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(54) **SYSTEM FOR TISSUE CAVITY CLOSURE**

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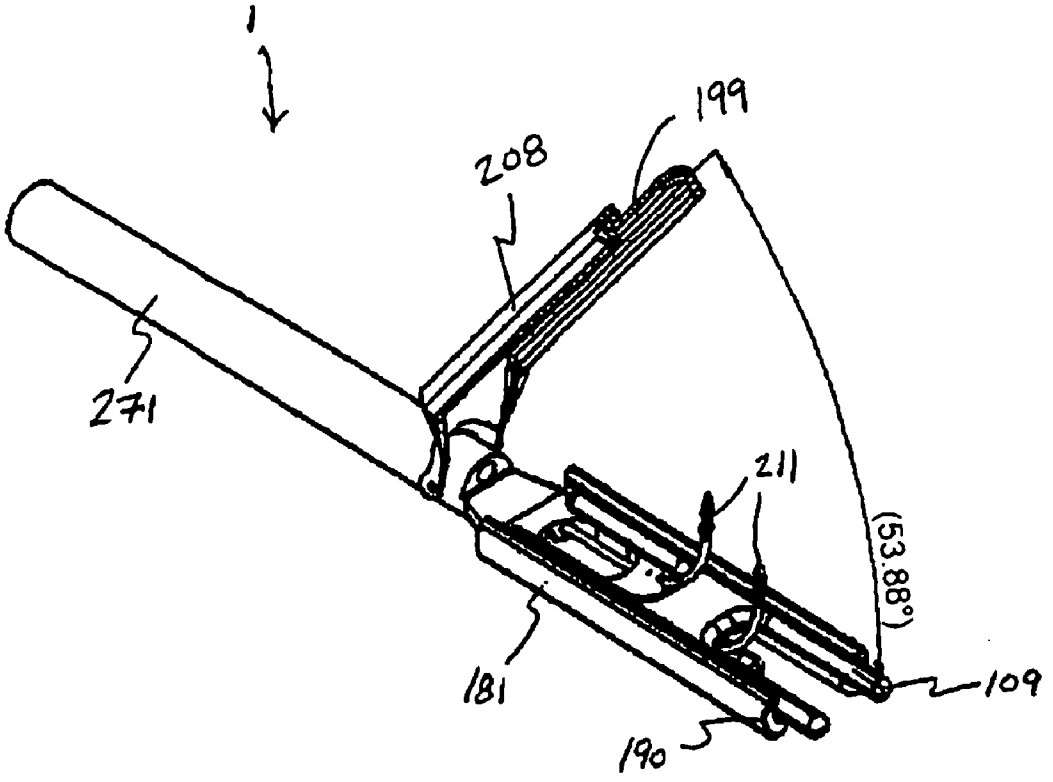
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(57) **ABSTRACT**

Surgical systems for less invasive access to and isolation of an atrial appendage are provided. A suturing grasper compresses soft tissue structures and deploys one or more sutures through complimentary pledget(s) carried by the grasper. The pledgets are reinforced, containing support members that define the profile of the stitch and distribute stresses applied by the stitch, once tightened, over a length of tissue. This hardware may be applicable to other surgical and catheter based applications as well including: compressing soft tissue structures lung resections and volume reductions; gastric procedures associated with reduction in volume, aneurysm repair, vessel ligation, or other procedure involving isolation of, resection of, and reduction of anatomic structures.



