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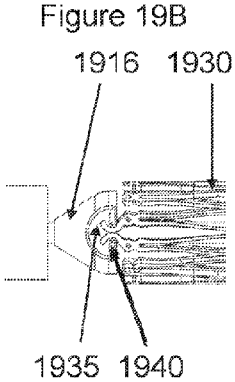
(54) Title: DEVICES AND METHODS FOR RELEASING AN IMPLANT ONTO A LUMENAL SURFACE

(57) Abstract: The instant invention, in some embodiments, describes delivery units for implants to a lumen surface. In some embodiments, a plurality of tabs are employed to engage an implant to each attachment point on an implant holder. The use of multiple tabs for each attachment point overcomes a possibility that a single tab may be spatially impeded from opening due to the shape of a lumenal space in which the implant is to be placed. At least one tab will necessarily be on a side opposite the lumenal wall and will disengage from an expanding implant, with a second tab necessarily falling off and allowing for complete separation between an implant and the delivery unit used in its deployment.

Figure 19B



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DEVICES AND METHODS FOR RELEASING AN IMPLANT ONTO A LUMENAL SURFACE

RELATED APPLICATION/S

This application claims the benefit of priority of U.S. Provisional Patent Application No. 63/460,671 filed on April 20, 2023, the contents of which are incorporated herein by reference in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to devices and methods for an implant in a lumen.

Delivery of stents and stent-based implants in arteries often requires delivery and release of implants in predetermine locations. In some locations, shape of an artery surface does not allow for facile implant release during surgical delivery. Curvature of a lumenal surface, for example, can prevent release of implant due to surface interference with implant release.

SUMMARY OF THE INVENTION

Following is a non-exclusive list including some examples of embodiments of the invention. The invention also includes embodiments which include fewer than all the features in an example and embodiments using features from multiple examples, also if not expressly listed below.

Example 1. A delivery unit, comprising:

a capsule including an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto;

an implant, comprising:

a first tab associated with a first circumferential location of said implant, wherein said first tab is sized and shaped for geometric engagement with said attachment point; and,

a second tab associated with a second circumferential location of said implant and sized and shaped for geometric engagement with said attachment point,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath and wherein said first location and said second location are further circumferentially apart in said expanded state than in said collapsed state,

wherein said first tab and said second tab hold said implant to said attachment point in said first, collapsed, state, and move circumferentially apart in said second, expanded, state, thereby weakening an engagement of said tabs to said attachment point.

Example 2. The delivery unit according to example 1, wherein said implant includes at least one stent.

Example 3. The delivery unit according to example 1 or example 2, comprising one or more additional first tab and additional second tab, provided as pairs, wherein each tab is located on a unique position on said implant.

Example 4. The delivery unit according to any one of examples 1-3, wherein said implant holder comprises a retractable deployment arm and said at least one attachment point comprises a plurality of attachment points.

Example 5. The delivery unit according to example 2, wherein said at least one stent is made partially or wholly of Nitinol.

Example 6. The delivery unit according to example 2 or example 5, wherein said first tab and said second tab are associated with crown-shaped structures at an end of said stent.

Example 7. The delivery unit according to any one of examples 1-6, wherein said first tab and said second tab are identical in shape or mirrored.

Example 8. The delivery unit according to any one of examples 1-7, wherein said first tab and said second tab have a rounded feature.

Example 9. The delivery unit according to any one of examples 1-8, wherein said first tab and said second tab have a rectangular feature.

Example 10. The delivery unit according to any one of examples 1-9, wherein said first tab and said second tab face each other around said attachment point.

Example 11. The delivery unit according to any one of examples 1-10, wherein said first tab and said second tab are associated with different geometries of the attachment point.

Example 12. The delivery unit according to anyone of examples 1-11, wherein said capsule has an open end at a distal end thereof, for implant passage therethrough.

Example 13. The delivery unit according to any of example 12, wherein the distal end lacks a conical tip.

Example 14. The delivery unit according to any one of examples 1-13, comprising a guide that protrudes beyond the open distal end of said capsule, wherein said guide passes through said inner implant holder, and wherein said implant is crimped over said guide and within said capsule.

Example 15. The delivery unit according to any one of examples 1-14, comprises a balloon, associated with said implant holder, and positioned adjacent to said first tab and said second tab, such that inflation of said balloon forces the separation of said first tab and said second tab.

Example 16. A method for releasing an implant from a delivery unit into a lumen, including:

providing a crimped implant in a delivery unit comprised of an outer sheath and an inner implant holder, wherein said implant is attached to said implant holder with a first tab and a second tab associated with said implant and geometrically engaged to a same attachment point on said implant holder;

releasing said implant from said outer sheath at a position in a lumen;

allowing said implant to expand radially after said release; and,

allowing said first tab and said second tab to circumferentially move away from each other, so that at least one tab moves circumferentially away from said attachment point thereby weakening a coupling between said first tab and said second tab with said attachment point.

Example 17. The method according to example 16, wherein said lumen is an artery.

Example 18. The method according to example 16 or 17, further including fluoroscopic monitoring of positions of said first tab and said second tab after said allowing said implant to expand.

Example 19. The method according to any one of examples 16-18, wherein said implant is made, in part, of a self-expanding material.

Example 20. The method according to any one of examples 16-19, further including expanding a balloon associated with said implant holder after said releasing.

Example 21. The method according to any one of examples 16-20, wherein said releasing is initiated by moving said inner implant holder out of said outer sheath.22. The method according to any of examples 16-18, wherein said releasing is initiated by a rotation of said implant holder.

Example 23. A delivery unit for a stent-like implant onto a lumenal surface, including:

a guide for directing insertion of an implant at a desired lumenal surface;

a capsule including an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto, wherein said capsule has an open end for implant passage out of said capsule;

an implant, comprising:

a cylindrical self-expanding body sized to be implanted in a pulmonary artery.

Example 24. The delivery unit according to example 23, wherein said implant comprises:

a first tab associated with a first circumferential location of said implant, wherein said first tab is sized and shaped for geometric engagement with said attachment point; and,

a second tab associated with a second circumferential location of said implant and sized and shaped for geometric engagement with said attachment point,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath and wherein said first location and said second location are further circumferentially apart in said expanded state than in said collapsed state,

wherein said first tab and said second tab hold said implant to said attachment point in said first, collapsed, state, and move circumferentially apart in said second, expanded, state, thereby weakening an engagement of said tabs to said attachment point.

Example 25. The delivery unit according to example 23 or 24, wherein said implant comprises:

a single tab associated with a circumferential location of said implant, wherein said single tab is sized and shaped for geometric engagement with a side of said attachment point; and,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath,

wherein said single tab holds said implant to said inner implant holder in said first, collapsed, state, and moves away from said attachment point in said second, expanded, state, thereby weakening an engagement of said single tab to said inner implant holder.

Example 26. The delivery unit according to any one of examples 23 to 25, wherein the guide comprises a guide wire tube.

Example 27. The delivery unit according to example 26, wherein said guide wire tube extends beyond said open end.

Example 28. The delivery unit according to any one of examples 23 to 27, wherein the proximal end lacks a conical tip.

Example 29. The delivery unit according to any one of examples 23 to 28, wherein said open end has a cross-section area of at least 70% of a maximal outer diameter of said delivery unit.

Example 30. A method for releasing an implant from a delivery unit into a lumen, including:

providing a crimped implant in a delivery unit comprised of a capsule and an inner implant holder, wherein said implant is attached to said implant holder with a single tab associated with said implant and geometrically engaged to a side of an attachment point on said implant holder;

releasing said implant from said capsule at a position in a lumen;

allowing said implant to expand radially after said release; and,

allowing said single tab to circumferentially move away from said attachment point, so that said single tab moves circumferentially away from said attachment point thereby weakening a coupling between said single tab with said attachment point.

Example 31. The method according to example 30, further including rotating a guide wire tube associated with said implant holder.

Example 32. The method according to example 30, comprising one or more additional single tabs, wherein each tab is associated with a unique position on said implant.

Example 33. A delivery unit, comprising:

a capsule having an inner volume defined by a wall of an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto;

an implant, comprising:

a first tab associated with a first circumferential location of said implant, wherein said first tab is sized and shaped for geometric engagement with said attachment point; and,

a second tab associated with a second circumferential location of said implant and sized and shaped for geometric engagement with a same or a different attachment point,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath and wherein said first location and said second location are further circumferentially apart in said expanded state than in said collapsed state,

wherein said first tab and said second tab hold said implant to said inner implant holder in said first, collapsed, state, and move circumferentially apart in said second, expanded, state, thereby weakening an engagement of said tabs to said inner implant holder.

Example 34. A delivery unit, comprising:

a capsule including an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto;

an implant, comprising:

a single tab associated with a circumferential location of said implant, wherein said single tab is sized and shaped for geometric engagement with a side of said attachment point; and,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath,

wherein said single tab holds said implant to said inner implant holder in said first, collapsed, state, and moves away from said attachment point in said second, expanded, state, thereby weakening an engagement of said single tab to said inner implant holder.

Example 35. The delivery unit according to example 34, comprises one or more additional single tabs, wherein each tab is associated with a unique position on said implant.

Biological and biomedical terms such as artery, lumen, stent, pulmonary, ventricular, interventricular, septum, and tissue may have their generally understood meanings in the medical arts.

Unless otherwise defined, all technical and/or scientific terms used herein may have the same meaning as commonly understood by one of ordinary skill in the art to which the invention

pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

Some embodiments of the present invention may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and products according to embodiments of the invention. The instant invention, in some embodiments may be practiced with one or a plurality of elements or steps as described herein. It is understood that the instant invention may have application to other implants and or physiological insertion locations and is described for a stent-like insertion in a pulmonary artery solely for the purpose of clarity.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced. Similar elements may have the same number, advanced by multiples of 100.

In the drawings:

Figure 1A & Figure 1B are schematic representations of an existing implant delivery system;

Figure 1C shows a version of a prior art implant delivery system;

Figure 2 is a flowchart of an exemplary method, according to some embodiments of the invention;

Figure 3 is a picture of an implant according to some embodiments of the invention;

Figure 4A is a picture of a crimped implant in a delivery sheath and attached to an implant holder according to some embodiments of the invention;

Figure 4B is a picture showing the relative position of tabs to implant holder during expansion of implant;

Figure 5 is a picture of an implant delivery system according to some embodiments of the invention;

Figure 6A & Figure 6B are schematic representations of attachment tabs and an attachment point according to some embodiments of the invention;

Figure 6C shows schematic views of possible shapes of mirror-image tab pairs;

Figure 6D shows schematic views of possible shapes of attachment points;

Figure 6E shows tabs around an attachment point for a device loaded into a catheter;

Figure 7 is a schematic representation of an exemplary implant delivery unit, according to some embodiments of the invention;

Figure 8A is a schematic representation of an exemplary implant delivery unit with implant deployment arm extended in a lumen;

Figure 8B is a cross-sectional view of the schematic representation from Figure 8A;

Figure 9 is a schematic representation of an exemplary implant delivery unit with implant expanded outside of an implant capsule, according to some embodiments of the invention;

Figure 10 is a schematic representation of an exemplary expanded implant implanted in a lumen, according to some embodiments of the invention;

Figure 11A & Figure 11B are schematic representations of an exemplary alternate tab pair, according to some embodiments of the invention;

Figure 12A & Figure 12B are schematic representations of forces related to separation of tabs by implant expansion, according to some embodiments of the invention;

Figure 13A is a schematic representation of an exemplary balloon-based implant delivery system, according to some embodiments of the invention;

Figure 13B is a schematic representation of an expanded balloon in a balloon-based implant delivery system, according to some embodiments of the invention;

Figure 14 is a schematic representation of a delivery unit as per an embodiment of the invention;

Figure 15 is a schematic representation of a guidance system used to delivery an implant capsule to a lumen according to an embodiment of the invention;

Figure 16 shows a schematic representation of a delivery system without a nose cone ready for deployment;

Figure 17 shows a flowchart for a method of the invention;

Figure 18A & Figure 18B show schematic views of single tab delivery systems with a nose cone unit; and,

Figures 19A – 19D show schematic views of a self-expanding implant and release of tabs from associated delivery unit.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to delivering an implant in a lumen, and, more particularly, but not exclusively, to using a pair of tabs for each attachment point to allow for more facile delivery of implant, especially in curved implantation positions.

Overview

An aspect of some embodiments of the invention relates to devices and methods for delivering a medical implant by using securing tab pairs that can move away from each other and/or an associated attachment point during an expansion of the implant in the body. The pairs may generally be located on different crowns associated with an implant and may either be held together or not. In some embodiments, the device allows for the precise delivery of an arterial implant with facile release of the expandable implant from its delivery system. In some embodiments, pairs of tabs are engaged to an implant holder at an attachment point to hold a crimped version of the implant in place prior to deployment. In some embodiments, the pairs of tabs release the implant holder concomitant or shortly after expansion of implant *in situ* in a lumen such as an artery. In some embodiments, a balloon is employed to release tab pairs. In some embodiments, additionally or alternatively, a physician may employ fluoroscopic monitoring to determine tab pair separation.

An aspect of some embodiments of the invention relates to facile separation of a medical implant from its delivery unit in the body. In some embodiments, an implant or a plurality of implants may be implanted in pulmonary arteries (PAs) by a designated delivery system during a transfemoral or transjugular venous procedure under fluoroscopy guidance. The instant invention, in some embodiments, overcomes a problem frequently encountered in stent and other implant procedures. An implant is routinely released from an implant delivery system. After implant release, there must be complete separation of implant and typically an deployment arm (also referred to herein as implant holder and/or engagement arm) that pushes implant out of a delivery vehicle and/or otherwise engages the implant during delivery. In some cases, for example, when the implant is released in a curved portion of a lumen and/or is delivered using a more rigid guidewire, the release tab connecting the deployment arm and the implant can at times fail to release due to physical blocking by the lumen surface (e.g., being trapped between the implant and the vessel wall. The result can be unintended movement or misplacement of the implant due to failed separation of the now-expanded implant and the deployment arm.

Upon crimping and loading of an implant according to some embodiments of the instant invention within a delivery unit, "half-tabs" or first and second tabs come together to form a full tab and engage the implant to an deployment arm (or implant holder). Upon deployment from an

outer sheath structure and/or other release, the two tabs will have a separation force from the expanding implant to distance one-half tab from its other half and thereby weaken their interaction with associated attachment point, thus effecting full implant release. In some cases, even if a tab is not released, when the delivery system is moved (e.g., retracted), the engagement of the single tab will not be enough to move the implant (which is expanded against the vessel walls) in a manner which might damage the walls. An implant that does not fully separate may be dragged through a vessel or might be misplaced in its location, possibly requiring further surgery for correction.

