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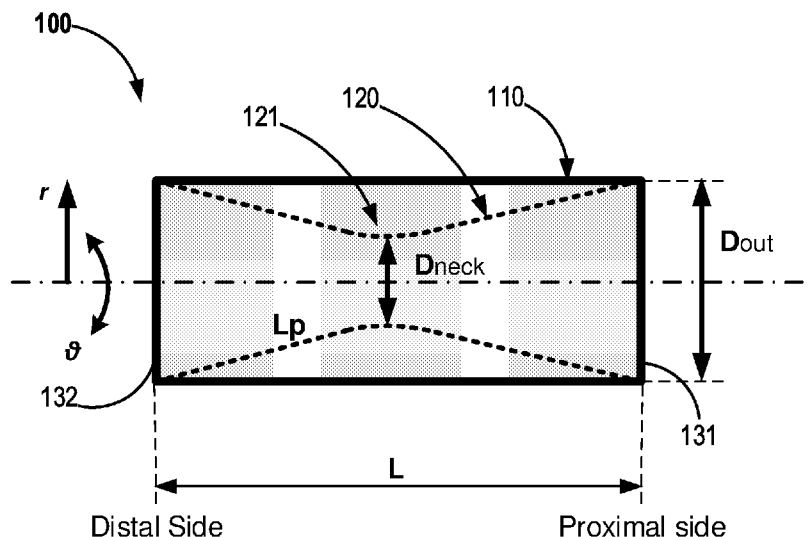


Fig. 1

(57) Abstract: A new medical apparatus for deployment within an anatomical blood vessel and methods of use thereof. The apparatus comprising: a first tubular wall; and a second tubular wall, placed within the first tubular wall; wherein the first and second tubular walls are firmly connected at their edges, therefore restricted to have same overall longitudinal length; and wherein the second tubular wall is configured to be partially constricted towards its inner radial axis, while maintaining its overall longitudinal length.



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DOUBLE WALLED FIXED LENGTH STENT LIKE APPARATUS  
AND METHODS OF USE THEREOF

FIELD OF THE INVENTION

[001] The current invention relates to a medical device to be positioned within the main pulmonary artery and/or the pulmonary artery branches, and to methods of use thereof for treating, reducing the severity of, or reducing symptoms associated with, or any combination thereof, congestive heart failure, including left ventricular failure, wherein use may in certain embodiments, affect the position and function of the interventricular septum during systole.

BACKGROUND OF THE INVENTION

[002] Congestive heart failure (CHF) is a condition in which the heart does not pump out sufficient blood to meet the body's demands. CHF can result from either a reduced ability of the heart muscle to contract (systolic failure) or from a mechanical problem that limits the ability of the heart's chambers to fill with blood (diastolic failure). When weakened, the heart is unable to keep up with the demands placed upon it and the left ventricle (LV) may get backed up or congested. CHF is a progressive disease. Failure of the left side of the heart (left-heart failure/left-sided failure/left-ventricle failure) is the most common form of the disease.

[003] CHF affects people of all ages including children, but it occurs most frequently in those over age 60, and is the leading cause of hospitalization and death in that age group. Current treatments of CHF include lifestyle changes, medications, and surgery to bypass blocked blood vessels, replace regurgitant or stenotic valves, install stents to open narrowed coronary vessels, install pump assist devices or transplantation of the heart.

[004] Normal cardiac contraction is a finely tuned orchestrated activity dependent on muscle function, ventricular geometry and loading conditions termed preload and afterload. When CHF due to LV systolic failure occurs it is typically associated with changes in the geometry of the ventricles, often called remodeling. The LV becomes dilated and the interventricular septum is deflected into the right ventricle (RV), resulting in decreased LV output/pumping efficiency. The efficient systolic function of the LV is dependent not only on the strength of the myocardium but also on the LV geometry, the position and shape of the interventricular septum and the geometry and function of the RV. Interventricular dependence has been documented in experimental studies which have evaluated

both normal and pathological preparations in animals. LV systolic function can be directly influenced by interventions affecting the RV and the position of the interventricular septum.

[005] Surgical pulmonary artery banding (PAB) is a technique that was described more than 60 years ago and is still in use today for children and infants with congenital heart defects, such as overflow of blood to the lungs and volume overload of the RV. PAB is typically performed through a thoracotomy and involves wrapping a band around the exterior of the main pulmonary artery (MPA) and fixing the band in place, often with the use of sutures. Once applied, the band is tightened, narrowing the diameter of the MPA, increasing resistance to flow, reducing blood flow to the lungs, and reducing downstream pulmonary artery (PA) pressure.

[006] