cavity 530.

[0039] Once in the wound, these components can deploy the wound plug 200 with the subfascial rivet head 202 below the fascia 750 of the wound and the suprafascial rivet head 204 above the fascia of the wound 748. As this occurs, the column 206 of the wound plug 200 can be stationed within the opening of the wound. Once the wound plug 200 is secured above, below, and within the fascial defect, the two components of the rivet heads 202 and 204 may be interlocked within an inner channel 260 of the column 206. As a result, the wound plug 200 may be implanted into the port-site wound's fascial defect, while the post 300, the rod 400, and the shield 500 may be removed from the wound and safely discarded.

[0040] The apparatus's design, consisting of its own deployment device and implant, creates a mechanical symbiosis that precludes the need for any other additional accessories (e.g., other tools or instruments), or conditions of the wound (e.g., pneumoperitoneum, telescopic visualization, wound retraction, or increasing the length of the skin incision).

Wound Plug

[0041] Figures 1B and 2A-2N illustrate a wound plug 200 according to embodiments of the disclosure. In some embodiments the wound plug includes a subfascial rivet head 202, a suprafascial rivet head 204, and a compressible column 206. In some embodiments, the subfascial rivet head 202 includes a subfascial extension 208 comprising a plurality of stays 210, and the suprafascial rivet head 204 includes a suprafascial extension 212 including a plurality of stays 214. In some embodiments, the wound plug 200 further includes a subfascial biohybrid scaffold 216 coupled to the subfascial extension 208 and a suprafascial biohybrid scaffold 218 coupled to the suprafascial extension 212.

[0042] Figures 2A-2D illustrate subfascial and suprafascial rivet heads 202 and 204 according to embodiments of the disclosure. The rivet heads 202 and 204 may be composed of natural polymers or copolymers like chitosan, gelatin, alginate, collagen and/or other wound healing promoters; as well as synthetic polymers or copolymers such as Polyglycolide (PGA), Polylactide (PLA), Polydioxanone (PDO), Polycaprolactone (PCL), or synthetic copolymers like L-lactide-co-glycolide (PLGA). The possibilities for such fabrication techniques may include but are not limited to polymeric blends, dip coating, adhesive layering, copolymerization, grafting, homogeneous mixtures, and/or electrospinning for creating a biosynthetic composite material.

[0043] This skeletal architecture can be manufactured from a polymeric composite for superior tissue engineering. A synthetic polymer or copolymer may be desirable because it demonstrates mechanical and physiochemical characteristics similar to those of the biological tissue it will temporarily replace. Additionally, synthetics can be tailored to control their microstructure and degradation rate. In contrast, however, natural polymers can have bioactivity-possessing growth factors and pertinent signals that may facilitate cellular adhesion, growth, and proliferation. Consequently, the strength of the former, and the bioactivity of the latter may mutually provide intrinsic benefits while diminishing each other's deficiencies.

[0044] The semi-rigid polymer composite of this skeletal architecture can be designed with microscopic perforations, which provide a gradient through which the native tissue cells may proliferate. As the device degrades within the body these perforations may be critical for tissue adherence and optimal cellular response and

healing. Moreover, a natural polymer may be adhered as a layer upon the synthetic polymer construct.

[0045] The subfascial rivet head 202 may be a part of the post 300 at a first end of the post, separated from the rest of the post by a breakaway point 320. The post 300 can be used to position the subfascial rivet head 202 below the fascia 750 into the pre-peritoneal space, and the post can be broken at the breakaway point 320 to separate the subfascial rivet head 202 from the rest of the post after the wound plug 200 is deployed in its entirety.

[0046] In some embodiments, the subfascial rivet head 202 may comprise an engaging ratchet configured to engage with a hollow receiving pawl of the suprafascial rivet head 204. For example, the engaging ratchet may include a number of flanges 256 configured along its exterior that correspond to a number of reciprocal annular grooves 258 within the interior of the receiving pawl. Once the rivet heads 202 and 204 are deployed, the subfascial and suprafascial portions of the wound plug 200 become interlocked by deployment of the unidirectional mechanism.

[0047] In some embodiments, the suprafascial rivet head 204 may comprise a hollow receiving pawl configured to engage with an engaging ratchet of the subfascial rivet head 202. For example, the receiving pawl may include a number of reciprocal annular grooves 258 configured within its interior that correspond to a number of flanges 256 on the exterior of the engaging ratchet. Further, the suprafascial rivet head 204 may be configured with a channel to allow the post 300 to pass through its hollow core.

[0048] In some embodiments, engagement of the subfascial and the suprafascial rivet heads 202 and 204 may be confirmed by three audible clicks synchronized with three tactile sensations. These effects confirm that the reciprocal annular grooves 258 of the receiving pawl have successfully interlocked with the flanges 256 of the engaging ratchet.

[0049] In some embodiments, extensions 208 and 212 surround the outer perimeters of each rivet head 202 and 204. For example, Figures 2E-2F illustrate each extension 208 and 212 including a plurality of stays 210 and 214. In some examples, the number of stays on each rivet head can be chosen relative to the size of each rivet head extension 208 and 212, as well as to the weight and size of their associated

biohybrid scaffold 216 and 218. The cross sectional profile of each stay may be tapered on one side 262 and non-tapered (e.g., flat) on the opposing side 264. This profile can be consistent throughout the length of each stay, terminating into a blunt-point end.

[0050] The stays 210 and 214 may be fabricated using shape memory properties, allowing for two different configurations during the implant's surgical application. Prior to deployment, the stays may project at 90° angles from the outer perimeter of each rivet head, offset relative to each other at a 45° angle of arc. In this second configuration, the stays may be superiorly and inferiorly convergent as they enclose an outer wall of the column 206 in an alternating fashion. Further, each stay may include two distinct surfaces 262 and 264. Within the apparatus 100, a first non-tapered surface 264 may be adjacent to the wall of the column 206, whereas a second tapered surface 262 may encircle an outer perimeter of the column 206 exteriorly.

[0051] Once the rivet heads 202 and 204 are deployed, however, the shape memory properties of the stays 210 and 214 can be immediately affected by the body's temperature and/or pH relative to a pre-determined time interval also inherent in their chemical properties. These physical and biological properties can cause each stay to automatically deploy its corresponding biohybrid scaffold (e.g., biohybrid scaffolds 216 and/or 218) into a full radial expansion above and below the fascial defect, thus orienting the stays' non-tapered surfaces 264 toward the abdominal fascia, while their tapered surfaces 262 are adjacent to the native tissues surrounding the port site wound (e.g., native tissues 768 in Figures 6C and 6D).

[0052] Although Figure 2E illustrates just the subfascial extension 208 including the plurality of stays 210, in some embodiments, the subfascial extension 208, the plurality of stays 210, the subfascial rivet head 202, and the post 300 are all formed of a single piece. Further, although Figure 2E illustrates just the suprafascial extension 212 including the plurality of stays 214, in some embodiments, the suprafascial extension 212, the plurality of stays 214, and the suprafascial rivet head 204 are all formed of a single piece.

[0053] In some embodiments, the rivet heads 202 and 204 may include a disc shape as illustrated in the figures. In some embodiments, the rivet heads may alternatively include other shapes, such as rectangular, oval, hexagonal, octagonal, star, square, etc.

[0054] In some embodiments, the rivet heads 202 and 204 may be manufactured from the same shape memory blend of natural and synthetic polymers (or copolymers) as the extensions 208 and 212. In this way, the rivet heads can change to a smaller or more compact profile, such as a cone or ball.

[0055] In some embodiments, the stays 210 and 214 may be profiled to be tapered or non-tapered, thick or thin, wide or narrow, etc. In some embodiments, the stays may be profiled in such a way that their central convergence forms the receiving pawl and engaging ratchet. In this embodiment, the stays may be configured in linear geometric shapes (i.e., spokes on a bicycle wheel, or a lattice-like network), or as a mosaic of crisscrossing curves (i.e., lace-like or snowflake designs) for establishing the skeletal framework of the rivet heads 202 and 204, as well as the rivet head extensions 208 and 212.

[0056] Although embodiments of the disclosure are described in terms of rivet heads comprising a receiving pawl and an engaging ratchet, embodiments are not so limited. Other embodiments are contemplated for attaching the suprafascial and subfascial portions of the wound plug 200, such as superior and inferior clasps, mechanical fasteners, crimp engagements, mechanical latches, suture tie(s) with a type of slip knot(s), post or bead-like snaps, a tapering pin that engages within a narrowing hole, hook and eye attachments, a type of buckling apparatus, or even a chemical tissue adhesive disseminating from the column 206.

[0057] Figures 2G-2J illustrate biohybrid scaffolds 216 and 218 according to embodiments of the disclosure. In some embodiments, the scaffolds 216 and 218 may comprise a collagen rich acellular non-crosslinked tissue sheet that is replete with vital components for wound healing, such as laminin, biometric proteins, carbohydrates, etc. When these multi-layered tissue sheets are applied to a wound site, a synergy between its scaffold and the native tissues can develop, causing specialized living cells to proliferate and regenerate new tissue into the wound site.

[0058] In some embodiments, the biohybrid scaffolds 216 and 218 include two distinct surfaces. A first surface 252, the lamina propria layer, may be conducive for tissue regeneration and healing. In contrast, the second surface 254, the epithelial basement membrane, may be beneficial as a collagen rich tissue scaffold. The scaffolds may be deployed such that the first surface 252 is in contact with the

abdominal fascia around the fascial defect 748 and 750, while the second surface 254 is in contact with surrounding native tissues of the wound (e.g., native tissues 768 in Figures 6C and 6D).

[0059] In some embodiments, the biohybrid scaffolds 216 and 218 may cover and embed only the flatter, larger surfaces of the rivet heads 202 and 204 and both sides of each of the stays 210 and 214 with the exception of the stays' distal blunt ends. The scaffolds 216 and 218 may include centralized openings to allow portions of the rivet heads 202 and 204 and the vertical axis of the post 300 to pass through the centers of the scaffolds.

[0060] In some embodiments, an electrospun layer may be applied between the tissue surfaces of each biohybrid scaffold 216 and 218 directly contacting the shape memory components of the stays 210 and 214. This may further promote cohesiveness between the two layers for strength and manageability.

[0061] Prior to deployment biohybrid scaffolds 216 and 218 can conform to the same constricted configuration presented by the embedded stays 210 and 214. In this deformed profile, the lamina propria layer 252 can be adjacent to the wall of the column 206, while the epithelial basement membrane 254 can encircle the column exteriorly. In this pre-deployment profile, the scaffold tissue sheets may appear as multiple vertical pleats, in the likeness of a pleated paper coffee filter, although pleats may be more rounded or larger in nature.