An aspect of some embodiments of the invention relates to an open-ended delivery system. In some embodiments of the invention, a delivery system for a vascular implant includes a capsule which is optionally open at a distal end thereof, optionally, other than a guide, such as a guide wire tube extending past an end of the capsule. Herein, a guide wire tube refers to an elongated element, that comprises a wall, which defines a lumen along the longitudinal axis thereof. In some embodiments, the capsule comprises an inner volume that is defined by a wall of an outer sheath. Such a delivery system may be usable in any size blood vessel or other biological vessel. A potential advantage of such a design is when delivering a stent with a narrowing section. In a delivery system with a closed leading edge, the leading edge represented as a nose cone or tip may need to be retracted back past the implant after deployment of the implant. In such retraction, the nose cone may either be trapped between the implant and lumen wall or get entangled with the narrowing of the implant, both generally bad outcomes, which may be avoided by not having any leading component beyond a guide wire tube and a retractable, outer capsule. Trapping and entanglement may cause dislodgment of the implant when such an entangled cone or tip are retracted.

Referring now to the drawings, attention is turned to Figure 1A which relates to a device without tab pairs. Figure 1A shows a schematic view of a cross-sectional view of a prior art implant delivery system **100**. A prior art implant delivery system **100** is located in a curved portion of a lumen **105**. The prior art implant delivery system **100** includes a delivery sheath which defines a capsule **110**, a retractable deployment arm **116**, a connector tab **120**, and an implant **125** in a retracted state held to deployment arm **116** via the connector tab **120**. (Deployment arm **116** can also be referred to herein as an implant holder, engagement arm, and/or delivery arm). In some embodiments, deployment arm **116**, is mounted on guide **115**, such as a guide wire tube, optionally, the guide is threaded through deployment arm **116**. In Figure 1A, the prior art implant delivery system **100** is in place for delivery of crimped implant **125** in lumen **105**. Attention is turned to Figure 1B. Attempted release of an expanded implant **130** fails due to singular connector tab **120** being hindered by its close physical proximity of a curved portion of lumen **105**. As connector tab

120 does not have the space to move to release expanded implant **130** from deployment arm **116**, the expanded implant **130** remains connected to the deployment arm **116**. If a physician believes that he/she has delivered the expanded implant **130** to the proper location in the lumen **105**, then he/she may simply drag the still-connected expanded implant **130** during removal of the delivery sheath and deployment arm **116**. The expanded implant **130**, which can be larger than the lumen **105** itself, may thus be mispositioned and in need of additional procedure to move it back into place. Spatial hindrance in lumen **105** of full connector tab **120** release can lead to significant medical issues that might require additional surgery to correct.

The instant invention, in some embodiments, addresses the weakness of traditional single connector tabs **120**. In some embodiments of the instant invention, a pair of "half-tabs" or "tab pairs", rather than a single "full" connector tab **120** are employed. A potential advantage of connector tab pairs, as herewith described, is that one of the connector tabs, in a deployed device, is typically on a side away from the curved lumen **105** or the like. Once one tab separates from a side of an attachment point **118** associated with deployment arm **116** (e.g., implant holder **116**), then perforce the second tab will disassociate, and the implant may be delivered fully free of its delivery apparatus. In other embodiments, a single tab is employed, wherein said single tab only sits on one side of a connection point (multiple such single tabs may be provided). Figure 1C shows a prior art delivery system **100** with a single connector tab **120** that is attached to an deployment arm **116** on at least two sides of a connection point **118** of the deployment arm **116**. Connector tab **120** may not fully separate from deployment arm **116** (e.g., from connection point **118** thereof) as previously described.

Attention is turned to Figure 2. Figure 2 illustrates a flowchart of an exemplary method, according to some embodiments of the invention. In some embodiments, an exemplary method for delivering an implant to a lumen, comprising: providing a crimped implant in a delivery unit comprised of an outer sheath and an inner implant holder, wherein the implant is attached to the implant holder with a first tab and a second tab associated with the implant and geometrically engaged to a same attachment point on the implant holder (202); releasing the implant from the outer sheath at a position in a lumen (204); allowing the implant to expand radially after the release (206); and, allowing the first tab and the second tab to circumferentially move away from each other, so that at least one tab moves circumferentially away from the attachment point thereby weakening a coupling between the first tab and the second tab with the attachment point (208).

In some embodiments, the method is applied in a lumen. In some embodiments, the lumen is a lumen of an artery. In some embodiments, the method includes fluoroscopic monitoring of positions of the first tab and the second tab after the allowing the implant to expand. In some

embodiments of the invention, one or more radiopaque markers are provided on the implant crown and/or on one or more tabs, so that spacing between them can be used to identify device deployment. Optionally or additionally, a radiopaque marker is provided on the deployment arm. Optionally or additionally, deployment is tracked by identifying (e.g., on an x-ray image) if the deployment arm is against one side of the expanded stent/implant (e.g., and the stent may be pushed against the wall). Optionally or additionally, an x-ray image can be taken (e.g., by rotating a c-arm x-ray imager to correct orientation) to see if the two tabs at the location where the deployment arm meets the stent are separated or not. If the stent is fully opened (the crown is fully open and separated, then at most one tab is trapped between the deployment arm and the vessel lumen wall. As per the design in accordance with some embodiments of the invention, such engagement of the deployment arm by such tab is not robust enough to cause movement of the stent when the deployment arm is retracted.

In some embodiments, the implant is made, in part, of a self-expanding material. In some embodiments, the self-expanding material includes Nitinol. In some embodiments, there may be an additional (or alternative) expanding of a balloon associated with the implant holder after the releasing. In some embodiments, the releasing is initiated by moving the inner implant holder out of the outer sheath.

Referring now to Figure 3, showing a schematic representation of a non-limiting example of an expanded implant **330** used in arterial procedures prior to crimping (not shown). The expanded implant **330** includes a first tab **335** and a second tab **340** located at an end of the implant **330** and are adapted to attach to an implant holder (not shown) at an attachment point during implant crimping. The specific implant **330** shown in Figure 3 is optionally used to treat heart failure by modifying pressures in a predetermined location in the heart. The implant **330** includes a covered inner frame **345** to create a constricted channel with a constriction mechanism **350** to hold the constricted configuration. The implant **330** is made of at least one inner stent inside an outer stent **360**. The first tab **335** and second tab **340** sit above adjacent crown-shaped structures **355** at one end of the outer stent **360**. Another pair of tabs is located on the side opposite. The crimping process brings the first tab **335** and second tab **340** sitting on nearby crowns **355** closer together so as to form a full tab around a joining point (not shown). There are generally twelve crown-shaped structures **355** on an end of the implant **330**. This number is not absolute and the number of crowns can be larger or smaller. The percentage of crowns with tab features may be between 10 and 80%, for example. Generally, tabs may be found on 25% of crowns. Tabs may also alternatively or additionally be found on valves.

Referring now to Figure 4A, showing a view of a crimped implant **425** partially deployed outside of its catheter capsule **410**. In some embodiments, capsule **410** comprises an inner volume that is defined by a wall of an outer sheath Capsule **410** (e.g., outer sheath) may generally be made of any material, though plastics are preferred, and PET is particularly preferred due its flexibility and ability to be sterilized. The implant **425** may be released up to 50% and still be brought back into the capsule **410** if need be. Tabs **435** and **440** are visible and are attached to an attachment point **418** associated with a deployment arm **416**. One may note that at the distal end **495** of the delivery system **400** there is no nose cone or tip present. Deployment arm **416** is connected and/or mounted on guide **415**, which optionally comprises an inner lumen along the longitudinal axis thereof. Herein the guide can also be referred to as a guide wire tube (as shown for example in Figure 4A). It is noted that the guide cross-section is not limited to a circular shape and may have any other cross-section shape. Deployment arm **416** comprises a passageway for guide **415** to pass therethrough, such that deployment arm **416** is positioned over guide **415**, as shown for example in the figure. In some embodiments, distal end **495** of delivery system **400** is defined by the distal end of guide **415**, alternatively or additionally, distal end **495** of delivery system **400** is defined by the distal end of capsule **410**.

Referring now to Figure 4B, tab **435** is still temporarily associated with attachment point **418** on the deployment arm **416** while tab **440** is completely removed from its original position. Implant **430** expansion leads to tab **435** & **440** disassociation with deployment arm, which in turn allows for potentially safe and successful deployment of implant **430** fixed into a lumenal position. In some embodiments, after the implant expansion, guide wire tube **415** is retracted to remove the delivery system. This dual-tab delivery system has the potential advantage of reducing and/or avoiding the risk of implant dislodgment from the deployment site, during the system retraction. This applies whether both tabs **435**, and **440** are disconnected from attachment point **418** or whether one of the tabs is still associated therewith. The connection between one tab (e.g., one tab of the tab pair) is potentially insufficient to pull (and dislodge) the implant during retraction of the delivery system. In some embodiments, the tabs (e.g., tabs **435**, **440**) are sized and/or shaped such that the withdrawal of guide **415** (e.g. the withdrawal of delivery system **400**) while one of the tabs is still associated with attachment point **418** results in the disconnection of said tab.

Referring now to Figure 5, showing a view of an implant delivery unit **500** with compacted implant **525** inside a nylon outer sheath (or capsule) **510**. The implant **525** is ready for delivery to patient where Nitinol of the implant **525** will expand after release of implant from the outer sheath (or capsule) **510** and exposure of the implant **525** within the lumen. First tab **535** and second tab

540 are visible through the outer sheath **510** and are in a closed arrangement to hold the implant **525** to the implant holder **516** until full deployment of the implant **525** outside the capsule **510**.

Referring now to Figure 6A, showing a schematic representation of tabs according to an embodiment of the invention. A first tab **635** and a second tab **640** are optionally mirror images of one another. Each tab is adapted to engage an attachment point associated with an implant holder (not shown) only on a single side of the attachment point (such that each tab is adapted to engage a different side of the attachment point). Thus neither first tab **635** nor second tab **640** is adapted to reliably engage an attachment point alone, but together they can engage one or more geometries of the attachment points which potentially leads to a secure association of a crimped implant (not shown) with an implant delivery unit. Figure 6B shows first tab **635** and second tab **640** both situated on either side of, and attached to, attachment point **618** associated with an implant holder **616**. As can be seen in Figure 6B, in some embodiments, neither tab is adapted to hold attachment point **618** alone, unlike the single tab shown in Figure 1 (Figure 1C, **120**). In Figure 6B, first tab **635** and second tab **640** combine to form a whole-tab (**660**) which holds an implant (not shown) firmly to the implant holder **616**. A particular feature of some embodiments of the invention is that when implant separates from attachment point **618**, only either the first tab **635** or second tab **640** maximally can be obstructed by a lumen wall. As such, the other tab will be free to separate from the attachment point **618**, and perforce, the obstructed tab will separate and the expanded implant will be fully free of the implant holder **616**. Implant expansion forces first tab **635** and second tab **640** apart for full implant release, thus removing the risk of dragging the implant to an incorrect location.

Figure 6C shows four pairs **642** of mirror image first and second tab pairs (e.g., each pair is defined by first and second tab **635, 640**). The shapes are not limiting but rather offer additional views of potential tab shapes for application in the instant invention. In some embodiments, at least one of first and second tabs **635, 640** comprises a rounded feature, for example, feature **643**, positioned at the contact with attachment point **618**. The rounded feature potentially allows first and/or second tabs **635, 640** to slide along attachment point **618**, upon expansion of the implant, while moving away from each other. In some embodiments, the rounded feature matches a rounded shape of at least a portion of attachment point **618**.

In some embodiments, at least one of first and second tabs **635, 640** comprises a rectangular feature, for example, feature **644**, positioned at the contact with attachment point **618**. The rectangular feature potentially allows first and/or second tabs **635,640** to grab attachment point **618**, having the potential advantage of reducing the risk of undesired release of first and/or second tabs **635,640** from attachment point **618**, for example before reaching a desired deployment site and/or

before implant expansion. In some embodiments, the rectangular feature matches a rectangular shape of at least a portion of attachment point **618**.

Figure 6D shows non-limiting attachment points **618** on an implant holder **616**. Figure 6E shows a crimped implant **625** attached via first tab **635** and second tab **640** to an attachment point **618** of an implant holder.

Referring now to Figure 7, showing a schematic representation of an implant delivery unit **700** including an outer plastic sheath **710** (e.g capsule), a flexible inner implant holder **716**, a crimped implant **725** having a first tab **735** and a second tab **740** secured during crimping around an attachment point **718** associated with the implant holder **716**. Figure 7 shows the implant delivery unit prior to a transfemoral venous procedure and prior to implant **725** delivery to a position on a lumen.

Referring now to Figure 8A, showing a schematic representation of a view through a lumen **805** of an implant delivery unit **800** in which an implant holder **816** is partially ejected from an outer sheath/capsule **810** in proximity to a lumen **805** onto which an implant **825** will be placed. First tab **835** and second tab **840** are still fully attached to attachment point **818** at end of implant holder **816**.

Referring to Figure 8B which shows a schematic representation of a cross-sectional view of an expanding **895** implant **830** in a lumenal vessel **806**. The lumenal vessel **806** may be, in a non-limiting example, an artery and the implant **830** may be a stent or stent-like device. In Figure 8B, the implant **830** is expanding **895** radially away from an implant holder **816**. Expanding **895** behavior is related to properties of Nitinol and other self-expanding materials. First tab **835** and second tab **840** are attached to the crown-shaped structure **855** at one end of the implant **830** while a second set **842** of tabs are already disconnected from the implant **830**. First tab **835** and second tab **840** move away radially from implant holder **816** due to forces **870** generated by the expanding **895** implant **830** outside of its capsule (not shown). These forces **870** are large enough to cause complete separation of first tab **835** and/or second tab **840** from the attachment point on the implant holder **816** and allow for clean separation of implant **830** from the implant holder **816** and associated capsule. The free implant **830** will implant into the lumenal vessel **806** and remain in place.

Referring now to Figure 9, showing a schematic representation of a self-expanding implant **930** outside of the delivery unit **900** outer sheath **910** (e.g., capsule **910**). The Nitinol in the implant **930** causes immediate expansion of implant **930** when the latter is freed from the restraint of a catheter capsule **910**. Tab **935** and tab **940** have already been released from the attachment point **918** on the implant holder **916** and thus the implant is safely free of its delivery unit **900**. Expansion

of implant **930** can lead to a size greater than the vesicle in which it is deployed, thus guaranteeing its lack of movement away from the deployment site.