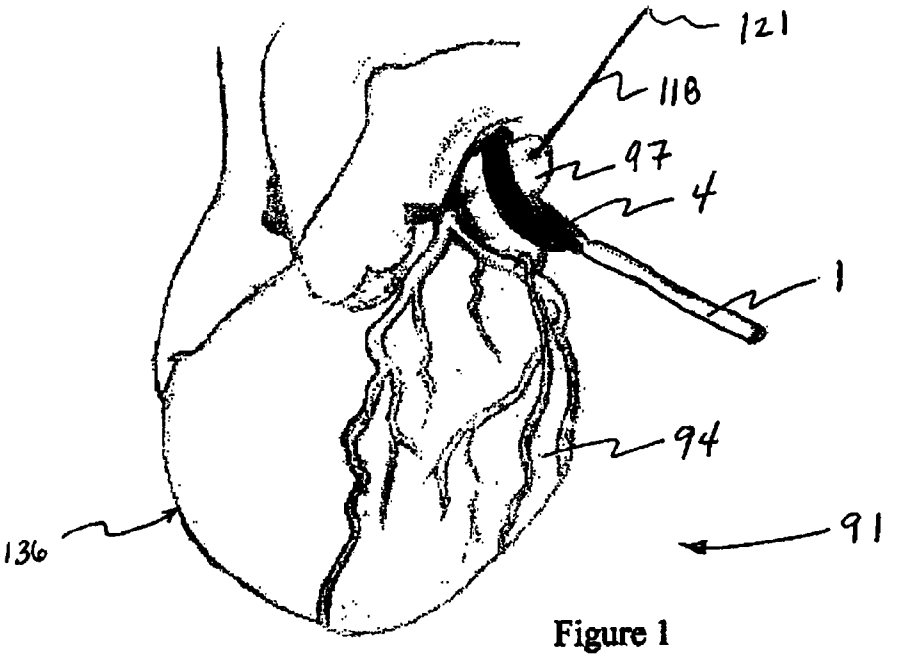


Figure 1

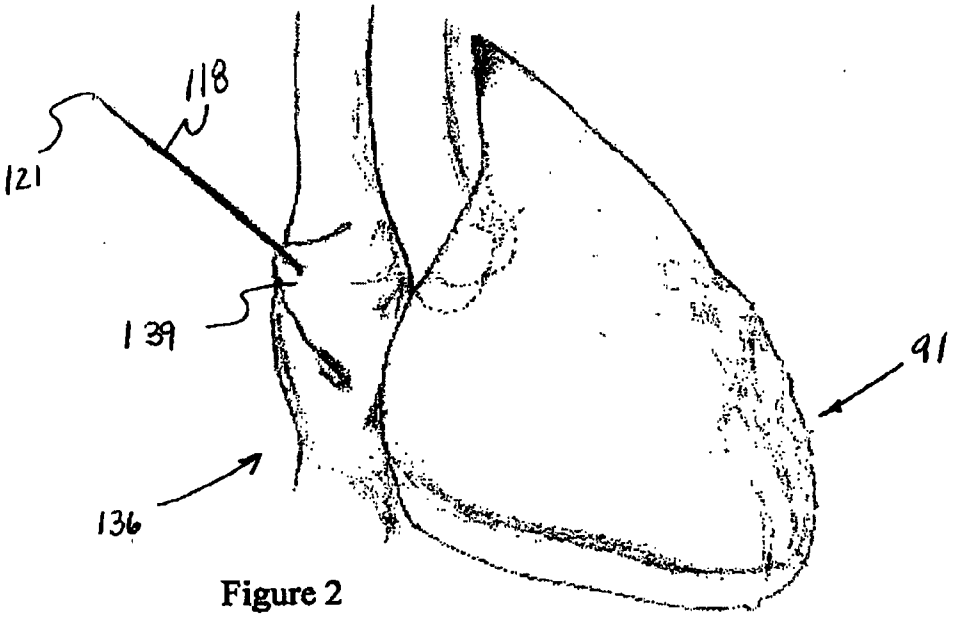


Figure 2

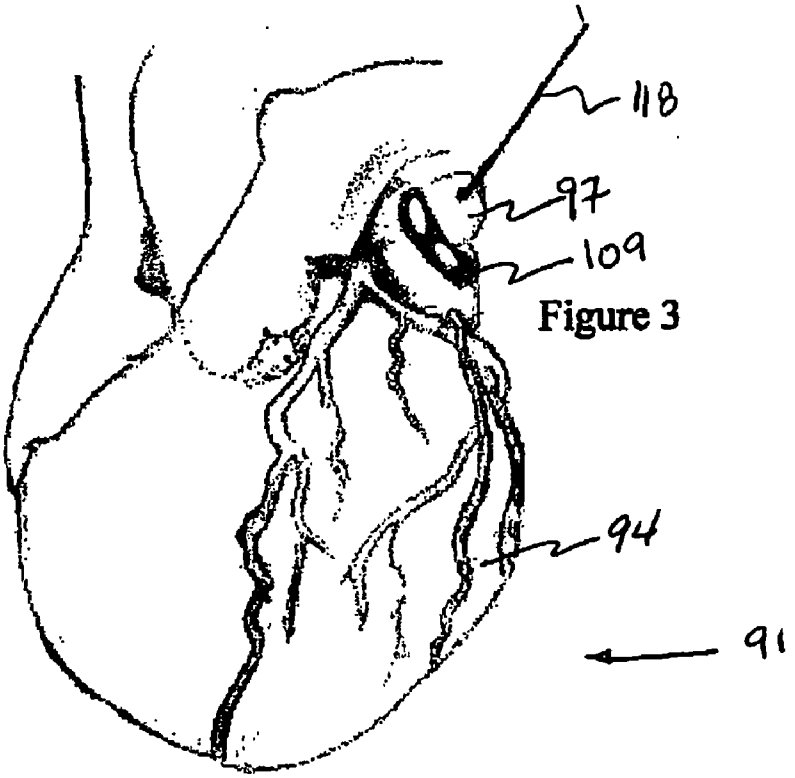


Figure 3

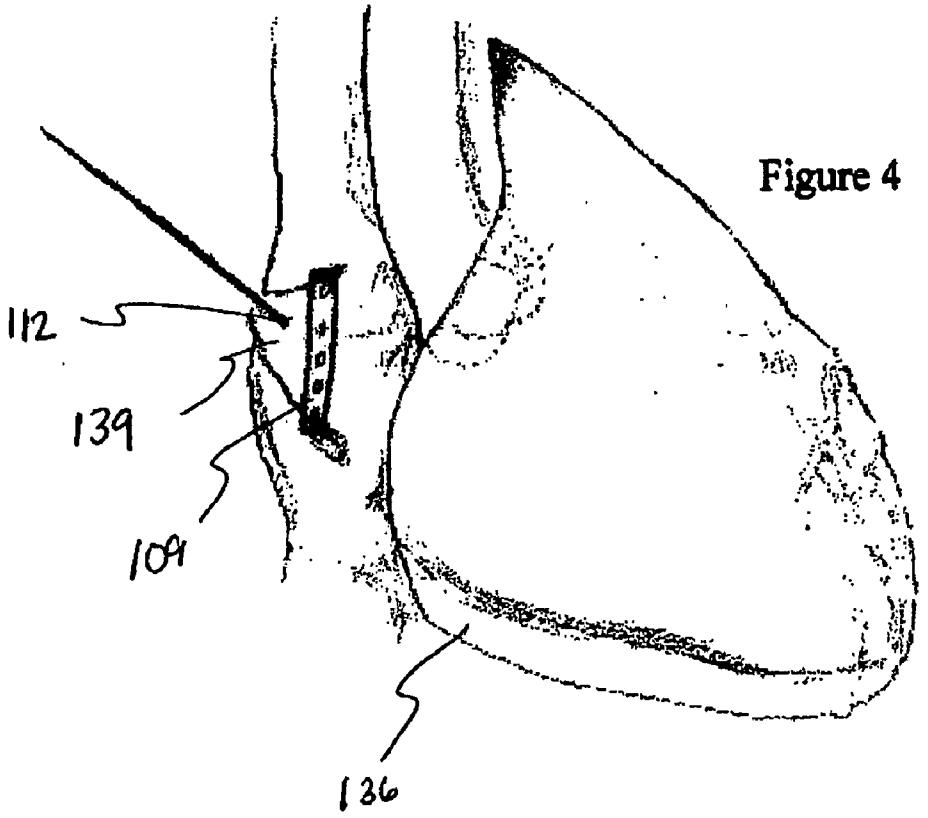


Figure 4

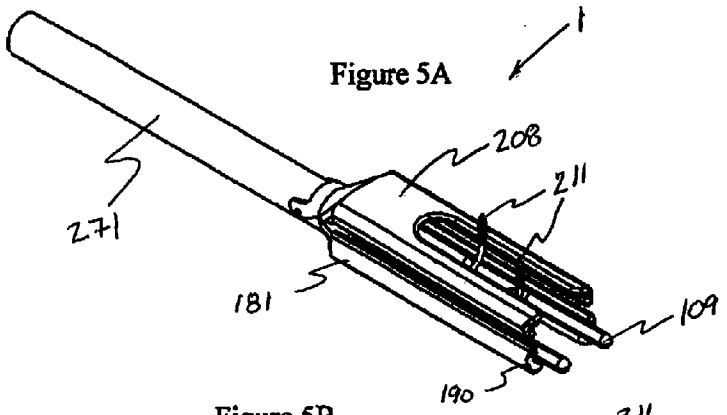


Figure 5A

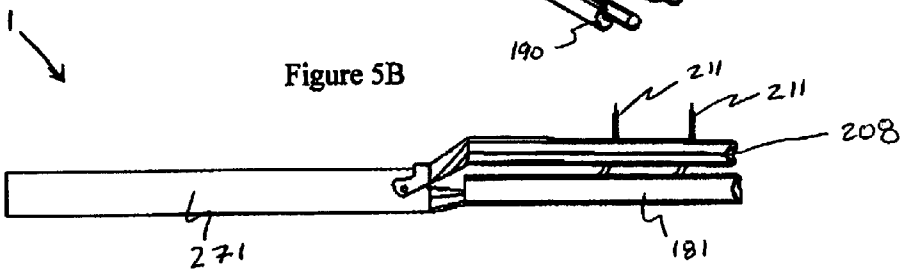


Figure 5B

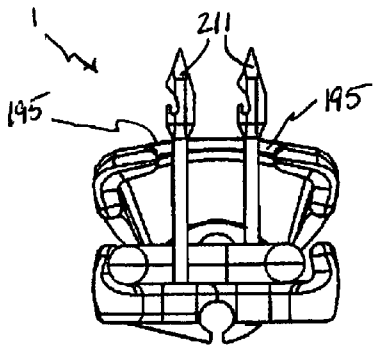


Figure 5C

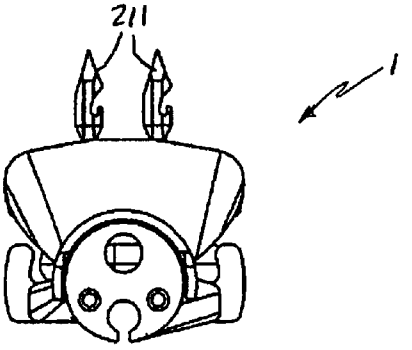


Figure 5D

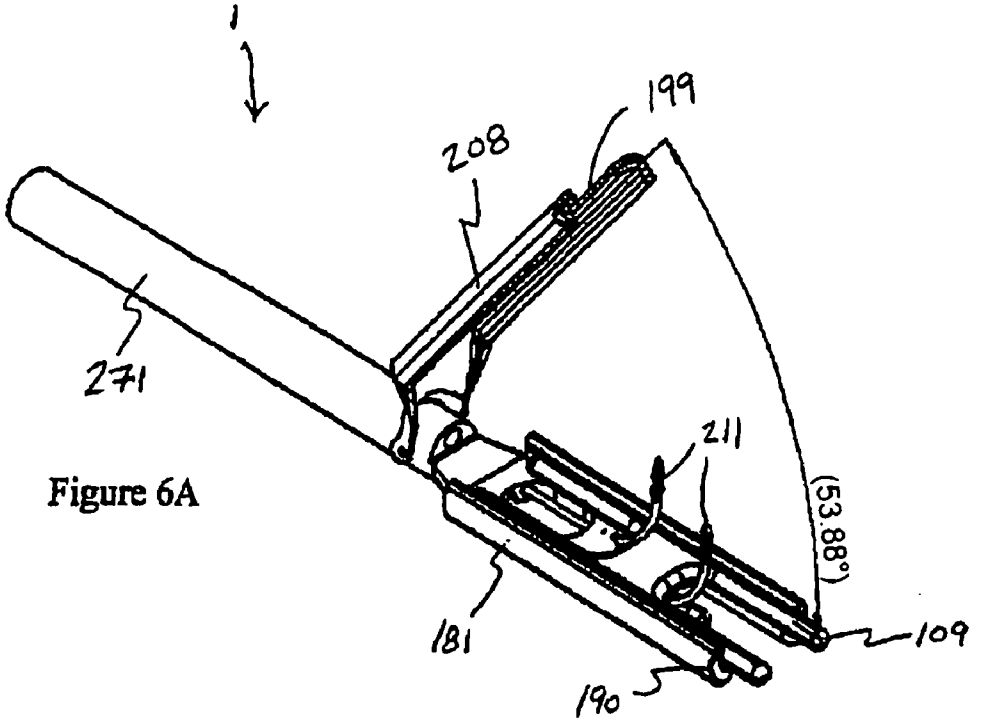


Figure 6A

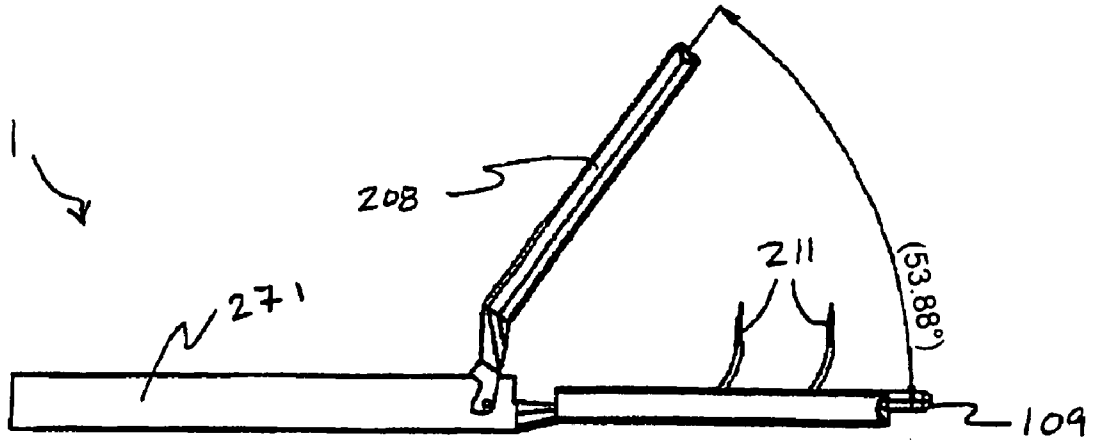


Figure 6B

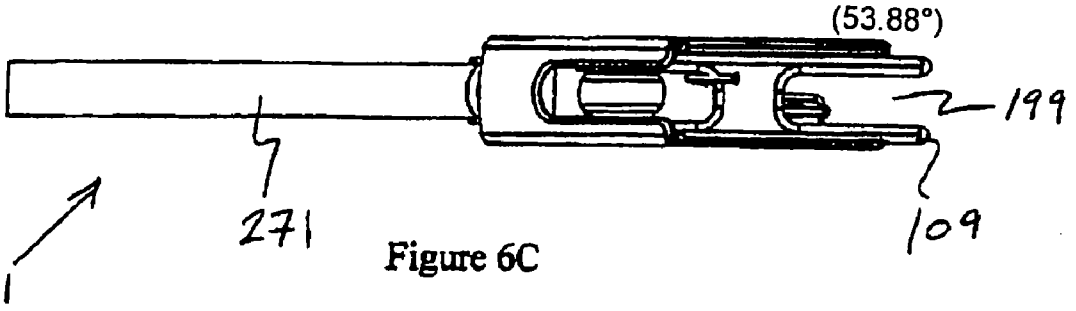


Figure 6C

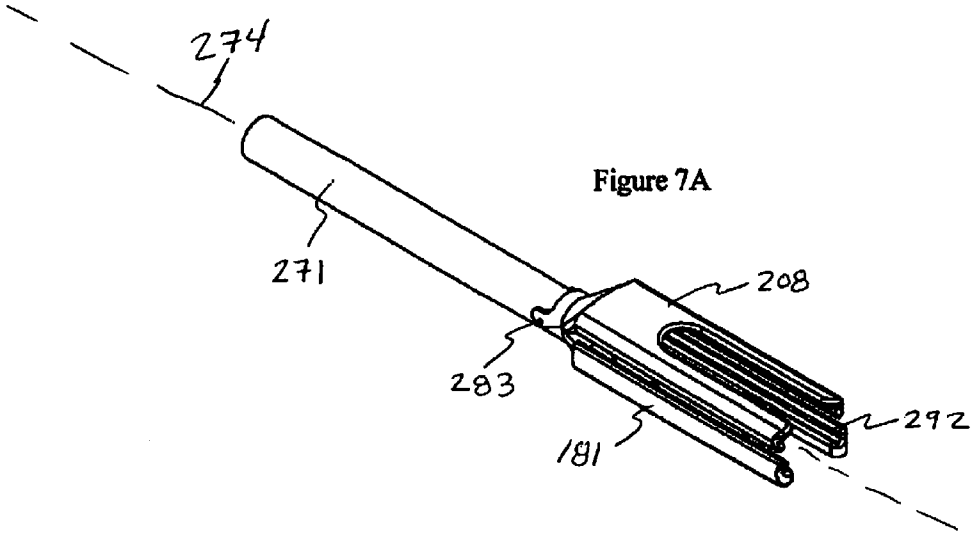