[0062] Once the rivet heads 202 and 204 are deployed, the bio-reactivity of the surrounding stays 210 and 214 can simultaneously spread its corresponding biohybrid scaffold 216 and 218 into full radial expansion. As a result, the lamina propria layer 252 that encases the inner (fascial) surfaces of the rivet heads and stays (e.g., the non-tapered surfaces 264) may be juxtaposed to one another as they cover the subfascial and suprafascial surfaces 750 and 748 surrounding the wound 744. Further, the epithelial basement membrane 254 covering the exterior sides of the rivet heads and the tapered surfaces 262 of the stays can buttress the surrounding native tissues (e.g., native tissues 768 in Figures 6C and 6D). Consequently, following deployment each rivet head's outer diameter may be large enough to thoroughly cover both sides of the defect.

[0063] In some embodiments, the scaffolds may be produced with other types of biological or synthetic (absorbable or nonabsorbable) scaffolding materials.

[0064] In some embodiments, the skeletal framework of the rivet heads and the stays may not be included, and instead the shape memory biohybrid scaffolds of each rivet head may be resilient enough to deform into a pre-deployment configuration without the necessity of any supportive skeletal framework.

[0065] In the absence of the skeletal framework, it may be beneficial for a tissue adhesive to be dispersed from the column 206 to cause the two biohybrid scaffolds to adhere locally to the wound. If a tissue adhesive is used for securing the wound plug to the wound, there may be no need for a mechanical fixation apparatus such as an engaging ratchet or a receiving pawl. As a result, this alternative suggests only a simple open-ended central opening within the suprafascial rivet head 204. Likewise, the post 300 may be a plain shaft (without an engaging ratchet or a breakaway point 320). The distal end of the post may need to be tenuously anchored to the electrospun network within the two layers 252 and 254 of the subfascial biohybrid scaffold 216 covering the subfascial rivet head 202. After deployment, and the local tissue adhesive from the column 206 is dispersed, the terminal end of the post may be twisted, torqued, pulled, or snapped from its temporary electrospun attachments within the subfascial biohybrid scaffold of the subfascial rivet head.

[0066] In some embodiments, the biohybrid scaffold 216 and 218 may be uniform, and may have wide or narrow shapes that may include oval, rectangular, star-like or flower-petal projections, etc. In some embodiments, the subfascial and suprafascial biohybrid scaffolds may be profiled in two entirely different geometric shapes and widths. Further, each scaffold may be fabricated from identical biological or chemical properties to that of other elements of the wound plug 200.

[0067] Figures 2K-2N illustrate a compressible column 206 according to embodiments of the disclosure. The column 206 may be a highly porous shape-memory structure, in the form of a sponge or foam, which provides a large surface area to promote cellular ingrowth, uniform cellular distribution, and neovascularization. The column may be centered between the two rivet heads 202 and 204. Prior to deployment, the receiving pawl and the engaging ratchet may be recessed within an inner channel 260 of the column. In some embodiments, the

column may further include an electrospun network between the terminal borders of the column and the fascial surfaces 252 of the biohybrid scaffold 216 and 218 to achieve an integrated fusion between these structures, thus uniting them together as a single unit. As a result, the column's inferior section may be deployed in unison with the subfascial rivet head 202, while the superior portion of the column may be deployed with the suprafascial rivet head 204. After deployment, the column's initial tube-like profile may be positioned within the border of the wound.

[0068] The wall of the column 206 may be constructed with multiple compact circumferential pleats, such that the column compresses in an accordion-like fashion as the subfascial and suprafascial portions of the wound plug become interlocked. Accordingly, the length of the column compresses while maintaining its outer diameter so as to not interfere with the interlocking of the rivet heads.

[0069] In some embodiments, once the pleats are mechanically compressed, the body's temperature and/or pH can affect shape memory properties of the column 206, causing the column to automatically expand and pervade the interior of the wound in a washer-like profile with an outer diameter that does not fill the central defect. This smaller diameter of the column's washer-like profile can allow for the porous network to absorb blood and body fluids, increasing in size to swell and pervade the wound like a seal. The final configuration of the column, therefore, may fill the central defect like a low-pressure seal or plug without exerting pressure on the bordering tissues of the wound. As a result of this seal, the inner channel 260 of the column may become completely obliterated, thus resulting in an adherence between the column and the engaged components of the rivet heads 202 and 204. The benefit of this adherence is that dead space and vacuums are averted within the interior of the wound plug 200, thereby encouraging tissue regeneration.

[0070] In some embodiments, the size, distribution, volume, shape, and roughness of pores within the column 206 may have a powerful influence on cellular penetration and growth. Further, the pores may be interconnected in order to facilitate the essential transfer of oxygen, nutrients, and other physiochemical elements and biological exchanges to and from the living cells.

[0071] In some embodiments, the porous structure of the column 206 may be saturated with either a bioactive cellular matrix powder or a biocompatible hydrogel.

Saturating the column with one or more of these materials can promote a synergistic interplay between it and the surrounding native tissues of the port-site wound.

Additionally, the column's porous construction can incorporate pharmaceutical enhancements into its design, such as tissue adhesives, stem cell recruitment adjuncts, regenerative biochemical factors, insulin growth factor, anesthetic or antibiotic time-released drugs, etc.

[0072] In some embodiments, the inner channel 260 of the column 206 surrounding the post 300 and portions of the rivet heads 202 and 204 may be filled with a tissue-healing hydrogel or liquefied state of the same. Following deployment, the locally applied tissue adhesive may be dispersed from the column to function as a chemical securing mechanism for sealing the wound plug to the wound. In some embodiments, the column 206 itself may be made of the hydrogel with an outer wall made of denser gelatinous material (or skin) which encases the more viscous and/or liquefied form.

[0073] In some embodiments, the column 206 may include a finely shredded or spider web-like form of the bioactive acellular tissue matrix and/or liquefied form of the same. In some embodiments, the column may be fabricated from any number of materials including a sponge, foam, hydrogel, acellular pig bladder xenograft, any other type of xenografts, synthetic-absorbable scaffolding material, or any combination of these options. In some embodiments, the column may occur as a hollow chamber (i.e., a small bladder) formed by either a xenograft or other type of tissue engineered material that may contain pharmaceutical and bioactive substances, hydrogel, and/or the possibility of a tissue adhesive within its interior.

[0074] In some embodiments, the column 206 may be formed by stacking multiple centrally-perforated washers, one on top of the other, around the post 300 and the mechanical securing mechanisms of the rivet heads 202 and 204.

[0075] In some embodiments, the pleats of the column 206 may be arranged in vertical columns, or curving these vertical columns into a spiraling, candy cane-like design. By arranging the folds or pleats in these configurations, the column may compress like a collapsed spring. Moreover, it may be advantageous to cut these vertical or horizontal lines rather than utilizing pleats and/or folds within the wall of the column. Additionally, a combination of cuts and/or pleats or folds may contribute to a more successful compression for the column during deployment.

Delivery and Deployment Apparatus

[0076] The post 300, the rod 400, and the shield 500 form an apparatus 100 for delivery and deployment of the wound plug 200. These three components may reside at different radial levels in the apparatus. The post 300 may be located in the core of the apparatus and may be the longest of the three components, with its handle 322 rising higher than the other two components. The rod 400 surrounds portions of the post 300 and includes a plate 426 at one end (e.g., approximately midway between the handle 322 of the post 300 and grips 538 of the shield 500). The shield 500 surrounds portions of the rod 400 and the post 300 in its shield cavity 530. The shield includes an implant chamber 532 that contains portions of the wound plug 200 before deployment. Each of the post, the rod, and the shield may include an alignment pin hole through which an alignment pin 600 may be placed to align the various components with respect to each other. The alignment pin 600 may be removed prior to deployment, as described below.

[0077] In some embodiments, each of the post 300, the rod 400, and the shield 500 may be made of synthetic polymers without the essential blends of polymer composites comprising the wound plug 200. As a result, the overall rigid construction of these elements (e.g., the elements that will not be implanted within the body) may be fabricated from non-critical, bio-safe materials. Once the post, the rod, and the shield are separated from the wound plug and removed from the wound, their byproducts may be safely discarded as environmentally friendly, non-toxic wastes.

[0078] Figures 3A-3B illustrate a post 300 according to embodiments of the disclosure. The post may be a vertical and most internal axis by which all the components of the apparatus 100 may be collectively aligned and integrated for deployment. In this unique position, the post may traverse proximally throughout a series of internal conduits of the column 206 (e.g., the inner channel 260 of the column), the suprafascial rivet head 204, the rod 400 (e.g., the inner channel 466 of the rod), and the shield 500 (e.g., the shield cavity 530). The alignment of these cannulated components can create a common passageway through which portions of the post 300 can move.

[0079] The post 300 may be an injected molded structure comprised of several diverse profiles along its vertical construct, including a subfascial rivet head 202 (e.g.,

the engaging ratchet) at a first end, and a handle 322 at a second end. The post may further include a breakaway point 320 between the subfascial rivet head and the handle. The breakaway point distinguishes the portion of the post included in the wound plug (i.e., the subfascial rivet head) from the rest of the post. In some embodiments, the breakaway point 320 may be configured to provide vertical stability and strength, thereby resisting compression or elongation during insertion and deployment. However, following the application of minimal twisting torque to the handle 322, the post 300 can break at the breakaway point.

[0080] In some embodiments, the post 300 retains a cruciate profile until it transitions into the inferior flanges 256 and distal base of the engaging ratchet. Although the subfascial rivet head 202 is illustrated as having three flanges 256, embodiments are not so limited and can have any number of flanges. The handle 322 may be knurled to facilitate gripping and cylindrical to prevent its descent into the rod 400. In some embodiments, the post 300 further includes an alignment pin hole 324.

[0081] In some embodiments, the handle 322 may be profiled in different shapes which include, but are not limited to, a round, flat plate or disc, T-handle, thumb plate, ball, bulb, laterally contoured projections, finger-ring holes, diamond, ribbed finger grip, a rod-like handle, etc. In some embodiments, the shaft of the post 300 may be formed in other non-cruciate shapes, such as geometric shapes like a triangle or diamond, or a simple round or oval profile. Moreover, one or more of the four cruciate crossarms may be added to or removed from the cruciate profile, thus allowing for a variety of shapes which include, but are not limited to, one crossarm projection, two crossarms similar to a dumb-bell shape, three crossarms like a rounded three-leaf clover or a pointed triangular shape, a diamond shape, or multiple rounded or pointed projections as seen in various flower or star-like profiles.

[0082] In some embodiments, the breakaway point 320 may be designed to sever either by a snap release, by pulling and/or twisting, or by other physical means, instead of the application of torque discussed above. Additionally, since many of the apparatus's components respond to the body's pH and/or temperature, the breakaway point's chemical properties may be engineered to release within a specific period of time, shortly after deploying the wound plug 200 within the wound.

[0083] Figure 4 illustrates a rod 400 according to embodiments of the disclosure. The rod 400 can include a plate 426 at a second end of the rod, and a first end of the rod can be in contact with the suprafascial rivet head 204 (e.g., the receiving pawl). Prior to deployment, the plate 426 may be positioned midway between the handle 322 of the post 300 and the grips 538 of the shield 500. The rod may further include an alignment pin hole 428. An inner channel 466 of the rod can match a cruciate profile of the post 300, allowing for the vertical movement of the post and the rod without twisting during deployment of each associated rivet head (subfascial rivet head 202 deployed by the post 300, and suprafascial rivet head 204 deployed by the rod 400). Further, the cruciate profile can facilitate fixation of the post 300 above its breakaway point 320, permitting the application of torque to sever the post at the breakaway point.

[0084] In some embodiments, the combination of the plate 426 of the rod 400 and the grips 538 of the shield 500 can allow for a syringe-like hold to deploy the suprafascial rivet head 204 and the superior section of the column 206, as described below. In some embodiments, the inner channel 466 of the rod 400 has a non-cruciate shape to match a corresponding non-cruciate shape of the post 300. In some embodiments, the suprafascial rivet head 204 can be a part of the rod 400, separated from the plate 426 by a breakaway point that functions similarly to the breakaway point 320 of the post 300. The breakaway point of the rod can align with the breakaway point of the post after deployment such that a single twisting motion can sever both.

[0085] Although the figures illustrate a single shape for the plate 426, variations in shapes, thicknesses, sizes, etc. are contemplated by this disclosure.

[0086] Figures 5A-5C illustrate a shield 500 according to embodiments of the disclosure. The shield 500 can include a shield cavity 530 and an implant chamber 532 that houses portions of the wound plug 200 prior to deployment. In some embodiments, the shield further includes grips 538 to allow a user to hold the device like a syringe with a comfortable grip for the deployment of the suprafascial rivet head 204 and the column 206. The implant chamber 532 may be profiled in an inverted cup-like configuration. A rim of the implant chamber may be wider than the wound in the fascia, such that the shield 500 can rest on the fascia without entering the wound 744, and so that the contact between the fascia and the rim provides physical feedback to the user indicating that the wound plug is correctly positioned

with respect to the depth of the fascia beneath the skin, allowing for use of the apparatus without internal or external direct vision of the wound 744. Further, the rim of the implant chamber may include an insertion lip 534 to facilitate easy insertion of the apparatus beneath a narrow skin incision.

[0087] In some embodiments, the shield 500 may further include an alignment pin hole 536. The linear arrangement of the three alignment pin holes in the post 300, the rod 400, and the shield 500 can create a common opening for insertion of an alignment pin 600 to keep the components in place until ready for deployment, as illustrated in Figure 5C. The alignment pin may be removed once the rim of the implant chamber 532 is centered over the wound in the fascia.

[0088] In some embodiments, the insertion lip 534 of the implant chamber 532 may project in shapes including a quarter or half circle, a quarter or half oval, a more pointed design, an encircling band or brim, a ring, or a ridge. One or more additional insertion lips may also be included on the rim of the implant chamber 532.

[0089] In some embodiments, a CO₂ sensor or pressure gauge may be devised along the rim and/or lip of the implant chamber 532 which can register a visual cue in a window constructed within the wall of the shield 500.

[0090] In some embodiments, concentric grooves appearing as screw-like threads or spiral-like grooves may be profiled to the exterior wall of the shield 500. The purpose of these grooves may be to promote an easier insertion of the device within the subcutaneous tunnel of the wound. However, it may be determined that vertically aligned grooves, in contrast to the horizontal grooves, like the screw or spiral-like profiles, may effect easier insertion of the apparatus into the wound.

[0091] In some embodiments, some or all of the shield 500 may be profiled in numerous shapes, sizes, thicknesses, etc. For example, the grips 538 may be profiled in any geometric shape for designing the laterally oriented projections or rings, and any number of grips are contemplated.

Method of Deployment

[0092] Figures 6A-6D illustrate the apparatus 100 during stages of deployment of the wound plug 200, and Figure 7 is a block diagram of a method for deploying a wound plug according to embodiments of the disclosure.

[0093] The shield 500 may be inserted (10) into a skin opening 742 in the skin 740. The shield's implant chamber 532 may be slightly larger than the skin opening 742, so holding the apparatus at a 45° angle may allow the apparatus to slip easily beneath the skin incision without extension of the wound or the need for skin retraction.

[0094] The shield may be positioned (20) such that the rim of the implant chamber 532 is in contact with a suprafascial surface 748 of fascia 746 surrounding a wound 744 in the fascia, as illustrated in Figures 6A-6B. In some embodiments, the rim of the implant chamber may be wider than the wound in the fascia, such that the shield can rest on the fascia 746 without entering the wound 744, and allowing for use of the apparatus without internal or external direct vision of the wound in the fascia. Further, the contact between the fascia and the rim may provide physical feedback to the user that the wound plug is correctly positioned with respect to the depth of the fascia 746 beneath the skin 740.

[0095] In some embodiments, the alignment pin 600 may be removed from the alignment pin holes 324, 428, and 536 of the post 300, the rod 400, and the shield 500, respectively.

[0096] The post 300 may be moved (30) towards the wound 744 (e.g., by gripping and moving the handle 322 of the post) such that a subfascial extension 208 coupled to the subfascial rivet head 202 (e.g., engaging ratchet) at the first end of the post passes through the wound. The subfascial rivet head 202, the subfascial biohybrid scaffold 216, and an inferior portion of the column 206 may thereby pass into the native tissues 768 of the pre-peritoneal space.

[0097] After the subfascial extension 208 passes through the wound 744, the post 300 may be moved (40) such that the subfascial extension is in contact with a subfascial surface 750 around the wound 744 (e.g., by gripping and pulling the handle 322 of the post until resistance is felt when the subfascial extension comes into contact with the subfascial surface). The subfascial biohybrid scaffold 216 and corresponding subfascial plurality of stays 210 of the subfascial extension may be fully radially expanded at this point below the fascial defect within the pre-peritoneal space. Further, the inferior portion of the column 206 containing a portion of the subfascial rivet head 202 may be positioned within the wound.

[0098] The rod 400 may be moved (50) toward the wound 744 (e.g., by holding the handle 322 of the post 300 in a stationary position with one hand, and with the opposite hand pushing together in a syringe-like manner the grips 538 of the shield 500 and the plate 426 of the rod). As a result of this motion, the receiving pawl 204 may be pushed by the rod towards the engaging ratchet 202, the engaging ratchet may interlock within the receiving pawl, the compressible column 206 may be compressed within the wound, and a suprafascial extension 212 (e.g., including a plurality of stays 214) coupled to the receiving pawl may be in contact with a suprafascial surface 748 around the wound 744, as illustrated in Figure 6C. The interlocking of the receiving pawl and the engaging ratchet within the inner channel 260 of the column 206 may cause the mechanical compression of the column within the wound 744, as illustrated in Figure 6D. Further, the suprafascial biohybrid scaffold 218 and corresponding suprafascial plurality of stays 214 of the suprafascial extension may be fully radially expanded at this point. As a further result of this motion, portions of the wound plug 200 may be driven out of the implant chamber 532, and the implant chamber may be lifted off the suprafascial surface 748 to allow for unrestricted clearance of the suprafascial rivet head 204 and the column 206 into the wound 744. Further, three consecutive clicks may be heard and felt by a user to indicate that the wound plug is fully deployed.

[0099] In some embodiments, the post 300 may be twisted to break the post at the breakaway point 320 such that the engaging ratchet is separated from the post, as illustrated in Figure 6D. In some embodiments, both an outer profile of the post and an inner profile of the rod cavity have a cruciate shape, such that post is prevented from rotating within the rod cavity (e.g., to facilitate the application of torque to a breakaway point of the post when the rod is twisted).

[00100] In some embodiments, any or all components of the apparatus may be assembled within any disposable or non-disposable surgical gun or applier, and these may be designed with automatic reloads of the wound plug, either within the apparatus or applied separately to it, for sequential and repetitive deployment.

[00101] In some embodiments, the wound plug 200 may afford stabilization and/or healing of any type of penetrating wound caused by traumatically impaling the fascia anywhere on the body. The wound plug may appropriately address various types of hernias within the abdominal wall. The wound plug's postoperative

antimicrobial benefits may be feasible for the primary closure of fistulated tracks or other types of reoccurring infected wounds. The wound plug's antimicrobial and anesthetic advantages, as well as its ability for completely healing these chronic wounds, may eliminate lengthy secondary or tertiary healing attempts, which often succumb to re-infection and reoccurrence. By application of the apparatus 100, the wound plug 200 may be considered possible for closing the abdominal fascial defect of a stoma (i.e., colostomy) following surgical re-anastomosis of the bowel. The wound plug may close any fascial defect following the removal of any large drainage tube, surgical tube, or port that is at high risk for herniation or poor wound healing, in general.

[00102] In some embodiments, the wound plug 200 may be made to address any length or shape of fascial incision anywhere on the body, with or without the incorporation of sutures for reinforcement. For example, the wound plug may be in a more rectangular and linear profile, thus allowing for its repetitive and sequential application along the fascial incision line. Fascial incisions may include, but are not limited to, any region of the abdomen (i.e., midline or transverse laparotomy incisions), any location on the extremities (i.e., incisions for repairing fractured bones or joint replacement arthroplasties), posterior or flank regions of the torso (i.e., spinal or kidney incisions), or fascial planes covering the anterior, lateral, or posterior areas of the chest wall (i.e., video assisted open thoracostomy port-site wounds or thoracostomy incisions).

[00103] In some embodiments, the apparatus 100 may be designed to incorporate a fiber optic cable with an optical lens to allow for direct visualization of the subcutaneous tunnel and anterior abdominal fascia during its insertion and deployment within the wound. Although embodiments of the disclosure are described without requirement of a pneumoperitoneum, intra-abdominal telescopic lens, or any other instrumentation, the apparatus may be used in conjunction with such devices.

[00104] In some embodiments, the apparatus 100 may further include one or more elements to enhance light (or visual), auditory, or palpatory sensations when the rim of the shield 500 reaches the wound in the fascia 746 and/or as confirmation of accurate completion of other various steps during deployment. For example, a rim or lip 534 of the shield 500 may further include a touch-sensitive surface (mechanical, capacitive, and/or resistive, among other possibilities) to confirm that the rim has

reached the wound in the fascia. Further, an audible sound may confirm the subfascial rivet head's placement below the fascia, and a light sensor may confirm engagement of the suprafascial and subfascial rivet heads (or any combination of sensor feedback).

[00105] In some embodiments, the apparatus 100 may further include a button-type retaining pin (either spring or manually designed) which, by virtue of its configuration, could function to lock and unlock the post 300. Once this retaining pin is pushed in to become flush with an external wall of the shield 500, a grooved configuration would release only the post 300, allowing its downward movement for deploying the subfascial rivet head 202.

[00106] In this embodiment, the alignment pin 600 can interlock the actuator rod 400 and shield 500 together prior to their deployment. After a user pushes the button of the retaining pin forward (toward the shield 500), the post 300 is released and may slide down as previously described. When the user pulls the post 300 upward in order to palpate the subfascial tissue 750, the retaining pin of the post may be pulled back toward the operator, out of its hole, until it engages the post in its locked configuration. Following the aforementioned activity of the post's retaining pin, the alignment pin 600 can be pulled out to release the rod 400 and the shield 500 for their deployment of the suprafascial rivet head 204. Naturally, with regards to this alternative, the profiles of the rod 400 and shield 500 would need to incorporate some sort of detent/horizontal slots or grooves to allow for their deployment activities over and alongside the presence of this stationary retaining pin. Such a configuration may allow for a more controlled and sequential release of the elements incorporated within the apparatus 100, freeing the user from needing to hold the post 300 stationary during the activation of the rod 400 and shield 500.

[00107] Although the disclosed examples have been fully described with reference to the accompanying drawings, it is to be noted that various changes and modifications will become apparent to those skilled in the art. Such changes and modifications are to be understood as being included within the scope of the disclosed examples as defined by the appended claims.

WHAT IS CLAIMED IS:

1. An apparatus for deploying a wound plug, the apparatus comprising:
a wound plug including an engaging ratchet, a receiving pawl, and a compressible column, wherein the compressible column surrounds and is coupled to each of the engaging ratchet and the receiving pawl;
a post including the engaging ratchet at a first end of the post and a handle at a second end of the post;
a rod including a plate at a second end of the rod, wherein the post is positioned through a rod cavity, and a first end of the rod is in contact with the receiving pawl of the wound plug; and
a shield containing portions of the wound plug, the post, and the rod in a shield cavity.
2. The apparatus of claim 1, wherein the shield cavity includes an implant chamber that is wider than an adjacent portion of the shield cavity, and the wound plug is positioned in the implant chamber.
3. The apparatus of claim 1, wherein both an outer profile of the post and an inner profile of the rod cavity have a cruciate shape, such that post is prevented from rotating within the rod cavity.
4. The apparatus of claim 1, wherein the post further includes a breakaway point between the engaging ratchet at the first end of the post and the handle at the second end of the post.
5. The apparatus of claim 1, wherein each of the post, the rod, and the shield includes an alignment pin hole, and the apparatus further comprises an alignment pin positioned in the alignment pin holes.
6. The apparatus of claim 1, wherein the shield includes an insertion lip on a rim of the shield.
7. The apparatus of claim 1, wherein the wound plug further comprises:

a subfascial extension coupled to the engaging ratchet; and
a suprafascial extension coupled to the receiving pawl.

8. The apparatus of claim 7, wherein portions of each of the subfascial extension and the suprafascial extension have a first configuration in the shield cavity and change to a second configuration in response to an increase in temperature or a change in pH.

9. The apparatus of claim 8, wherein each of the subfascial extension and the suprafascial extension include a plurality of stays that, in the second configuration, are extended radially around an axis of the post, and the plurality of stays of the subfascial extension are radially offset with respect to the plurality of stays of the suprafascial extension.

10. The apparatus of claim 7, wherein the wound plug further comprises:
a subfascial biohybrid scaffold coupled to the subfascial extension; and
a suprafascial biohybrid scaffold coupled to the suprafascial extension.

11. A method for deploying a wound plug, the method comprising:
inserting a shield into a skin opening, wherein the shield contains portions of a wound plug, a post, and a rod in a shield cavity, the wound plug is positioned in an implant chamber of the shield cavity that is wider than an adjacent portion of the shield cavity, and the wound plug includes an engaging ratchet, a receiving pawl, and a compressible column;

positioning the shield such that a rim of the implant chamber is in contact with a suprafascial surface of fascia surrounding a wound in the fascia;

moving the post towards the wound such that a subfascial extension coupled to the engaging ratchet at a first end of the post passes through the wound;

after the subfascial extension passes through the wound, moving the post such that the subfascial extension is in contact with a subfascial surface around the wound;
and

moving the rod towards the wound such that:

the receiving pawl is pushed by the rod towards the engaging ratchet,
the engaging ratchet engages within the receiving pawl,

the compressible column is compressed within the wound, and
a suprafascial extension coupled to the receiving pawl is in contact
with a suprafascial surface around the wound.

12. The method of claim 11, wherein both an outer profile of the post and an inner profile of the rod cavity have a cruciate shape, such that post is prevented from rotating within the rod cavity.

13. The method of claim 11, wherein the post further includes a breakaway point between the engaging ratchet at the first end of the post and a handle at a second end of the post, the method further comprising:

twisting the post to break the post at the breakaway point such that the engaging ratchet is separated from the post.

14. The method of claim 11, wherein each of the post, the rod, and the shield includes an alignment pin hole, and the apparatus further comprises an alignment pin positioned in the alignment pin holes, the method further comprising:

prior to moving the post towards the wound such that the subfascial extension passes through the wound, removing the alignment pin from the alignment pin holes.

15. The method of claim 11, wherein the shield includes an insertion lip on the rim of the shield.

16. The method of claim 11, wherein portions of each of the subfascial extension and the suprafascial extension have a first configuration in the shield cavity and change to a second configuration in response to an increase in temperature or a change in pH.

17. The method of claim 16, wherein each of the subfascial extension and the suprafascial extension include a plurality of stays that, in the second configuration, are extended radially around an axis of the post, and the plurality of stays of the subfascial extension are radially offset with respect to the plurality of stays of the suprafascial extension.

18. The method of claim 11, wherein the wound plug further comprises:
a subfascial biohybrid scaffold coupled to the subfascial extension; and
a suprafascial biohybrid scaffold coupled to the suprafascial extension.

19. An apparatus for deploying a wound plug, the apparatus comprising:
a wound plug including a subfascial rivet head, a suprafascial rivet head, and a compressible column, wherein the compressible column surrounds and is coupled to each of the subfascial rivet head and the suprafascial rivet head;
a post including the subfascial rivet head at a first end of the post and a handle at a second end of the post;
a rod including a plate at a second end of the rod, wherein the post is positioned through a rod cavity, and a first end of the rod is in contact with the suprafascial rivet head of the wound plug; and
a shield containing portions of the wound plug, the post, and the rod in a shield cavity.

20. A method for deploying a wound plug, the method comprising:
inserting a shield into a skin opening, wherein the shield contains portions of a wound plug, a post, and a rod in a shield cavity, the wound plug is positioned in an implant chamber of the shield cavity that is wider than an adjacent portion of the shield cavity, and the wound plug includes a subfascial rivet head, a suprafascial rivet head, and a compressible column;
positioning the shield such that a rim of the implant chamber is in contact with a suprafascial surface of fascia surrounding a wound in the fascia;
moving the post towards the wound such that a subfascial extension coupled to the subfascial rivet head at a first end of the post passes through the wound;
after the subfascial extension passes through the wound, moving the post such that the subfascial extension is in contact with a subfascial surface around the wound;
and
moving the rod towards the wound such that:
the suprafascial rivet head is pushed by the rod towards the subfascial rivet head,
the subfascial rivet head engages within the suprafascial rivet head,
the compressible column is compressed within the wound, and

a suprafascial extension coupled to the suprafascial rivet head is in contact with a suprafascial surface around the wound.