Referring now to Figure 10, showing a schematic representation of a fully-expanded implant **1030** implanted into a lumen **1005**. The view is again looking through the lumen **1005**. First tab **1035** and second tab **1040** remain associated with implanted implant **1030** and outer sheath **1010** and inner implant holder **1016** may be safely removed without dragging or disturbing implant **1030**. First tab **1035** and second tab **1040** are of no medical relevance when associated with the implant **1030** in the lumen **1005**. The implant **1030** tends to fill the entire space of the lumen **1005** where it is located.

Referring now to Figure 11A, showing a schematic representation of a second embodiment of a first tab **1135** and a second tab **1140** again having mirror symmetry as shown. In some embodiments, the attachment point is defined by a geometry, such as a protrusion, for example, attachment point **618** shown in Figure 6B. In other embodiments, the attachment point, for example, attachment point **1118,** comprises more than one geometry, such as more than one protrusion. Figure 11B shows the instant embodiment of tabs and their association with attachment point **1118** (shown in Figure 11B), which comprises a pair of distinct geometries (e.g., protrusions) **1119** and **1121**. Each tab is associated with a different geometry, for example, first tab **1135** with geometry **1119** and second tab **1140** with geometry **1121** on the inner implant holder **1116**. The pair of tabs are physically next to one another as shown schematically in Figure 11B. Expansion of an associated implant (not shown for ease of viewing) leads to radial separation of first tab **1135** and second tab **1140** and their disassociation from the implant holder **1116**. Forces generated by expanding Nitinol or similar implant material perforce separate adjacent tabs **1135** and **1140** and potentially lead to full separation of the tabs and associated implant with the implant holder **1116**. It is understood that in some embodiments, a plurality of tab pairs are employed to secure an implant with an implant holder **1116** via a plurality of attachment points. In some embodiments, an expanding balloon in conjunction with a stiff implant can drive separation of tabs **1135** and **1140**.

Referring now to Figure 12A, showing a schematic representation of forces applied to first tab **1235** and second tab **1240** when both tabs are associated with attachment point **1218** defined by a single geometry (e.g., a single protrusion). Expanding implant (not shown) applies forces **1270** of an expanding circumference of the implant on the tabs to lead to their physical separation and distancing one from another. The self-expansion of the implant leads to the forced separation of the first tab **1235** and second tab **1240** from the attachment point **1218** on the implant holder **1216**. The movement from a collapsed to an expanded state by virtue of the forces **1270** applied to first tab **1235** and second tab **1240** leads to greater circumferential separation of the tabs in the

expanded state of the implant. Figure 12B shows similar forces **1270** as applied to an alternative embodiment of the first tab **1235** and second tab **1240**. In some applications, the guide of the delivery system (for example, guide **415**, shown in figure 4B)may be rotated so as to further facilitate separation of first tab **1235** and/or second tab **1240** from attachment point **1218,** which is defined by two geometries (e.g., two protrusions) **1218, 1221**. One may note that since the first tab **1235** and second tab **1240** are not associated with the same geometry of attachment point **1218**, the rotation allows the release of the tabs to guarantee full device deployment.

Referring now to Figure 13A, showing a schematic representation of an embodiment of the invention employing a balloon **1390**. The balloon **1390** is optionally located on a catheter (or guide-wire lumen) associated with the implant holder **1316**. The implant holder **1316** is visible as extended from the external sheath **1310** prior to balloon **1390** inflation. In this non-limiting embodiment, first tab **1335** and second tab **1340** are associated with different geometries (e.g., protrusions) **1319** & **1321**, of attachment pointassociated with the implant holder **1316**. After the implant is fully deployed from the external sheath, inflation of a balloon **1390** may be employed to ensure that the first tab **1335** and second tab **1340** are forced to separate, thereby releasing the implant from the implant holder.

Referring now to Figure 13B, showing a schematic representation of the embodiment associated with Figure 13A in which the balloon (Figure 13B, **1390**) has been inflated. Inflation of the balloon distances the first tab and second tab (not shown) from the implant holder **1316**, which in turn ensures disengagement of the implant from the delivery system.

Referring now to Figure 14, showing a schematic view of a pre-insertion implant delivery system **1400** including capsule **1410** optionally defined by an outer sheath with a cylindrical and/or substantially cylindrical shape, holding a crimped implant **1425**, tabs **1435** & **1440** and an implant holder **1416**. In some embodiments, capsule **1410** is attached to a guidance unit (for example, as shown in Figure 15) and/or another guidance element which is connected and/or comprises a guide (e.g., guide wire tube **415**) at a proximal end of capsule **1410** and has an open end at the distal end thereof, for implant passage therethrough. In some embodiments, the open end has a cross-section area of at least 70% of a maximal outer diameter of delivery system **1400**. The guidance element is used for directing the insertion of implant **1452** to a desired deployment site (e.g., lumenal surface). For example, the guidance element can be used for directing a cylindrical self-expanding body sized to be implanted in a pulmonary artery, to the pulmonary artery.

In the figure, one notes that the end **1495** is open and does not make use of a distal conical tip (e.g., a nose cone) as is common in delivery systems. In some embodiments the guide, (such as guide **415**) (not shown for clarity purposes) may protrude beyond the end **1495** but there is no need

for a nose cone over the end **1495** of the outer sheath of capsule **1410** to close the capsule. The lack of a distal conical tip has the potential advantage of reducing and/or avoiding the risk of the nose cone dislodging the deployed implant while withdrawing the nose cone through the implant during retraction of the delivery system. The lack of a nose cone may have a particular use for an implant that forms a diametrical constriction, as shown for example in Figure 3, in which the risk of dislodgement during retraction of the nose cose is greater.

In some embodiments, first, a guide sheath is introduced until it reaches the deployment site and then delivery system **1400** (e.g., capsule **1410**) is inserted therethrough. Using a guide sheath has the potential advantage of reducing and/or avoiding trauma to surrounding tissue and/or vasculature, for example, caused by a sharp edge of the capsule advanced without a guide sheath. Upon reaching the deployment site, first, the guide sheath is retracted to reveal capsule 1410 (and/or capsule 1410 is pushed through the guide sheath), and then the deployment is performed by retracting the capsule to expose the implant.

As noted, the delivery unit is generally associated with and/or comprises a guide (e.g., guide wire tube), optionally, the guide is part of an implant insertion guidance unit. Figure 15 shows such a guidance unit **1596** with implant capsule **1510** including crimped implant (not visible) in the capsule **1510** and present and ready for delivery to an artery and/or other lumenal surface.

Referring now to Figure 16, an implant delivery system **1600** includes a catheter capsule **1610** with a crimped implant **1625** held in place with tabs **1635** & **1640** attached to an implant holder **1616**, such that the implant is crimped over guide wire tube **1615** that is optionally under control of a doctor during implant **1625** delivery. There is no nose cone or tip at the distal end **1695** of the instant embodiment. In some embodiments, a catheter shaft **1617** is attached to catheter capsule **1610**, such that retraction of catheter shaft **1617** retracts catheter capsule **1610** and allows the implant to expand. Until the retraction of catheter shaft **1617**, the implant is held from moving back by implant holder **1616** which is mounted over guidewire tube **1615** and which is held stationary (e.g., both guidewire tube **1615** and implant holder **1616**) during said retraction of the catheter shaft **1617**. In some embodiments, guidewire tube **1615** passes axially and optionally concentrically within catheter shaft **1617**, as shown for example in Figure 16.

Figure 17 shows a flowchart for an additional method of the invention. The invention includes a method for releasing an implant from a delivery unit into a lumen, including: providing a crimped implant in a delivery unit comprised of an outer sheath and an inner implant holder, wherein the implant is attached to said implant holder with a single tab associated with the implant and geometrically engaged to a side of an attachment point on the implant holder (702); releasing the implant from the outer sheath at a position in a lumen (704); allowing the implant to expand

radially after said release (706); and, allowing the single tab to circumferentially move away from the attachment point, so that the single tab moves (circumferentially, radially, and/or axially relative to the attachment point) away from the attachment point thereby weakening a coupling between the singular tab with the attachment point (708).

In one aspect of the method, there is further including rotating the guide wire tube (e.g., guide **415**, **1615**) associated with the implant holder. In another aspect of the method, the single tab is realized as a plurality of single tabs.

Attention is turned to Figure 18A which shows a schematic view of an embodiment of the invention. A single tab **1838** is associated with an attachment point **1818** on an implant holder **1816**. Optionally, attachment point **1818** is defined by a single geometry, such as a single protrusion. The single tab **1838** differs from prior art tabs in that its association with attachment point **1818** is on one side. In this embodiment, a plurality of single tabs **1838** are associated with a plurality of implant crowns and attachment points **1818**. Typically, 2, 4, or 6 single tabs **1838** are employed. To help release of the single tab **1838**, the guidewire tube (for example guide **415**, shown in Figure 4A) might be rotated to facilitate disassociation of single tab **1838** and implant holder **1816**. Rotating the guidewire tube moves (e.g., rotates) implant holder **1816** and potentially prompts disassociation of single tab **1838** and attachment point **1818**. Figure 18B shows an alternative version of a single tab **1838** and its association with an attachment point **1818** connected to an implant holder **1816**. Self-expansion of the Nitinol (or similar material) causes release of most of the tabs **1838**. Even if a single tab **1838** is still attached to attachment point **1818**, its release will be most likely. Figure 18A shows a small portion of the tab **1838** wrapped around the attachment point **1818**. This overhang **1839** is generally between 0.1 and 2 times the axial thickness of the attachment point, and preferably less than 1.

Attention is turned to Figures 19A, 19B, 19C and 19D, which show in self-expansion of a Nitonil-based implant **1930** and the concomitant release of first tab **1935** and second tab **1940** from associated implant holder **1916**. In Figures 19C & 19D, the first tab **1935** and second tab **1940** are no longer in physical contact with the attachment points (not visible in these figures) on the deployment arm **1915**.

It is expected that during the life of a patent maturing from this application many relevant lumen implant delivery units will be described; the scope of the term implant delivery unit is intended to include all such new technologies *a priori*. It is understood that additional devices and methods combining elements of the above embodiments may be employed without straying from the spirit of the invention.

As used herein with reference to quantity or value, the term "about" means "within 20% of".

The terms "comprises", "comprising", "includes", "including", "has", "having" and their conjugates mean "including but not limited to".

The term "consisting of" means "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular forms "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, embodiments of this invention may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as "from 1 to 6" should be considered to have specifically disclosed subranges such as "from 1 to 3", "from 1 to 4", "from 1 to 5", "from 2 to 4", "from 2 to 6", "from 3 to 6", etc.; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein (for example "10-15", "10 to 15", or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases "range/ranging/ranges between" a first indicate number and a second indicate number and "range/ranging/ranges from" a first indicate number "to", "up to", "until" or "through" (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

Unless otherwise indicated, numbers used herein and any number ranges based thereon are approximations within the accuracy of reasonable measurement and rounding errors as understood by persons skilled in the art.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques

and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term "treating" includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

It is the intent of the applicant(s) that all publications, patents and patent applications referred to in this specification are to be incorporated in their entirety by reference into the specification, as if each individual publication, patent or patent application was specifically and individually noted when referenced that it is to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting. In addition, any priority document(s) of this application is/are hereby incorporated herein by reference in its/their entirety.

WHAT IS CLAIMED IS:

1. A delivery unit, comprising:

a capsule including an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto;

an implant, comprising:

a first tab associated with a first circumferential location of said implant, wherein said first tab is sized and shaped for geometric engagement with said attachment point; and,

a second tab associated with a second circumferential location of said implant and sized and shaped for geometric engagement with said attachment point,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath and wherein said first location and said second location are further circumferentially apart in said expanded state than in said collapsed state,

wherein said first tab and said second tab hold said implant to said attachment point in said first, collapsed, state, and move circumferentially apart in said second, expanded, state, thereby weakening an engagement of said tabs to said attachment point.

2. The delivery unit according to claim 1, wherein said implant includes at least one stent.

3. The delivery unit according to claim 1 or claim 2, comprising one or more additional first tab and additional second tab, provided as pairs, wherein each tab is located on a unique position on said implant.

4. The delivery unit according to any one of claims 1-3, wherein said implant holder comprises a retractable deployment arm and said at least one attachment point comprises a plurality of attachment points.

5. The delivery unit according to claim 2, wherein said at least one stent is made partially or wholly of Nitinol.

6. The delivery unit according to claim 2 or claim 5, wherein said first tab and said second tab are associated with crown-shaped structures at an end of said stent.

7. The delivery unit according to any one of claims 1-6, wherein said first tab and said second tab are identical in shape or mirrored.

8. The delivery unit according to any one of claims 1-7, wherein said first tab and said second tab have a rounded feature.

9. The delivery unit according to any one of claims 1-8, wherein said first tab and said second tab have a rectangular feature.

10. The delivery unit according to any one of claims 1-9, wherein said first tab and said second tab face each other around said attachment point.

11. The delivery unit according to any one of claims 1-10, wherein said first tab and said second tab are associated with different geometries of the attachment point.

12. The delivery unit according to anyone of claims 1-11, wherein said capsule has an open end at a distal end thereof, for implant passage therethrough.

13. The delivery unit according to claim 12, wherein the distal end lacks a conical tip.

14. The delivery unit according to any one of claims 1-13, comprising a guide that protrudes beyond the open distal end of said capsule, wherein said guide passes through said inner implant holder, and wherein said implant is crimped over said guide and within said capsule.

15. The delivery unit according to any one of claims 1-14, comprises a balloon, associated with said implant holder, and positioned adjacent to said first tab and said second tab, such that inflation of said balloon forces the separation of said first tab and said second tab.

16. A method for releasing an implant from a delivery unit into a lumen, including:

providing a crimped implant in a delivery unit comprised of an outer sheath and an inner implant holder, wherein said implant is attached to said implant holder with a first tab and a second tab associated with said implant and geometrically engaged to a same attachment point on said implant holder;

releasing said implant from said outer sheath at a position in a lumen;

allowing said implant to expand radially after said release; and,

allowing said first tab and said second tab to circumferentially move away from each other, so that at least one tab moves circumferentially away from said attachment point thereby weakening a coupling between said first tab and said second tab with said attachment point.

17. The method according to claim 16, wherein said lumen is an artery.

18. The method according to claim 16 or 17, further including fluoroscopic monitoring of positions of said first tab and said second tab after said allowing said implant to expand.

19. The method according to any one of claims 16-18, wherein said implant is made, in part, of a self-expanding material.

20. The method according to any one of claims 16-19, further including expanding a balloon associated with said implant holder after said releasing.

21. The method according to any one of claims 16-20, wherein said releasing is initiated by moving said inner implant holder out of said outer sheath.

22. The method according to any of claims 16-18, wherein said releasing is initiated by a rotation of said implant holder.

23. A delivery unit for a stent-like implant onto a lumenal surface, including:

a guide for directing insertion of an implant at a desired lumenal surface;

a capsule including an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto, wherein said capsule has an open end for implant passage out of said capsule;

an implant, comprising:

a cylindrical self-expanding body sized to be implanted in a pulmonary artery.

24. The delivery unit according to claim 23, wherein said implant comprises:

a first tab associated with a first circumferential location of said implant, wherein said first tab is sized and shaped for geometric engagement with said attachment point; and,

a second tab associated with a second circumferential location of said implant and sized and shaped for geometric engagement with said attachment point,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath and wherein said first location and said second location are further circumferentially apart in said expanded state than in said collapsed state,

wherein said first tab and said second tab hold said implant to said attachment point in said first, collapsed, state, and move circumferentially apart in said second, expanded, state, thereby weakening an engagement of said tabs to said attachment point.

25. The delivery unit according to claim 23 or 24, wherein said implant comprises:

a single tab associated with a circumferential location of said implant, wherein said single tab is sized and shaped for geometric engagement with a side of said attachment point; and,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath,

wherein said single tab holds said implant to said inner implant holder in said first, collapsed, state, and moves away from said attachment point in said second, expanded, state, thereby weakening an engagement of said single tab to said inner implant holder.

26. The delivery unit according to any one of claims 23 to 25, wherein the guide comprises a guide wire tube.

27. The delivery unit according to claim 26, wherein said guide wire tube extends beyond said open end.

28. The delivery unit according to any one of claims 23 to 27, wherein the proximal end lacks a conical tip.

29. The delivery unit according to any one of claims 23 to 28, wherein said open end has a cross-section area of at least 70% of a maximal outer diameter of said delivery unit.

30. A method for releasing an implant from a delivery unit into a lumen, including:

providing a crimped implant in a delivery unit comprised of a capsule and an inner implant holder, wherein said implant is attached to said implant holder with a single tab associated with said implant and geometrically engaged to a side of an attachment point on said implant holder;

releasing said implant from said capsule at a position in a lumen;

allowing said implant to expand radially after said release; and,

allowing said single tab to circumferentially move away from said attachment point, so that said single tab moves circumferentially away from said attachment point thereby weakening a coupling between said single tab with said attachment point.

31. The method according to claim 30, further including rotating a guide wire tube associated with said implant holder.

32. The method according to claim 30, comprising one or more additional single tabs, wherein each tab is associated with a unique position on said implant.

33. A delivery unit, comprising:

a capsule having an inner volume defined by a wall of an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto;

an implant, comprising:

a first tab associated with a first circumferential location of said implant, wherein said first tab is sized and shaped for geometric engagement with said attachment point; and,

a second tab associated with a second circumferential location of said implant and sized and shaped for geometric engagement with a same or a different attachment point,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath and wherein said first location and said second location are further circumferentially apart in said expanded state than in said collapsed state,

wherein said first tab and said second tab hold said implant to said inner implant holder in said first, collapsed, state, and move circumferentially apart in said second, expanded, state, thereby weakening an engagement of said tabs to said inner implant holder.

34. A delivery unit, comprising:

a capsule including an outer sheath and an inner implant holder having at least one attachment point for attaching an implant thereto;

an implant, comprising:

a single tab associated with a circumferential location of said implant, wherein said single tab is sized and shaped for geometric engagement with a side of said attachment point; and,

wherein said implant has a first, collapsed state within said sheath and a second, expanded state outside said sheath,

wherein said single tab holds said implant to said inner implant holder in said first, collapsed, state, and moves away from said attachment point in said second, expanded, state, thereby weakening an engagement of said single tab to said inner implant holder.

35. The delivery unit according to claim 34, comprises one or more additional single tabs, wherein each tab is associated with a unique position on said implant.

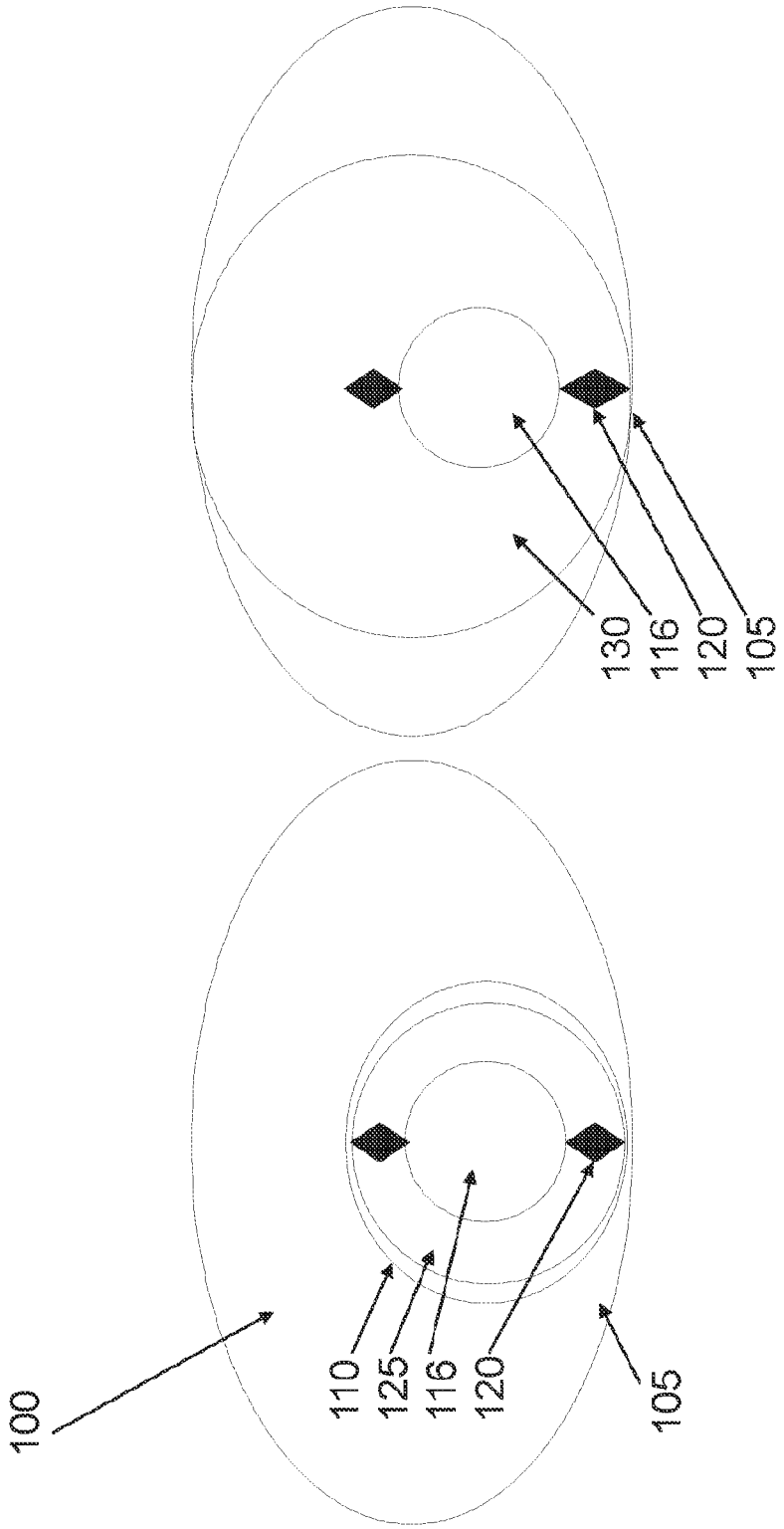


Figure 1A

Figure 1B

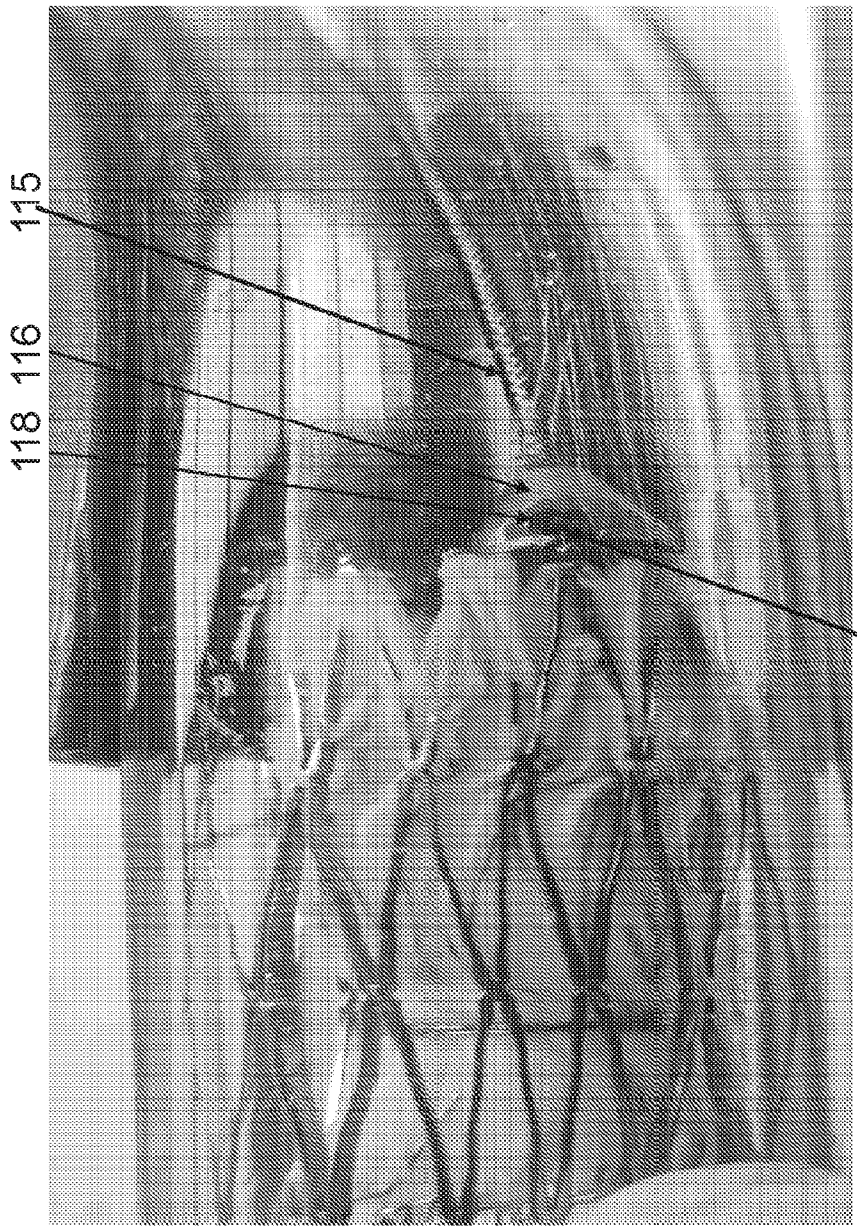


Figure 1C

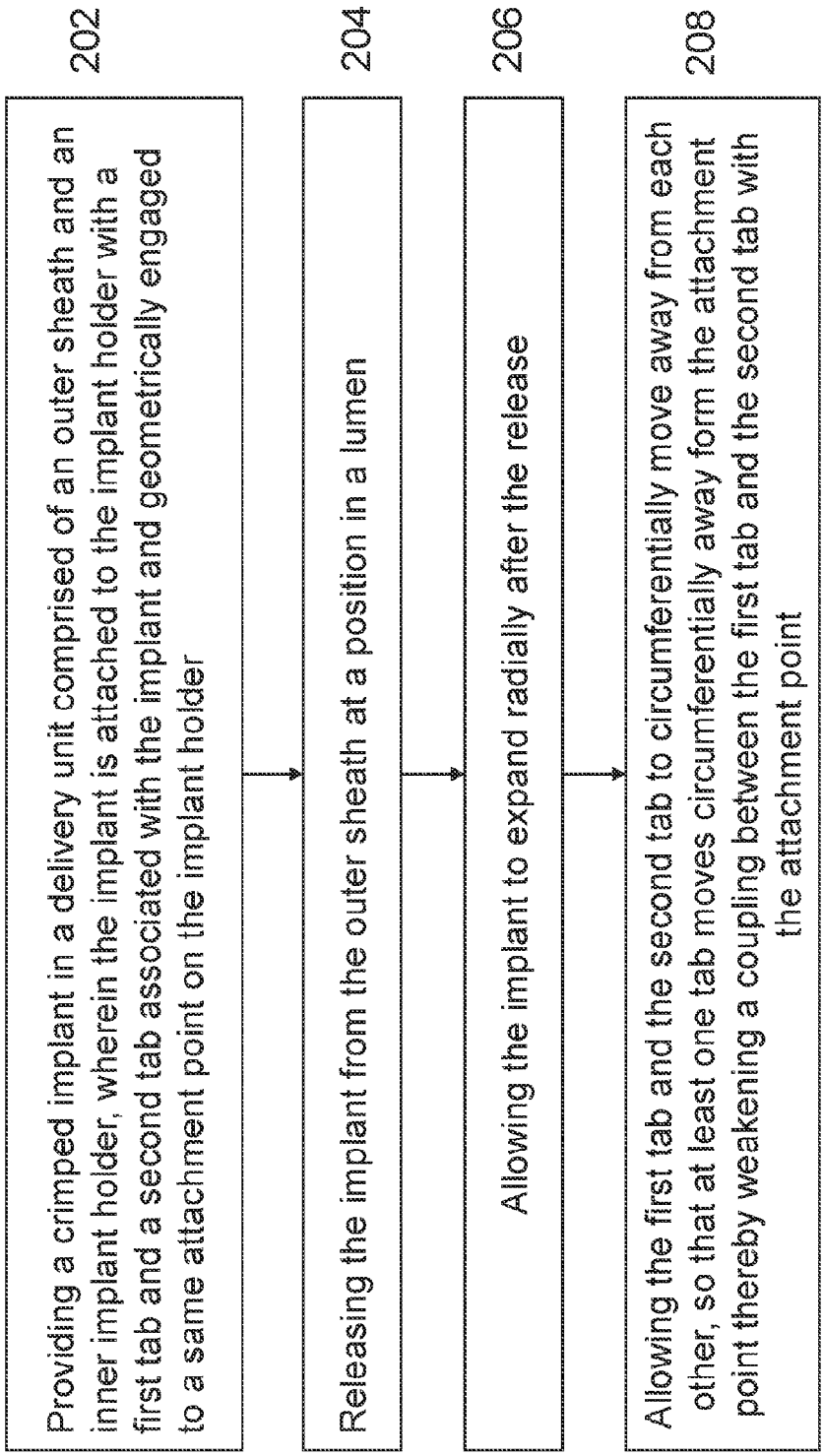
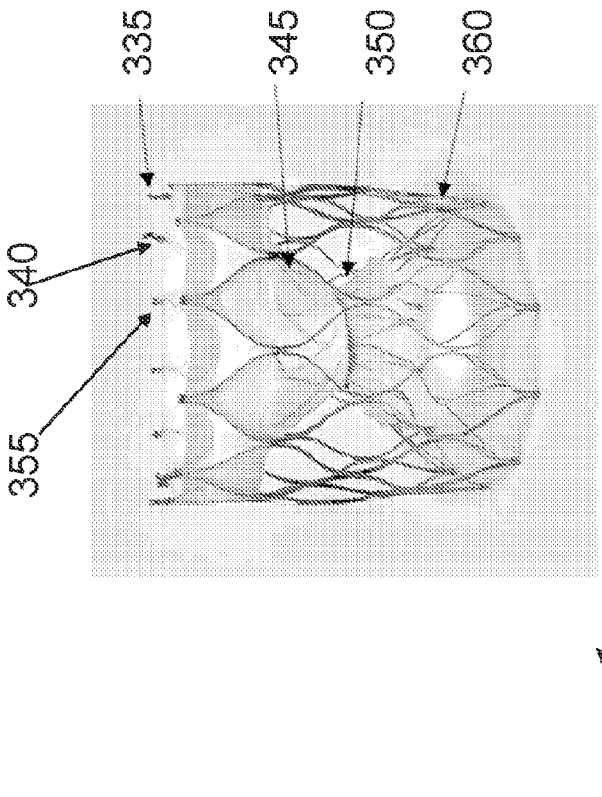

202
Providing a crimped implant in a delivery unit comprised of an outer sheath and an inner implant holder, wherein the implant is attached to the implant holder with a first tab and a second tab associated with the implant and geometrically engaged to a same attachment point on the implant holder
204
Releasing the implant from the outer sheath at a position in a lumen
206
Allowing the implant to expand radially after the release
208
Allowing the first tab and the second tab to circumferentially move away from each other, so that at least one tab moves circumferentially away form the attachment point thereby weakening a coupling between the first tab and the second tab with the attachment point

Figure 2



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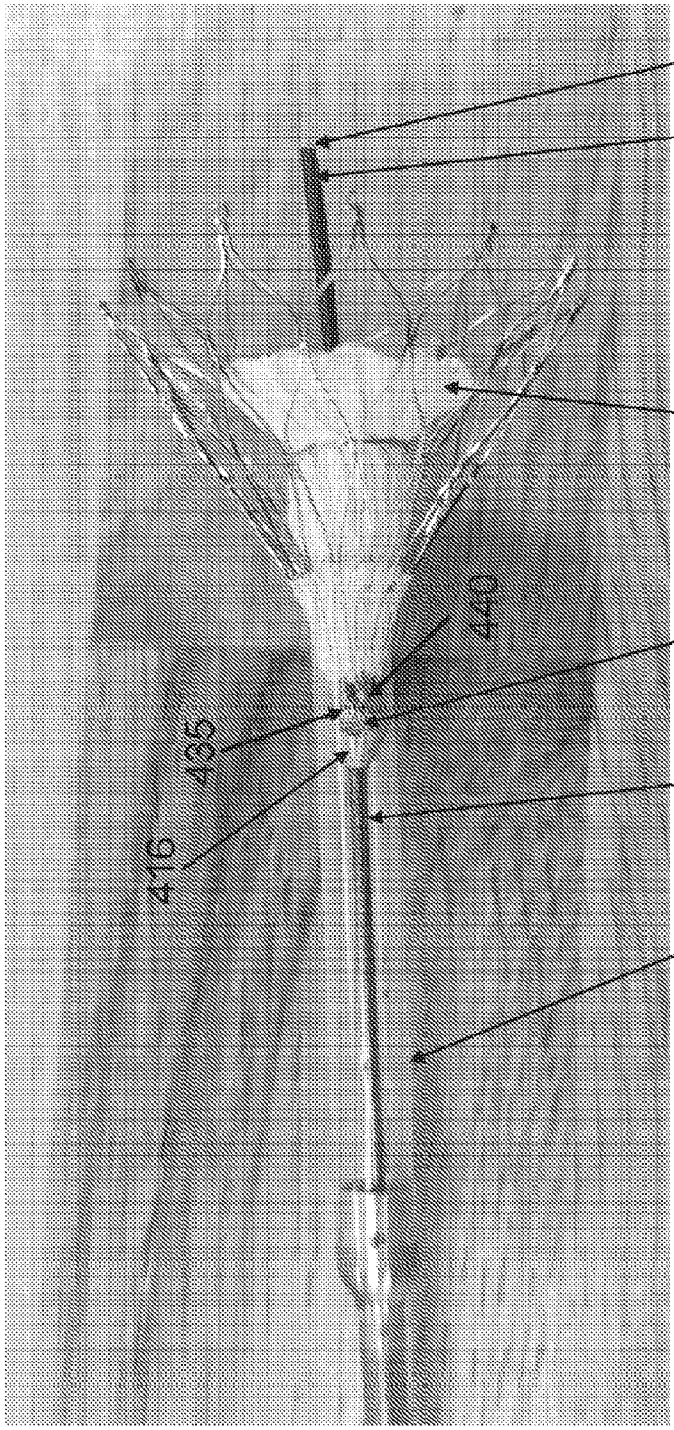


Figure 4A

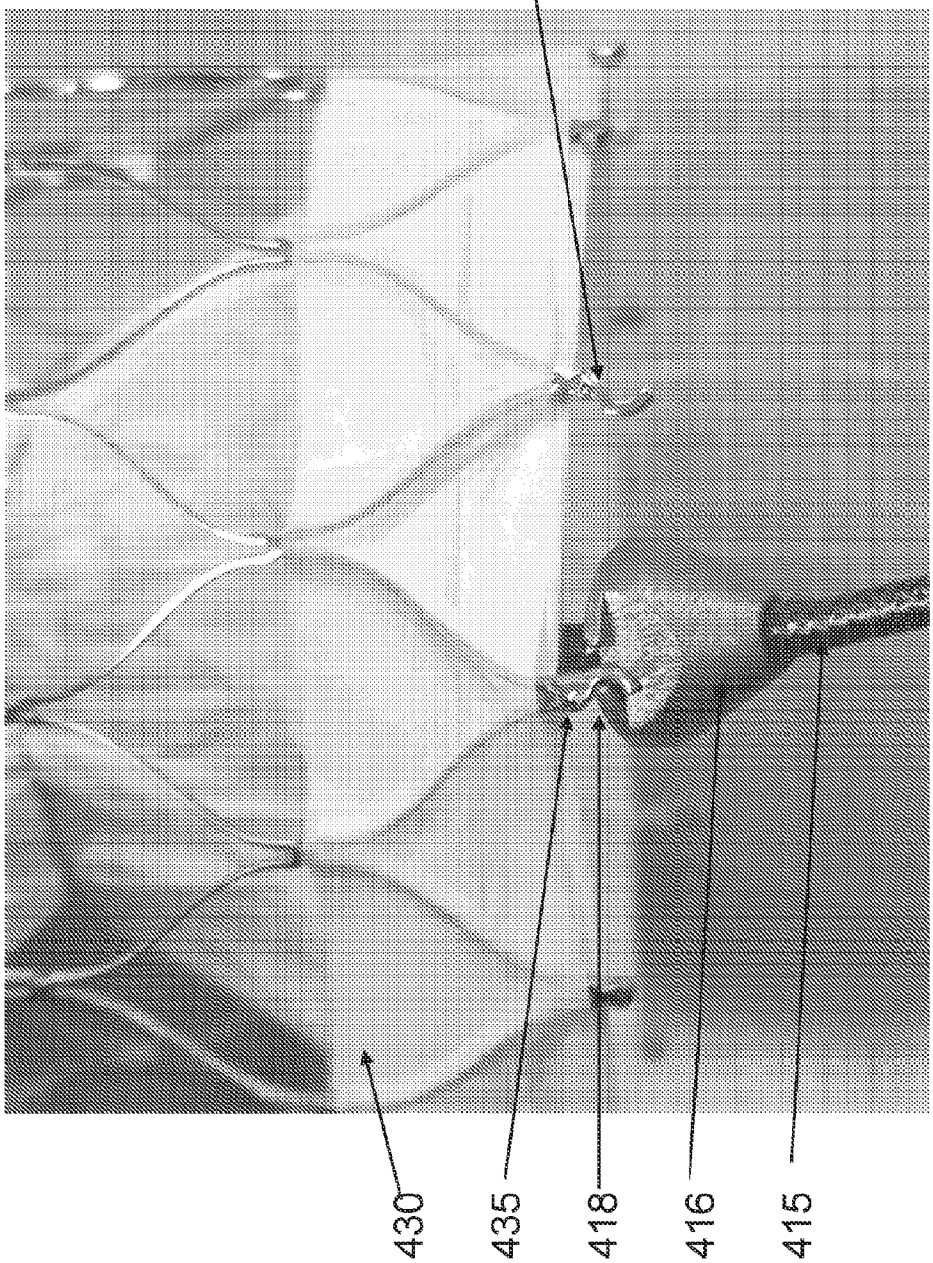
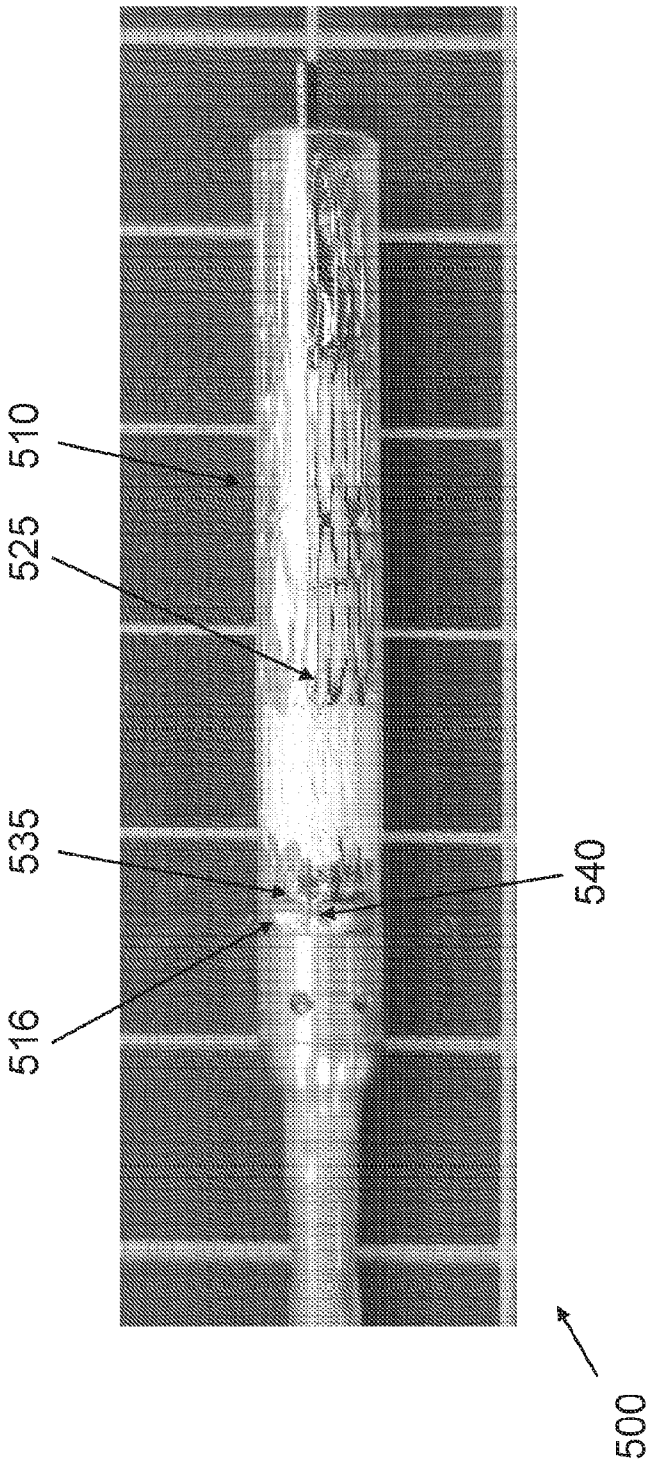


Figure 4B



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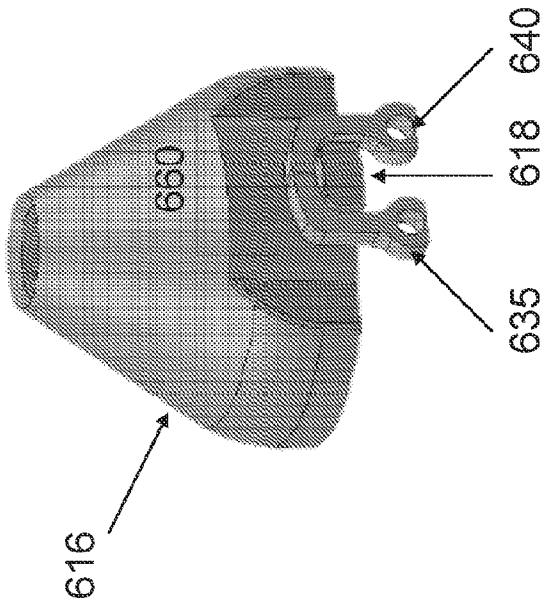