Figure 7A

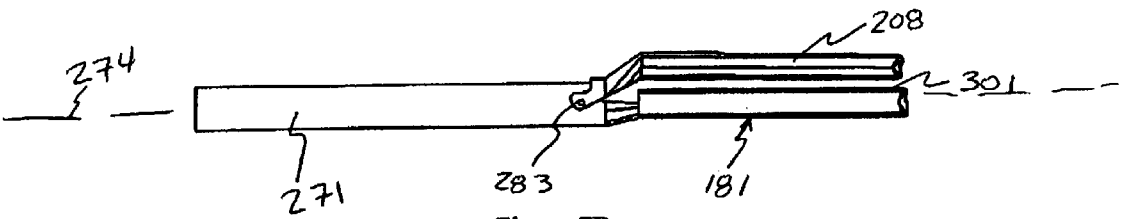


Figure 7B

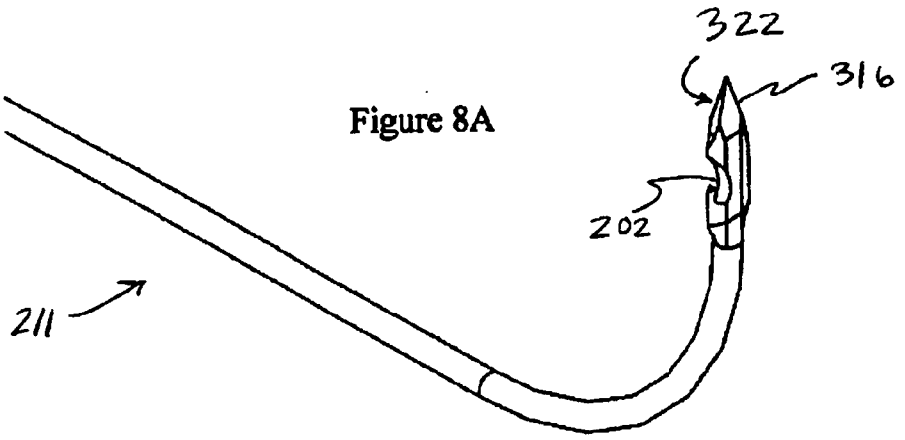


Figure 8A

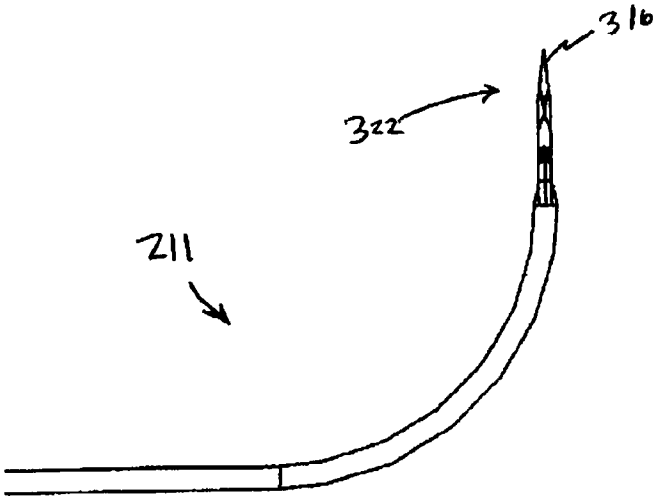


Figure 8B

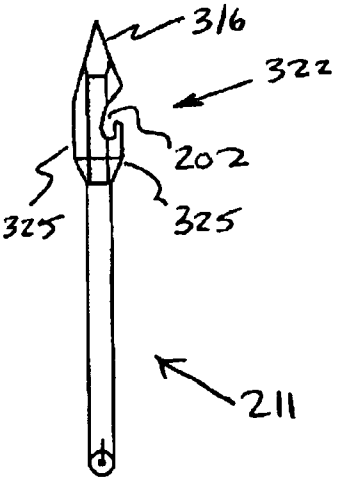


Figure 8C

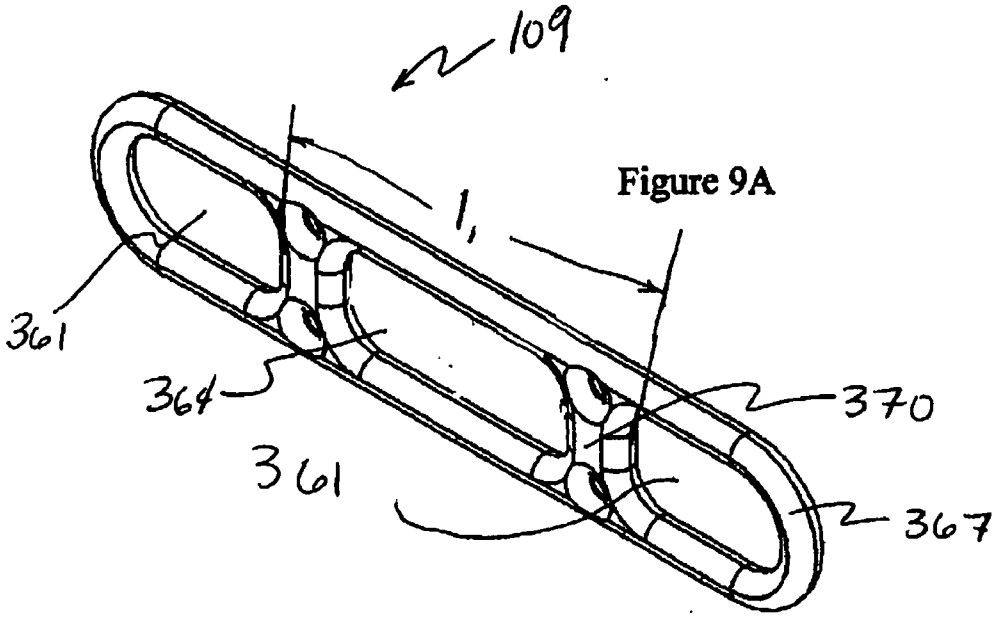


Figure 9A

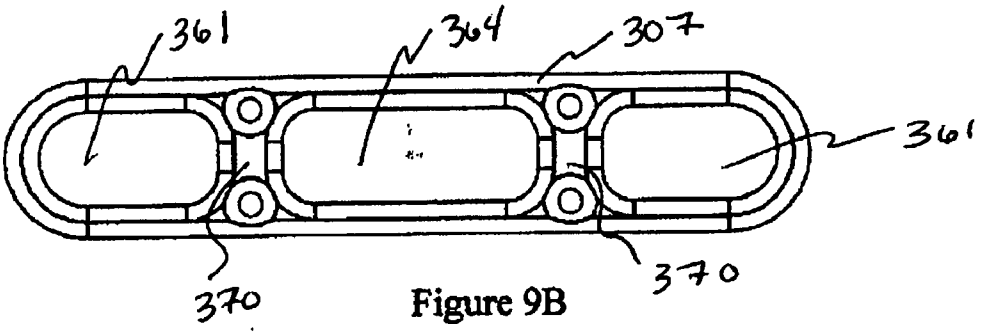


Figure 9B

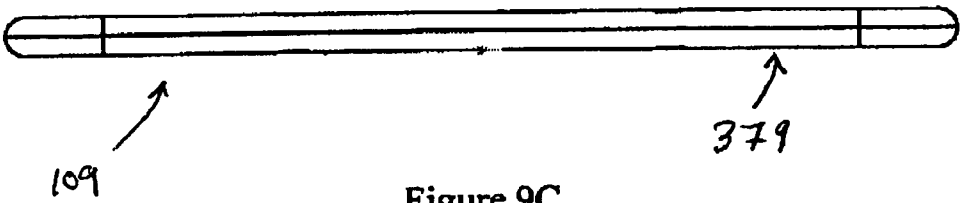


Figure 9C

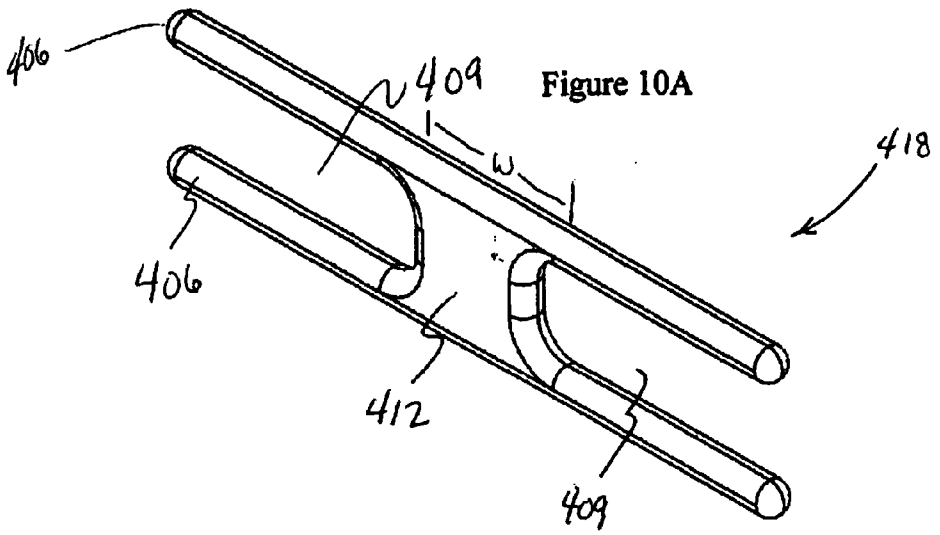


Figure 10A

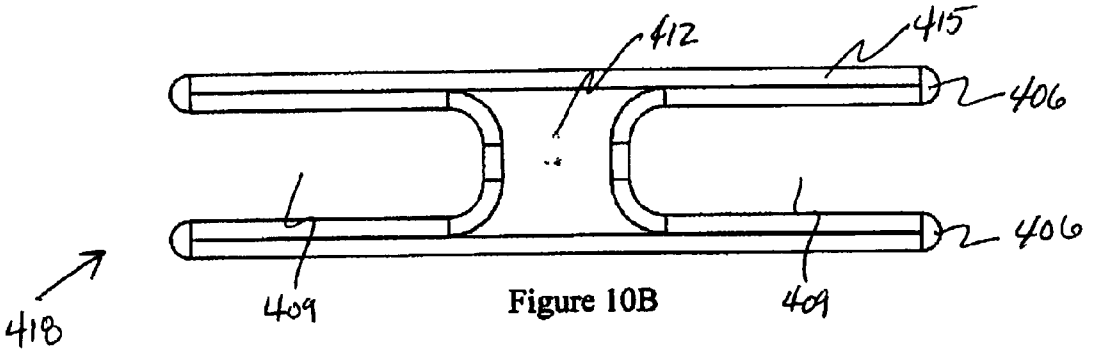


Figure 10B

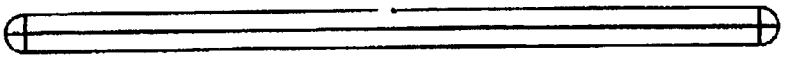


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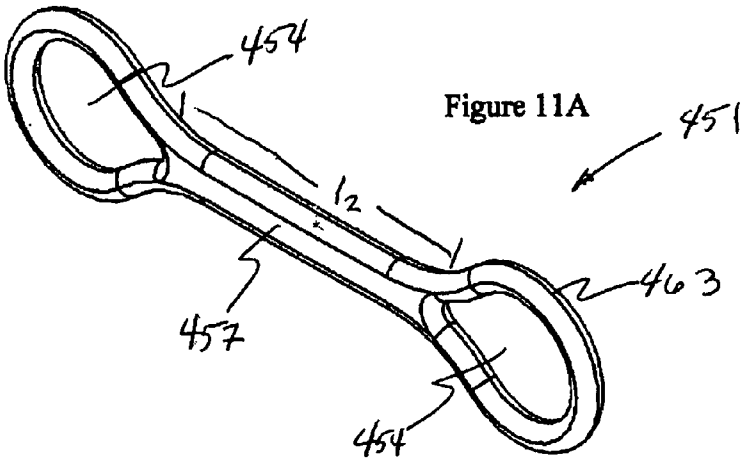


Figure 11A

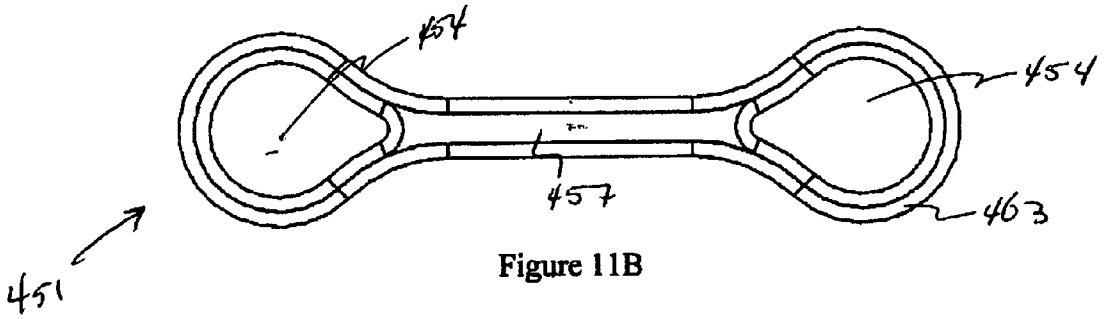


Figure 11B

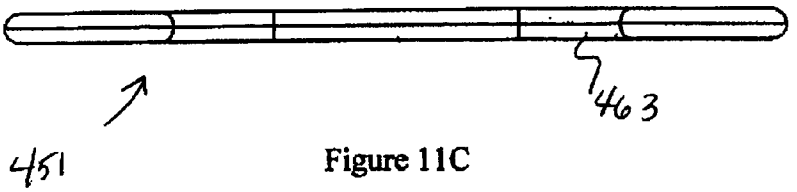


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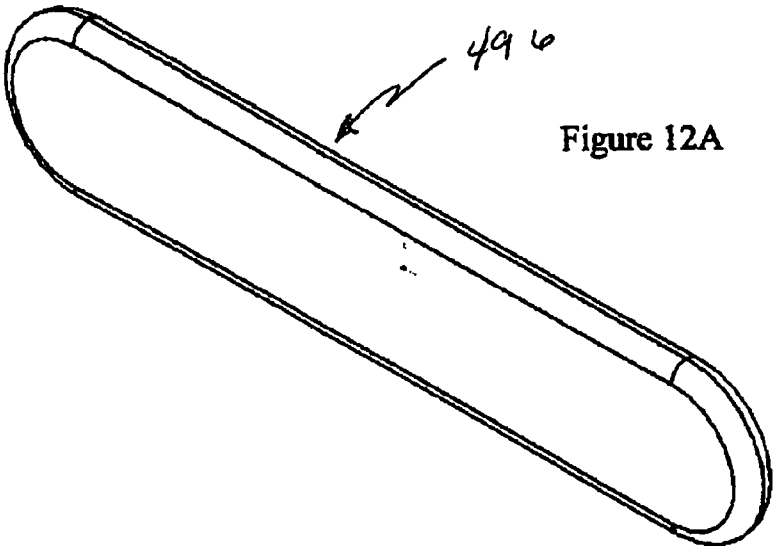


Figure 12A

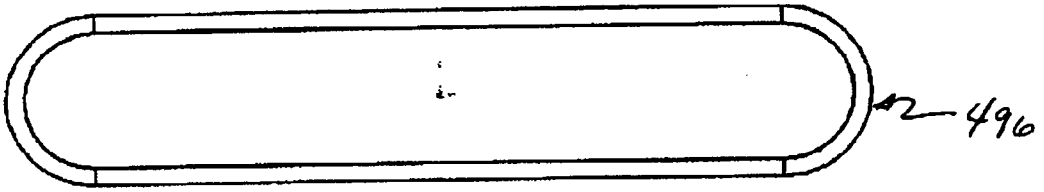


Figure 12B

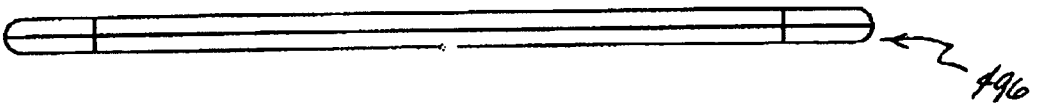


Figure 12C

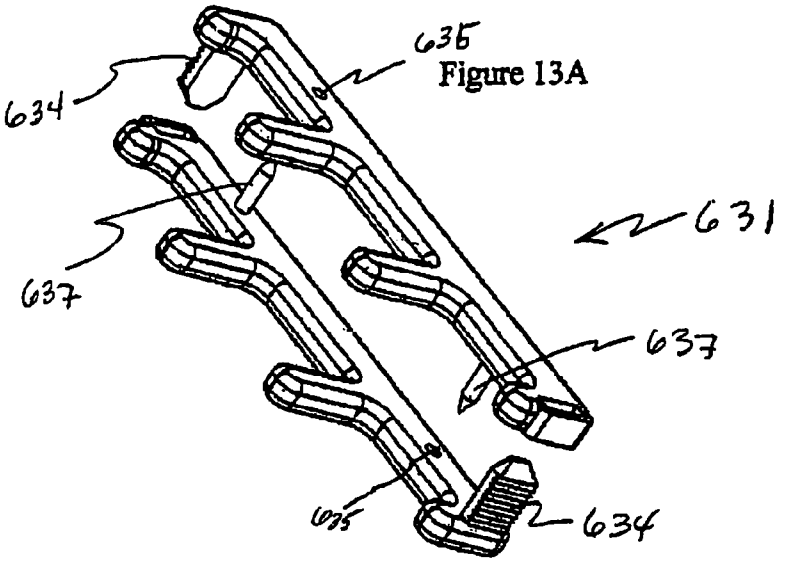


Figure 13A

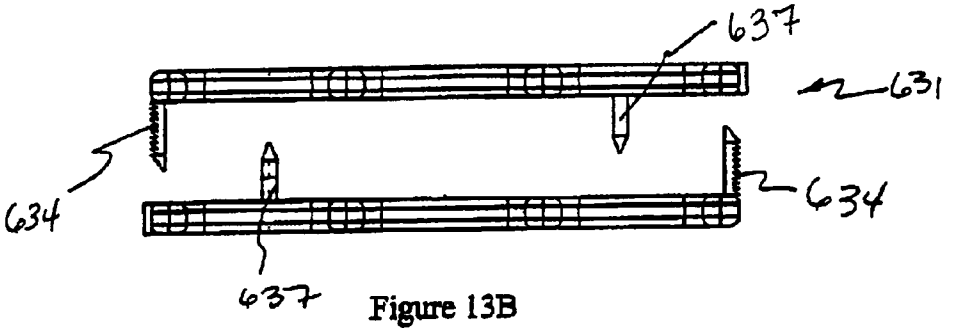


Figure 13B

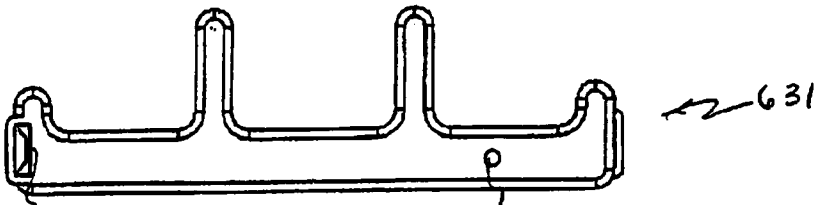


Figure 13C

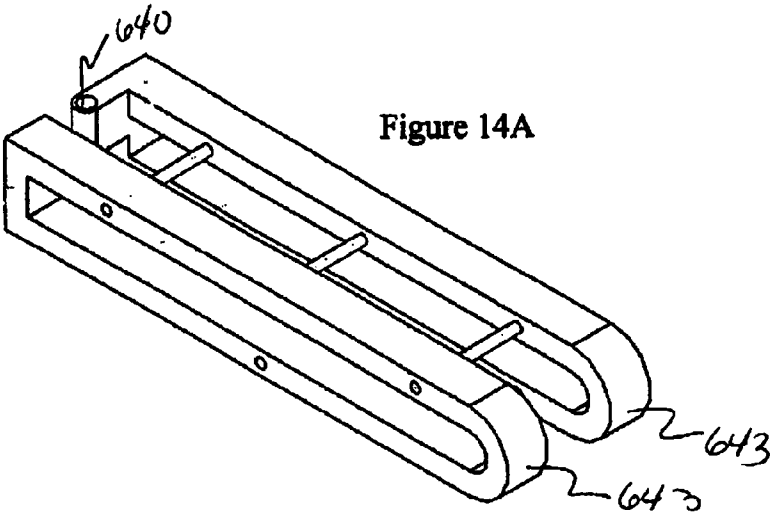


Figure 14A

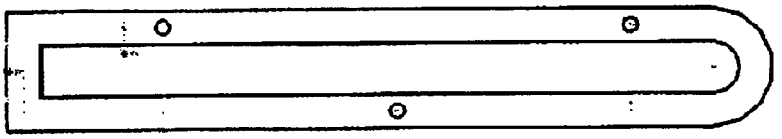


Figure 14B

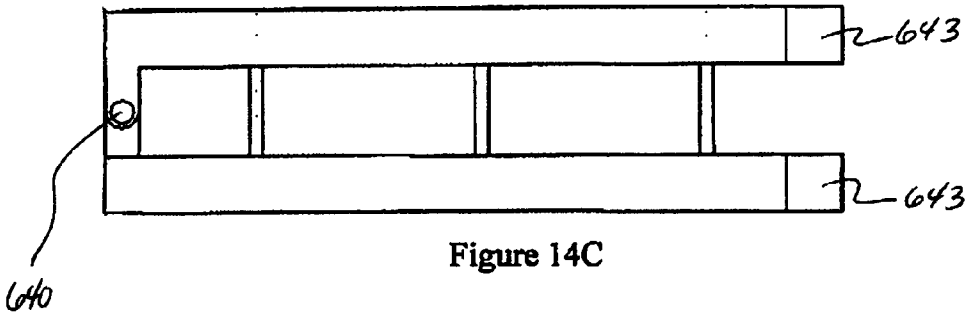


Figure 14C

SYSTEM FOR TISSUE CAVITY CLOSURE

RELATED APPLICATION

[0001] This application is a non-provisional of U.S. Provisional Application No. 60,580,890 filed Jun. 18, 2004, the entirety of which is incorporated by reference.