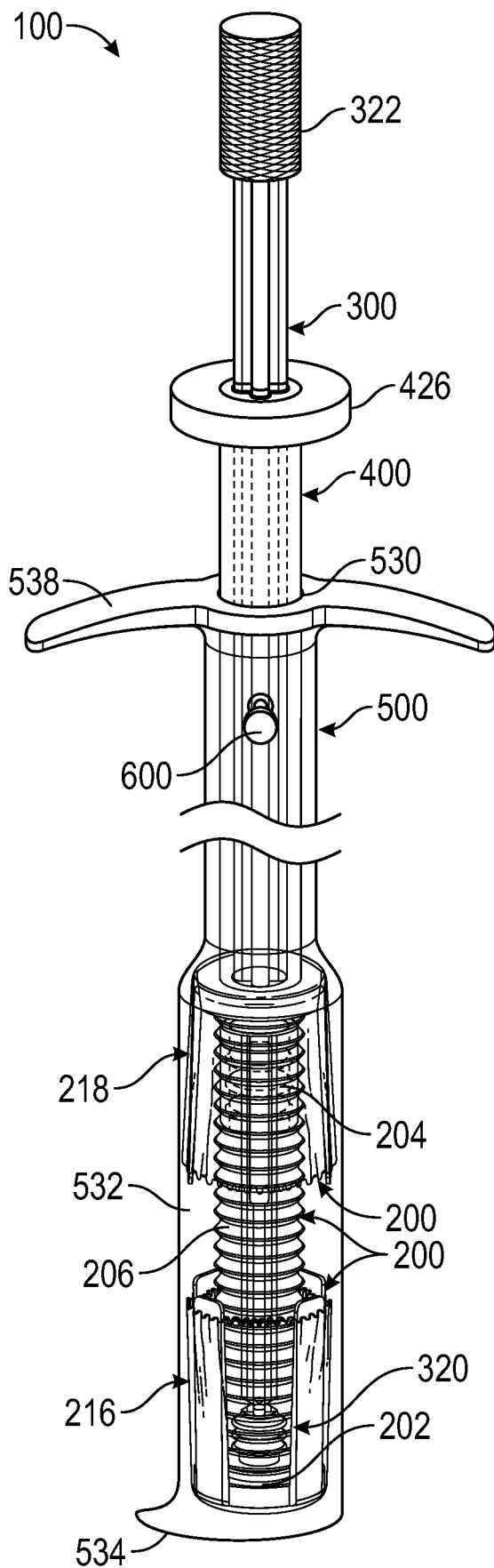


FIG. 1A

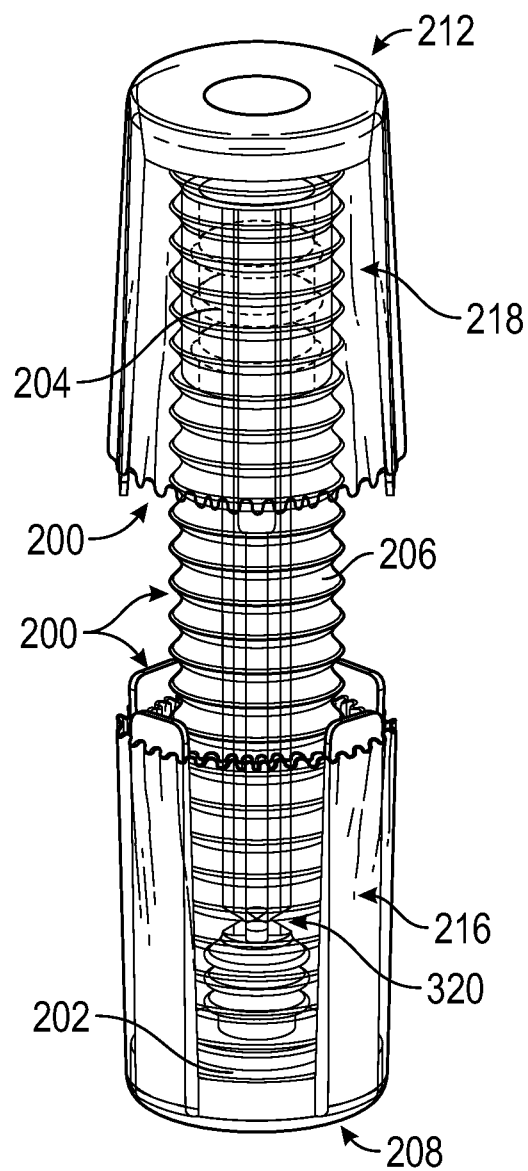


FIG. 1B

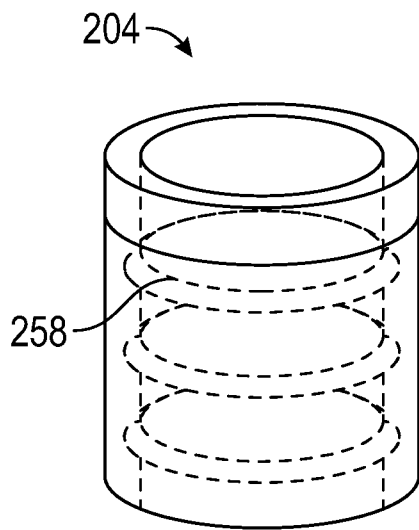


FIG. 2A

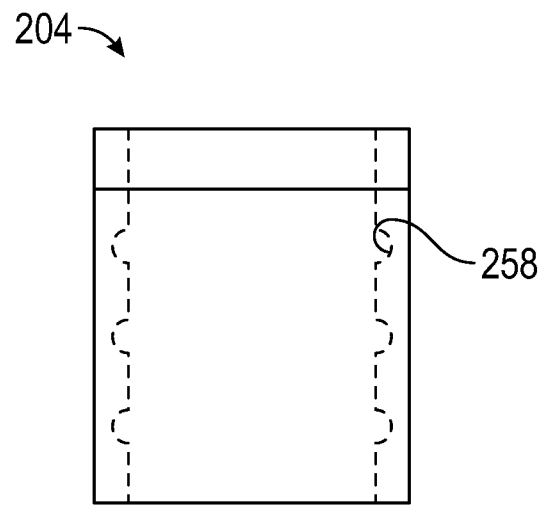


FIG. 2B

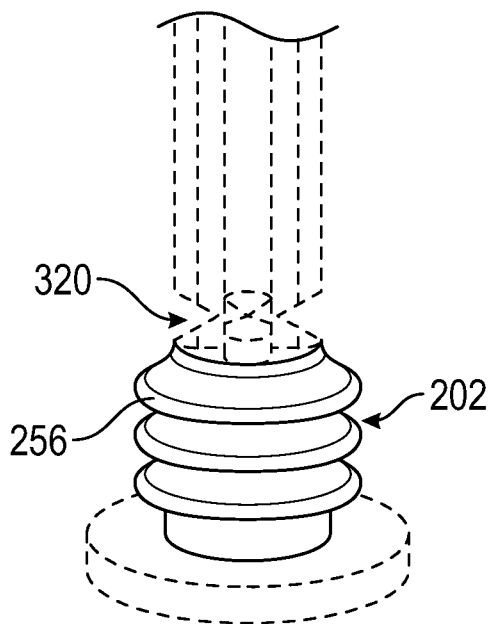


FIG. 2C

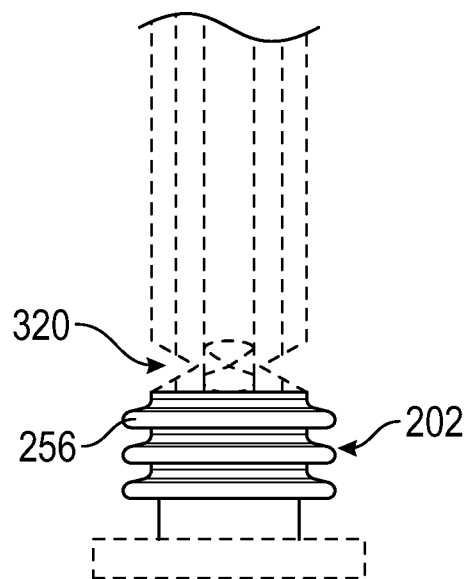
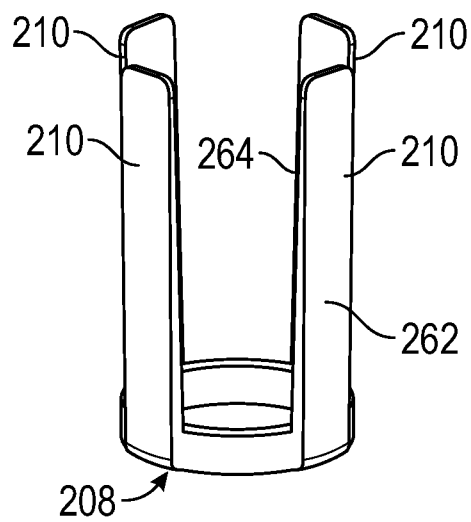
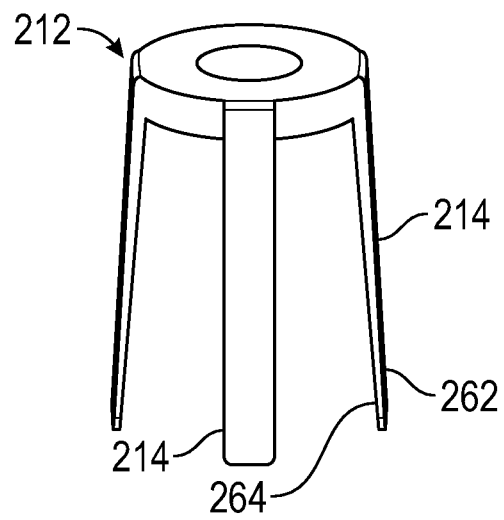
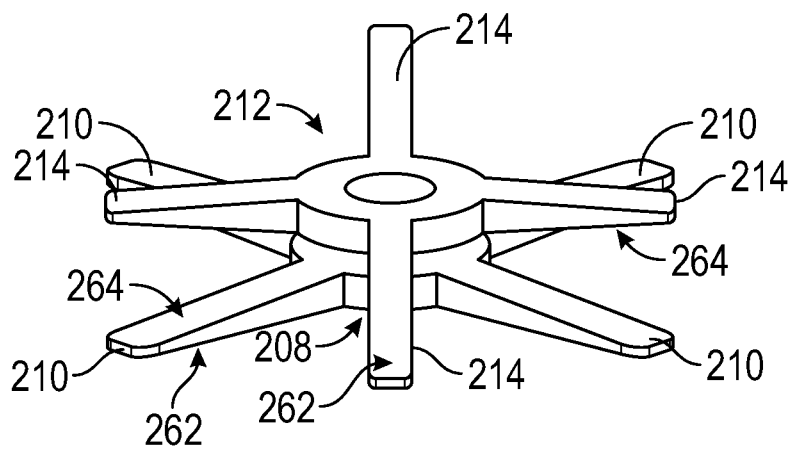


FIG. 2D

**FIG. 2E****FIG. 2F**

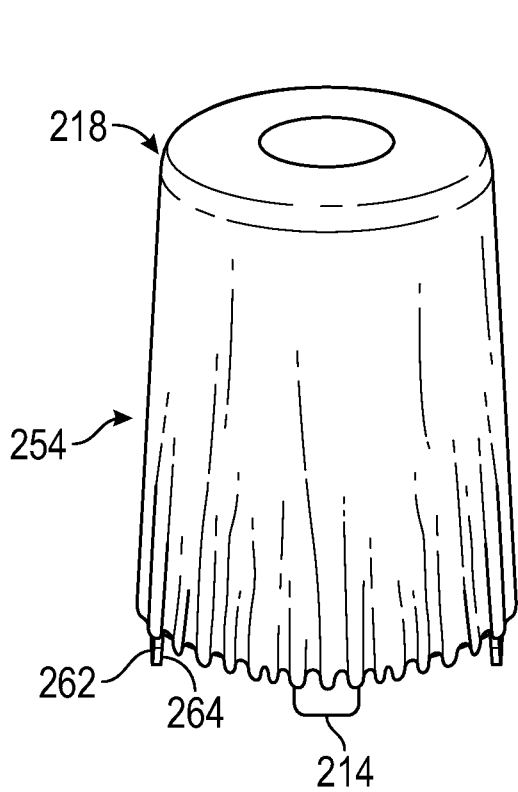


FIG. 2G

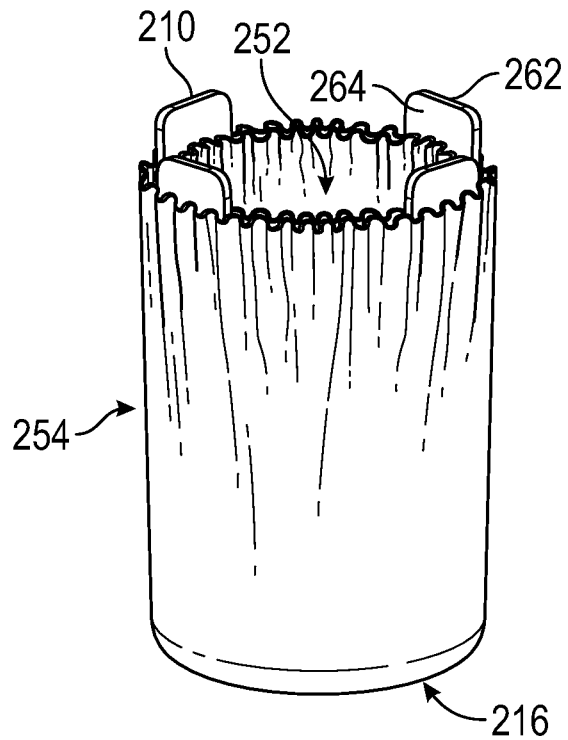


FIG. 2H

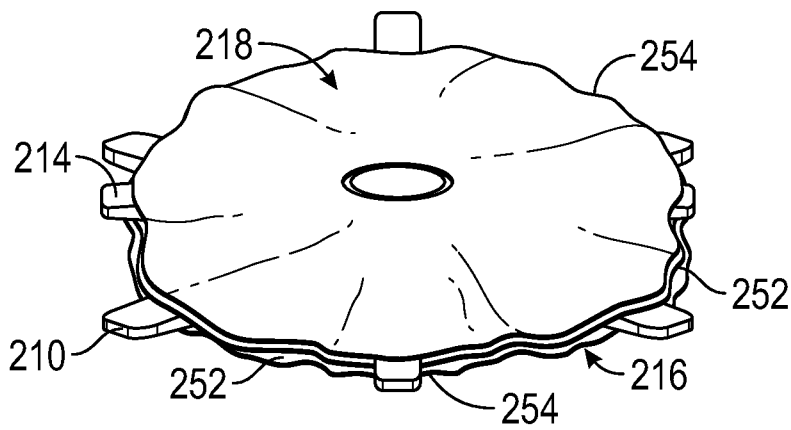


FIG. 21

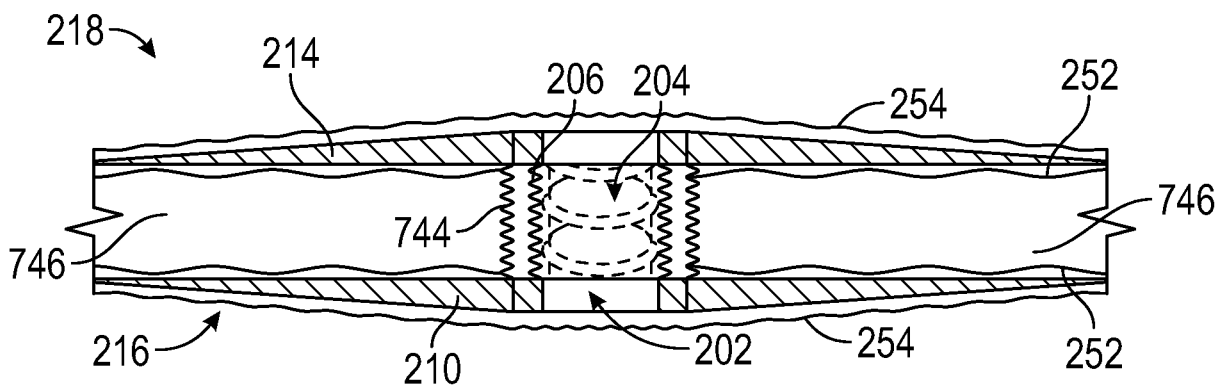


FIG. 2J

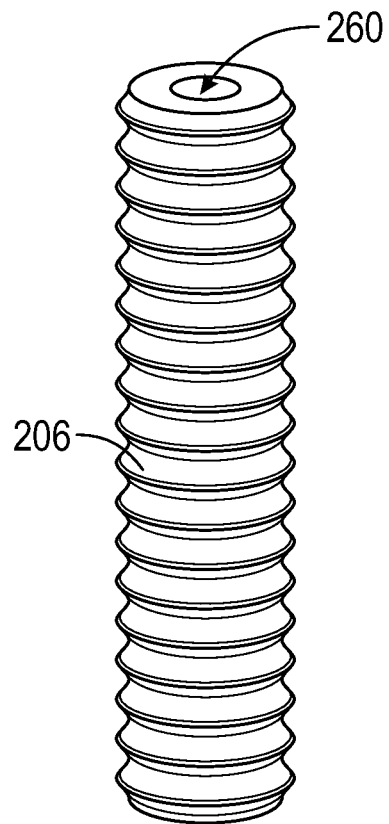


FIG. 2K

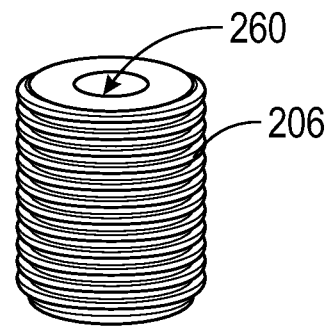


FIG. 2L

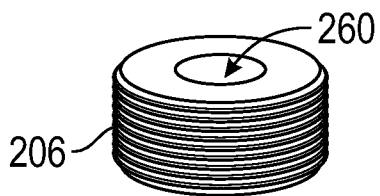


FIG. 2M

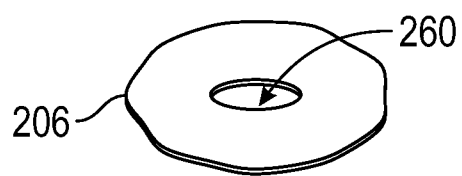


FIG. 2N

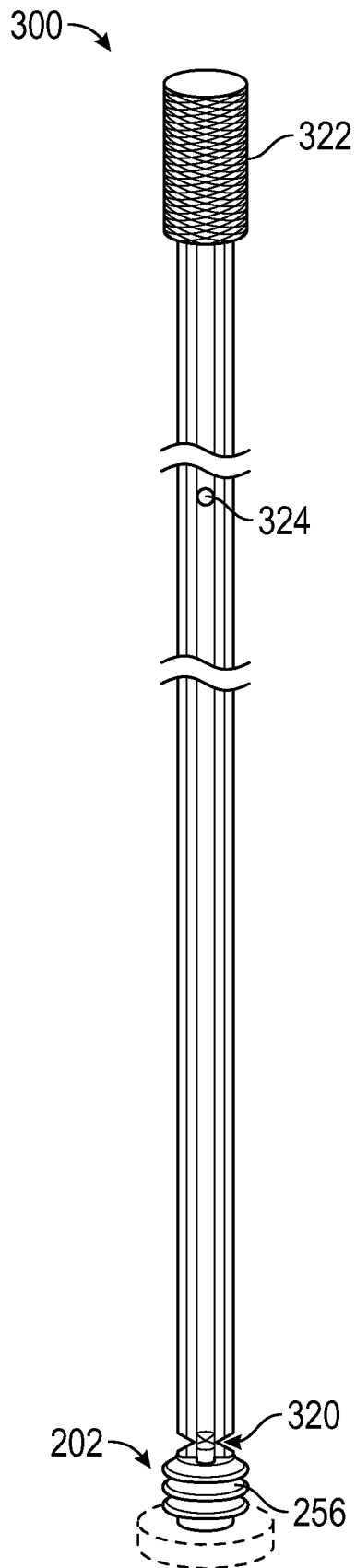


FIG. 3A

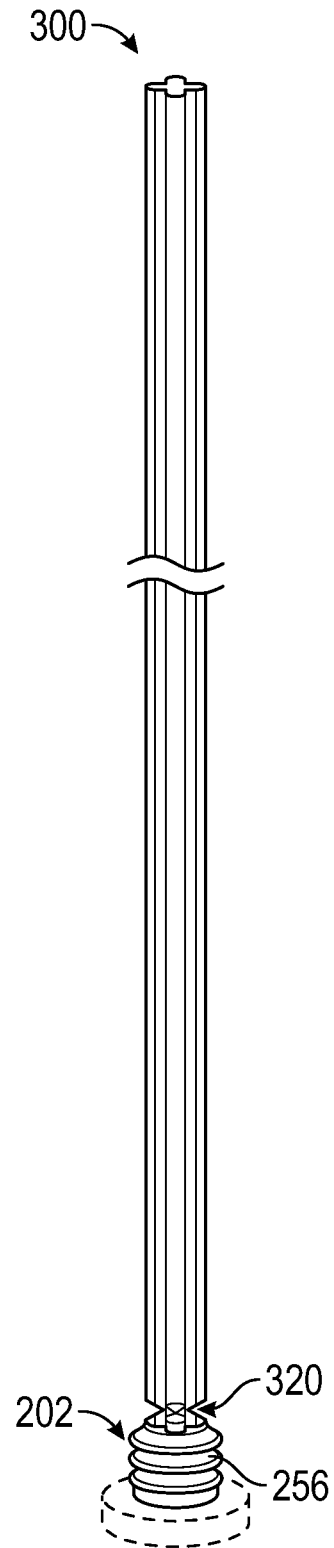


FIG. 3B

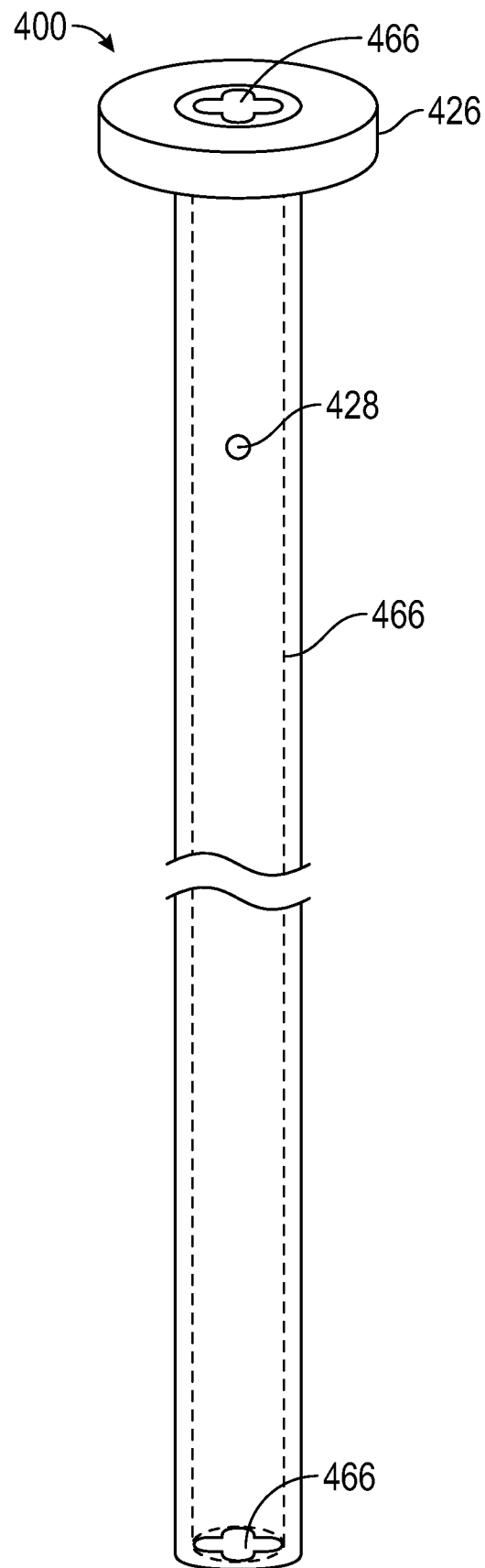


FIG. 4

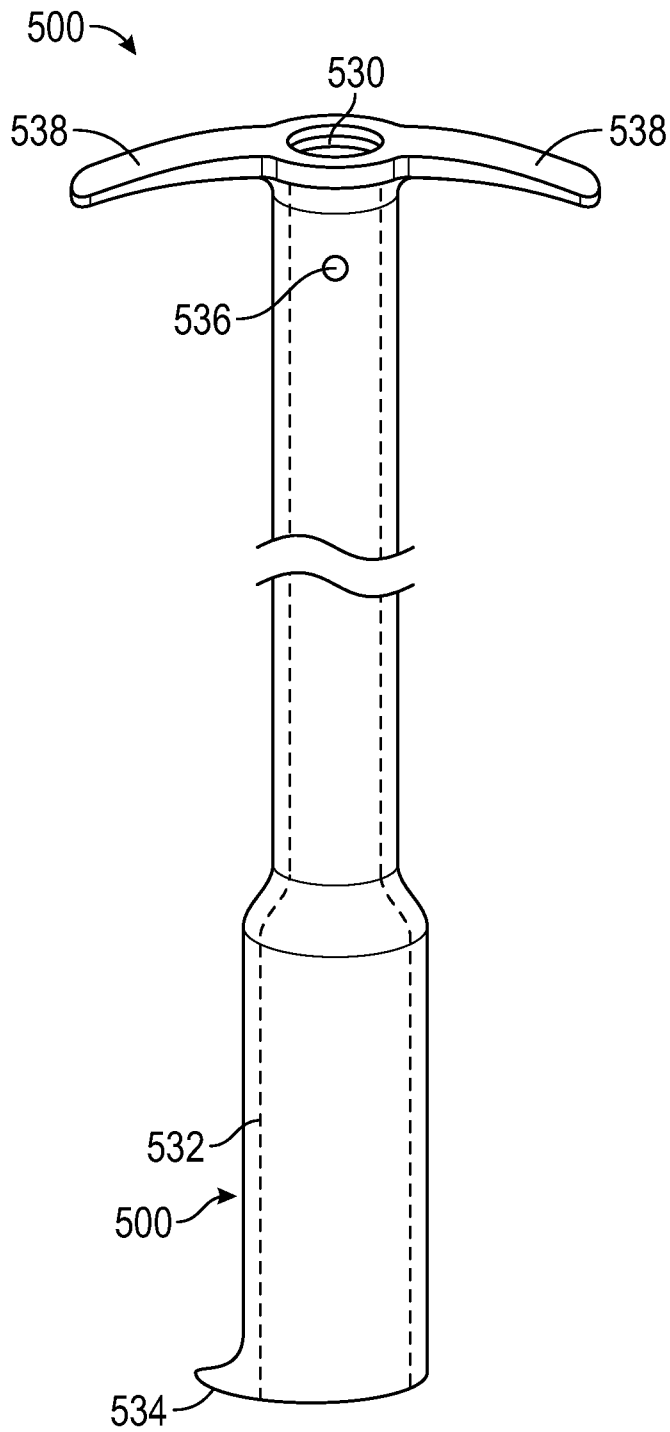


FIG. 5A

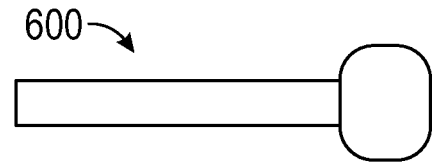


FIG. 5B

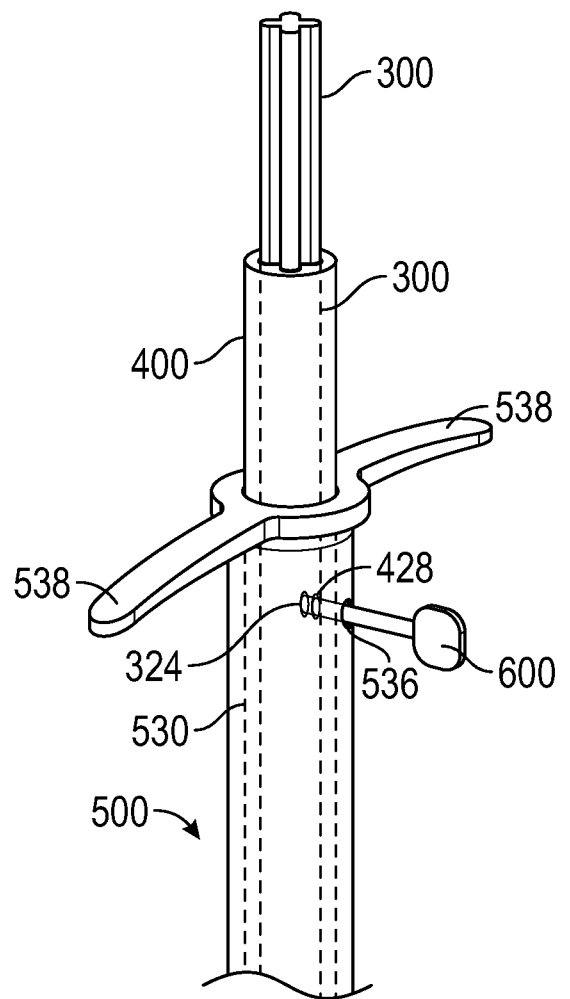


FIG. 5C

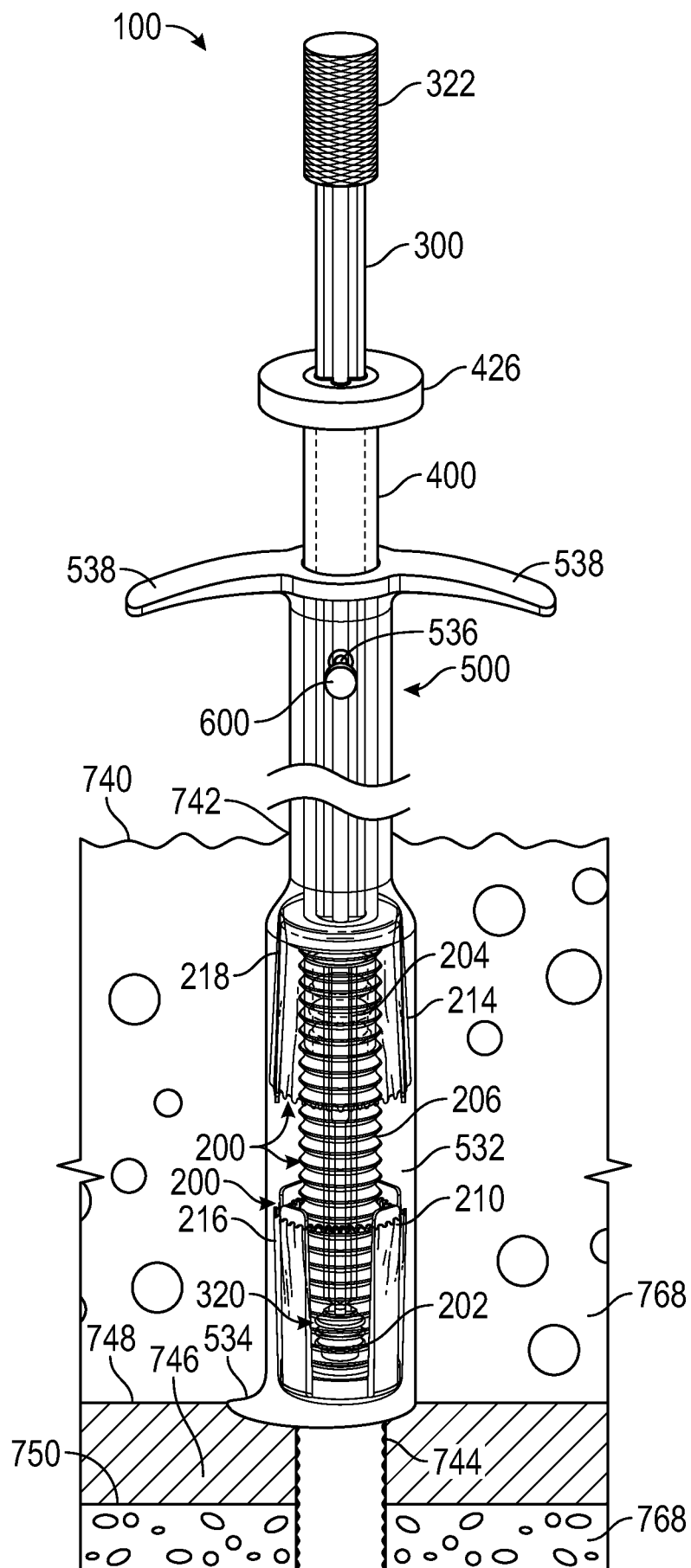


FIG. 6A

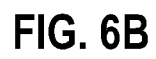


FIG. 6B

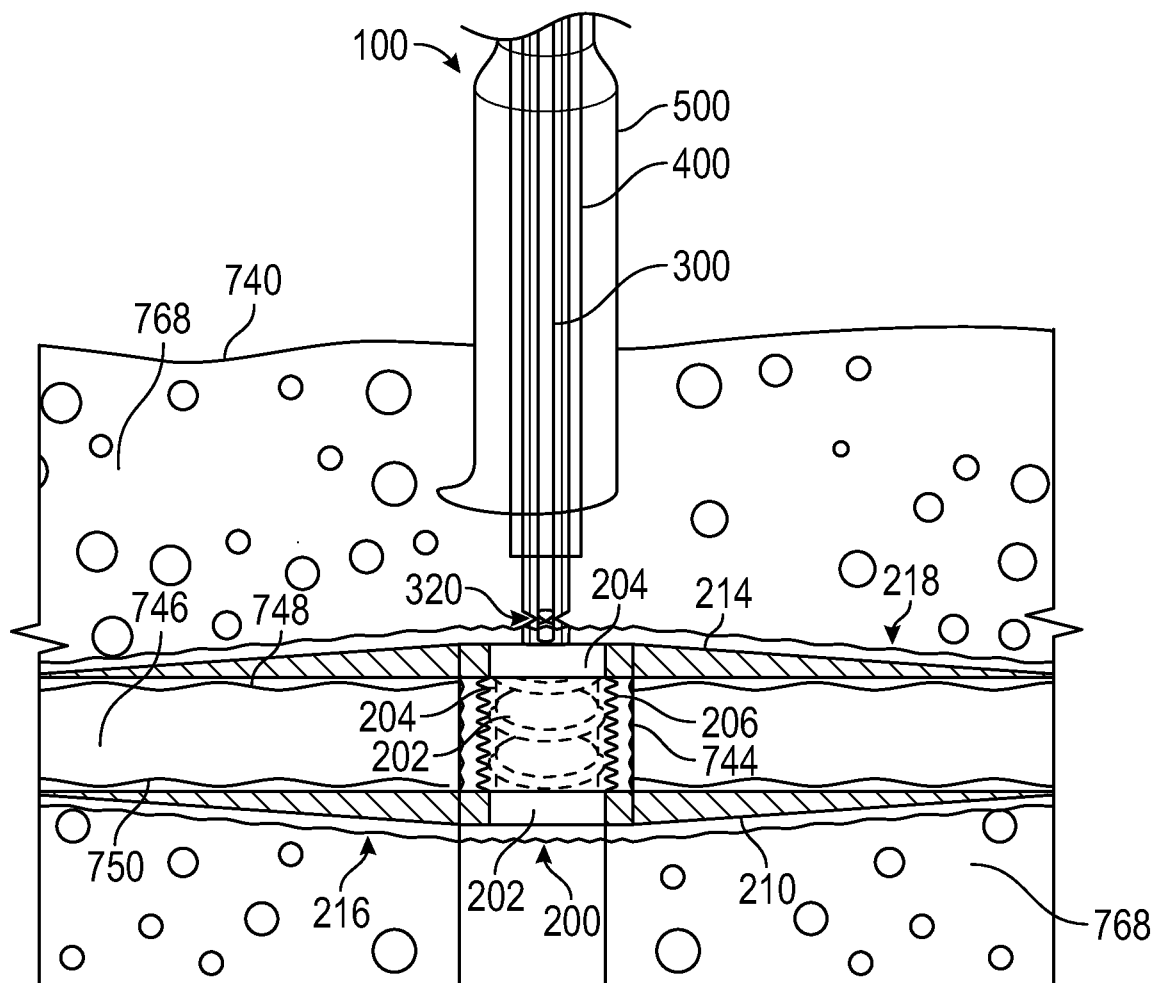
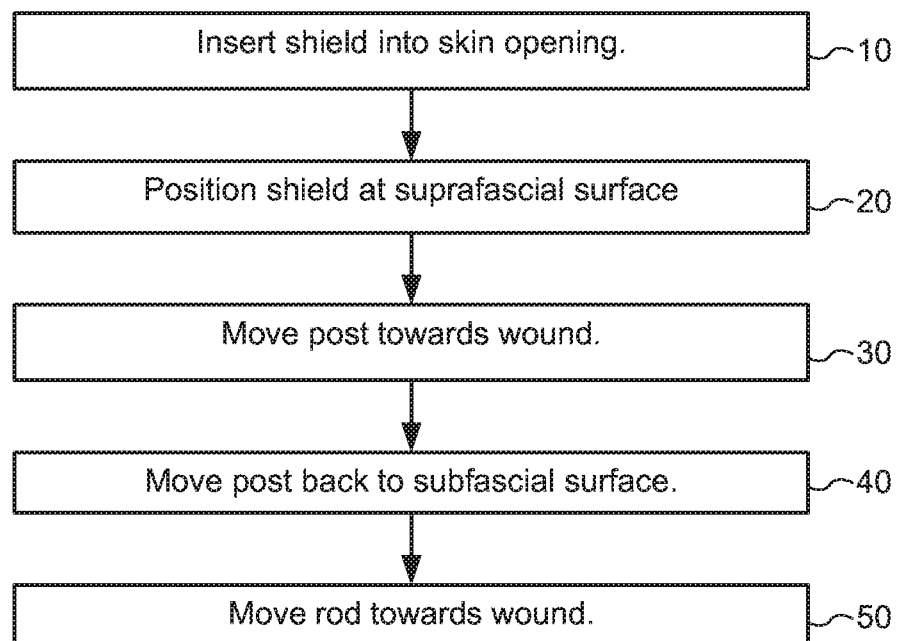


FIG. 6C



FIG. 6D

**FIG. 7**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/067489**A. CLASSIFICATION OF SUBJECT MATTER****A61B 17/04(2006.01)i, A61B 17/03(2006.01)i**

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

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
A61B 17/04; A61M 31/00; A61B 17/03; B23P 11/00; A61B 17/12; A61B 17/00; A61B 17/08Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: wound plug, engaging ratchet, receiving pawl, subfascial rivet head, suprafascial rivet head, compressible column, post, handle, rod, plate, shield**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008-0208226 A1 (SEIBOLD et al.) 28 August 2008 See paragraphs [0058]-[0078]; and figures 7-10D.	1-10, 19
A	US 2007-0123817 A1 (KHOSRAVI et al.) 31 May 2007 See paragraphs [0098]-[0115]; and figures 8-9D.	1-10, 19
A	US 2011-0077683 A1 (HUSS, BRAD D.) 31 March 2011 See paragraphs [0046]-[0056]; and figures 5-14.	1-10, 19
A	US 2010-0016885 A1 (EIDENSCHINK et al.) 21 January 2010 See paragraphs [0050]-[0053], [0060]-[0066]; and figures 2, 4A-8.	1-10, 19
A	US 2006-0190036 A1 (WENDEL et al.) 24 August 2006 See paragraphs [0082]-[0104], [0107]-[0116]; and figures 1-3, 6.	1-10, 19