Figure 6B

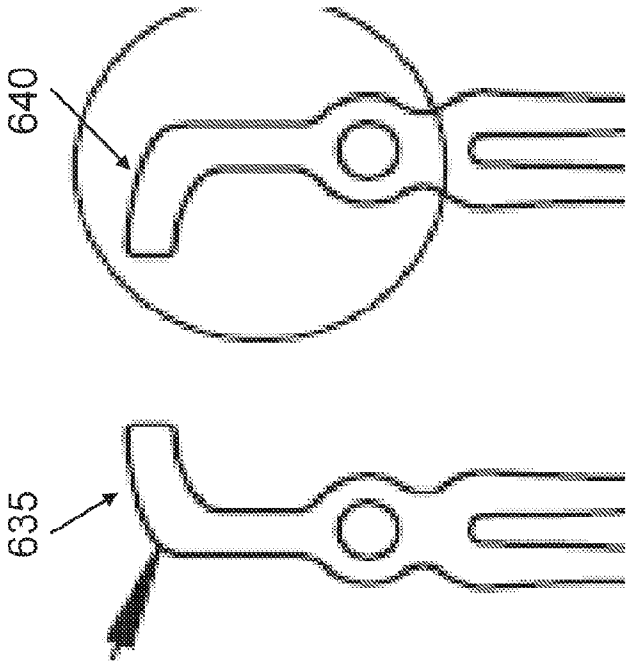


Figure 6A

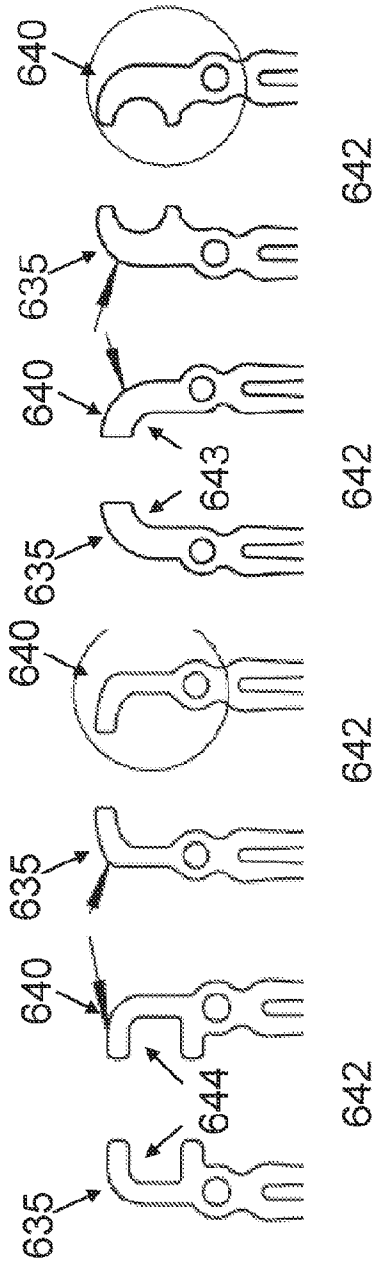


Figure 6C

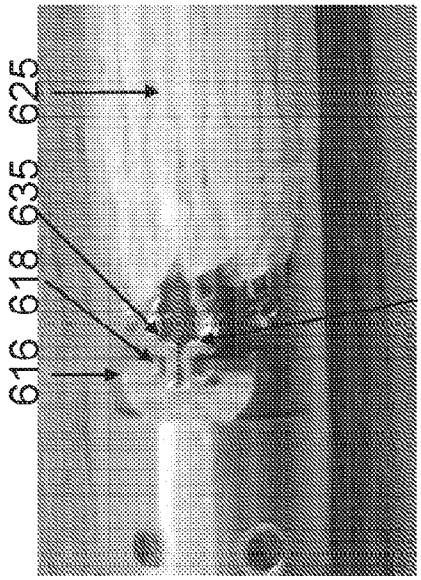


Figure 6E

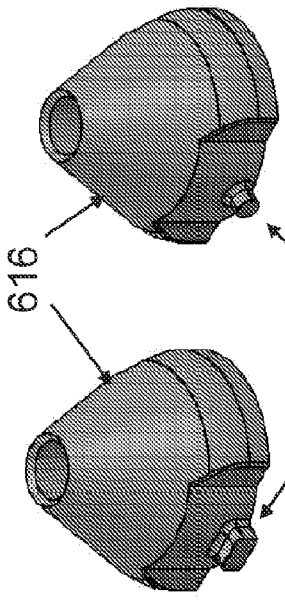
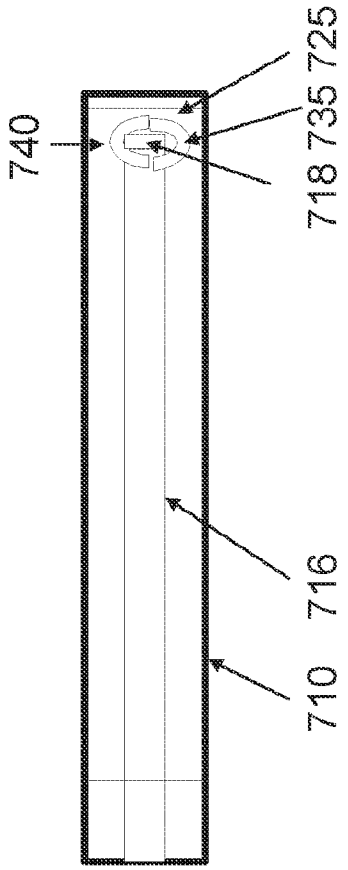


Figure 6D



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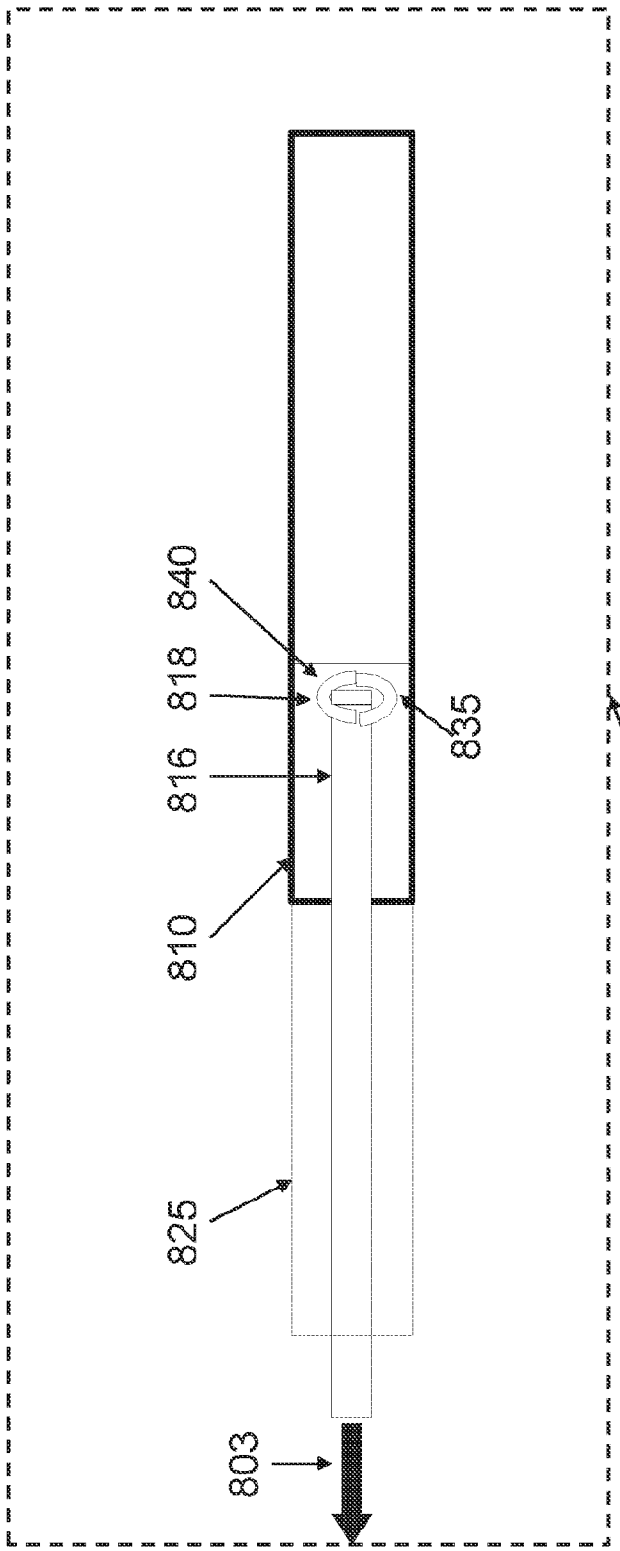