FIELD OF THE INVENTION

[0002] This invention relates to devices and methods for less invasive treatment of atrial fibrillation or other application involving placing a pledgeted mattress suture stitch(es) to compress opposing tissue or to prevent its expansion.

BACKGROUND OF THE INVENTION

[0003] Surgical atrial fibrillation treatment involves eliminating the electrical propagation wavelets that trigger and sustain atrial fibrillation, and mitigating the risk of stroke by reducing the volume of enlarged the atria through isolation or resection of the atrial appendages. A previous surgical technique for resecting an atrial appendage involves manually advancing a suture, via an attached, curved, fixed needle, through the atrial appendage. This approach is performed under direct visualization during open heart surgery involving a media sternotomy or lateral thoracostomy. To advance the suture through tissue, the surgeon clamps the solid suture needle with a needle driver clamp and rotates the needle via twisting of the needle driver until the needle and attached suture are advanced through the soft tissue. Once the needle punctures through the soft tissue, the surgeon uses a forcep or the needle driver to grab the distal end of the needle and pull the suture through the puncture site. Once tightened, the suture or sutures employed bear down on the opposing tissue walls of the atrial apendage, thereby closing it off or isolating its interior from the remaining blood pool of the heart.

[0004] This technique is adequate when the patient is on cardiopulmonary bypass support and access to the heart is not restricted by the opening into the thoracic cavity, characteristic of a median sternotomy and long lateral thoracotomies. However, during beating heart procedures and minimally invasive access to the heart commonly associated with mini-sternotomies, mini-thoracotomies, port access, and subxiphoid access, such manual surgical techniques require too much time, are accompanied with significant bleeding, and are not able to adequately create the desired suture stitch to completely close the orifice into the atrial appendage.

[0005] Less invasive approaches, surgical and catheter-based have been identified to isolate the atrial appendage by a variety of techniques and methodologies. One such approach, as described in U.S. Pat. No. 5,306,234 entitled "Method for closing an atrial appendage", involves delivering multiple staples through an endoscopic stapler that clamps the atrial appendage and delivers staples between opposite tissue layers to compress the layers together. The stapling approach, however successful, causes abrasion and trauma between the metallic staple and the soft tissue surface. In addition, spacing of the staples determines whether the appendage is completely isolated.

[0006] Catheter-based approaches, such as those described in U.S. Pat. No. 6,730,108 entitled "Barrier device for ostium of left atrial appendage", U.S. Pat. No. 6,689,150 entitled "Filter apparatus for ostium of left atrial appendage", U.S. Pat. No. 6,652,555 entitled "Barrier device for covering the ostium of left atrial appendage", U.S. Pat. No. 6,152,144 entitled "Method and device for left atrial appendage occlusion", U.S. Pat. No. 6,231,561 entitled "Method and apparatus for closing a body lumen", and U.S. Pat. No. 6,419,669 entitled "Method and apparatus for patching a tissue opening", describe patches that are positioned at the opening into the atrial appendage to prevent blood and/or clots residing in the atrial appendage from escaping into the blood pool. These approaches leave foreign material exposed to blood flow which material increases the risk of thromboembolism and increases the possibility that patients undergoing this procedure still require anticoagulation regimen such as Coumadin to prevent clots from forming in the heart. In addition, the risk of dislodgement for such patches is high, whether associated with fracture of the patch attachment means, degradation of the patch materials, mechanical damage to the device during manual compression of the heart (e.g. CPR) or other unexpected mechanical manipulation. Any dislodgement of such patch-type devices is life-threatening.

[0007] Other approaches such as taught by U.S. Pat. No. 5,865,791 entitled, "Atrial appendage stasis reduction procedure and devices", U.S. Pat. No. 6,132,438 entitled, "Devices for installing stasis reducing means in body tissue", describe devices and techniques that place a tie around the atrial appendage and close the opening by tightening the tie into a small diameter loop, or by inserting anchors into tissue separated around the circumference of the opening such that once tightened, the diameter of the opening is decreased until the appendage is isolated from blood flow. These approaches either do not adequately attach the isolation device to the tissue surface or are associated with high stresses at the attachment point, which can lead to tissue abrasion, tearing, or other unwanted tissue response. The latter observation is also true in regard to the simple emplacement of sutures through the opposing atrial appendage walls to close-off the structure, where at the place where the sutures turn they can cut into the tissue.

[0008] U.S. Patent Application Publication No. 2003/0078465 addresses this problem with regard to mattress sutures employed for supporting or reshaping the heart muscle for treatment of congestive heart failure. However, this invention does not teach modes of treatment that are applicable specifically to atrial appendage isolation in terms of placing a pledgeted mattress suture stitch(es) to compress opposing tissue or to prevent its expansion.

[0009] As such there exists a need for the present invention in connection with addressing the various deficiencies of known atrial appendage isolation modes as well as extending the applicability of mattress suture applications as applicable to supporting, closing or reshaping tissue cavity regions such as in reduction or isolation of orifices or anatomic cavities such as lung reductions or resections, gastric reductions, and other soft tissue manipulation procedures. As such, the present invention offers a significant advance in the art.

SUMMARY OF THE INVENTION

[0010] Embodiments of the invention relate to devices and methods for less invasive treatment of atrial fibrillation or

other application involving placing a pledgeted mattress suture stitch to compress opposing tissue together or prevent tissue expansion. More particularly, certain embodiments of the invention relate to appendage isolation suturing devices that enable reducing the volume of the atria, or isolating the atrial appendage to prevent clots from forming in the cavity and dislodging into an embolus capable of causing a thromboembolic event (e.g. stroke, myocardial infarction, pulmonary embolus, peripheral embolus). Furthermore the invention offers a means of improving hemodynamics during atrial fibrillation treatment procedures by virtue of its efficient operation avoidance of a requirement for bypass support.

[0011] Aspects of the invention also enable appendage isolation procedures to be performed less invasively through limited incisions that previously required large, open incisions with inherent morbidity and risks to other anatomic structures. The appendage isolation suture devices according to the present invetion are capable of altering the geometry of an atrial appendage (or other soft tissue structure), via a median sternotomy, lateral thoracotomy, intercostals port-access, mini-sternotomy, other less invasive approaches involving subxiphoid access, inguinal approaches, or subthoracic approaches adjacent the diaphram. It should be noted that, thought the disclosure makes reference to sutures, the devices herein may be affixed with other fastening devices and/or fastening means. Such devices and/or means being readily understood by those skilled in the art. Alternatively, the appendage isolation suturing devices according to the present invention can be modified for catheter-based applications by reconfiguring the device, and incorporating other feature tailored for intravascular access. As such, the inventive devices and methods may enable patients to undergo therapeutic surgical procedures while enduring less pain, expedited hospital stays, and shorter rehabilitative and recovery times.

[0012] To facilitate such activity, surgical systems according to the present invention are used to create a reinforced stitch that distributes forces along a length of compressed soft tissue surfaces. The surgical systems comprise a suturing grasper that compresses soft tissue structures and deploys suture through reinforced pledgets, housed by the grasper, and the soft tissue. The reinforced pledgets contain support members that define the profile of the stitch and distribute stresses applied by the tightened stitch over a length of tissue, as opposed to conventional suture knots and non-reinforced pledgeted suture knots that apply high stresses to localized puncture sites.

[0013] In the present invention, methods and devices are provided in which one or more deformable or resilient needles, and suture (one, two, or multiple strands) are passed through the atrial appendage (or other tissue) during a less invasive procedures. It should also be noted that the needles described herein may be standard needles that are attached to sutures. Furthermore, the invention contemplates sutures having stiffened ends which effectively function as needles. To accomplish this, the subject devices advance or retract needles (deformable or superelastic) such that they can be compressed into small lumens incorporated in a grasper having a small cross-sectional profile to facilitate utility during less invasive access procedures. Use of the needles enable advancing or retracting suture material through the atrial appendage and creating pledgeted stitches that distribute the stresses exerted by the stitch against the treated soft tissue.

[0014] In forming these subject product structures, one or more suture strands is advanced (sequentially or simultaneously) through the atrial appendage at a single location or multiple strategically distributed locations. The reinfoced pledgets employed direct the compression of the treated anatomical structure to distribute the stresses applied by the stitches along a larger tissue surface. As such, the embodiments of the invention provide isolation devices capable of creating pledgeted stitches that increase reliability of the stitch, distribute the applied forces over a much greater length of soft tissue, and—in the case of performing an atrial appendage isolation procedure—ensure consistent closure of the appendage orifice. Embodiments of the invention also enable contacting and penetrating the atrial appendage, for creating pledgeted stitches capable of isolating the atrial appendage (or closing any other anatomic cavity), during less invasive access to anatomic regions where exposure is compromised by the confined space or difficult to reach anatomic surface.

[0015] When using superelastic needles in the subject (e.g., appendage isolation) devices, the needles are deflected into a straightened, low profile when compressed into a tubular constraint and return towards their preformed, resting, curved shape upon removal of the compressive forces. Alternatively, the needles are fabricated of malleable material such that they can be deformed from the straight, low profile configuration (for passing through a confining tube) into a curved or bent configuration by forcing the needle against a curved guide member incorporated in the appendage isolation device.

[0016] Nevertheless, it should be appreciated that the devices described herein can be applicable for use in other indications involving devices that are used to create a reinforced pledgeted stitch through soft tissue where access to the tissue is limited by a small opening into the cavity, confined space at the soft tissue interface, difficult to reach locations, or other anatomic limitation. The embodiments of the invention can be configured for the human anatomy; however, it should be noted that the embodiments of the invention can, in some cases, be tailored to other species, such as horses, by changing the geometry and sizes of the structures. Features of the invention also enable creating reinforced pledgeted stitches through the stomach for gastric reduction procedures, and through the lung lobes for lung reduction or resection procedures.