☐ Further documents are listed in the continuation of Box C.☒ 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

12 May 2016 (12.05.2016)

Date of mailing of the international search report

13 May 2016 (13.05.2016)

Name and mailing address of the ISA/KR

International Application Division

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/067489

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. ☒ Claims Nos.: 11-18, 20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 11-18 and 20 pertain to methods for treatment of the human body by surgery and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).
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 any 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/US2015/067489

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008-0208226 A1	28/08/2008	AT 428351 T	15/05/2009
		AU 2003-266954 A1	23/02/2004
		AU 2003-266954 A8	23/02/2004
		CA 2492700 A1	12/02/2004
		CA 2492700 C	12/10/2010
		EP 1526810 A2	04/05/2005
		EP 1526810 B1	15/04/2009
		JP 04425135 B2	03/03/2010
		JP 2005-534390 A	17/11/2005
		US 2006-0106418 A1	18/05/2006
		US 2008-0208225 A1	28/08/2008
		US 8114125 B2	14/02/2012
		US 8118833 B2	21/02/2012
		US 8147513 B2	03/04/2012
		WO 2004-012603 A2	12/02/2004
		WO 2004-012603 A3	21/05/2004
US 2007-0123817 A1	31/05/2007	CA 2583235 A1	18/05/2006
		CA 2583235 C	08/07/2014
		EP 1807132 A1	18/07/2007
		EP 2845613 A1	11/03/2015
		JP 05243036 B2	24/07/2013
		JP 05777110 B2	09/09/2015
		JP 2008-518742 A	05/06/2008
		JP 2013-056172 A	28/03/2013
		JP 2015-128602 A	16/07/2015
		JP 2015-231542 A	24/12/2015
		US 2001-0046518 A1	29/11/2001
		US 2002-0106409 A1	08/08/2002
		US 2004-0009205 A1	15/01/2004
		US 2004-0191277 A1	30/09/2004
		US 2006-0034930 A1	16/02/2006
		US 2006-0099238 A1	11/05/2006
		US 2006-0193899 A1	31/08/2006
		US 2008-0017201 A1	24/01/2008
		US 2008-0097521 A1	24/04/2008
		US 2010-0119451 A1	13/05/2010
		US 2011-0066183 A1	17/03/2011
		US 2013-0267996 A1	10/10/2013
		US 2014-0100605 A1	10/04/2014
		US 2014-0180333 A1	26/06/2014