Figure 8A

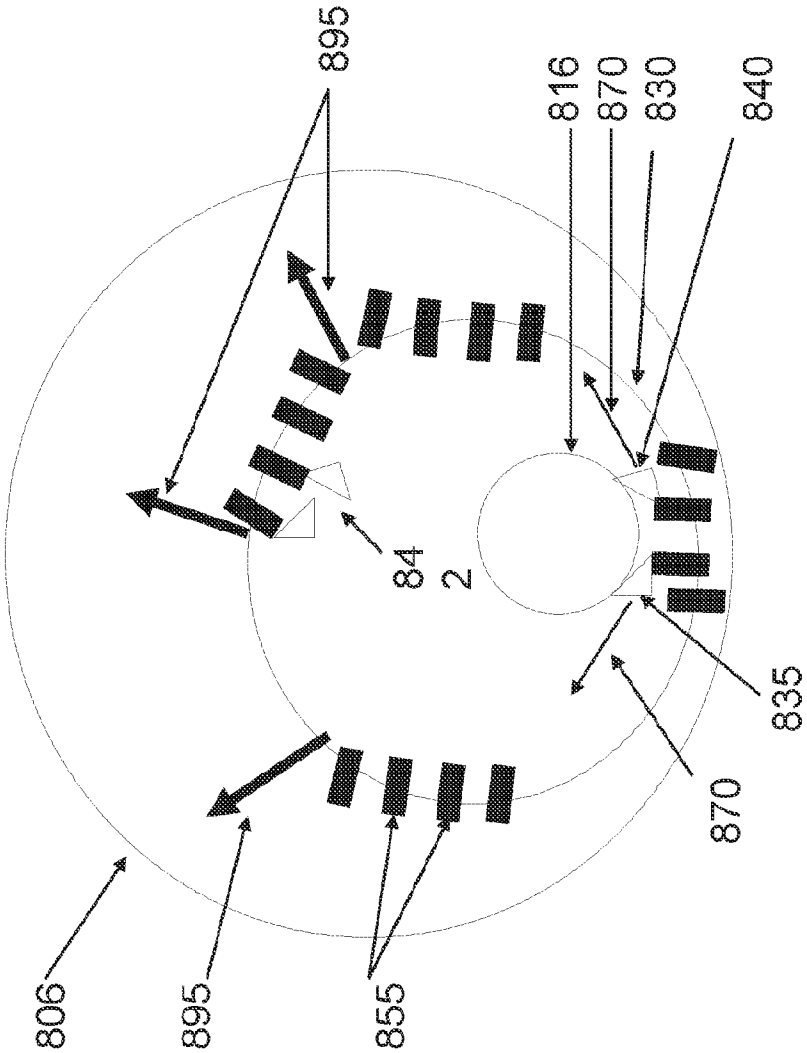

Figure 8B

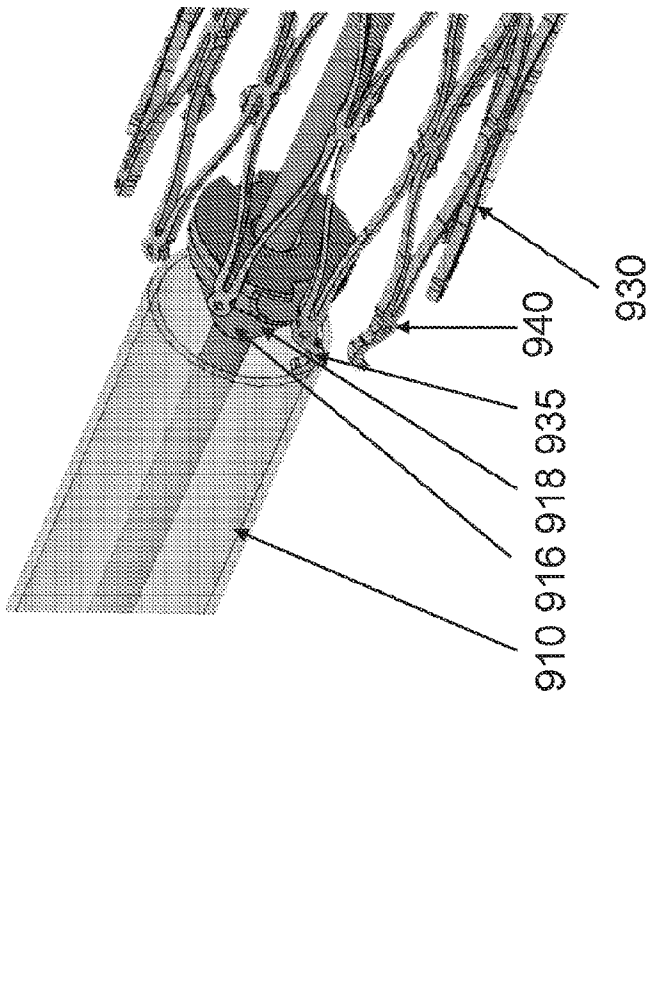

Figure 9

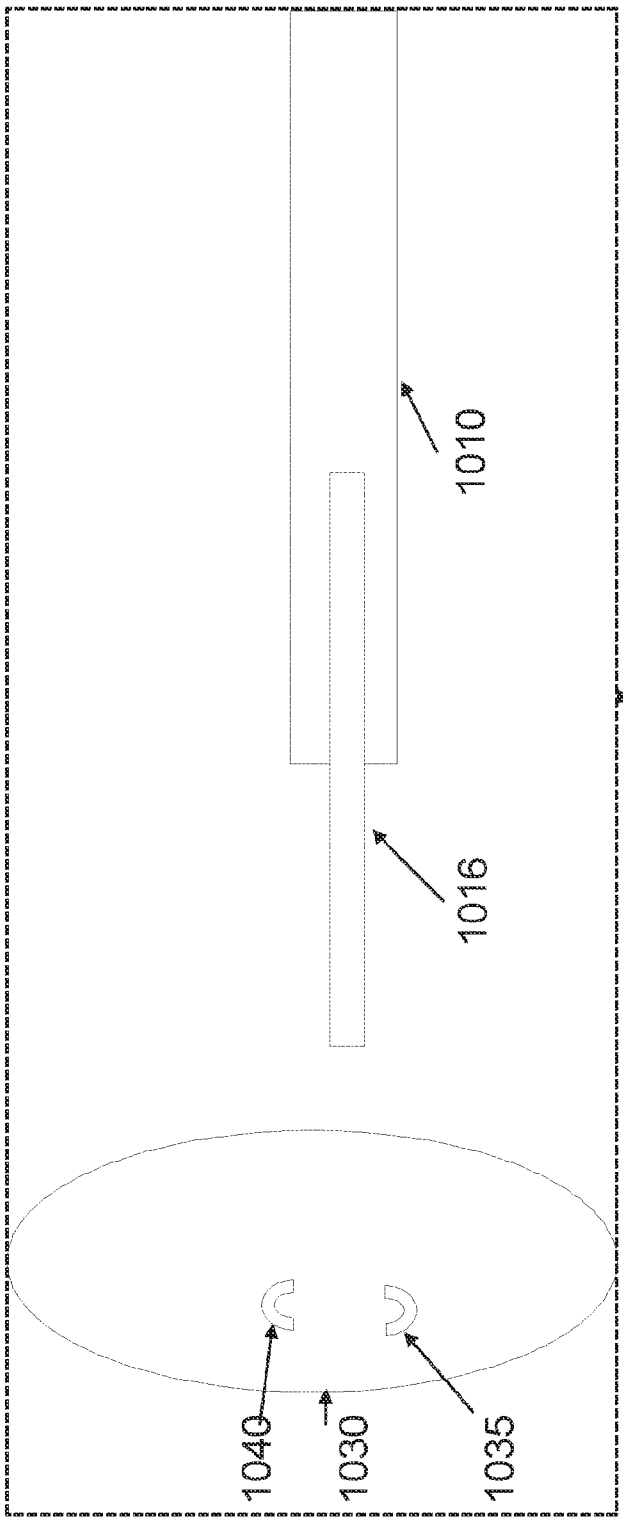

Figure 10

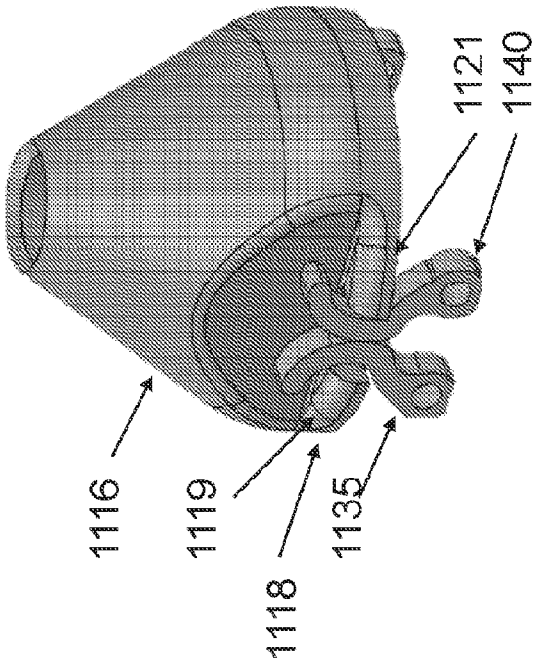

Figure 11B

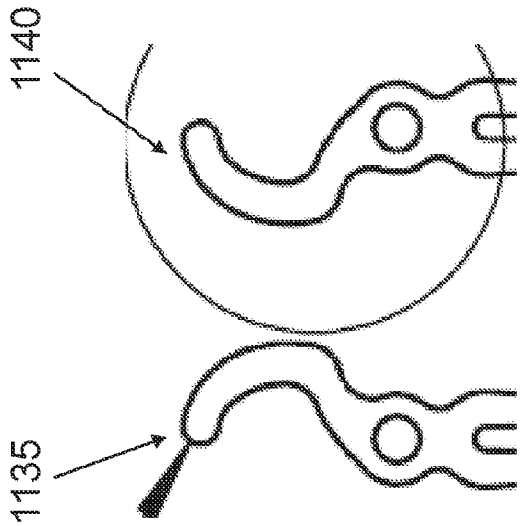

Figure 11A

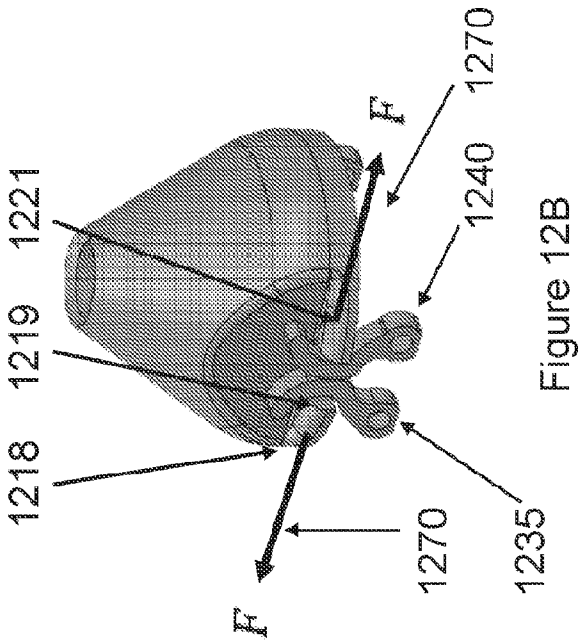

Figure 12B

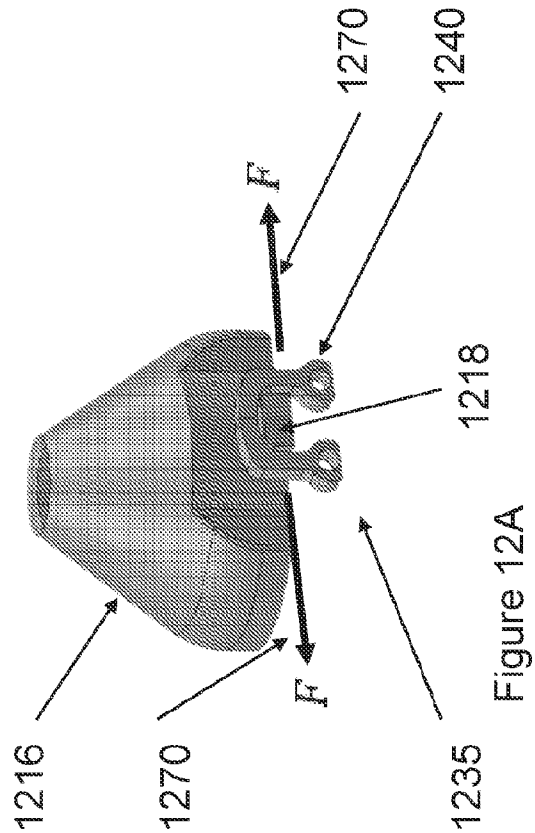

Figure 12A

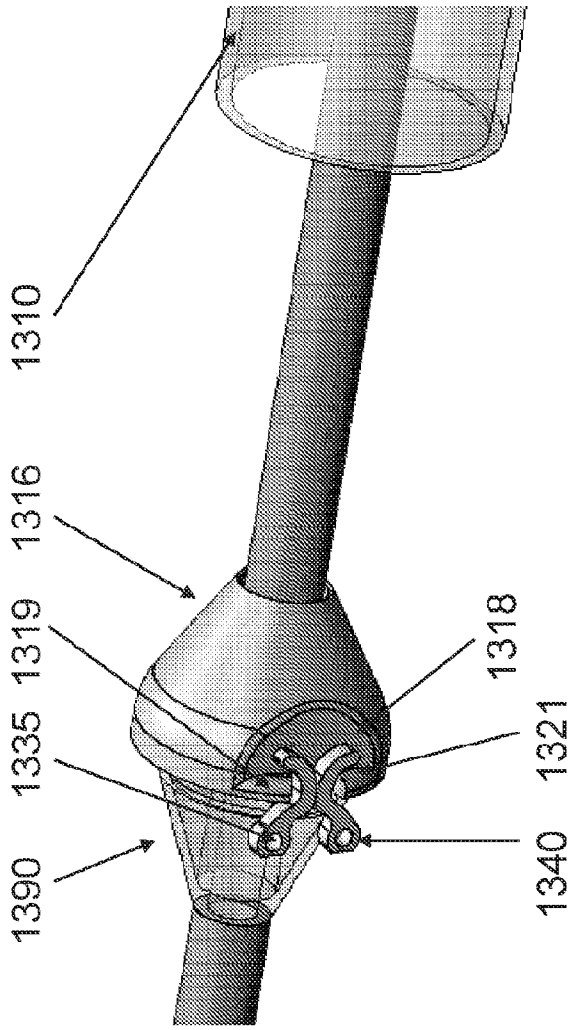

Figure 13A

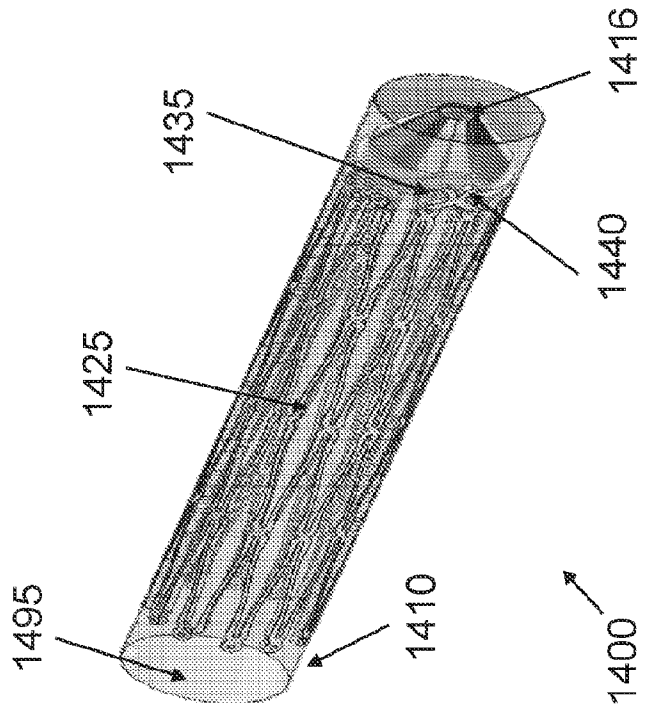

Figure 14

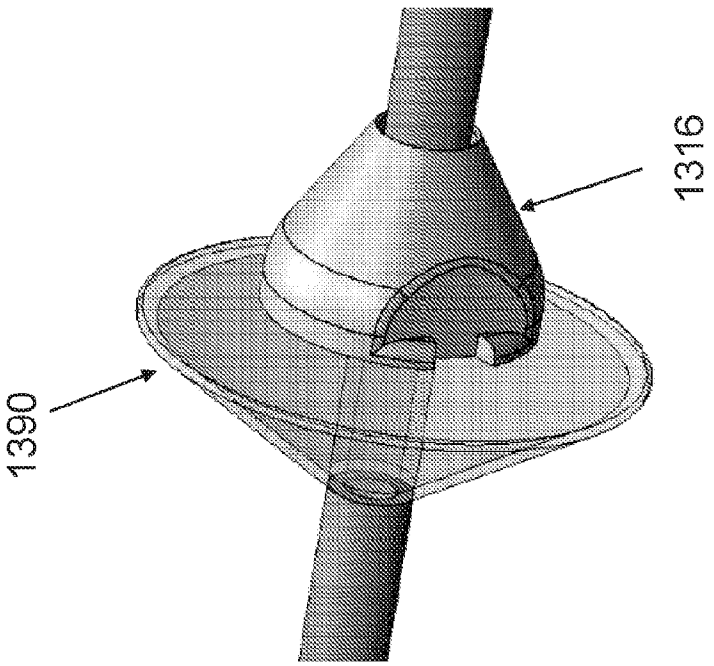

Figure 13B

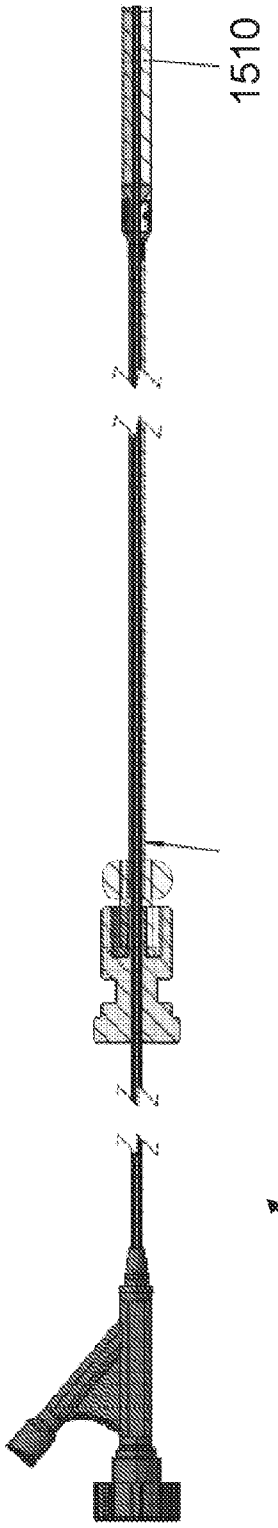

Figure 15

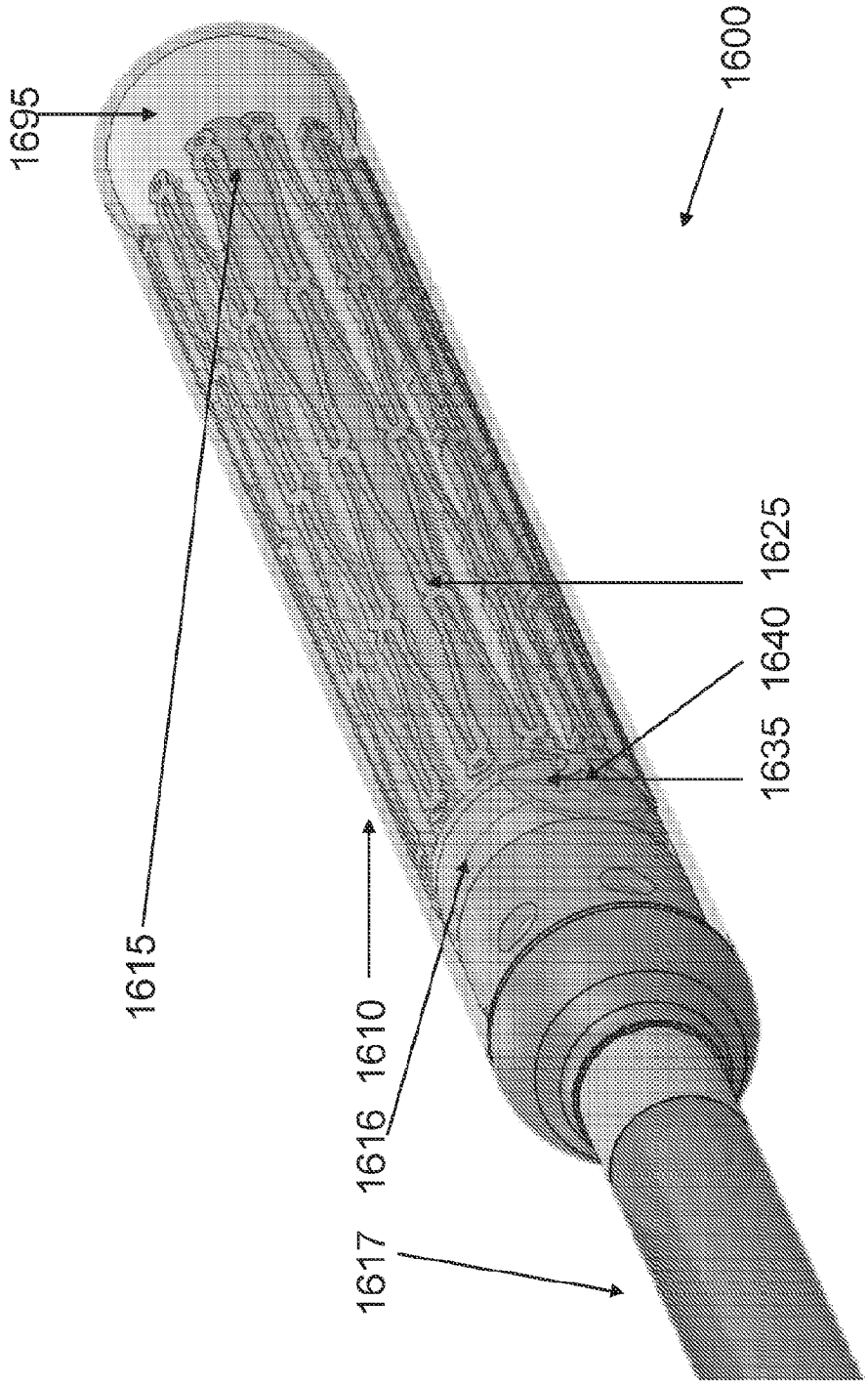

Figure 16

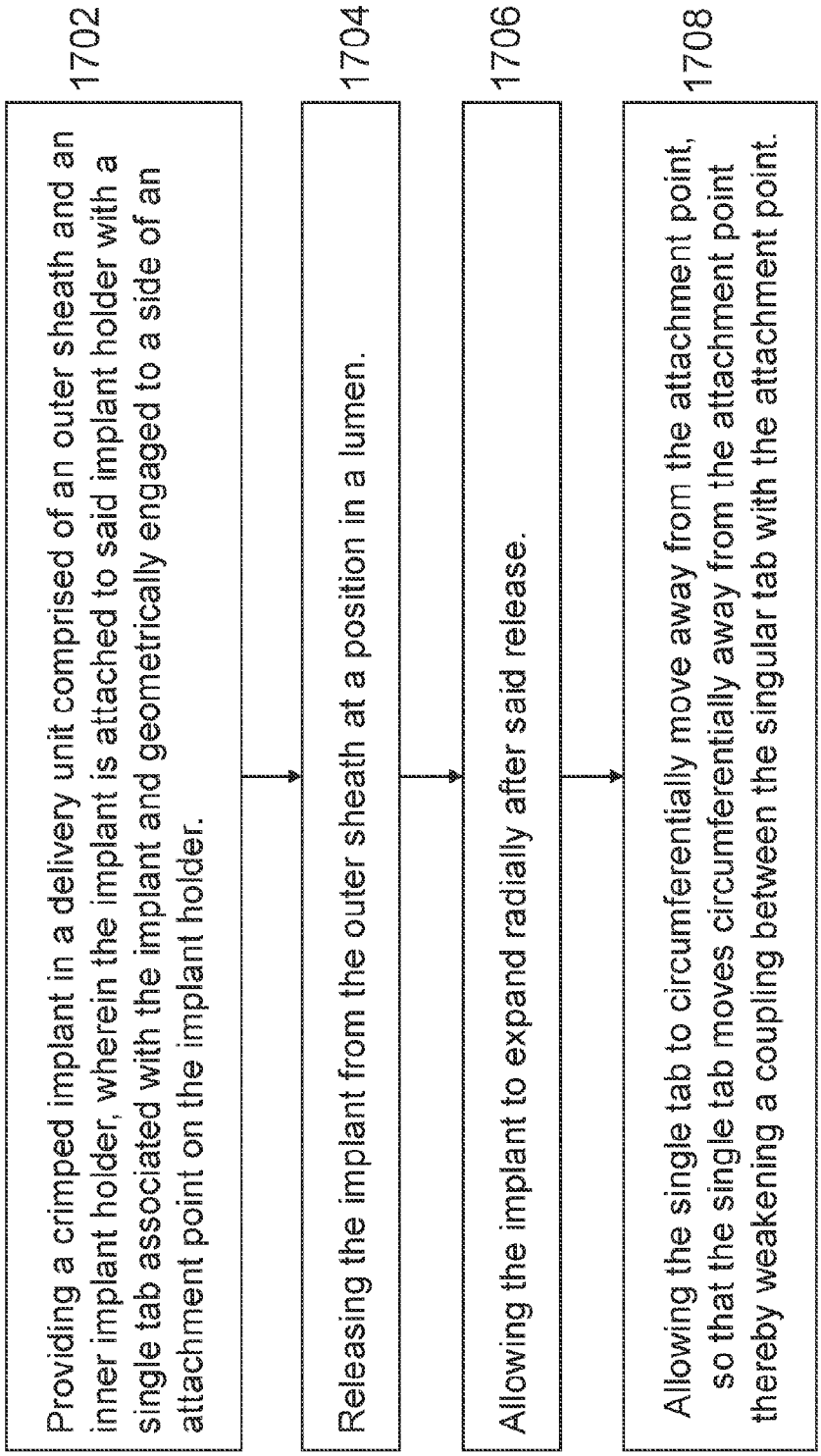
Providing a crimped implant in a delivery unit comprised of an outer sheath and an inner implant holder, wherein the implant is attached to said implant holder with a single tab associated with the implant and geometrically engaged to a side of an attachment point on the implant holder.
1702
Releasing the implant from the outer sheath at a position in a lumen.
1704
Allowing the implant to expand radially after said release.
1706
Allowing the single tab to circumferentially move away from the attachment point, so that the single tab moves circumferentially away from the attachment point thereby weakening a coupling between the singular tab with the attachment point.
1708

Figure 17