[0017] In sum, the present invention includes systems comprising any of the features described herein. Methodology, especially in connection with atrial appendage isolation also forms part of the invention. Further details associated with such a procedure are provided below. The invention is, however, directed towards or applicable to compressing soft tissue structures for a variety of applications including lung resections and volume reductions; gastric procedures associated with reduction in volume, aneurysm repair, vessel ligation, or other procedure involving isolation of, resection of, and reduction of anatomic structures. In regard to such procedures, those with skill in the art will easily appreciate the applicability of the present invention as well as grasp such details as omitted herefrom that are applicable in practicing the subject procedures.

[0018] Methods related to the present invention are discussed in METHODS AND SYSTEMS FOR TISSUE CAVITY CLOSURE filed Jun. 17, 2005 (Attorney Docket No. ABLX-004), the entirety of which is incorporated by reference herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Each of the figures diagrammatically illustrates aspects of the invention. Of these:

[0020] **FIG. 1** shows a side view of a heart with the left atrial appendage engaged with the appendage isolation grasper embodiment of the invention;

[0021] **FIG. 2** shows a side view of a heart with the right atrial appendage pulled away from the right atrium;

[0022] **FIG. 3** shows a side view of a heart with the left atrial appendage isolated from blood flow by the appendage isolation pledgeted stitch embodiment of the invention;

[0023] **FIG. 4** shows a side view of a heart with the right atrial appendage isolated from blood flow by the appendage isolation pledgeted stitch embodiment of the invention;

[0024] **FIGS. 5A** to **5**D show a perspective view, a side view, and two end views of an appendage isolation grasper and associated pledget embodiment of the invention;

[0025] **FIGS. 6A** to **6**C show a perspective view, a side view, and a top view of the appendage isolation grasper and associated pledget embodiment with the upper jaw in an opened orientation;

[0026] **FIGS. 7A** and B show a perspective view and a side view of the appendage isolation grasper embodiment with the upper jaw in a closed orientation;

[0027] **FIGS. 8A** to **8**C show a perspective view, a side view, and an end view of the suture passer component of the appendage isolation grasper embodiment in a deployed orientation;

[0028] **FIGS. 9A** to **9**C show a perspective view, a top view, and a side view of a reinforced pledget embodiment that contains a support structure to distribute the stresses exerted by the stitch;

[0029] **FIGS. 10A** to **10**C show a perspective view, a top view, and a side view of an alternative reinforced pledget embodiment;

[0030] **FIGS. 11A** to **11**C show a perspective view, a top view, and a side view of another reinforced pledget embodiment;

[0031] **FIGS. 12A** to **12**C show a perspective view, a top view, and a side view of another reinforced pledget embodiment;

[0032] **FIGS. 13A** to **13**C show a perspective view, a top view, and a side view of a penetrating atrial appendage isolation clip embodiment; and

[0033] **FIGS. 14A** to **14**C show a perspective view, a top view, and a side view of another penetrating atrial appendage isolation clip embodiment.

[0034] Variation of the invention from that shown in the figures is contemplated. The figures and following detailed description are provided merely for illustrative purposes of selected non-limiting examples of the present invention. This subject matter is not to be taken in a limiting sense, but is made merely for the purpose of explaining certain general principles of the inventions.

DETAILED DESCRIPTION

[0035] The following description focuses on the atrial appendage isolation aspect of the present invention. In this regard, a description of the subject methodology is first presented, then additional constructional details regarding a system adapted to accomplish the subject procedure. Finally, component materials and processing as may be used to achieve the desired component performance are disclosed.

[0036] All existing subject matter mentioned herein (e.g., publications, patents, patent applications and hardware) is incorporated by reference herein in its entirety except insofar as the subject matter may conflict with that of the present invention (in which case what is present herein shall prevail). The referenced items are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such material by virtue of prior invention.

[0037] Terms such as proximal, distal, near and far, are given meaning relative to the point of the operator. For example, the distal/far descriptions connote structures or portions of the device that are farther from the operator of the device. While, the proximal/near descriptions connote structures or portions of the device that are closer to the operator of the device.

Appendage Isolation Procedure

[0038] During less invasive procedures a trocar or introducer is inserted into the thoracic cavity. Access can be attained through an intercostal incision during a mini-thoracotomy or thoracostomy, a sub-xiphoid puncture, a mini-sternotomy incision, or other method to create an opening into the thoracic cavity. The pericardium is then opened by creating an initial incision into the pericardium and opening the incision to expose a heart **91**, and primarily a left atrial appendage **97**. When the right atrial appendage is targeted, the pericardium incision will be lengthened to expose a right atrial appendage **139**.

[0039] As shown in **FIG. 1**, an appendage isolation grasper I is used to clamp a section of left atrial appendage **97** and bring the opposing atrial walls together. Alternatively, as shown in **FIG. 2**, right atrial appendage **139** can be targeted. A clamp **4** is positioned near the orifice of the atrial appendage (right or left) to ensure the maximum reduction in volume of the atrium (right **136** or left **94**) and the isolation of the trabeculated, enlarged appendage without compromising apposition of the valve leaflets (tricuspid or mitral). As will be discussed below, appendage isolation device **1** houses a first reinforced pledget **109** on the lower jaw and a second reinforced pledget on a upper jaw **208** such that once needles **211** are actuated, deployed suture strand free end(s) **121** are passed through the first reinforced pledget, juxtaposed atrial appendage walls, and the second reinforced pledget. This ensures that, once tied, the stresses placed on the atrial appendage are distributed over a length of soft tissue, as opposed to conventional approaches where point forces are applied at suture penetration sites. Prior to

a tying pledgeted stitch **112**, the suture strand free ends can be brought outside a cannulae or introducer, and the suture strands are tied into a knot. Alternatively, a locking member can be advanced over the suture strand free ends to tighten a knot and prevent slipping of tightened suture strands **118**. Multiple suture strands can be utilized during a single reinforced pledgeted stitch and can be interconnected or otherwise aligned to increase the tensile strength of the stitch.

[**0040**] **FIG. 3** shows a side view of heart **91** that contains pledgeted stitch **109** isolating left atrial appendage **97** by juxtaposing opposing endocardial walls of left atrium **94** between two reinforced pledgets **109** such that clots within and the trabeculated interior surface of the left atrial appendage is separated from blood flow. In addition, left atrial volume is significantly reduced. Each suture strand **118** extends from outside the first reinforced pledget where continuous length of strand **115** defines an anchor, through an opening or puncture site in the first reinforced pledget, through the juxtaposed atrial walls, through an opening or puncture site in the second reinforced pledget, and outside the second reinforced pledget where suture strand free ends are tied into a knot or otherwise anchored to prevent relaxation of tightened stitch **112**. Once the stitch is tightened, the reinforced pledgets are positioned intimately against the epicardial surfaces of the left atrial appendage and define the cross-sectional shape of the compressed atrial appendage. In embodiment **109** shown in **FIG. 3**, the reinforced pledgets are planar such that a flattened profile of the atrial appendage is maintained. This profile distributes the stresses applied to the soft tissue of the atrial appendage over the entire length of the reinforced pledget stitch. Alternatively, the reinforced pledget can incorporate a curved side section (e.g. profile).

[**0041**] **FIG. 4** shows a side view of heart I that contains pledgeted stitch **112** isolating the right atrial appendage **139** by juxtaposing opposing endocardial walls of a right atrium **136** between two reinforced pledgets **109** positioned against the epicardial surfaces of the right atrium. As with isolating left atrial appendage **97**, the reinforced pledgeted stitch comprises at least one suture strand **118** extending from outside the first reinforced pledget where the continuous length of strand defines an anchor, through an opening or puncture site in the first reinforced pledget, through the juxtaposed atrial walls, through an opening or puncture site in the second reinforced pledget, and outside the second reinforced pledget where suture strand free ends are tied into a knot or otherwise anchored to prevent relaxation of the tightened stitch.

Appendage Isolation System

[**0042**] In embodiment **1** in **FIGS. 5A** to **5**D and **FIGS. 6A** to **6**C, appendage isolation grasper **1** is shown with single reinforced pledget **109** housed in lower jaw **181** (upper jaw **208** does not show a reinforced pledget purely for illustration purposes; in practice the upper jaw may or may not contain a reinforced pledget, depending on the application), and two resilient (or deformable) needles **211**. **FIGS. 5A** to **5**D show the grasper with the jaws in a closed orientation and with two resilient (or deformable) needles fully deployed. **FIGS. 6A** to **6**C show the grasper with the upper jaw in an open orientation.

[**0043**] Appendage isolation grasper **1** incorporates two lumens into which the needles are compressed into a low profile for insertion through trocar, cannulae, or introducer. Lower jaw **181** incorporates two separate channels **190** associated with confining lumens and containing exit points **195** through which needles **211** pass. The lower jaw channels are curved to guide/direct the needles upward through reinforcing pledget **109** housed by the lower jaw, past clamped soft tissue structures, through the second reinforcing pledget (not shown) housed by the upper jaw, and beyond the upper jaw from where free ends **121** can be tied into a knot or anchored in a tightened configuration. The exit points are separated by an axial distance, Xsep, and a lateral distance Ysep that are specified according to the application, mechanical requirements of the grasper, and properties of the anatomy. At least one of Xsep and Ysep must be greater than 5 mm for isolating the atrial appendage and preferably one is greater than 10 mm.

[**0044**] For example, when clamping is to be axially aligned, such as when isolating atrial appendage **97** by clamping parallel to an orifice, Xsep is greater than 5 mm (preferably greater than 10 mm) and Ysep depends on the orientation of the channel lumens and the material properties; if the channels are oriented with one on top of the other, then Ysep is zero and a Zsep oriented perpendicular to the X-Y plane has a non-zero value. Otherwise Ysep is greater than maximum channel lumen diameter.

[**0045**] When clamping perpendicular to an orifice, Ysep is greater than 5 mm (preferably greater than 10 mm) and Xsep depends on the orientation of channel lumens **190** and the material properties, as remarked above. When clamping at a 45 degree angle to the orifice, Xsep equals Ysep and the square root of the sum of the squares (i.e. the hypotenuse) is greater than 5 mm and preferably greater than 10 mm.

[**0046**] Upper jaw **208** defines an open area **199** for needles **211**, and accompanying suture **118**, to pass. The needles are advanced enough through the upper jaw, as shown in **FIGS. 5A** to **5**C to pass the suture strand fully through the opening of the upper jaw. Once an eyelet **202** containing the suture strand(s) is passed through reinforced pledgets **109** and clamped soft tissue (e.g. atrial appendage **97** or **139**), the suture is grabbed with a separate forceps or other mechanism and is pulled through the cannulae to facilitate tying the free ends of the suture strands or anchoring into a tightened orientation with a separate locking mechanism (not shown). The appendage isolation grasper is then withdrawn through trocar, cannulae, or introducer leaving reinforced pledgeted stitch **112** around the compressed, isolated atrial appendage.

