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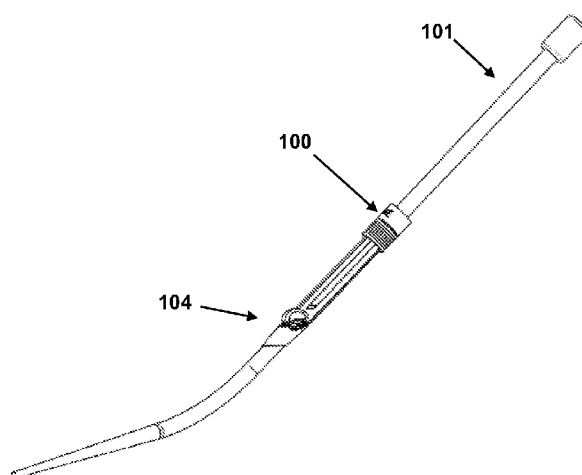


FIG. 9A

(57) Abstract: A tissue engagement and suturing device is provided that includes a tissue capture and engagement assembly that is slidably attachable or integrated with an access sheath, a tissue support structure of the engagement assembly includes a deformable support shelf, and an echogenic location feature, the deformable support shelf provides a surface on which a tissue layer may be secured during manipulation or suturing, the support shelf may be deformed to lay flush with the access sheath during transit into and out of a body lumen, the echogenic location feature is configured relative to the support shelf to provide visual indication of the position of the support shelf relative to a facial layer using traditional non-invasive imaging techniques.



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INTERLOCKING SHELF AND FASCIA RELEASE MECHANISM

FIELD OF THE INVENTION

- 5 The invention relates generally to a suturing device. More specifically, the invention relates to a device and method for suturing a fascial connective tissue layer that is proximal to a region under treatment.

BACKGROUND OF THE INVENTION

- 10 Closure of large-bore access sites in the femoral artery following endovascular procedures such as Transcatheter Aortic Valve Replacement (TAVR) and Endovascular Aneurysm Repair (EVAR) is a decades-old challenge with limited solutions outside of invasive, open surgical repair of the artery. In addition to TAVR and EVAR, other surgical procedures are being adapted
- 15 from manual/open procedures to a minimally invasive endovascular approach. In order to perform many of these procedures, a large-bore sheath is used to access the vascular system of a patient through the femoral artery. This sheath is placed over a dilator and inserted through the wall of a blood vessel in order to obtain this access, and may thereafter be used for guiding medical
- 20 instruments such as catheters, guide wires and the endovascular devices into the circulatory system of a living being.

To perform these procedures, access into the body through layers of tissue is required to reach the femoral artery. In gaining access to different portions of the body, different layers of tissue must be separated or penetrated. These layers can include skin, subcutaneous fat, fascia (e.g., connective tissue), muscle, arteries, veins, intestine, and other organs. Often, after access through these layers is achieved and the procedure is completed, these tissues must be approximated and sealed. The function of reapproximation can vary to include hemostasis, prevent hernia, contain gastrointestinal contents, etc.

Known in the art is the “Fascia Suture Technique” that uses a suture to reapproximate the fascial layers in the roof of the femoral triangle, which may include the fascia lata, cribriform fascia, and femoral sheath with the purpose of achieving hemostasis after arteriotomy is made in the femoral artery. This technique is employed by dissecting the dermal and adipose layers of tissue along the femoral access sheath, which remains in place following the procedure. Dissection is performed both proximal and distal to the femoral sheath until the fascia layers are exposed and visually identified. A suture is passed through the fascial layers surrounding the access site, and knotted in such a way as to create a purse-string closure surrounding the femoral access sheath. As the tapered sheath is withdrawn, the knot is tightened to achieve hemostasis by closing the fascia thus containing femoral blood loss to the space bounded by the tissues that define the femoral triangle (e.g. inguinal ligament, sartorius muscle, adductor longus muscle, cribriform fascia, fascia

lata, psoas major muscle, iliacus muscle, and pectineus muscle) and by resisting systolic blood pressure within the enclosed space. The wire is left in place until hemostasis is confirmed, the wire is then removed and the knot is subsequently tightened and locked. What is needed is a fascia suture technique for enabling a percutaneous, device-based solution that precludes the requirement for manual dissection and visualization of the fascial layers during closure.

SUMMARY OF THE INVENTION

To address the needs in the art, a suturing device is provided to close a defect in the femoral artery or overlying fascia lata region of the femoral triangle; the defect may be created during percutaneous access to the femoral artery for trans-catheter interventions in the vascular system. The mechanisms described in this disclosure pertain to the identification and isolation of target tissue, the fascia lata and/or cribriform fascia, such that the defect can be closed by the passage of a suture around the circumference of the defect in the fascia lata and/or cribriform fascia. The device will enable safe and reliable closure of defects and ensure that large-bore interventions can be effectively deployed without fear of bleeding complications following the case. By offering a closure solution that is agnostic to the anatomical tortuosity of vessels and progression of disease in aging vessels, the current invention facilitates and enables large-bore trans-catheter procedures to remain minimally invasive, by avoiding the requirement for the invasive surgical closure of tortuous and

diseased vessels, or of vascular access sites that are otherwise incompatible with current percutaneous closure techniques.

The current invention provides a device that includes a suture positioning
5 assembly that is slidably attachable to an exterior of a sheath or integrated
with a sheath, where a housing of the suture positioning assembly includes a
housing nose, a primary suture having primary suture connectors, an end
effector, and an end effector actuator, where a distal end of the housing nose
includes an intravascular tip, a slide limiter, a fascia receiving surface, and a
10 fascial isolation and support mechanism,, where the housing or housing nose
includes fiducial markers for visible location and positioning of the housing
relative to the fascia and underlying artery, where the intravascular tip
includes a blood contact indicator to receive blood flow from an artery, where
the intravascular tip is configured for insertion into the artery when disposed
15 beneath a fascial layer, where the fascia receiving surface is configured for
accepting a perimeter edge of a dilated hole of the fascial layer, where the
housing nose further includes an intermediary suture having intermediary
suture connectors, where the primary suture connectors are configured for
connection to the intermediary suture connectors, where the end effector
20 actuator is disposed to operate the end effector to hold the facial layer hole in
a position for suturing by the intermediary suture connected to the primary
suture.

In one aspect of the invention, the end effector can include a straight needle, or a curved needle.

In a further aspect of the invention, a curved needle in the end effector may be
5 configured with an attached arm connecting the curved needle to a central axis of rotation, allowing the needle to rotate in a constrained path defined by the curvature of the needle.

In yet another aspect of the invention, a curved needle in the end effector may
10 be configured in a helical shape, allowing the needle to rotate in a path that is longer is distance that that defined by a needle rotating within a single plane.

In another aspect of the invention, the housing nose further includes a tissue capturing device that is configured to deploy from the housing nose into,
15 beneath, or above the fascial layer and draw the dilated hole in the fascial layer to the fascia receiving surface. The tissue capturing device may include a fascial isolation and support mechanism, where the fascia isolation and support mechanism is configured for deployment to create space between the fascia and a neighboring body lumen or tissue layer. Here, the body lumen can
20 include an artery, a vein, or a bowel, and the tissue layer can include a fascia, connective tissue, loose adipose tissue, or skin.

In a further aspect of the invention, the housing nose further includes a dilation controller, where the dilation controller is configured to change in size to alter a diameter of the dilated hole in the facial layer, where the dilation controller is configured to create resistance to the suture positioning assembly in being retracted from the facial layer along the lumen access sheath, where the created resistance is sufficient to indicate that the housing nose is securely held in place by circumferential tension of the dilated hole of the fascial layer on the fascia receiving surface. Here, the dilation control element can include an inflatable membrane, an expandable umbrella, a compliant metallic element comprised of metallic wire, interlocking metallic members, interlocking members of a rigid polymer, or a shape changing collar.

In yet another aspect of the invention, the slide limiter is configured to induce an insertion resistance along the access sheath when the housing nose is desirably positioned on the facial layer, where the desirably positioned slide limiter establishes an upper bound against which the fascia will be stabilized and prevented from creeping further up the housing nose, where the desirably positioned slide limiter prevents the housing nose from passing through the fascia beyond the fascia receiving surface.

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According to one aspect of the invention, the assembly slide limiter is a material that includes an elastomer, a complaint polymer, a complaint metallic

element, or an assembly of rigid elements designed to change shape upon contact with fascial layer.

5 In another aspect of the invention, the blood contact indicator includes a capillary, where the capillary spans from the housing nose to a proximal end of the housing, where a distal end of the capillary at the housing nose is configured to enter the body lumen, where blood flow through the capillary, or blood pressure in the capillary, or a presence of blood in the capillary is an indicator of the sheath being desirably positioned in an artery.

10

In a further aspect of the invention, the slidable attachment of the suture positioning assembly on the sheath includes clamping, hinged clamping, snap-fitting, stitching, or coaxial mating.

15 In on embodiment, the invention includes a suturing device that is slidably attachable to a sheath device, where the slidable attachment of the suturing device is configured to position a suture in an approximated state on a defect in a body lumen for suturing. Here, the body lumen can include an artery, a vein, or a bowel.

20

In yet another embodiment, the suturing device may be integrated with an access sheath, such that insertion of the access sheath for delivery of an intravascular device may coincide with delivery and desirable positioning of

the tissue suturing device relative to the defect in the defect in a body lumen or fascia tissue layer. Here, the body lumen can include an artery, a vein, or a bowel.

- 5 In one aspect of the invention, the suture housing or housing nose may incorporate fiducial marking features, or contrast-enhancing elements, for use in visibly positioning the suture housing in relation to the desired tissue to be manipulated. Visible identification of fiducial markers may be assisted by imaging modalities such as ultrasound, computed tomography imaging,
10 radiographic imaging, or fluoroscopic imaging.

BRIEF DESCRIPTION OF THE DRAWINGS

- FIGs. 1A-1C** show different views of a suture positioning assembly, according to embodiment of the current invention.
- 15 **FIGs. 2A-2C** show the intravascular tip inserted to an artery when disposed beneath a fascial layer, according to the current invention.
- FIGs. 3A-3G** show an exemplary detailed procedure of the device operation of the internal structures of the device, according
20 to the current invention.
- FIGs. 4A-4C** show embodiments of the shapes of example end effector shapes, according to the current invention.

- FIGs. 5A-5C** show different views of an alternate suture positioning assembly, according to embodiment of the current invention.
- FIGs. 6A-6E** show alternative mating mechanisms of the suture positioning assembly with the sheath, according to the current invention.
- FIGs. 7A-7C** show different embodiments of the housing nose having a dilation controller that is configured to change in size to alter a diameter of said dilated hole in facial layer, according to the current invention.
- FIG. 8** shows a flow diagram of the implementation and use of the current invention.
- FIGs. 9A-9E** show an embodiment of the suture positioning assembly comprised of interlocking but independently sliding members so as to control the dilation of a fascial defect in a fascial layer so as to remove the fascial layer from the fascia receiving surface following manipulation and passing of sutures to close the fascial defect.
- FIGs. 10A-10E** show several embodiments of a tissue capturing device, deployable distal to the fascia layer so as form mechanical support distal to the fascial layer and allow it to be drawn up and into the fascia receiving surface, while providing geometry to allow for the unimpeded passage of end

effectors during puncturing of the fascia for the passing of sutures in order to close a defect in the fascia layer.

FIGs. 11A-11G show the use of imaging techniques to reflect a signal from an imaging probe off of a locating feature designed to accommodate and receive a fascia layer for manipulation and suturing. Several embodiments of a locating feature that is visible using current imaging modalities are presented.

FIGs. 12A-12C show an embodiment of an end effector wherein the travel of the end effector is constrained by mechanical mating with a rotating axis, such that the end effector may reliably reach its target to form a barb/cuff complex for subsequent threading through a fascia layer and resultant suture passing.

FIGs. 13A-13C show an embodiment of end effectors in a helical configuration so as to offset the destination of the end effectors from the starting plane, whereby the offset permits a greater degree of rotation of end effectors at their proximal end without interference with their target along a semicircular path, the cuffs that are used to form a barb/cuff complex during suture passing and subsequent closure of a fascial defect.

DETAILED DESCRIPTION

The current invention provides a surgical procedure and closure device that approximates and closes a defect in a tissue layer, such as a tissue layer superior to a blood vessel. In one example, the tissue defect may arise from

5 the external introduction of an instrument for vascular or otherwise internal access to the body, e.g. percutaneous or surgical intervention. The tissue layer may be the femoral sheath, fascia lata and/or cribriform fascia that covers the roof of the femoral triangle, or other connective tissue layer e.g. abdominal fascia. The closure of such a tissue may allow for hemostasis to occur in the

10 enclosed femoral triangle in order to create a natural method of tamponade around the femoral artery after removal of the procedural sheath. The ability to exert a greater compressive force around the arteriotomy from closure of the fascia above and the surrounding borders of the femoral triangle may allow the arteriotomy to naturally resolve. The anatomy of the femoral

15 triangle includes the floor made up of the following muscles from lateral to medial: iliacus, psoas major, pectineus, and adductor longus; the superior border is made up of the inguinal ligament; the medial border is the adductor longus muscle; and the lateral border is comprised of the sartorius muscle.

The current invention eliminates procedural steps that include opening the

20 skin, manually dissecting down to the fascia, and directly suturing the fascia to close these internal tissues.

Turning now to the drawings, **FIGs. 1A-1C** show different views of a suture positioning assembly **100** that is slidably attachable to an exterior of a sheath **101**. As shown in **FIGs. 1B-1C**, the housing **102** of the suture positioning assembly **100** includes a housing nose **104**, a primary suture **106** having primary suture connectors **108**, end effector **110** that can be independently deployed, and an end effector actuator **112**, wherein a distal end of said housing nose comprises an intravascular tip **114**, a slide limiter **116**, and a fascia receiving surface **118**, where the intravascular tip **114** comprises a capillary tube **120** to receive blood flow from an artery.

In one aspect of the invention, the assembly slide limiter includes a material that includes a compliant elastomer that, upon contact with the proximal surface of the fascia, will deform and/or buckle, adding additional cross-sectional area to the upper bounding surface of the slide limiter, creating a broader upper bound of the slide limiter with which to prevent the fascia from creeping up further up the housing nose beyond the fascia receiving surface. Here, the slide limiter can be the elastomer, complaint polymer, complaint metallic element comprising nitinol, or an assembly of rigid elements designed to change shape upon contact with fascial layer.

FIG. 2A, shows the intravascular tip **114** inserted to artery **200** when disposed beneath a fascial layer **202**, where the fascia receiving surface **118** (for example having a ledge-shape) is configured for accepting a perimeter edge of

a dilated hole (defect) **204** of the fascial layer as shown in **FIGs. 2B-2C**, where in **FIG. 2B** the slide limiter **116** is not shown for clarity. Further shown in **FIG. 2C** is an alternate embodiment of the suture positioning assembly **100** that has a conical housing nose **104**, and linear elements for the end effectors
5 **400** and suture assemblies described below.

FIG. 1C shows the housing nose **104** further including an intermediary suture **122** having intermediary suture connectors **124**, where the primary suture connectors **108** are configured for connection to the intermediary suture
10 connectors **124**. According to the invention, the end effector actuator **112** is disposed to operate the end effector **110** to hold the facial layer hole in a position for suturing by the intermediary suture connected **112** to said primary suture **106**.

15 The current invention enables one to approximate tissues during or following interventional medical procedures, such as open surgery, laparoscopic surgery, endoscopy, endovascular surgery and procedures, and cardiac catheterizations is portrayed. The invention may be used in a percutaneous or open surgical fashion and approximate a variety of tissues, such as skin, subcutaneous fat,
20 fascia, muscle, or vascular tissue. Further, the tissue approximation device may be used with the intent of sealing tissue to achieve vascular hemostasis, prevent hernias, obtain watertight or airtight closure of tissue layers, or approximate and close disjointed tissues, for example. Tissue sealing of any

of the previously described tissues may be achieved by a variety of mechanical techniques such as suture-like materials, clips, hook-and-loop fasteners, patches, plugs, clamps, and/or biological and synthetic adhesives. The invention may be placed directly on the tissue of interest or be integrated
5 with an instrument of preference, such as a cardiovascular sheath, a guidewire for maintaining access to a vessel or procedural space, or a laparoscopic surgery port, trocar, or other surgical or procedural access instrument.

FIG. 1A shows an example interface of the suture positioning assembly **100**
10 as coaxially mated with a tubular access instrument **101**, in this case, a cardiovascular access sheath. The cardiovascular sheath **101** serves as a guide along which the device **100** travels during operation. The coaxial mate enables the device **100** to follow the path of the access instrument **101** through the skin, and any subcutaneous adipose or loose connective tissues, in order to
15 position itself against an access-induced defect in a known anatomical structure, e.g. the cribriform fascia, fascia lata, or femoral sheath. The device **100** may be used to manipulate a known anatomical structure in order to approximate and close an access-induced defect in the structure. The device is inserted, manipulated, and subsequently removed to induce the desired tissue
20 closure effect, leaving behind only the mechanical components necessary to maintain tissue closure.

FIGs. 3A-3G show an exemplary detailed procedure of the device operation of the internal structures of the device **100** and their designated operations to deliver suture-mediated closure to a tissue defect in a subcutaneous tissue layer of interest. In this example, once the user has passed the streamlined or tapered device nose **104** around the access instrument **101** and through the superficial tissue layers to reach the level of the subcutaneous tissue of interest **200**, the user may deploy end effectors **400** (see **FIGs. 4A-4C**) to capture the tissue of interest **202** (e.g., fascia) and then retract the tissue of interest **202** into the receiving feature of the device nose **104** effecting the desired fold or “tent” in the tissue of interest. The device is now primed for suture deployment.

FIGs. 3A-3G show a schematic views of the internal structures and mechanisms of the device **100** as stored for transportation and handling. Reference position **300** indicates the stored position of end effectors **400**. End effector **400** may be a barbed suture needle that is mechanically mated with its axial shaft **301** via a press-fit or similarly tenuous junction **302** capable of releasing end effector **400** from its axial shaft **301** upon the application of tension to the three-part system that resides and travels within device body lumen **200**. One end **314** of a suture system (**314**, **311**, **312**), which in combination make up the primary suture **106**, may be permanently affixed to end effector **303** such that any movement of end effector **303** is followed by its attached suture end **314**. As shown previously, **FIG. 3A** details intermediary suture **122** as attached on both ends to suture cuffs **124**. The stored portion of intermediary suture **122** may reside in the nose **104** of the

device body **100**, where upon the application of tension to one end of the intermediary suture **122**, the entirety of intermediary suture **122** will travel within and follow the curved path of an interior feature **307** of device nose **104**. The interior feature **307** may be a shelf or channel that provides a radial
5 force to the intermediary suture and subsequent flexible sutures as they are drawn through the feature around the cylindrical access instrument, so as to prevent contact of the suture with the device body. The interior feature **307** may not restrict any suture from dropping out of the “active surface” of device body **100**.

10

End effector **400**, which may be a barbed needle tip, is permanently affixed to its axial shaft **310** housed within device body lumen **304**. The axial shaft **310** of the end effector **400**, as described previously, is stored such that it passes through a pre-tied surgical knot **311** comprised of the junction between a
15 suture end **314** that is stored internal to the device within device lumen **304** and an opposing suture end **312** that may be stored external to the device or within lumen **304**.

When tissue has been folded or tented into the receiving surface, for example
20 a concave feature or planar shelf, of device nose **104** via deployment and retraction of end effectors **400**, the user may actuate end effectors **400** by applying compressive force to their axial shafts **301** and **310** via handles or actuators **315** to pass the end effectors through the fold in the tissue of interest,

as shown in **FIG. 3B**. The passing of end effectors **400** creates two straight passages through folded tissue on either side of the access instrument e.g. cardiovascular sheath for a total of four holes radially arranged around the defect in the tissue of interest. As such, the end effectors enter the tissue from the side of the tissue layer that is proximal to the device user, puncture into and return out of the tissue on the side of the tissue layer that is proximal to the device user. The actuators of axial shafts **301** and **310** may now reside in reference position **300** as shown in **FIG. 3B**. End effector **400** may have now formed a mechanical mate with suture cuff **124** forming barb/cuff complex (**400**, **124**), and the opposing effector **400** may have likewise mated with suture cuff **309**. Stored suture end **314** may have been partially drawn out from lumen **307**.

Shown in **FIG. 3C**, axial shafts **301** and **310** may be retracted from the tissue. Due to the suture/cuff complexes **303**, **124**, the axial shaft **301** and tenuous mechanical junction (e.g. socket, or cradle) **302** may be allowed to travel back through the tissue having detached from end effector **400**. Actuator **315** of axial shaft **301** may return to reference position **300** and remain there. Axial shaft **310** is now mechanically coupled to barb/ suture cuff complex **309**, **124**, stored and resident intermediary suture **305**, **122**, barb/suture cuff complex **303**, **124** and previously stored suture end **314**. This 6-part system may now be drawn in tension, as shown in **FIG. 3D**, by actuator handle **315** of axial shaft **310** through the pre-tied suture knot **311**, which remains housed in the

distal end of the axial shaft port. Actuator handle **315** may now surpass reference position **300** as the 6 part system is drawn through the tissue, and axial shaft **310** is drawn away from the device, towards the device user. By drawing this 6 part system through the structural guide channel **307** in the nose **104** of the device **100**, the intermediary suture and cuff complexes draw the suture end **314** through pre-tied surgical knot **311**, the remaining end of which belongs to the same filament of suture **312**. The tissue defect is now surgically tied, and while, in the event of a cardiovascular access closure, the guiding wire must remain intraarterial, the access instrument may be removed by the user while the user applies tension to suture end **312**, the suture “rail”, and pushes suture knot **311** towards the defect **204** in the tissue of interest **202**, as shown in **FIG. 3F**. The intermediary suture **112** and cuff complexes may now be trimmed from the single knotted suture, and the knot may be further pushed either manually or via a user-activated tensioning mechanism within the device so as to create a purse-string closure of defect **204** using a U-stitch or analogous surgical closure pattern in the tissue of interest **202** as shown in **FIG. 3G**. In the case of a cardiovascular access closure, the guidewire is still in place. As the user determines the closure to be effective, the user or device may continue to apply tension to suture “rail” **312**, and compressive force to knot **311** as the user removes the guiding wire and completes the knotted, purse-string closure of the tissue of interest. For the indication of achieving hemostasis after closure of the tissue of interest, the device may embed indicators in the housing, such as a cannula, needle or wick

to inform the user if hemostasis was or was not achieved after securing the approximated tissue.

To achieve a coaxial mate with the suture positioning assembly **100** as shown in **FIG. 1A**, the tissue approximation device may be snapped, pressed, or otherwise mechanically secured onto the instrument, e.g. a cardiovascular access sheath **101** via an axial slit **124** (see **FIG. 1C**, **FIGs. 5A-5C**). The axial slit **124** and corresponding structural boundaries may be, but are not limited to a blunt, sharp, circular, convex, or cone shape to allow tissue, such as subcutaneous fat, to slide over the tissue approximation device and mitigate damage, entanglement or interference with the tissue before reaching the desired tissue layer and tissue defect to be approximated, which may include a subcutaneous tissue layer such as the fascia or arterial wall.

In a further aspect of the invention, the slidable attachment of the suture positioning assembly on the sheath to achieve coaxial mating of the suture positioning assembly with the sheath includes clamping, hinged clamping, clamping via hinged cams, springed hinges, snap-fitting, stitching, tongue-and-groove mating, dove-tail mating, ratchet mating, threaded connectors or coaxial mating. The suture positioning assembly may be a single deformable component so as to achieve the coaxial mate with the sheath, or it may be comprised of discrete halves to be radially/circumferentially oriented around the sheath so as to mate with each other and create a coaxial mate, or a mate

with which the central axes of the suture positioning assembly and of the sheath are offset but remain parallel.

Shown in **FIGs. 5A-5C** is one possible embodiment of a suture positioning assembly **100** to achieve vascular hemostasis. **FIG. 5A** shows one embodiment of the invention, where a device is provided as an integrated sheath and closure device. In further embodiments, the device may be equipped with a streamlined or tapered introductory access nose **104** intended to dilate any tissue (e.g. skin and adipose tissues) that surrounds the access sheath while traveling along the sheath towards the tissue defect of interest. To appropriately approximate to and manipulate the tissue of interest, the tissue-facing surface, or “active surface” of the device nose **104** may be angled relative to the axis of the device body **100** so as to achieve a parallel approximation with the tissue layer of interest. The “active surface” of the device may thus be oriented relative to the anterior longitudinal surface of the device body **100** at an angle of between 14 and 61 degrees. The active surface of the device may also follow convex contours designed to mate seamlessly with the tissue layer of interest, around the defect of interest. The device is equipped with two symmetrical, axial lumens **103** through which tissue end-effectors may pass and be articulated, directed, or manipulated. The device is equipped with two additional symmetrical lumens **105** that likewise house tissue end effectors that may be passed, articulated, directed or manipulated to puncture the tissue of interest and deploy mechanical closure components, e.g.

sutures. Lumens **105** may contain baffles interior to the lumen in order to guide any flexible internal tissue end effectors in the appropriate direction. The device is equipped with a concave feature **107** within the nose **104** that will serve as a contour along which to shape the tissue and tissue defect, as well as providing a dedicated volume of space within which the tissue may be manipulated during the closure operation. In no way is the dedicated volume created by concave feature **107** restrictive of the area in which end effectors may pass or within which tissue may be manipulated.

10 The material of the device, particularly in, but not limited to the location of the nose **104** may be sufficiently flexible so as to allow the elastic deformation of the nose or device body and subsequent coaxial mating of the suture positioning assembly **100** with the access sheath **101**. The mating surfaces of the suture positioning assembly **100** with sheath **101** may incorporate gaskets, bushings, springs, hydrophilic coatings or other mechanism(s) to ensure a tight, coaxial sliding junction with the access instrument. The independence of the suture positioning assembly **100** from the sheath **101** enables the device to perform the intended tissue manipulation either at the start of a procedure or at the end of a procedure, without the mandate that the access sheath be removed and “threaded” through the device in order to obtain a coaxial orientation of the two components.

15
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FIGs. 6A-6E show alternative mating mechanisms of the suture positioning assembly **100** with sheath **101**, e.g. cardiovascular sheath. The device **100** may coaxially mate to a cylindrical instrument **101** via a single hinge (**FIG. 6A**) or dual-hinge (**FIG. 6B**) clamshell-type approximation mechanism, such

5 that one or both halves of the end effector of the device may swing open, allowing the device to be placed around the sheath and subsequently closed and secured. Rather than an axial slit or clamshell, the device may also occupy a modular form factor as depicted in **FIG. 6C**. In one embodiment, the nose **104** or the body of the device **100** to be mated with an access instrument may

10 be removed or disconnected from the device (**FIG. 6D**) to allow coaxial mating with the sheath, and subsequently replaced to form a circumferential sliding junction with the access instrument. The device body may also be split on the transverse plane as in **FIG. 6D** such that one half of the device is bound to the other around the access instrument, or such that each half is

15 bound to a core body member. **FIG. 6E** depicts one half of the device bound to a core body member; the remaining modular half may be joined to the core body member around the access instrument.

According to further embodiments of the invention, the housing nose **104** can

20 also include a dilation controller, where the dilation controller is configured to change in size to alter a diameter of said dilated hole in facial layer **202**, where the dilation controller is configured to create resistance when the suture positioning assembly **100** is retracted from the facial layer **201** along said

lumen access sheath **101**, where the created resistance is sufficient to indicate that the housing nose **104** is securely held in place by circumferential tension of the dilated hole **204** of said fascial layer on said fascia receiving surface. **FIGs. 7A-7C** show different embodiments dilation control element **700** that

5 can include an expandable umbrella (see **FIG. 7A**), an inflatable membrane (see **FIG. 7B**), and a shape changing collar (see **FIG. 7C**). Here, the dilation control element can be deformable underneath the fascia layer so as to form an “anchor” or “T-tag”-style expansion device so as to prevent the user from pulling the device out of position while operating. In one embodiment, this

10 feature could then be relaxed to reduce its cross section to original size and allow the device to be removed/slid back along the sheath towards the user thus disengaging from the fascia.

In one embodiment, the end effectors may be a coiled wire with sufficient

15 stiffness to puncture and secure into a biological tissue of interest for subsequent pushing, pulling, and analogous tissue manipulation. The end effectors may embody or utilize similar tissue securement mechanisms such as opposing graspers, hooks, barbs, suction, or adhesives. After approximation of the suture positioning assembly **100** to the tissue of interest **202**, the end

20 effectors **400** may be secured to the tissue of interest by rotating and applying axial compression to their axial shafts via handles/actuators at the end of the end-effector axial shaft proximal to the user, in the direction of the tissue of interest, which effectively captures the tissue of interest e.g. fascia. The travel

of the end effectors is limited by a mechanical hard stop, or “shoulder” feature **113** (see **FIG. 1B**) on the axial shaft of the end effectors. Once in contact with the device body **100**, the “shoulder” **113** will stop travel of the end effectors so as to avoid damage of delicate tissues or structures beneath the tissue of interest, e.g. fascia. The tissue of interest may then be retracted into the interface surface, such as the concave feature **401** of **FIGs. 4A-4C** of the device nose **104** by applying tension to shaft of the end effectors (not shown), creating a folding or “tenting” effect of the tissue of interest within the nose **104** of the device body **100**.

10

FIG. 8 shows a flow diagram of the implementation and use of the current invention that includes increasing the incision size, co-axially mating the device with a sheath, sliding the device down over the sheath, then obtaining visual confirmation of the correct positioning of the device by an arterial indicator, and/or confirming the fascia positioning by use of a tactile feedback, such as snapping fascia in receiving surface or a tensile feedback. The next steps include deploying the needles, retrieving the suture, cinching down the knot and approximating the tissue while removing the suturing device, then further cinching down the knot and approximating the tissue while removing the sheath, and finally cutting the suture.

20

FIG. 9A shows an embodiment of a suture positioning assembly **100** that is slidably attachable to an exterior of a sheath **101**. In **FIG. 9B**, housing nose

104 of suture positioning assembly **100** incorporates a dilation controller with radially oriented interlocking members **901** and **902**, where member **901** is axially distensible relative to **902** such that a tapered dilation tip **903** on the distal end of member **901** may be advanced distal to fixed member **902**, where

5 fixed member **902** is mechanically integrated to housing nose **104**. Shown in **FIGs. 9C-9D**, tapered dilation tip **903**, when advanced by the deployment of interlocking member **901** relative to fixed interlocking member **902**, may increase the dilation of fascial hole **204** in fascial layer **202** such that the fascial layer may be disengaged from the fascia receiving surface **118** until

10 fascial layer **202** may be disengaged from housing nose **104**. **FIG. 9D** shows dilation tip **903** advancing fascial layer **202** off of fascial receiving surface **118** via dilation of fascial hole **204**. In **FIG. 9E**, fascial layer is sufficiently disengaged from fascia receiving surface **118** such that housing nose **104** in conjunction with suture positioning assembly **100** may be slidably withdrawn

15 from engagement with fascia layer **202** following deployment of sutures, and suture positioning assembly **100** may be withdrawn from the body lumen or access site such that sutures may be cinched and secured for completion of suture passing and closure of fascial hole **204** in fascial layer **202**.

20 **FIG. 10A** depicts a tissue capturing device embodied by a circumferential array of shaped metallic wires **1001** around and housing nose **104** of suture positioning assembly **100**. The array of shaped metallic wires **1001** is an embodiment of a fascia isolation and support mechanism that may be

deployed from a stored configuration, where the array of shaped metallic wires **1001** may be tensioned against suture positioning assembly **100** until such time as they need to be deployed proximal or distal to fascia layer **202**. Once deployed distal to fascia layer **202**, the array of shaped metallic wires **1001** may be retracted by drawing housing nose **104** and thus fascial layer **202** up to the fascia receiving surface for manipulation and suturing. In **FIG. 10B**, the arrangement of end effectors **400** may be seen relative to the array of shaped metallic wires **1001** such that end effectors **400** may travel along their path through fascia layer **202**, which is supported distally by the deployment of the array of shaped metallic wires **1001**, unimpeded by the deployed array of shaped metallic wires **1001**. As such, fascial layer **202** may be supported both proximally and distally during manipulation, puncturing, and suturing.

FIGs. 10C-10E depict an alternate embodiment of a tissue capturing device, wherein the tissue capturing device is comprised of a deployable array of shaped metallic wires in a braided configuration. As such, the braided array of shaped metallic wires **1002** may be deployed identically to the array of shaped metallic wires **1001** in order to provide support of fascial layer **202** during manipulation and suturing, yet the braided array of wires **1002** may provide additional circumferential support of fascial layer **202** relative to wires **1001**.

FIGs. 10D-10E depict the shape of a braided array of shaped metallic wires **1002** such that end effectors **400** may deploy through fascia layer **202** unimpeded by the support structure formed after deployment of the braided

array of shaped metallic wires **1002** in order for end effectors **400** to complete suturing and closure of fascial defect **204** in fascial layer **202**.

FIGs. 11A-11G show the identification, location and positioning of suture positioning assembly **100** and fascia receiving surface **118** relative to fascia layer **202**. **FIG. 11A** indicates the positioning of an ultrasound imagery probe **1100**, oriented such that the field of view of the ultrasound image is parallel and coincident with the central axis of sheath **101**. **FIG. 11B** depicts suture positioning assembly **100** slidably engaged with sheath **101** at its entry point through fascia layer **202** and further distally into a body lumen **1101**. **FIG. 11C** depicts the field of view under ultrasound imagery comprising multiple echogenic features that generate contrast in the ultrasound image, primarily fascia layer **202**, body lumen **1101** and an echogenic locating feature **1102** that coincides with fascia receiving surface **118**. By the integration of echogenic location feature **1102** with fascia receiving surface **118**, the use of ultrasound imaging via probe **1100** will allow for the visual confirmation of engagement of fascia layer **202** with fascia receiving surface **118** such that deployment of end effectors **400** for the passing of a suture through the fascia layer may be performed with visual affirmation of appropriate positioning and deployment of end effectors **400** through fascia layer **202**. **FIG. 11D** depicts one embodiment of echogenic location feature **1102**, wherein topographical indentations in a metallic or otherwise echogenic material along the body of suture positioning assembly **118** that is just proximal to fascia layer **202**, as

well as topographical indentations in a metallic or otherwise echogenic material along the body of housing nose **104** that is just distal to fascia layer **202**, between which lies the fascia receiving surface **118**, form a proximal and distal visual indicator of the engagement of fascia layer **202** with fascia receiving surface **118**. **FIG. 11E** shows another embodiment of echogenic location feature **1102** comprised of linear metallic or otherwise echogenic features both proximal and distal to fascia layer **202**. **FIG. 11F** shows yet another embodiment of echogenic location feature **1102** wherein metallic or otherwise echogenic features are arranged on suture positioning assembly **100** and housing nose **104** in a semicircular configuration within the visual plane of imagery, so as to straddle or cradle the fascia layer **202** with the visible features of the echogenic location feature **1102**. Visibility of echogenic location feature **1102** in this embodiment may be achieved via texturing of a metallic or otherwise echogenic material comprising the echogenic location feature **1102**. In yet another embodiment of echogenic location feature **1102**, **FIG. 11G** depicts a texturization of the location feature **1102** in a bulk indicator that seeks to provide visual confirmation of linear alignment of echogenic location feature **1102** which coincides geometrically with fascia receiving surface **118**, with fascia layer **202**. Echogenicity of the location feature **1102** may again be achieved by texturization of a metallic or otherwise echogenic material comprising the feature so as to be visible in the imaging plane.

FIG. 12A shows an alternative embodiment of suture positioning assembly 101 slidably attached to sheath 100. In **FIG. 12B**, End effectors 400 located within housing nose 104 are shown in a semicircular geometry in this embodiment, joined by a connecting arm 1200 to a central axis of rotation 1201. The fixed geometry of end effector 400 joined by connecting arm 1200 to axis of rotation 1201 ensures that upon deployment and rotation of end effectors 400, the barbed component of end effector 400 may travel along a preset path of rotation so as to ultimately mate with cuff 124 to form suture/cuff complex 303,124 as shown in **FIGs. 3B-3C**. **FIG. 12C** depicts penetration of fascial layer 202 by end effectors 400 along their path to form the mating suture/cuff complex 303,124.

FIG. 13A shows yet another embodiment of a suture positioning assembly 100 slidably attached to sheath 101 passing through fascia layer 202. In this embodiment, end effectors 400 are shown in **FIG. 13B** to pass through fascia layer 202 around fascial defect 204, where **FIG. 13C** depicts end effectors 400 in a helical configuration, such that the deployment of end effectors 400 along a helical path allows for the formation of barb/cuff complex 303, 124 while allowing the distal end of end effector 400 to occupy the same lateral space as cuff 124, albeit with an offset. As such, end effector 400 may be configured in a longer arc length in this embodiment than that permitted in **FIGs. 12A-12C**, Given that the path of travel of the helical end effector in **FIG. 13C** does not

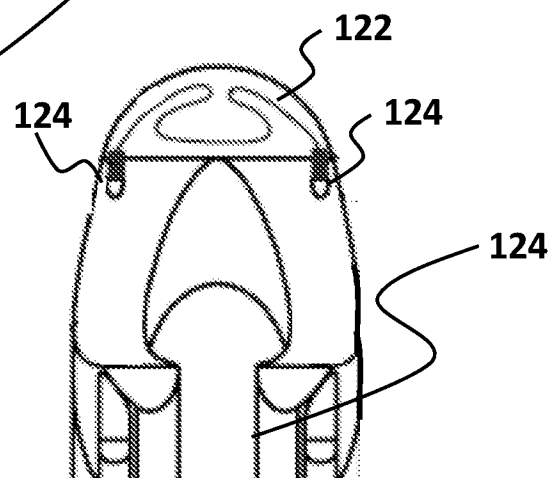
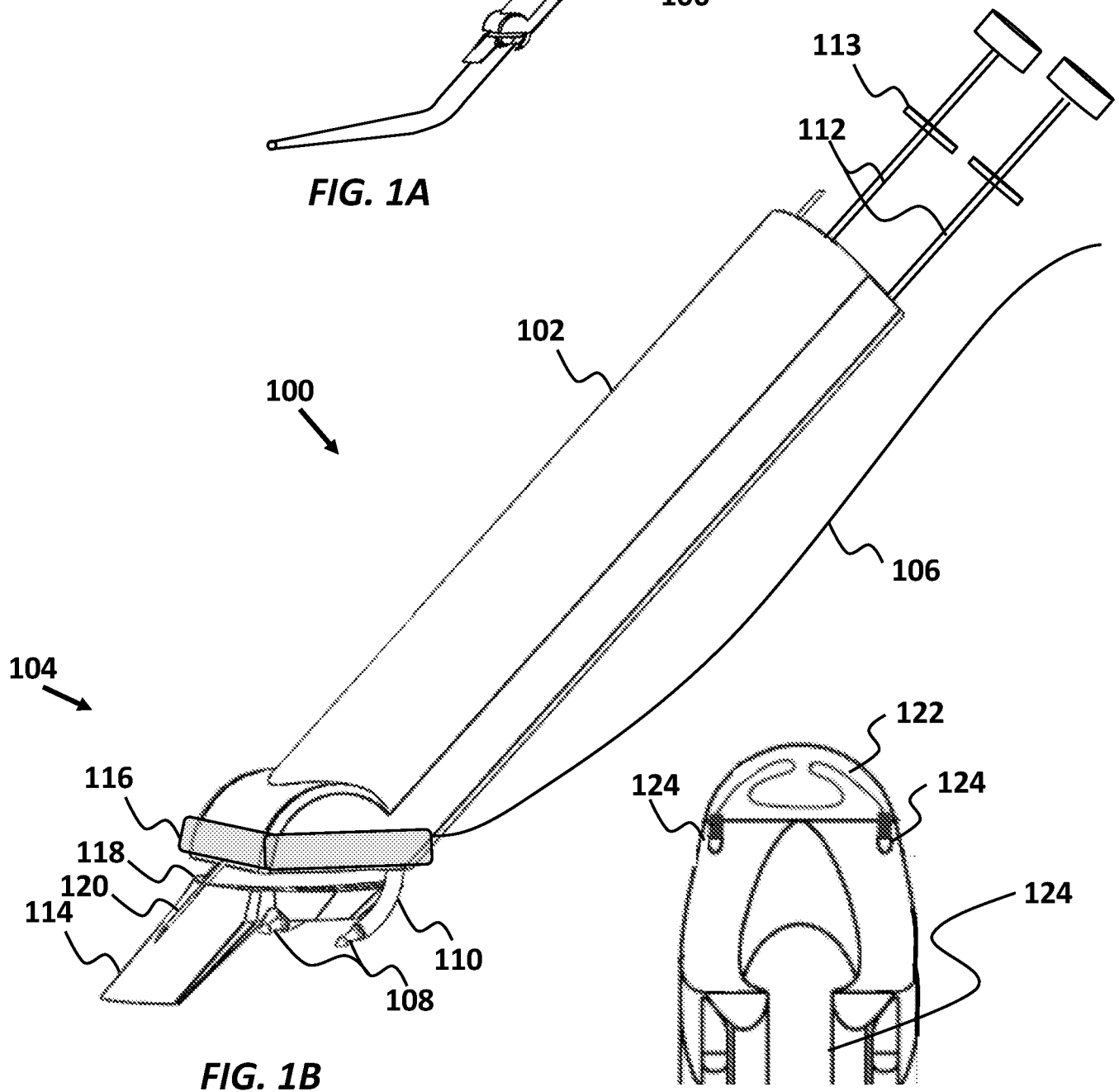
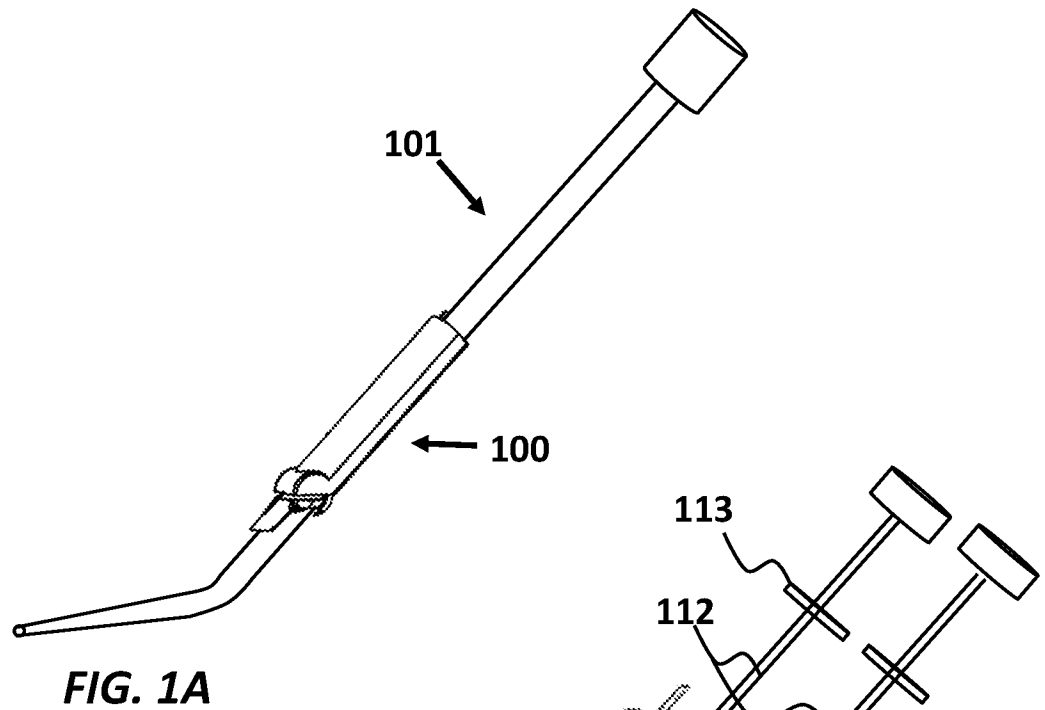
interfere with the target destination of cuff **124** as end effector **400** travels along its path of deployment to form barb/suture complex **303, 124**.

The present invention is capable of many variations in detailed
5 implementation, which may be derived from the description contained herein by a person of ordinary skill in the art. For example, the needles themselves could be curved or straight, flexible or rigid, etc. while still performing the mating of “barb” with “cuff” by traversing the tissue layer once, twice, or up to four times per needle.

CLAIMS

What is claimed:

- 1) A tissue layer engagement device, comprising:
 - a tissue capture and disengagement assembly that is slidably attachable
 - 5 or integrated with the exterior of a sheath, wherein a tissue support structure of the tissue capture and disengagement assembly comprises a static or deformable support shelf, wherein the support shelf is configured to deform itself to enable or limit travel of the tissue support structure relative to a tissue layer along the tract of an access conduit
 - 10 into a body lumen, wherein the tissue support structure further comprises an echogenic location feature with a contrast enhancing geometry to be visible when using traditional non-invasive imaging techniques, wherein the echogenic location feature is used to visually confirm the position of the tissue support structure relative to a tissue layer to be engaged along
 - 15 the tract of an access conduit through the skin into the body lumen.



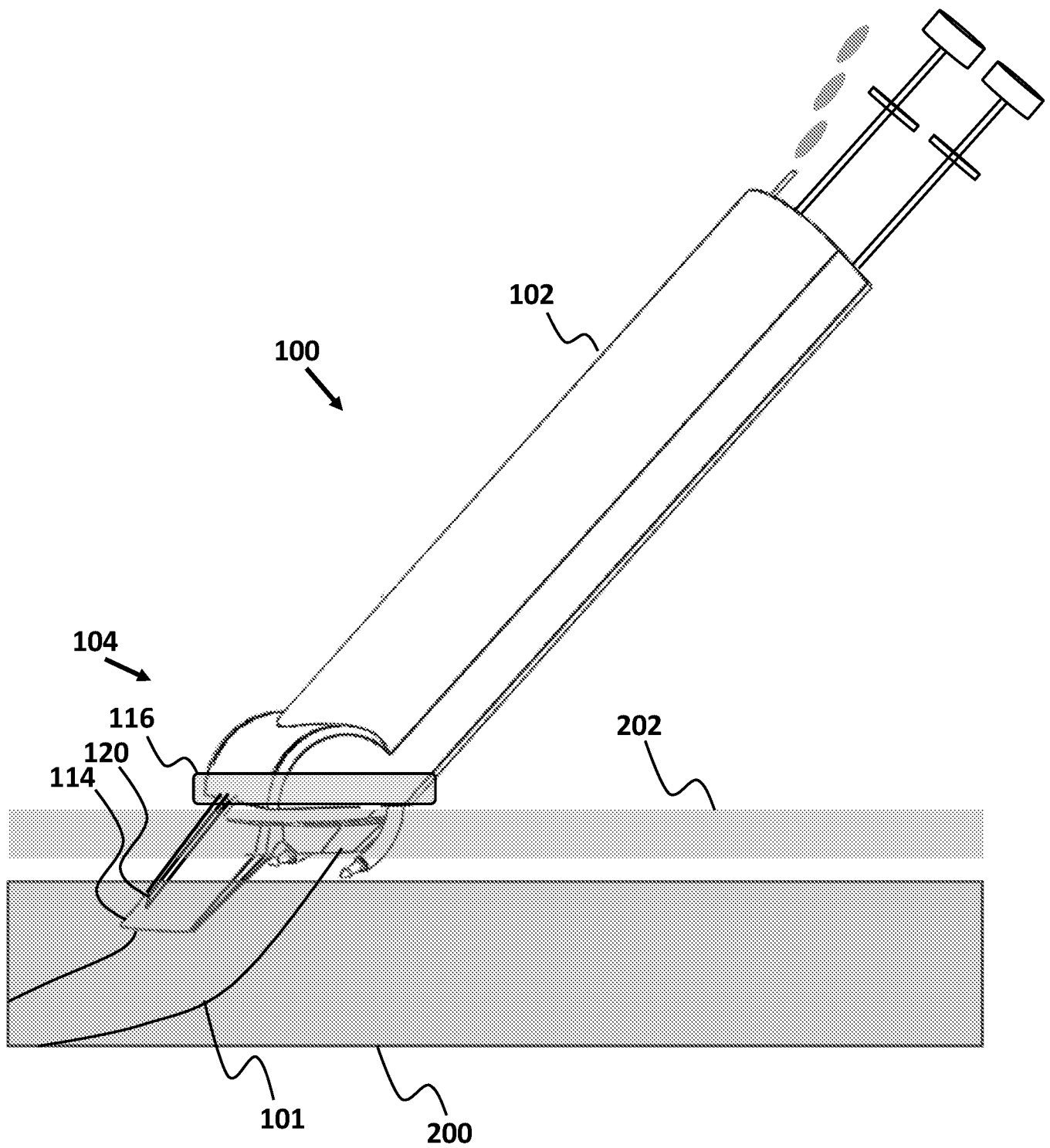


FIG. 2A

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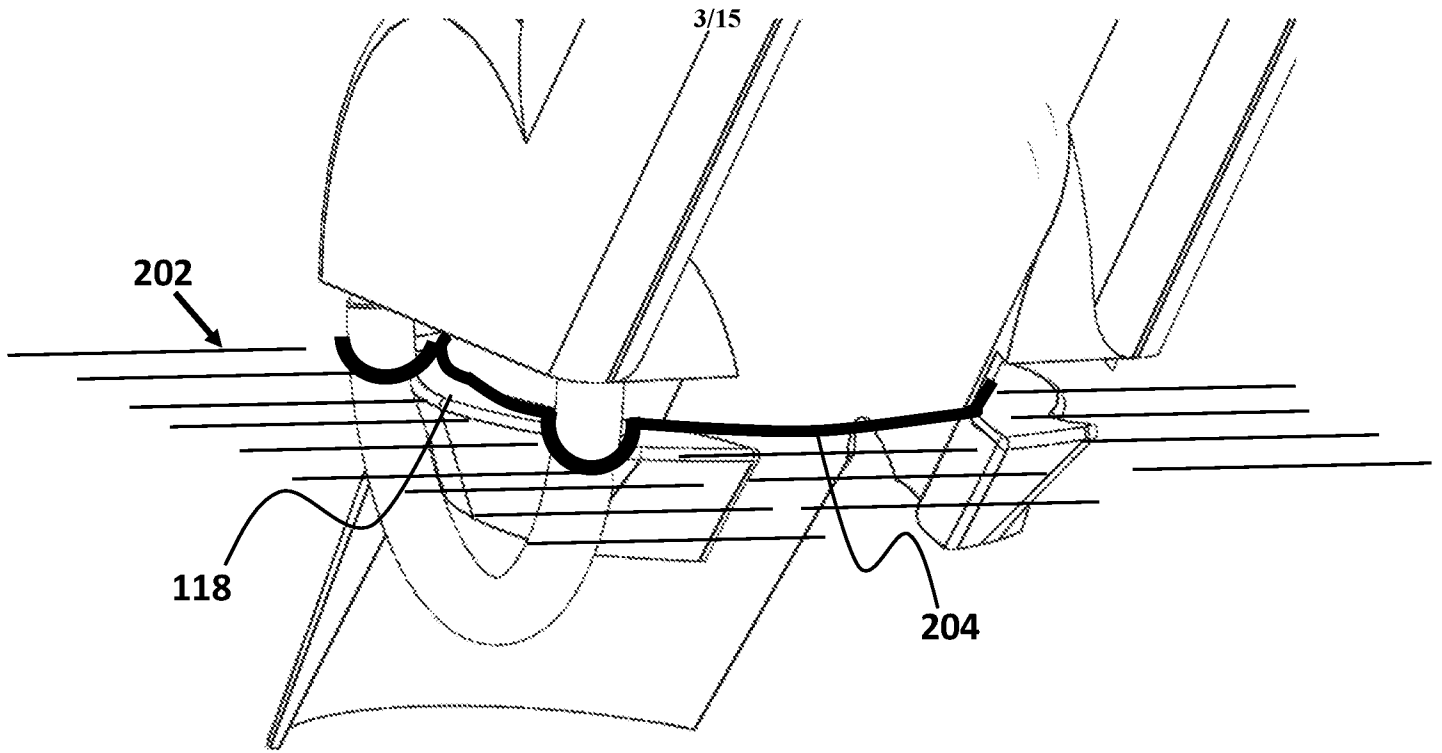


FIG. 2B

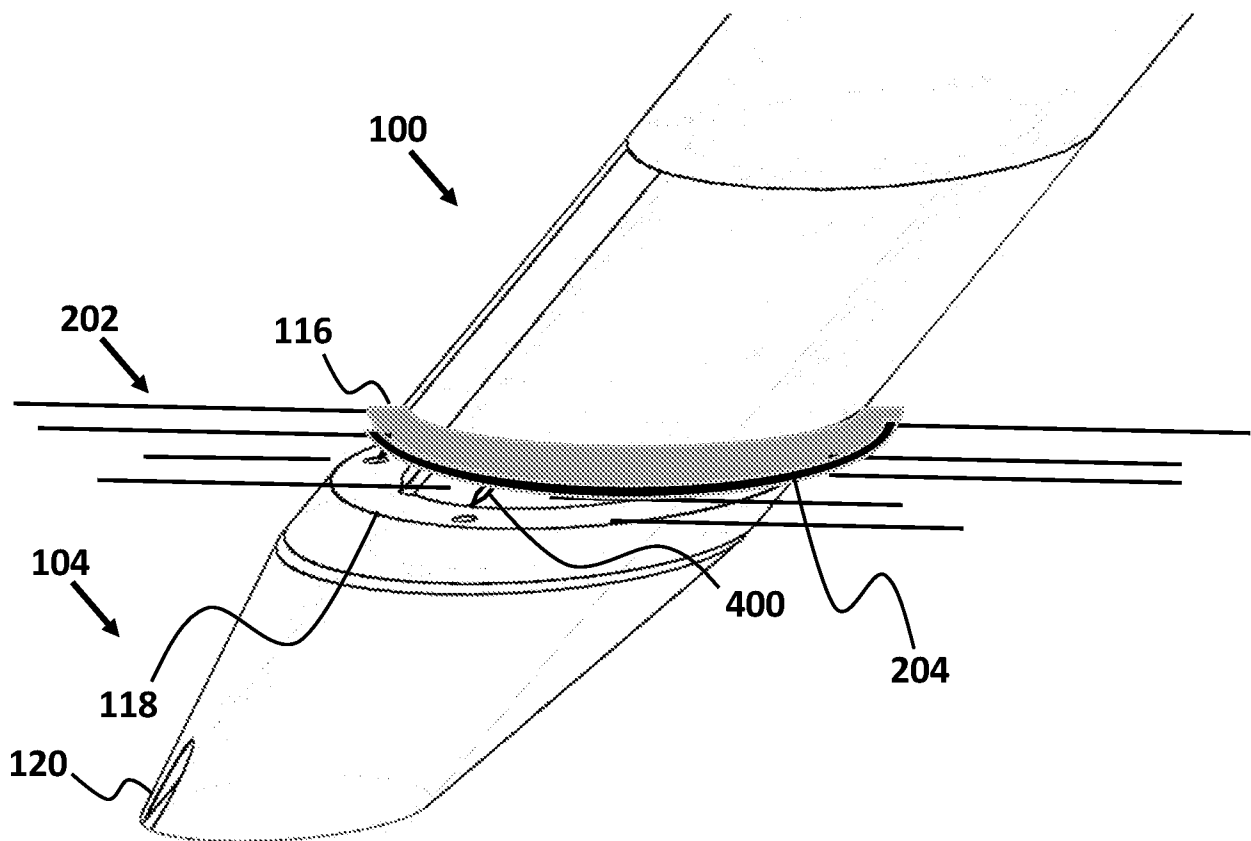


FIG. 2C

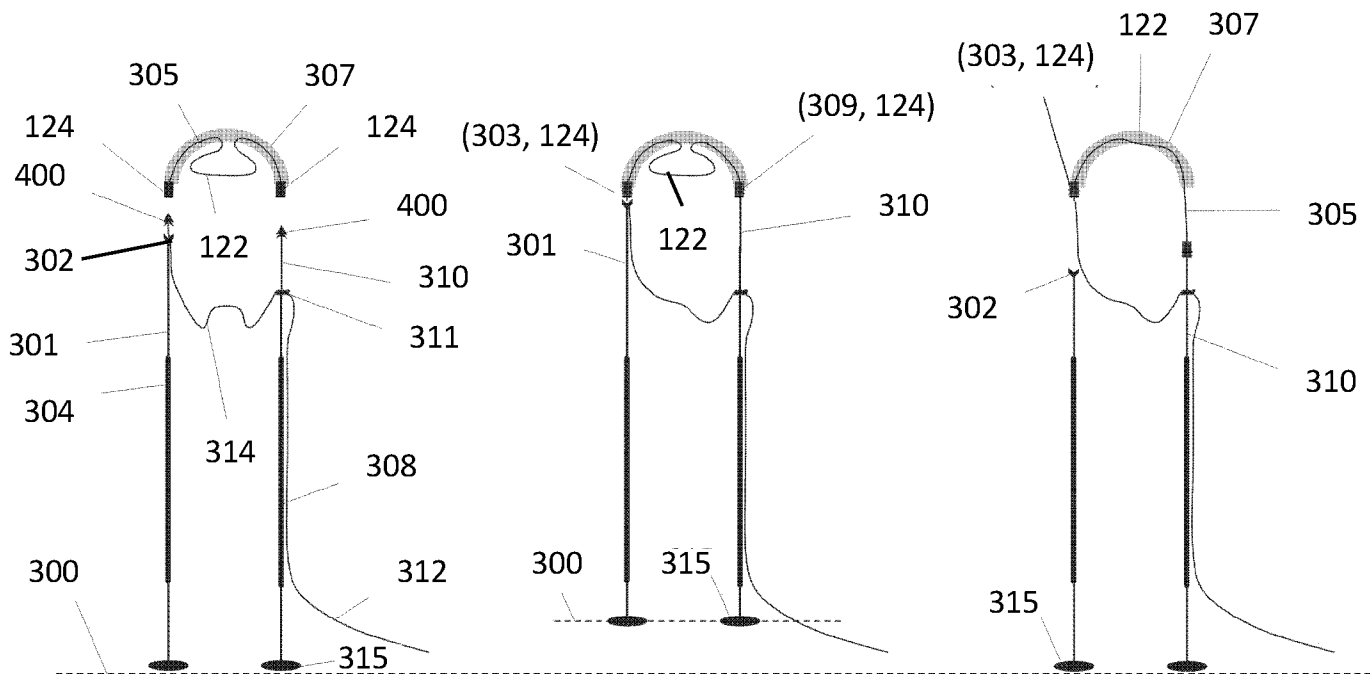


FIG. 3A

FIG. 3B

FIG. 3C

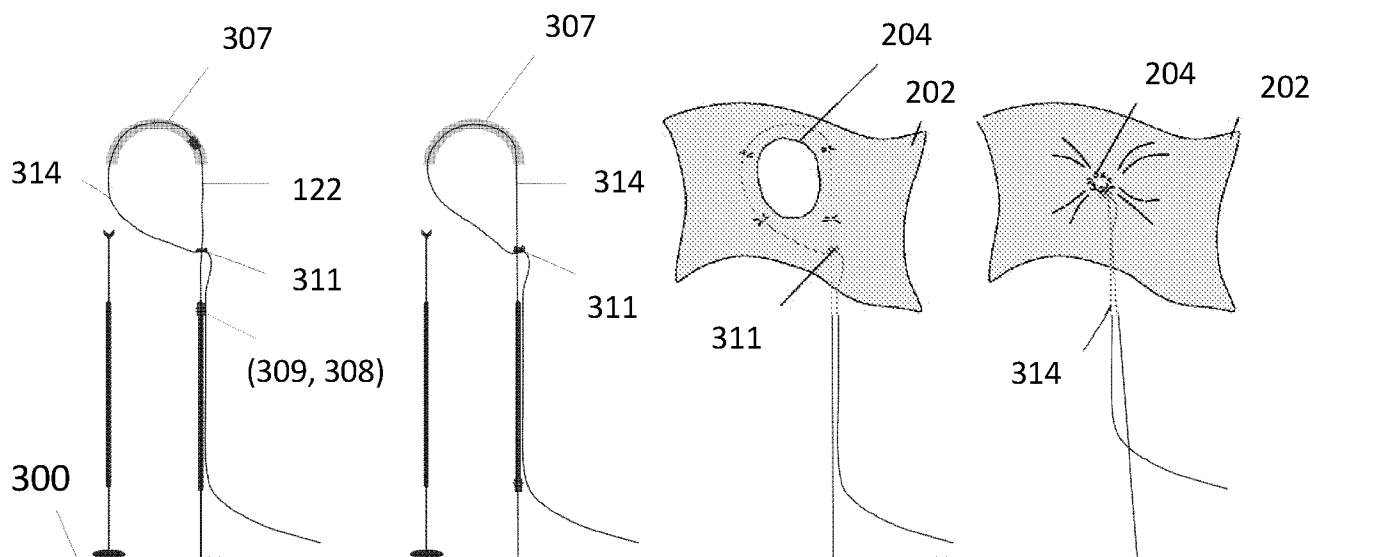
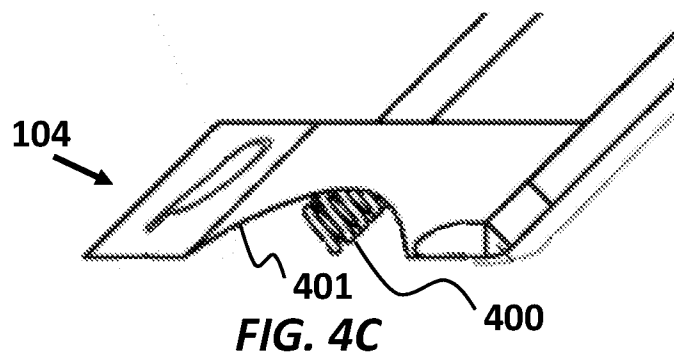
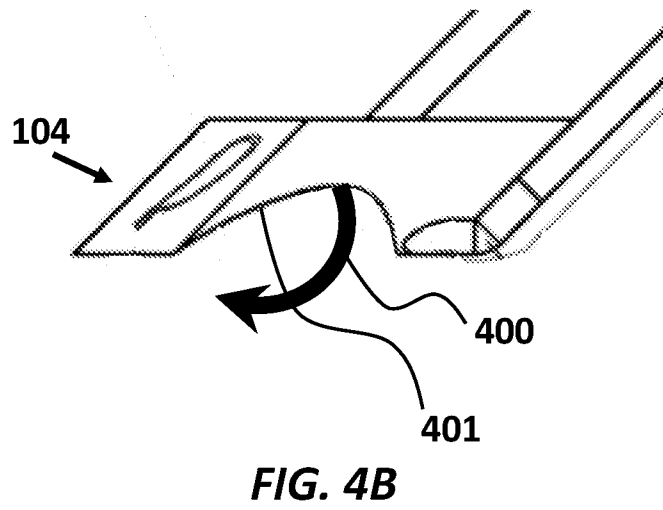
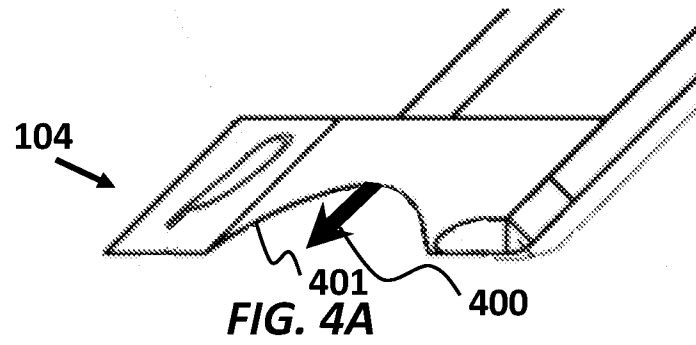


FIG. 3D

FIG. 3E

FIG. 3F

FIG. 3G



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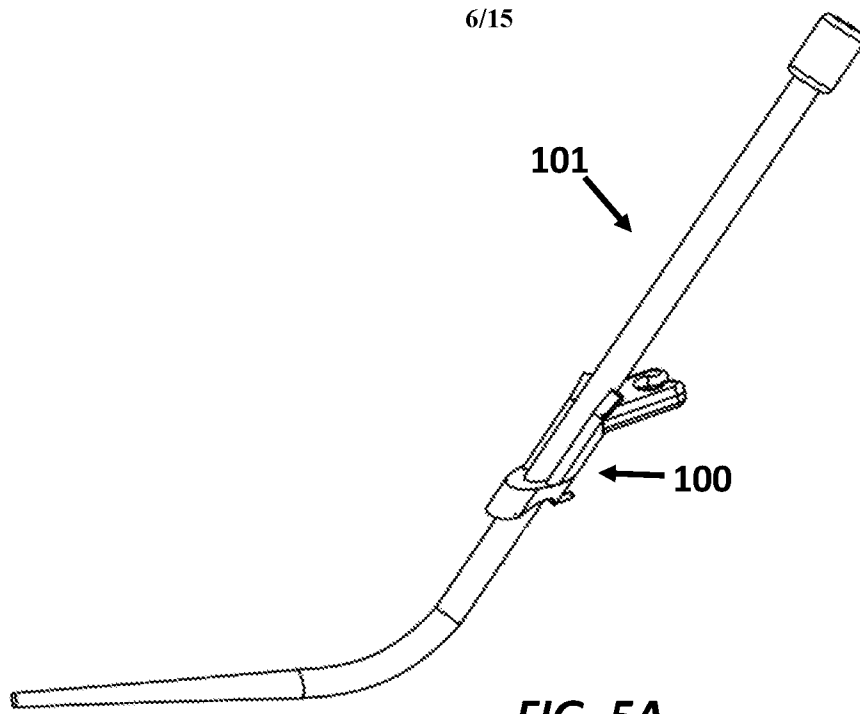