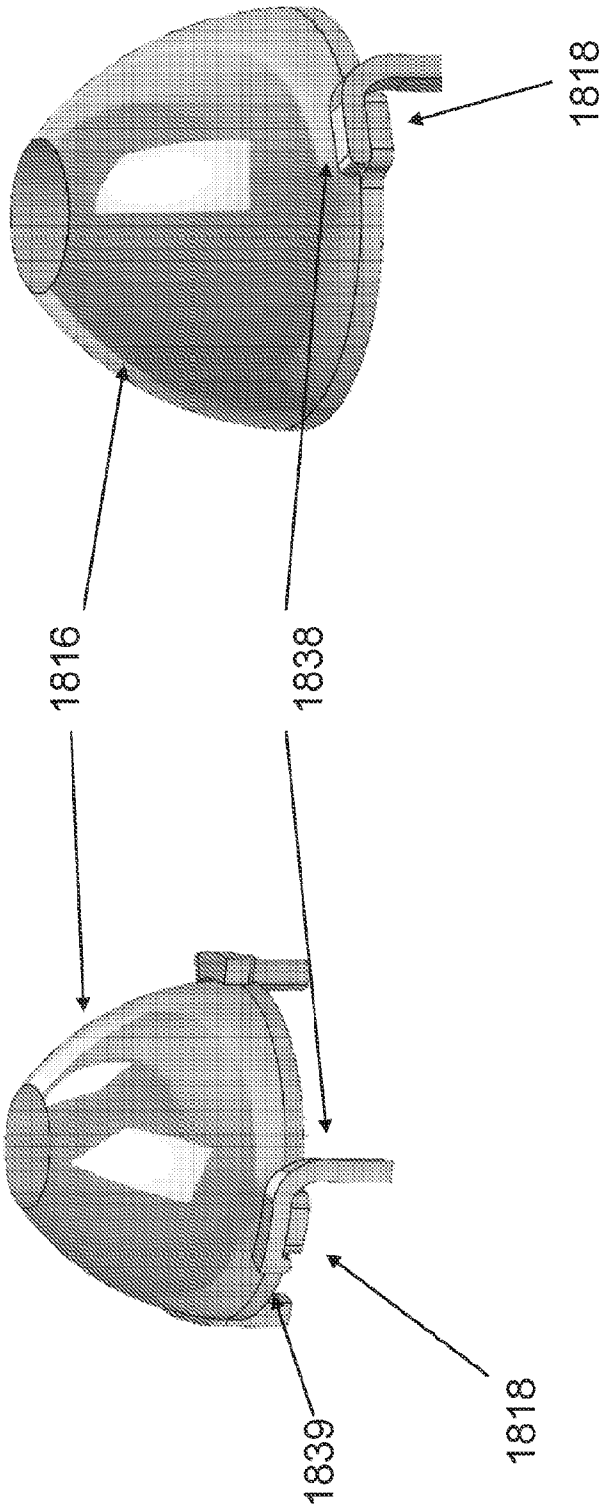

Figure 18B

Figure 18A

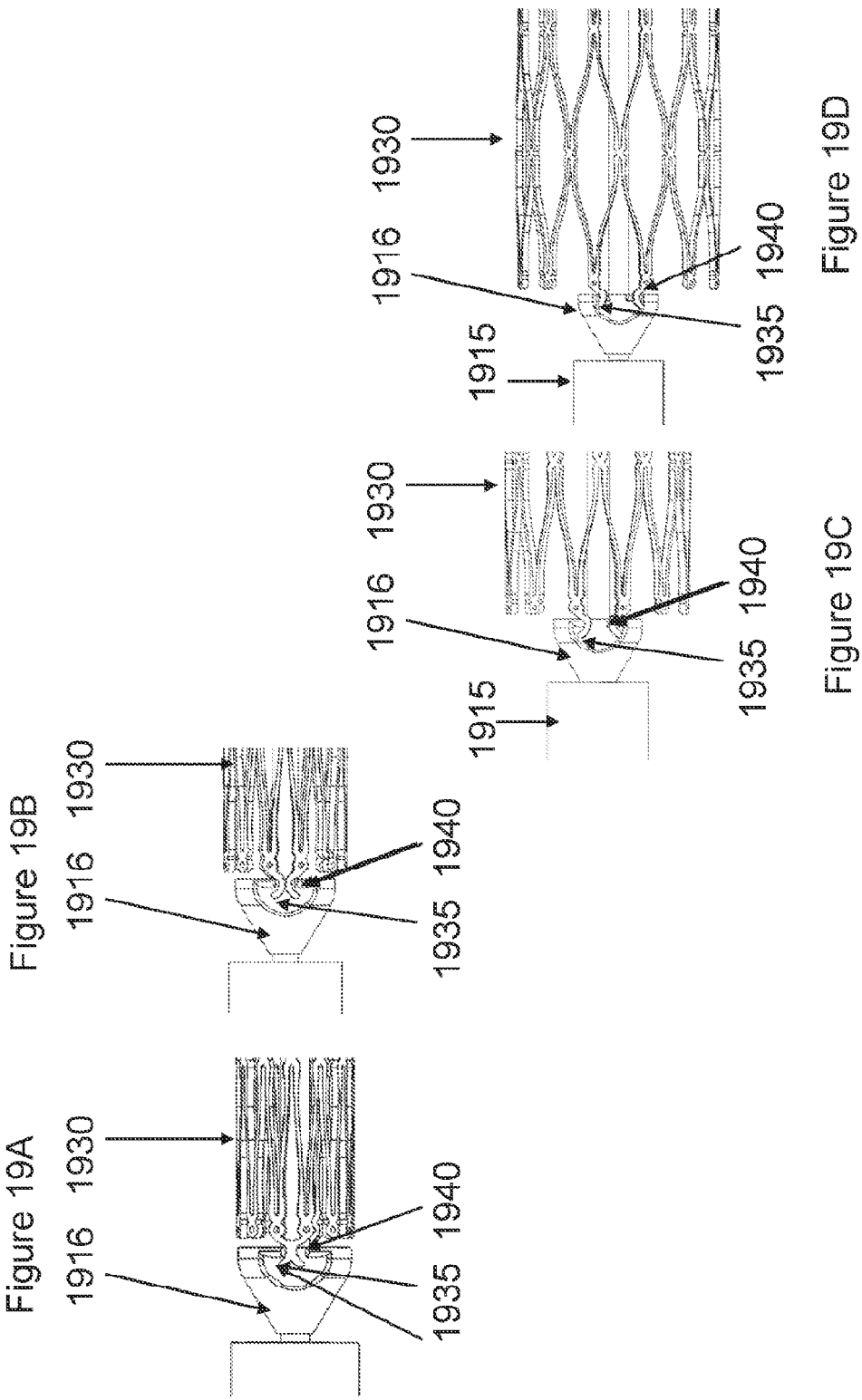

Figure 19A

Figure 19B

Figure 19C

Figure 19D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2024/050393

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/24(2024.01)i; ***A61F 2/82***(2024.01)i; ***A61F 2/844***(2024.01)i
CPC: A61F 2/24; A61F 2/82; A61F 2/844

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F 2/24; A61M 29/00
CPC: A61F 2/24; A61M 29/00

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)

Databases consulted: Esp@cenet, Google Patents, Orbit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CA 2756049 A1 (CARDIAQ VALVE TECHNOLOGIES INC et al) 21 October 2010 (2010-10-21) Fig.14	1-35
A	US 2019083242 A1 (CARDIOVALVE LTD et al) 21 March 2019 (2019-03-21) whole document	1-35
A	US 2014331475 A1 (MEDTRONIC WASCULAR GALWAY et al) 13 November 2014 (2014-11-13) whole document	1-35

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

☑ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 June 2024	**13 June 2024**

Name and mailing address of the ISA/IL	Authorized officer
Israel Patent Office **Technology Park, Bldg.5, Malcha, Jerusalem, 9695101,** **Israel** **Israel** Telephone No. **972-73-3927253** Email: **pctoffice@justice.gov.il**	**ZOZULYA Irina** Telephone No.

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