[**0047**] An embodiment **1** shown in **FIGS. 5A** to **5**D and **FIGS. 6A** to **6**C incorporates two needles **211** aligned axially therefore, both suture strands free ends **121** can be advanced through reinforced pledget **109** and soft tissue (e.g. atrial appendage **97** or **139**) simultaneously. However, if appendage isolation system **1** only incorporates a single needle, then the steps above can be repeated for positioning each suture strand free end to enable creating reinforced pledgeted stitch **112**.

[**0048**] **FIG. 7A and 7B** show a perspective view and a side view of appendage isolation grasper **1** with jaws **181** and **208** closed. In this embodiment, the lower jaw is fixed to a shaft **271** of the grasper to define fixed channels/lumens **190** through which the fneedles traverse. The lower jaw incorporates a curved distal profile **292** in a channels adjacent exit point **193** to the lumen that parallels a grasper shaft

axis **274**. Curved distal channel ends **295** provide a surface off which the needles deflect, whether the needles are malleable or resilient. Incorporating curved ends also aids in compressing the needles into a low profile by gradually straightening as opposed to abruptly bending the needles. In addition, the curved channel profile better mimics the motion of rotating a needle through soft tissue. Finally, the curved channel profile prevents slipping of the needle into a gap **301** between the upper and lower jaw.

[**0049**] Upper jaw **208** pivots relative to shaft **271** and lower jaw **181** to enable opening the upper jaw to position around the anatomic surface and closing to clamp the anatomic structure in a compressed orientation. A stylet **277** connects to the upper jaw and is routed to an actuation knob (not shown) in the shaft **271**. Pins **283** pivotably connect the upper jaw to the lower jaw or shaft to enable rotation of the upper jaw relative to the lower jaw and the upper jaw to the stylet to enable rotation of the stylet relative to the upper jaw during movement of the upper jaw as the stylet is actuated. A handle mechanism used to actuate the stylet, thus the upper jaw, and/or the superelastic puncturing components **211**, can be a scissors type handle characteristic of a Rongeur device, a locking or non-locking forceps type handle characteristic of Castro Viejo Drivers, or other mechansism capable of independently or simultaneously actuating these components. If the handle mechanism is intended to simultaneously actuate the stylet and the needles, predetermined delays in the actuation of these components can be achieved by incorporating axial slots that the handle mechanism passes links through and springs that determine the engagement location of the links to the components. These approaches and similar type mechanisms permit actuating the upper jaw prior to advancing the needles and maintain clamping pressure on the soft tissue (e.g. atrial appendage **97** or **139**) as the needles are advanced through the soft tissue. The mechanism reverses as the handle is released by retracting the needles prior to releasing the soft tissue with the upper jaw.

[**0050**] **FIGS. 8A** to **8**C show a resilient or malleable needle **211** used with appendage isolation grasper **1** to advance or retract suture strand free ends. The needle incorporates a flattened distal end **316** (oriented parallel or perpendicular to a axis of the grasper) with eyelet **202** created along one (or both) sides **325** of a needle tip **322**. The distal tip is beveled and sharpened to create a cutting tip capable of penetrating through the soft tissue (e.g. atrial appendage **97** or **139**).

[**0051**] **FIGS. 9A** to **9**C show a perspective view, a top view and a side view of reinforced pledget embodiment **109**. This reinforced pledget embodiment incorporates three openings **361** and **364** in a support structure **367** through which suture strand free ends **121** are advanced using actuated needles **211** of appendage isolation system **1**. The openings through the support structure are spaced to accommodate channel exit point **193** spacing for the grasper **1**. The axial length ("I_1") of central opening **364** including the adjacent links **370** is chosen based on the stress distribution requirements and the size of soft tissue structure. As the flattened profile requirements are increased, the chosen length of the central link **370** is increased to accommodate the desire to distribute the forces along a greater length.

[**0052**] In general, the dimension of I_1 is chosen to accommodate the properties of the tissue on which the pledget is placed. For example, in cases where the pledget is placed over the atrial appendage, because of the friable and delicate nature of the tissue involved, the stress distribution should occur distances greater than approximately 2 mm. At distances of 2 mm or less, the tissue may not hold fasteners and sutures. However, to accommodate the varying geometry of the appendage, the maximum length of the stress distribution area should be approximately 7 mm. For example, better results may occur with two pledgets having I_1 spacing of 7 mm rather than a single pledget having spacing of 14 mm. In the latter case, the single larger pledget may not properly seat against the atrial tissue because of its varying geometry. Two smaller pledgets may better accommodate the varying geometry. In view of the above, while the spacing of the stress relief (and suture or faster spacing) may be between 3 and 7 mm for an atrial appendage application, the spacing may incorporate other ranges depending upon the application.

[**0053**] A covering (not shown) encapsulates the support structure to provide a compressible surface against soft tissue. Alternatively, the covering is not incorporated or the covering encapsulates only a portion of the support structure of is attached to one section of the support structure.

[**0054**] A profile **379** for embodiment **109** shown in **FIG. 9C** is planar to match the flattened profile of compressed atrial appendage **97** or **139**. For other applications or for atrial appendages that have a more cylindrical orifice, the profile of the reinforced pledget can be curved into an arc, sinusoid, or other pattern capable of matching the inherent compressed geometry of the anatomy.

[**0055**] **FIGS. 10A** to **10**C show a perspective view, a top view and a side view of another reinforced pledget embodiment **418**. This reinforced pledget embodiment incorporates two openings **409** separated by a perpendicular central link **412** (having a width ("w") oriented axially to the reinforced pledget) and defining lateral barriers **406** in a support structure **415** through which suture strand free ends **121** are advanced using actuated needles **211** of appendage isolation system **1**. The width of the central link is chosen based on the distribution requirements. For soft tissue structures (e.g. atrial appendages **97** or **139**) whose flattened profile is wide, the width of the central link is increased to accommodate the desire to distribute the forces along a greater length. The openings through the support structure match channel exit point spacing **93** for the grasper. Ranges for the width are selected based on the application of the pledget (see the above discussion.) For example, for an atrial appendage application, w may range from between 3 and 7 mm.

[**0056**] **FIGS. 11A** to **11**C show a perspective view, a top view and a side view of another reinforced pledget embodiment **451**. This reinforced pledget embodiment incorporates two openings **454** separated by an axially oriented central link **457** and defining spaces through a support structure **463** through which suture strand free ends **121** are advanced using actuated needles **211** of appendage isolation system **1**. The length ("I_2") of the central link is chosen based on the distribution requirements. As the flattened profile increases, the length of the central link is increased to accommodate the desire to distribute the forces along a greater length. The openings through the support structure match channel exit point spacing **193** for the grasper.

[**0057**] **FIGS. 12A** to **12**C show a perspective view, a top view and a side view of a reinforced pledget embodiment

496. This reinforced pledget embodiment is fabricated from a resilient polymer through which suture strand free ends **121** can be advanced using actuated needles **211** of appendage isolation system **1**.

[**0058**] Appendage isolation device embodiments 1 described above can be capable of creating other complex knots that compress opposing soft tissue structures in an atraumatic and consistent fashion during appendage isolation, gastric reduction, lung reduction or resection, or other application involving bringing opposing soft tissue surfaces together to invoke a physiologic response. By coordinating the movements of one or more needles **211**, these appendage isolation device embodiments can place at least one suture strand **118** through soft tissue such that the path the suture strand(s) follows through the soft tissue produces a complex knot once the suture strand(s) can be tied. For example, a figure eight knot can be created by passing a single suture strand through eyelets of two puncturing components and passing the components through soft tissue such that they can be angled inward relative to each other and cause the suture strand ends to criss-cross once they are advanced or retracted through soft tissue. Once positioned, the free ends of the suture strand can be pulled from the eyelet and tied together thereby producing a figure eight knot. This same device can further be used to pass the free ends of the positioned suture strands through the soft tissue another time to further complicate the knot and increase the pull force and reliability of the knot, once tied. Other knots involving one or more passes of suture strands through the soft tissue can be created with the appendage isolation device embodiments of the invention (involving one or more malleable or resilient needles) by enabling passing the suture strands any number of times and at any position through the soft tissue.

[**0059**] **FIGS. 13A** to **13**C and **FIGS. 14A** to **14**C show perspective views, top views, and side views of penetrating clips **631** capable of isolating atrial appendages **97** or **139** and maintaining the position of the clip relative to the atrial appendage. Each of the two embodiments incorporate locking mechanisms **634** (such as a pair of surfaces as shown that allows movement in a first direction but not in a second), to maintain the clip in a compressed orientation around the atrial appendage. These embodiments incorporate pins **637** to penetrate through the juxtaposed atrial walls to maintain the placement of the appendage isolation clips relative to the atrial appendage. The appendage isolation clips may also have pockets **635** that receive the pins **637** of the opposing or joining clip. Non-penetrating devices have the ability to slip off the atrial appendage. The embodiment in **FIGS. 13A** to **13**C incorporates two locking mechanisms. The embodiment in **FIGS. 14A** to **14**C incorporates a pivot **640** and a single locking mechanism. These clip embodiments can be deployed using a mating clamp that positions the clips relative to the soft tissue structure (e.g. atrial appendage **97** or **139**) and upon actuation of the deployment clamp, ends **643** of the clip engage thereby compressing the soft tissue (e.g. atrial appendage) and distributing the compressive forces along the length of the clip.

[**0060**] Although the present inventions have been described in terms of the preferred embodiments above, numerous modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art. It is intended that the scope of the present inventions extend to all such modifications and/or additions and that the scope of the present inventions is limited solely by the claims of the invention.

Component Material and Processing

[**0061**] Needles or other appendage isolation device components that require the resilience to be deflected into a curved or bent orientation and return to the preformed shape once the deflection force is removed can be fabricated from superelastic or shape memory alloys (e.g. nickel titanium). Superelastic components can elastically deform upon exposure to an external force (e.g. retracting the needle into a confining lumen) and return towards their preformed shape upon reduction or removal of the external force (e.g. advancing beyond the confines of the small diameter lumen, or tubular opening). Superelastic components can exhibit stress-induced martensite characteristics in that they transform from the preshaped austenite form to the more soft and ductile martensite form upon application of stress and transform back toward the more strong and hard austenite form once the stress is released or reduced.