		US 2015-0164490 A1	18/06/2015
		US 2015-0297202 A1	22/10/2015
		US 6605294 B2	12/08/2003
		US 6703047 B2	09/03/2004
		US 7335220 B2	26/02/2008
		US 7648713 B2	19/01/2010
		US 7780980 B2	24/08/2010
		US 7790192 B2	07/09/2010

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2015/067489

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011-0077683 A1	31/03/2011	US 7803172 B2	28/09/2010
		US 8105622 B2	31/01/2012
		US 8470362 B2	25/06/2013
		US 8512749 B2	20/08/2013
		US 8951283 B2	10/02/2015
		US 8986730 B2	24/03/2015
		US 9039735 B2	26/05/2015
		WO 02-062276 A1	15/08/2002
		WO 2006-052611 A1	18/05/2006
US 2010-0016885 A1	21/01/2010	CA 2652835 A1	06/12/2007
		CR 10516 A	05/02/2009
		EP 2019631 A2	04/02/2009
		EP 2019631 A4	13/03/2013
		US 2007-0276433 A1	29/11/2007
		US 7850710 B2	14/12/2010
		WO 2007-139755 A2	06/12/2007
		WO 2007-139755 A3	20/11/2008
US 2006-0190036 A1	24/08/2006	CA 2731223 A1	28/01/2010
		EP 2317930 A2	11/05/2011
		EP 2647338 A1	09/10/2013
		JP 05816551 B2	18/11/2015
		JP 2011-528604 A	24/11/2011
		JP 2014-054561 A	27/03/2014
		WO 2010-011530 A2	28/01/2010
		WO 2010-011530 A3	11/03/2010
		AT 487424 T	15/11/2010
		DE 10335648 A1	03/03/2005
		EP 1648308 A2	26/04/2006
		EP 1648308 B1	10/11/2010
		ES 2355385 T3	25/03/2011
		WO 2005-011352 A2	10/02/2005
		WO 2005-011352 A3	21/04/2005

专利名称(译)	伤口闭合装置和方法		
公开(公告)号	EP3261556A4	公开(公告)日	2018-12-05
申请号	EP2015883638	申请日	2015-12-22
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[标]发明人	BIPART PETER E KINDRED DIANE S		
发明人	BIPART, PETER, E. KINDRED, DIANE, S.		
IPC分类号	A61B17/04 A61B17/03		
CPC分类号	A61B17/0057 A61B1/07 A61B2017/00004 A61B2017/00115 A61B2017/00407 A61B2017/00526 A61B2017/00606 A61B2017/00623 A61B2017/00637 A61B2017/00871 A61B2017/00884 A61B2017/ /00889 A61B2090/037		
代理机构(译)	LANG , JOHANNES		
优先权	14/634421 2015-02-27 US		
其他公开文献	EP3261556A1		
外部链接	Espacenet		

摘要(译)

伤口闭合装置可以是用于输送和部署组织工程伤口塞的独立装置，其可以固定腹腔镜端口部位伤口的筋膜闭合。伤口塞可包括副筋膜铆钉头，超临床铆钉头和可压缩柱。一旦进入伤口，伤口塞可以与伤口筋膜下方的筋膜下铆钉头部和伤口筋膜上方的超筋膜铆钉头部署。当这发生时，伤口塞的柱可以位于伤口的开口内。一旦将缠绕的塞子固定在筋膜缺陷的上方，下方和内部，铆钉头可以在柱的内部通道内互锁，并且可以移除和丢弃该装置的其余元件。