FIG. 5A

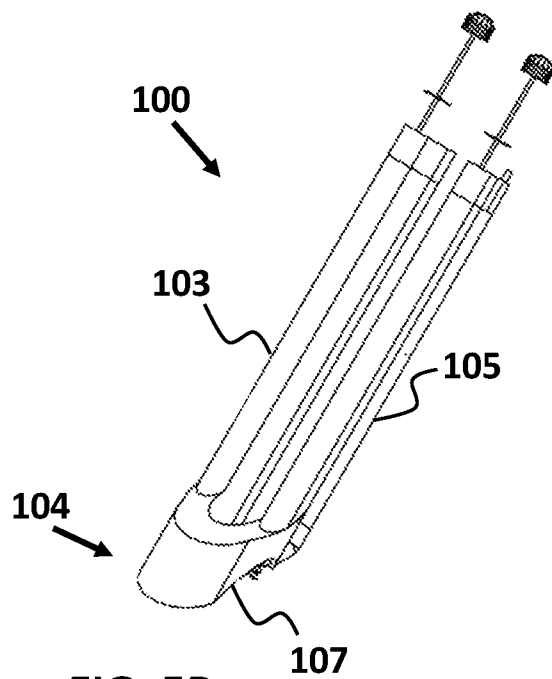


FIG. 5B

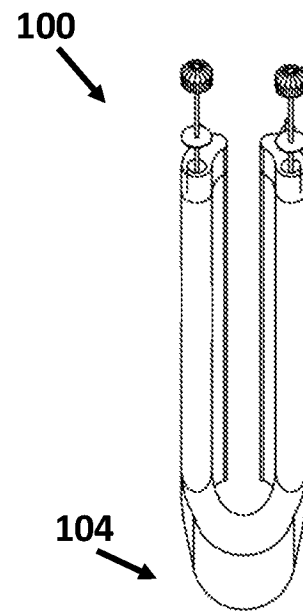
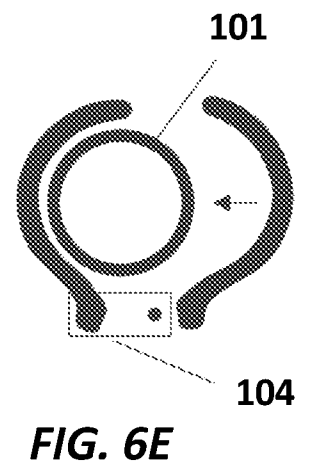
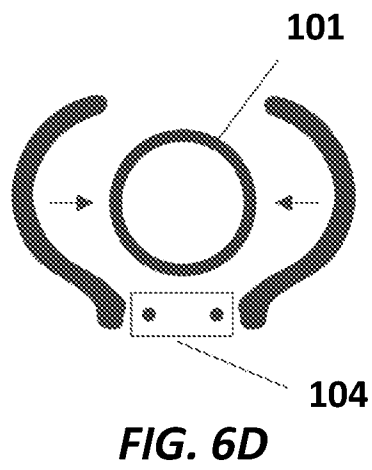
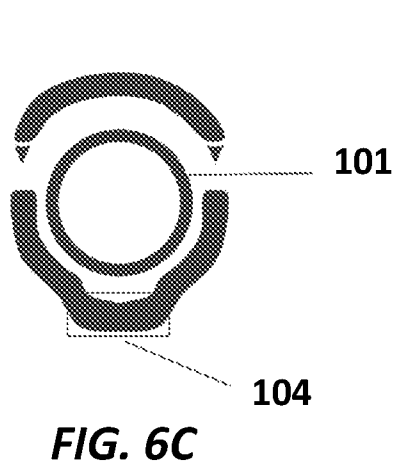
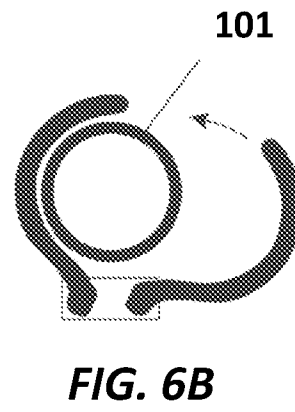
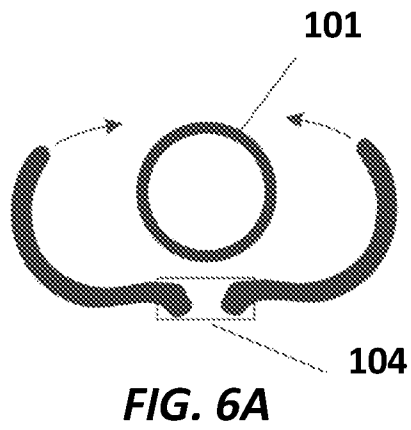