[**0062**] Superelastic components can alternatively exhibit austenite or martensite properties at ambient temperature depending on whether the component needs to demonstrate resilience or malleability, respectively. The composition of the shape memory alloy defines the finish and start martensite transformation temperatures (Mf and Ms) and the start and finish austenite transformation temperatures (As and AfD to accommodate the desired material response. When fabricating shape memory alloys that exhibit stress induced martensite the material composition can be chosen such that the maximum temperature that the material exhibits stress-induced martensite properties (Md) is greater than Af and the range of temperatures between Af and Md can cover the range of ambient temperatures to which the support members are exposed. When fabricating shape memory alloys that exhibit austenite properties and do not transform to martensite in response to stress, the material composition can be chosen such that both Af and Md are less than the range of temperatures to which the supports are exposed. Of course, Af and Md can be chosen at any temperatures provided the shape memory alloy exhibits superelastic properties throughout the temperature range to which they are exposed. Nickel titanium having an atomic ratio of 51.2% Ni and 48.8% Ti exhibits an Af of approximately −20° C.; nickel titanium having an atomic ratio of 50% Ni to 50% Ti exhibits an Af of approximately 100° C. Melzer A, Pelton A. Superelastic Shape-Memory Technology of Nitinol in Medicine. Min Invas Ther & Allied Technol. 2000: 9(2) 59-60].

[**0063**] Such superelastic materials are able to withstand strain (e.g. 8% strain or greater, depending on the number flexion cycles) without plastically deforming. As such, these superelastic materials can be capable of elastically exerting a force upon deflection. Materials other than superelastic shape memory alloys can be used provided that they can be elastically deformed within the anticipated temperature, stress, and strain parameters. Such materials can include other shape memory alloys, bulk metallic glasses, amorphous Beryllium, suitable ceramic compositions, spring stainless steel 17-7, Elgiloy™, superelastic polymers, etc.

[**0064**] The appendage isolation device components (e.g. needle, stylett, jaws, shaft, pledget support, etc) can be fabricated from at least one rod, wire, band, bar, tube, sheet, ribbon, other raw material having the desired pattern, cross-

sectional profile, and dimensions, or a combination of cross-sections. The rod, wire, band, bar, sheet, tube, ribbon, or other raw material can be fabricated by extruding, press-forging, rotary forging, bar rolling, sheet rolling, cold drawing, cold rolling, using multiple cold-working and annealing steps, casting, or otherwise forming into the desired shape. The components can be cut or incorporate cut features by conventional abrasive sawing, water jet cutting, laser cutting, EDM machining, photochemical etching, or other etching techniques.

[0065] Components of the appendage isolation device that need to be attached can be bonded by laser welding, adhesively bonding, soldering, spot welding, mechanically engaging, using shrink tubing, or other attachment means. Multiple components can be bonded to produce various subassemblies or components.

[0066] For several of the components (e.g. needles), at least one wire, tube, ribbon, sheet, rod, band or bar of raw material is cut to the desired length and thermally formed into the desired 3-dimensional configuration. When thermally forming superelastic components, or features fabricated into superelastic components, the raw material can be stressed into the desired resting configuration using forming fixtures, and the material is heated to 300-600 degrees Celsius for a period of time, typically between 15 seconds and 2 minutes. Once the volume of superelastic material reaches the desired temperature, the superelastic material is quenched by inserting into chilled or room temperature water or other fluid. Multiple thermal forming steps can be utilized to sequentially bend the raw material into a resting shape where the bend or curve exceeds the material limits achieved during a single thermal forming process.

[0067] Once the components are fabricated and formed into the desired 3-dimensional geometry, they can be tumbled, sand blasted, bead blasted, chemically etched, ground, mechanically polished, electropolished, or otherwise treated to remove any edges and/or produce a smooth surface.

[0068] Coverings for appendage isolation device components (e.g. support structures of the reinforced pledgets) can be fabricated from biocompatible polymer such as expanded PTFE, PEBAX®, polyester, polyurethane, urethane, silicone, polyimide, other thermoplastic, thermoset plastic, or elastomer. The support structure of the reinforced pledgets comprise a metal (e.g. titanium, tantalum, tungsten, etc.), metal alloy (e.g. stainless steel, spring steel, nickel titanium, etc.), or resilient polymer. The support structures may or may not be encapsulated in a covering, such as those listed above. The coverings can be extruded, injection molded, dipped, or applied using another manufacturing process involving embedding the support structure within the covering. The covering can alternatively comprise a bioabsorbable material that is broken down over a period of time leaving the support structure in place. The coating can be encapsulated within the covering or carried by the covering. Such pharmacologic coatings include antiproliferative substances, or agents designed to prevent adhesions, affect thrombosis, inhibit hyperplasia, or promote or discourage platelet congregation around the reinforced pledget.

[0069] Such agents may include: rapamycin, dactinomycin, sirolimus, everolimus, Abt-578, tacrolimus, taxanes (such as paclitaxel), pyrolitic carbon, titanium-nitride-oxide, steroids, non-steroidal anti-inflammatories, paclitaxel, fibrinogen, thrombin, phosphorylcholine, heparin, rapamycin, radioactive 188Re and 32P, silver nitrate, camptothecin, etoposide, fluorouracil, vincristine, vinblastine, podophylotoxin, estramustine, noscapine, griseofulvin, and dicoumarol. It is noted that the composition or implant may also include additional substance as required by the location of the implantlpledgetlclip/etc. It should be understood that the bio-active substances includes all forms of the substances (e.g., analogs and derivatives, etc.)

[0070] Needle components can be fabricated from wire, ribbon, rod, band, bar, or other cross-sectional geometry having a diameter between 0.010" and 0.200". The wire (or other geometry raw material) is flattened along certain sections, cut to define an eyelet, and ground to form a sharpened tip. In this case a beveled tip is illustrated; it should be noted that alternative sharpened tips (e.g. cutting edge, pointed, etc.) can be fabricated.

[0071] The methods herein may be performed using the subject devices or by other means. The methods may all comprise the act of providing a suitable device. Such provision may be performed by the end user. In other words, the "providing" (e.g., a delivery system) merely requires the end user obtain, access, approach, position, set-up, activate, power-up or otherwise act to provide the requisite device in the subject method. Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events.

[0072] Exemplary aspects of the invention, together with details regarding material selection and manufacture have been set forth above. As for other details of the present invention, these may be appreciated in connection with the above-referenced patents and publications as well as generally know or appreciated by those with skill in the art.

[0073] The same may hold true with respect to method-based aspects of the invention in terms of additional acts as commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention. Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. In addition, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention.

[0074] Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a,""an,""said," and "the" include plural referents unless the specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may be drafted to exclude any optional element. As such, this

statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely,""only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[0075] Without the use of such exclusive terminology, the term "comprising" in the claims shall allow for the inclusion of any additional element—irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth n the claims. Stated otherwise, except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

[0076] The breadth of the present invention is not to be limited by the examples provided and/or the subject specification, but rather only by the plain meaning (and any definitions provided herein) of the claim terms employed.

1. A system for compressing tissue surrounding a cavity, the system comprising:

a plurality of jaw members;

at least one implantable member removably placed on one or more jaw members, where the implantable member is sized to match the compressed tissue; and

at least one tissue piercing member attached to or passable through the implantable member.

2. The system of claim 1, where the implantable member comprises a first clip having a plurality of the tissue piercing members attached thereto, the first clip further comprising a plurality of pockets.

3. The system of claim 2, further comprising a second clip having a plurality of the tissue piercing members attached thereto, the second clip further comprising a plurality of pockets, such that when mated with the first clip, the tissue piercing members of each clip nest in the plurality of pockets of the other clip to align the first and second clips.

4. The system of claim 3, where the first and second clips each include mating locking surfaces that prevent decoupling of the device once joined.

5. The system of claim 3, where the first and second clips are joined via a hinge.

6. The system of claim 2, where the first clip comprises a material selected from PTFE, PEBAX, polyester, polyurethane, urethane, silicone, polyimide, a thermoplastic polymer, a thermoset polymer, an elastomer.

7. The system of claim 6, where the first clip comprises a support structure selected from a metal, a metal alloy, and a polymer.

8. The system of claim 6, further comprising a pharmacological substance located on or in the clip.

9. The system of claim 8, where the pharmacological substance comprises an agent selected from an antiproliferative agent, an agent to prevent adhesions, an anti-thrombosis agent, an agent that inhibits hyperplasia, an agent that affects platelet congregation.

10. The system of claim 1, where the implantable member comprises a pledget body and where the tissue piercing member comprises a needle having a suture attached thereto.

11. The system of claim 10, where the pledget body comprises a plurality of openings.

12. The system of claim 11, where the plurality of openings comprises at least one eyelet for passage of a needle and suture.

13. The system of claim 1, where each jaw member has at least one of the implantable members removably placed thereon.

14. The system of claim 10, where the pledget body comprises first profile selected from: planar, arc, sinusoid, or other profile matching the compressed geometry of the appendage.

15. The system of claim 10, where the pledget body further comprises a material selected from PTFE, PEBAX, polyester, polyurethane, urethane, silicone, polyimide, a thermoplastic polymer, a thermoset polymer, an elastomer.

16. The system of claim 10, where the pledget body comprises a support structure selected from a metal, a metal alloy, and a polymer.

17. The system of claim 10, where the pledget body comprises a pharmacological substance located on or in the clip.

18. The system of claim 17, where the pharmacological substance comprises an agent selected from an antiproliferative agent, an agent to prevent adhesions, an anti-thrombosis agent, an agent that inhibits hyperplasia, an agent that affects platelet congregation.

19. The system of claim 10, where the pledget body comprise an "H" shape.

20. The system of claim 1, where the tissue piercing members comprise at least one needle.

21. The system of claim 20, where the needle comprises a material selected from a shape memory alloy, a metal, and a metal alloy.

22. A pledget for compressing tissue surrounding a cavity in the tissue, the pledget body comprising:

a body comprising a compressible material;

a reinforcing member at least partially enclosed within the body;

where the body and reinforcing member define a size and a profile such that the size and the profile matches the compressed geometry of the tissue.

23. The pledget of claim 22, further comprising a plurality of openings where the spacing between the openings is chose to accommodate the stress distribution and size of the tissue being compressed.

24. The pledget of claim 23, where the plurality of openings comprises two openings separated by a central link.

25. The pledget of claim 23, where the plurality of openings comprises two openings such that the shape of the body forms an "H".

26. The pledget of claim 22, further comprising a plurality of fastener eyelets.

27. The pledget of claim 22, where the body comprises a profile selected from: planar, arc, sinusoid, or other profile matching the compressed geometry of the appendage.

28. The pledget of claim 22, where the body comprises a material selected from PTFE, PEBAX, polyester, polyure-

thane, urethane, silicone, polyimide, a thermoplastic polymer, a thermoset polymer, an elastomer.

29. The pledget of claim 22, where the reinforcing member comprises a material selected from a metal, a metal alloy, and a polymer.

30. The pledget of claim 22, where the body carries a pharmacological substance.

31. The pledget of claim 30, where the pharmacological substance comprises an agent selected from an antiproliferative agent, an agent to prevent adhesions, an anti-thrombosis agent, an agent that inhibits hyperplasia, an agent that affects platelet congregation.

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