FIG. 5C



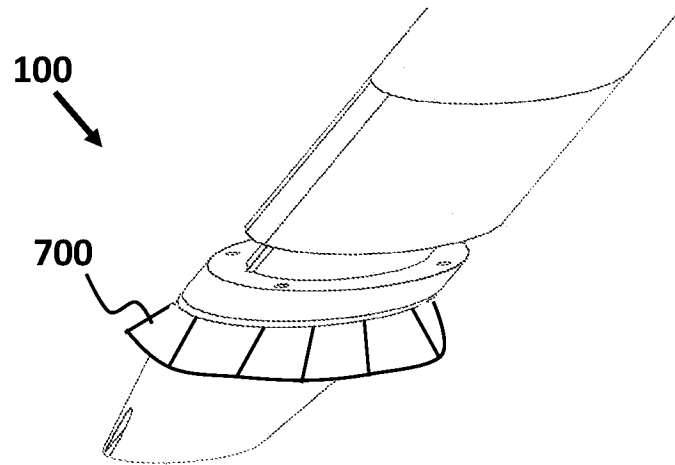


FIG. 7A

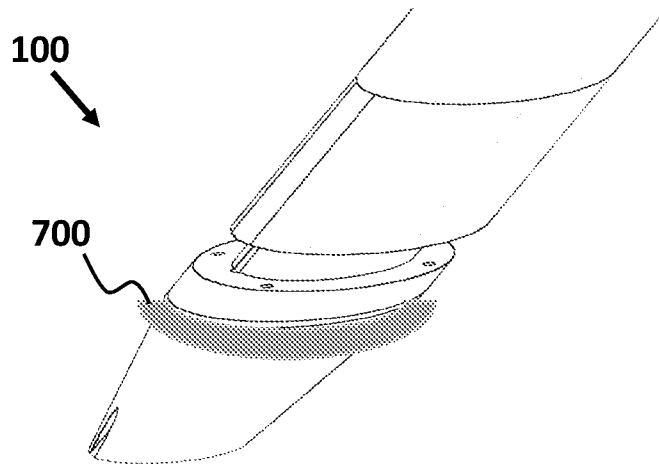


FIG. 7B

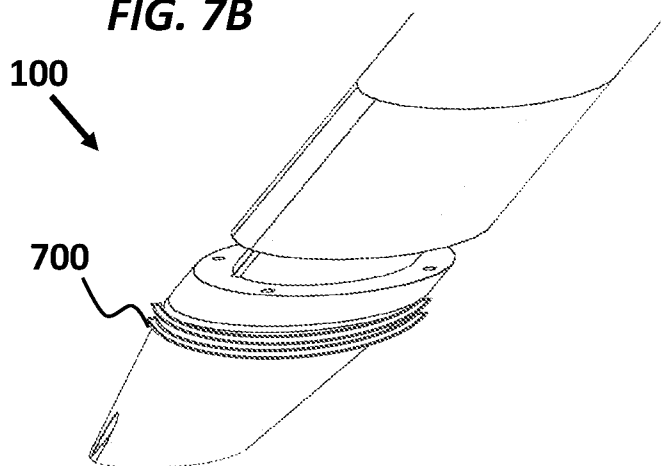


FIG. 7C

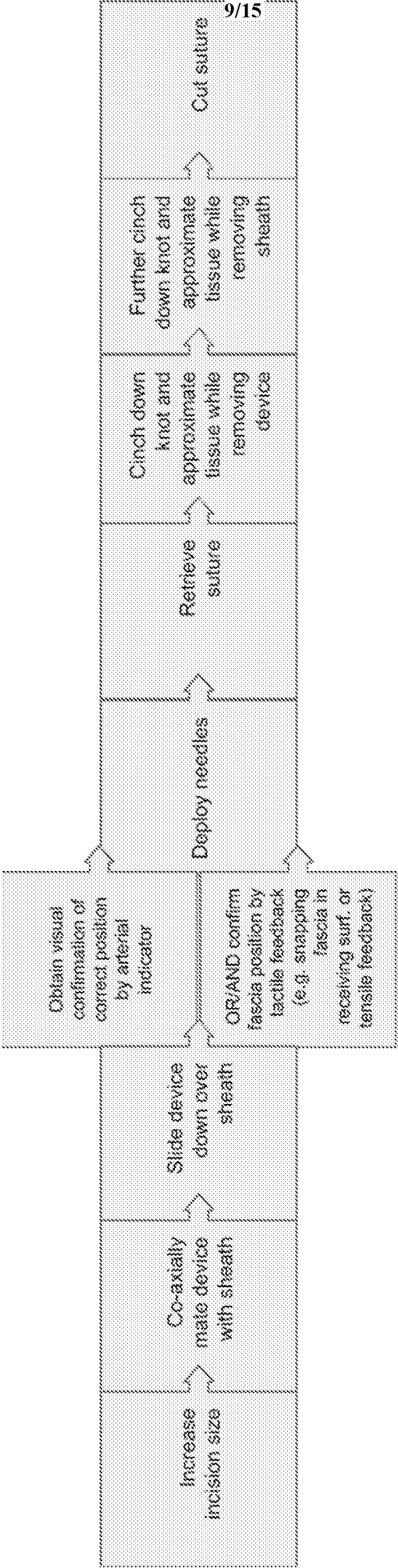


FIG. 8

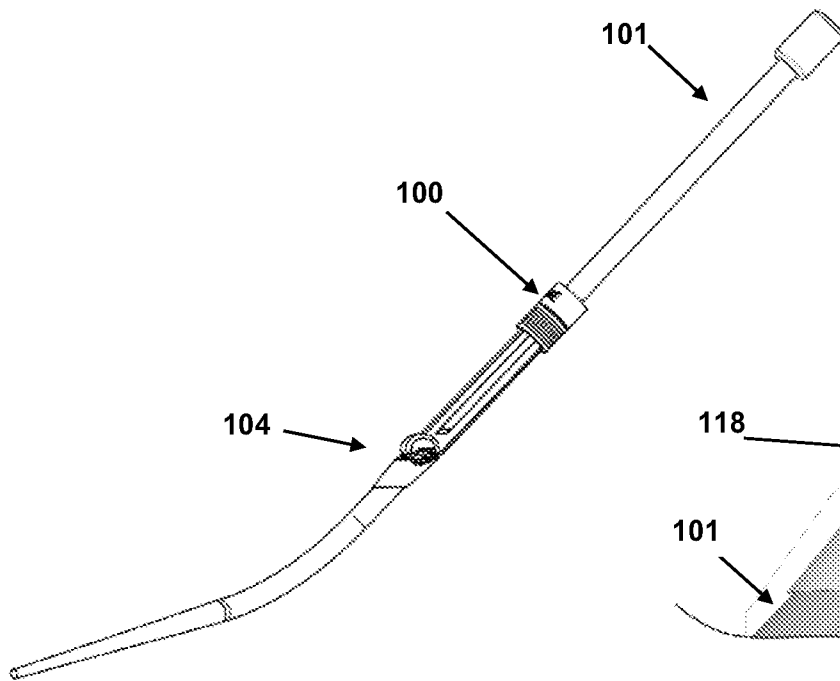


FIG. 9A

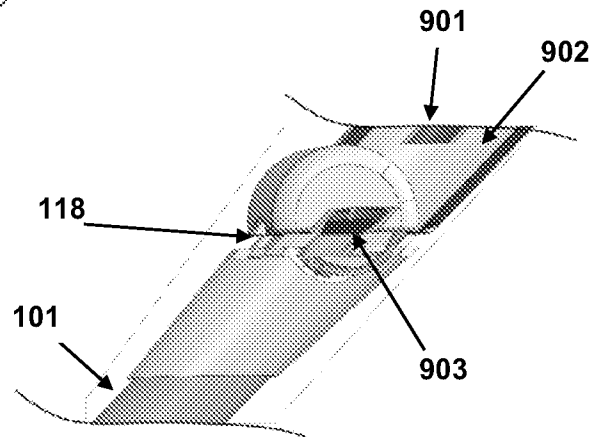


FIG. 9B

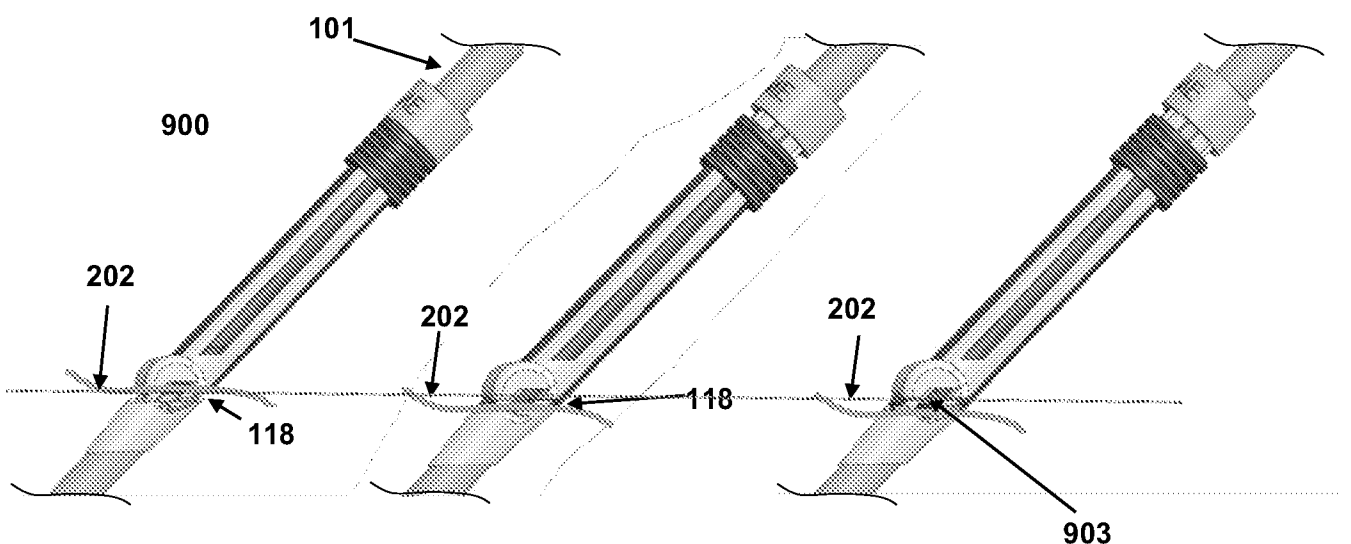


FIG. 9C

FIG. 9D

FIG. 9E

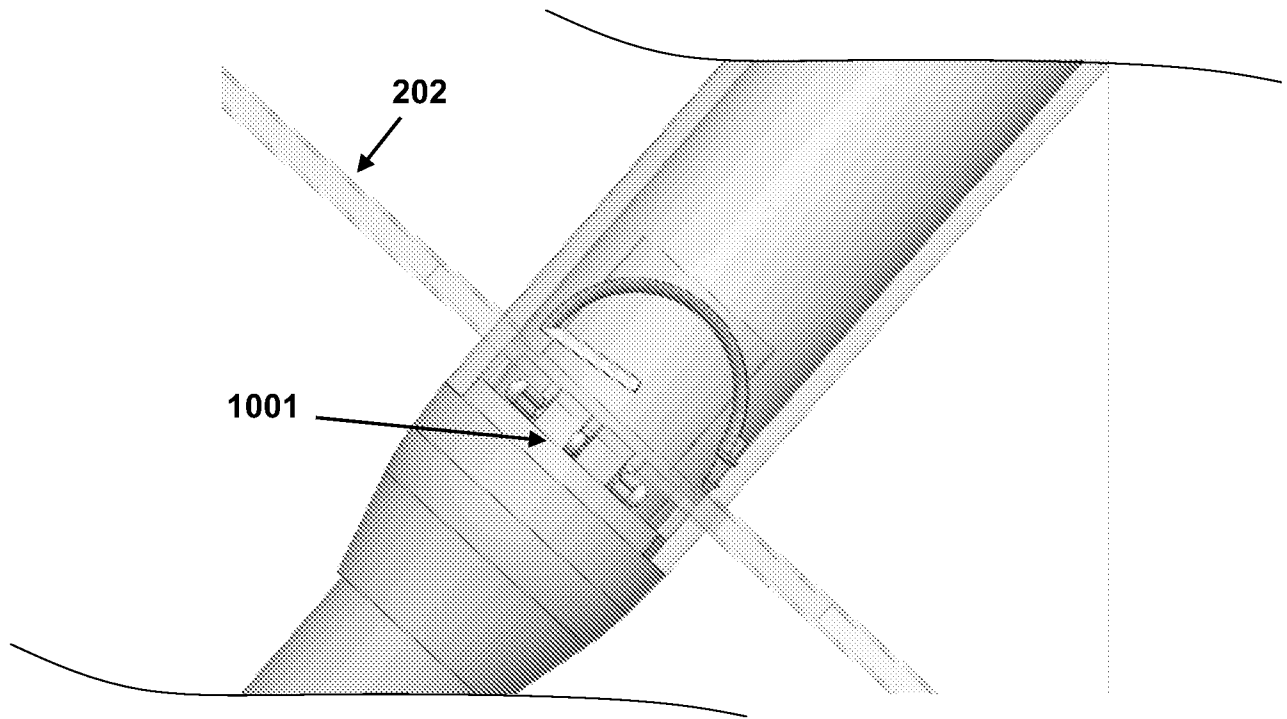


FIG. 10A

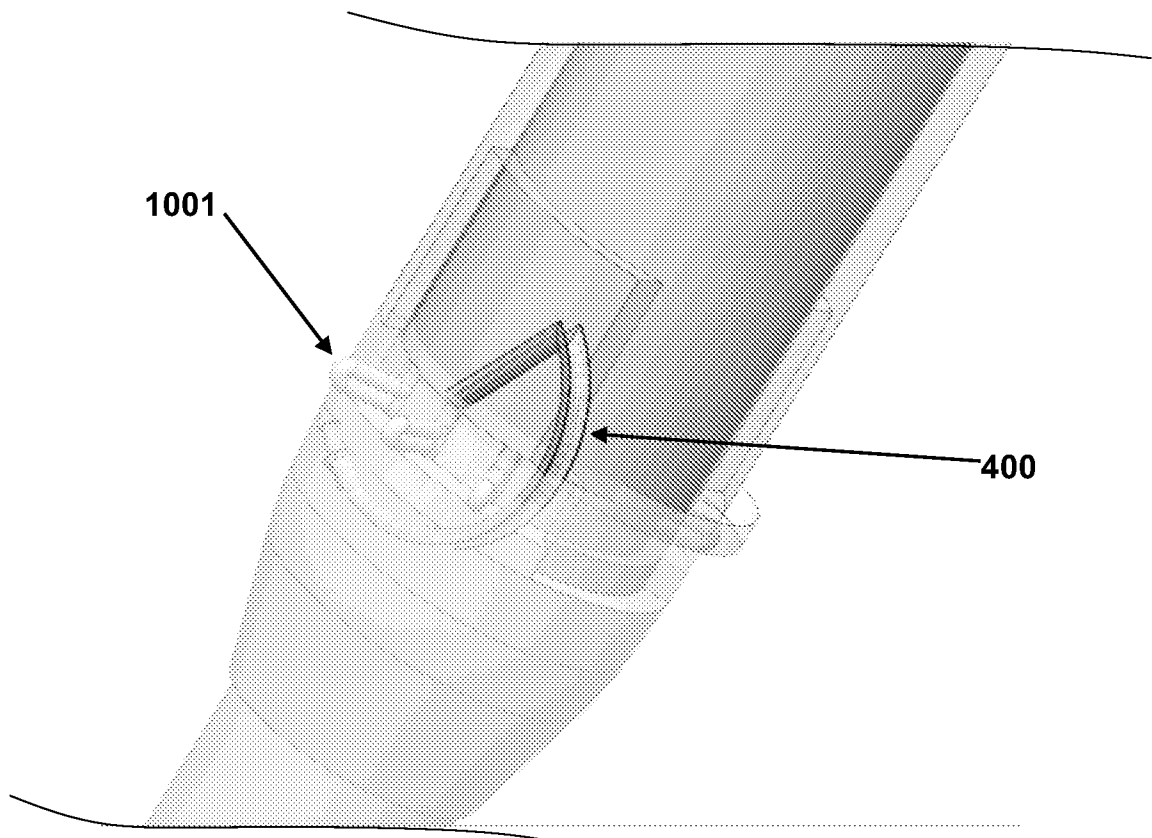


FIG. 10B

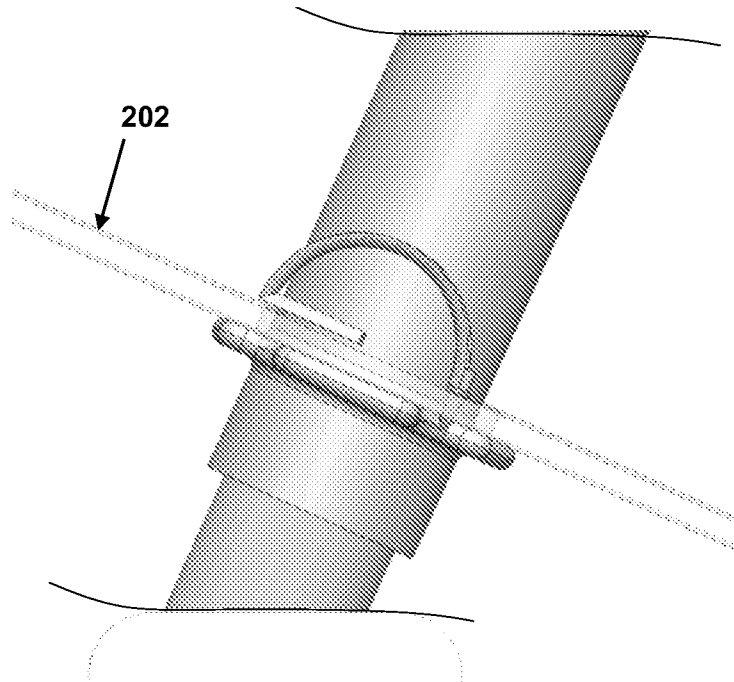


FIG. 10C

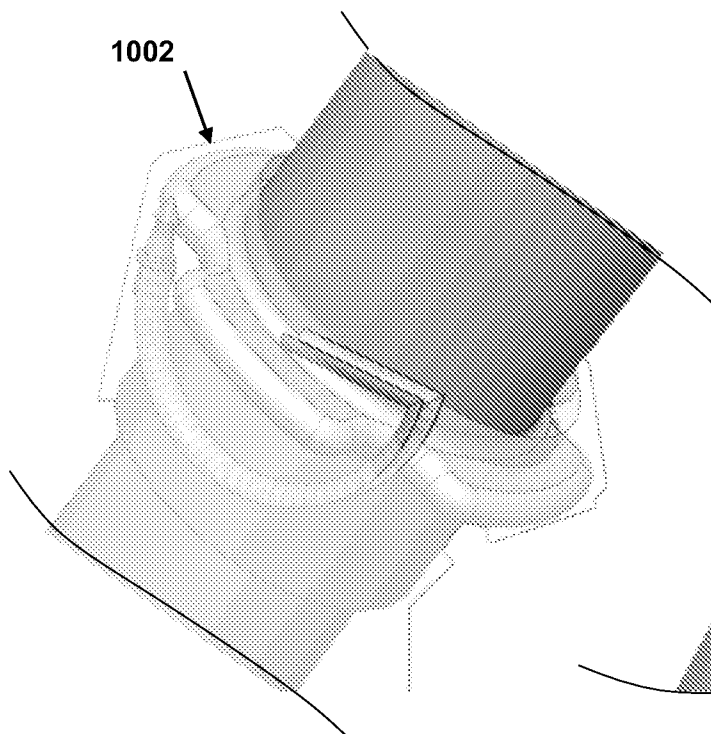


FIG. 10D

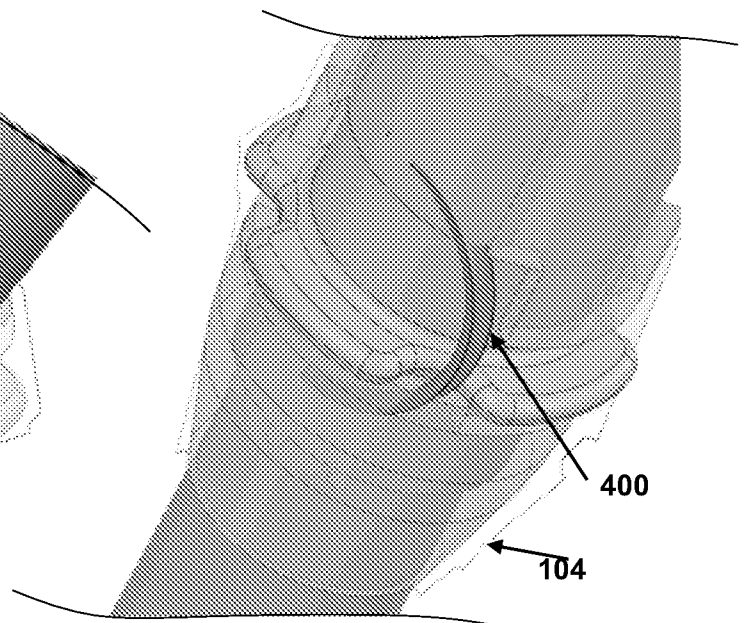


FIG. 10E

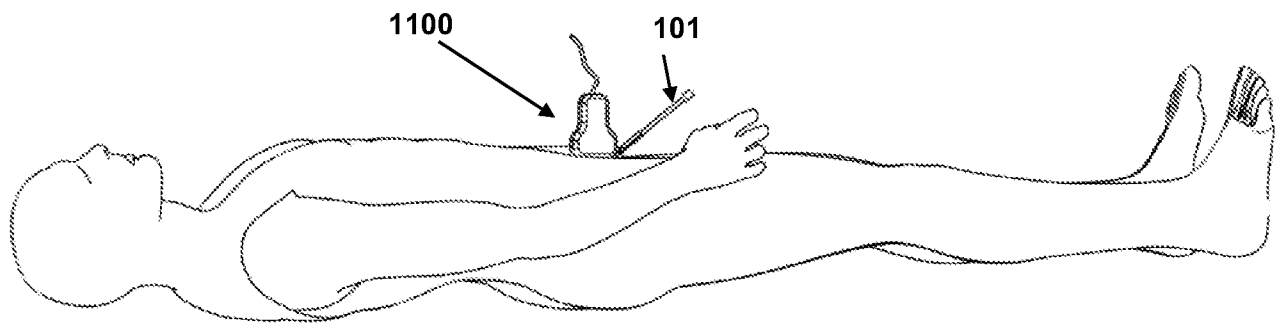


FIG. 11A

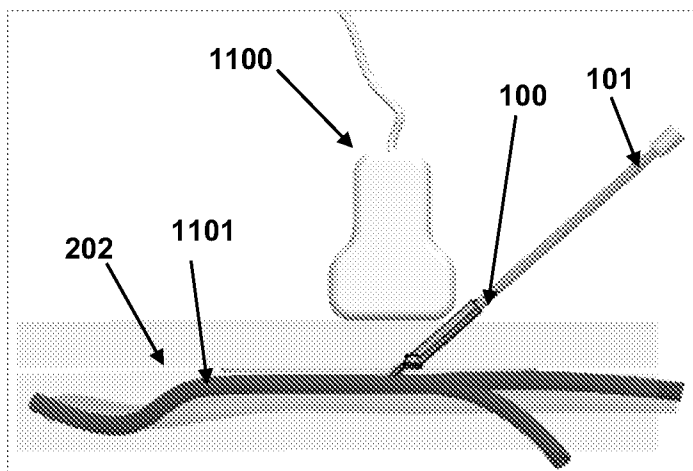


FIG. 11B

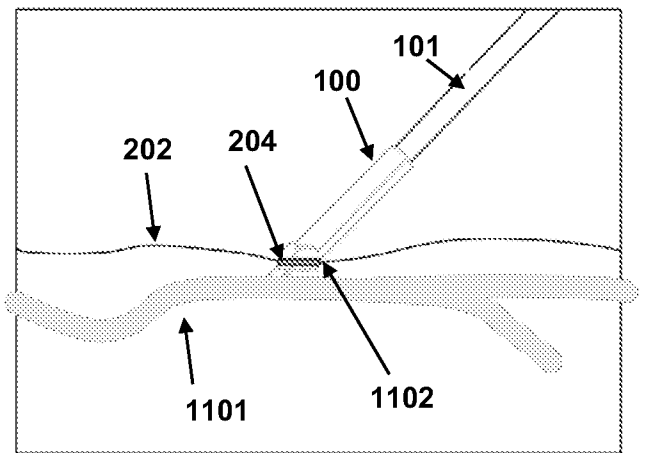


FIG. 11C

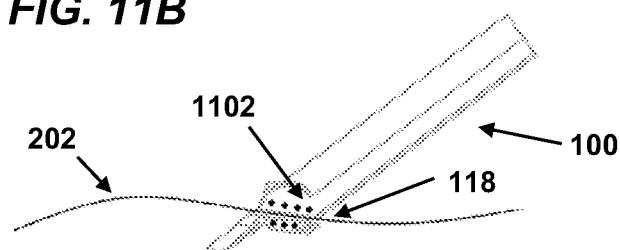


FIG. 11D

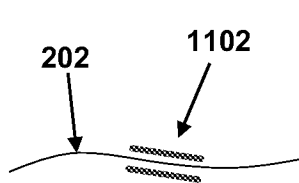


FIG. 11E

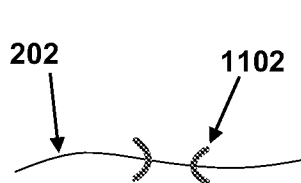


FIG. 11F

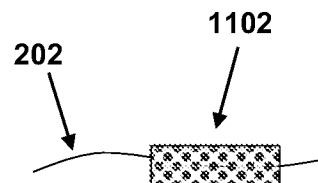


FIG. 11G

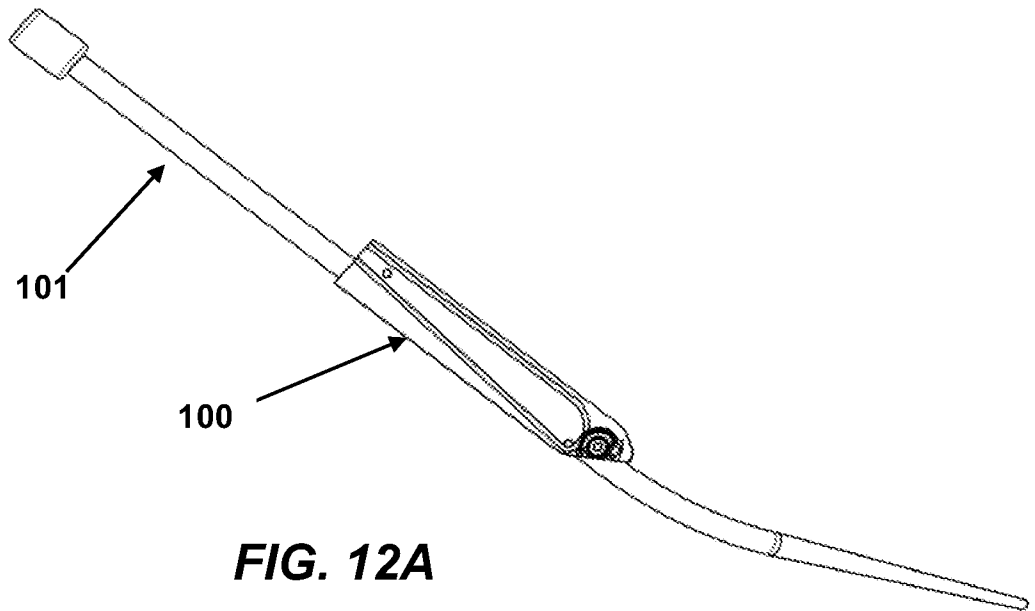


FIG. 12A

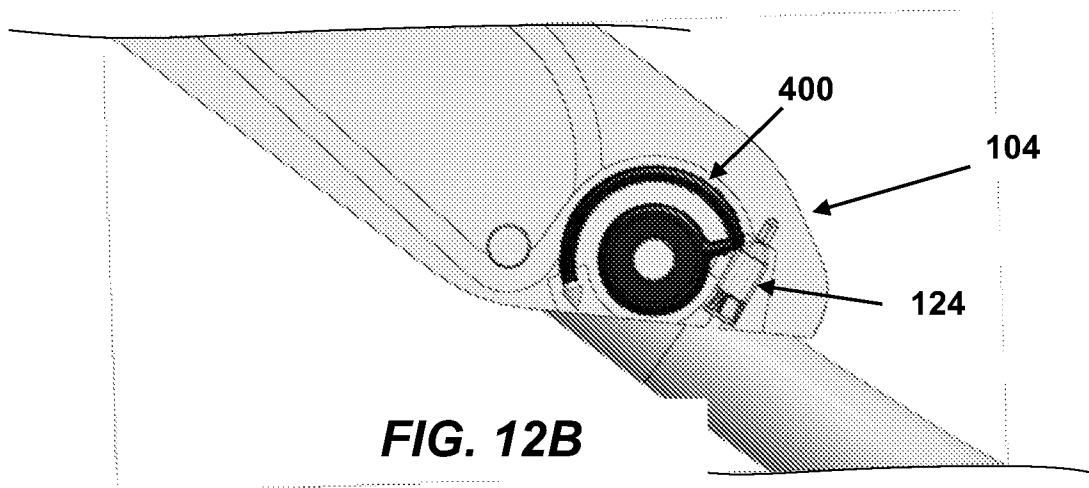


FIG. 12B

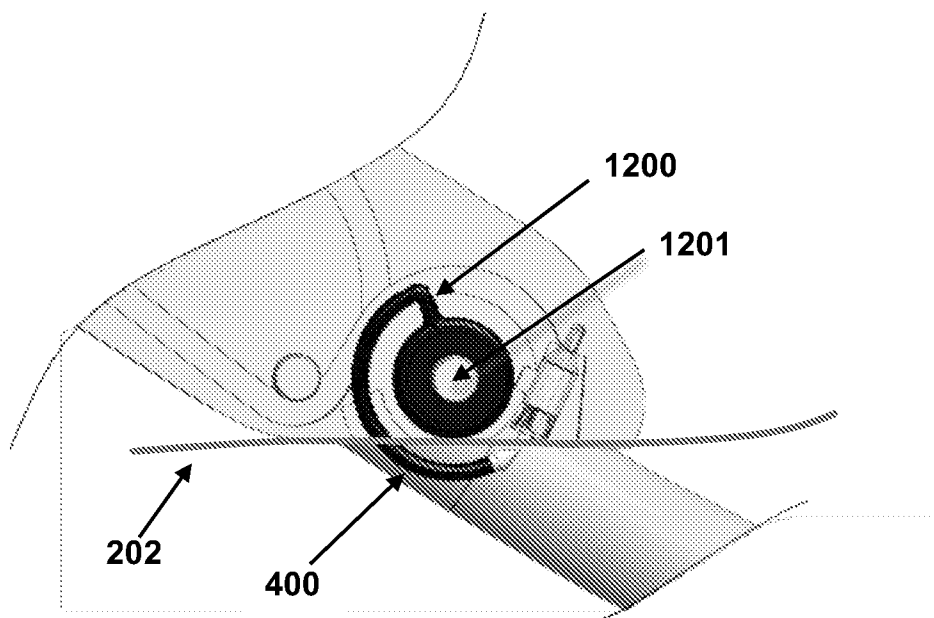


FIG. 12C

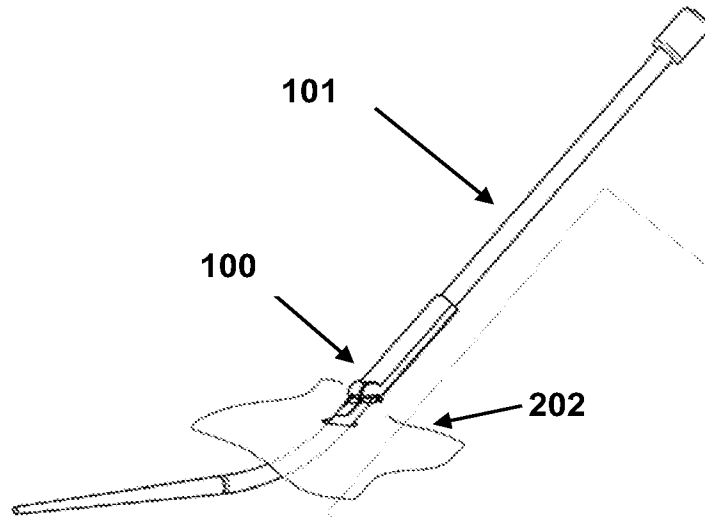


FIG. 13A

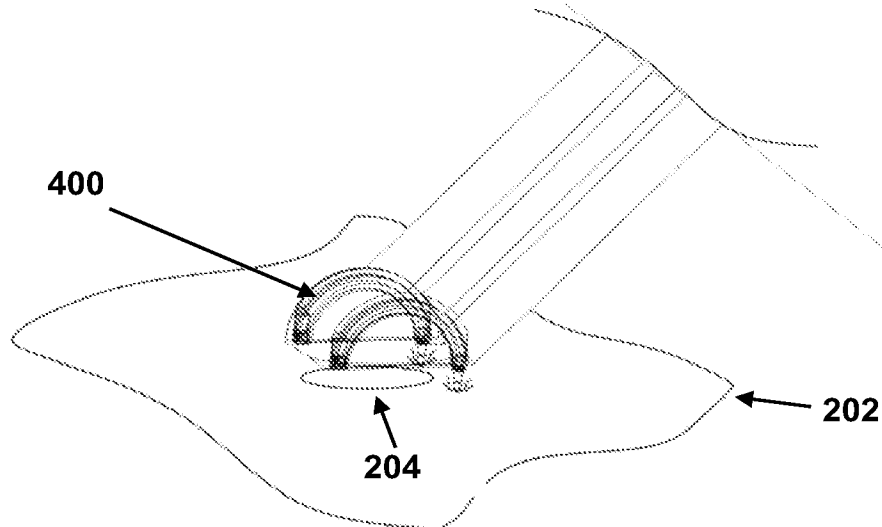


FIG. 13B

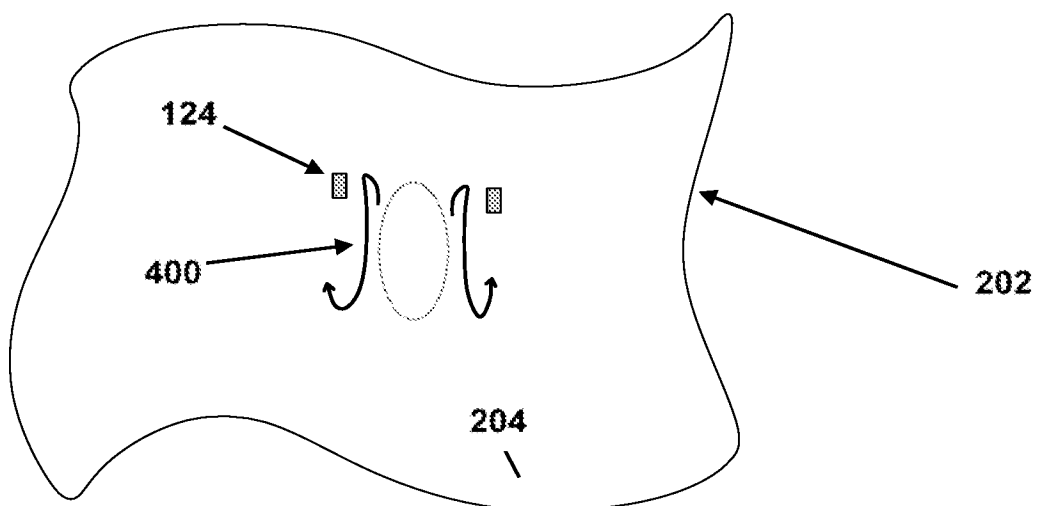


FIG. 13C

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2019/056813

A. CLASSIFICATION OF SUBJECT MATTER		
<i>A61B 17/03 (2006.01)</i> <i>A61B 17/04 (2006.01)</i> <i>A61B 17/062 (2006.01)</i>		
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)		
A61B 17/03, 17/04, 17/062		
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)		
Espacenet, USPTO, PatSearch (RUPTO Internal), CIPO		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/063242 A1 (ERODIUM MEDICAL LTD.) 18.05.2012, claims 1, 14, 23, 158	1
Y	US 2004/0044329 A1 (TRUDELL, LEONARD A.) 04.03.2004, claim 3	1
Y	WO 2008/117276 A1 (KEREN MEDICAL LTD.) 02.10.2008, claim 1	1
Y	CA 2559872 A1 (COAPT SYSTEMS, INC.) 10.11.2005, claim 10	1
A	US 2005/0154402 A1 (LSI SOLUTIONS, INC.) 14.07.2005	1
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents:	“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	
“A” document defining the general state of the art which is not considered to be of particular relevance	“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	
“E” earlier document but published on or after the international filing date	“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	
“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)	“&” document member of the same patent family	
“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		
Date of the actual completion of the international search 10 January 2020 (10.01.2020)	Date of mailing of the international search report 23 January 2020 (23.01.2020)	
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhevskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer A. Isamova Telephone No. (495) 531-64-81	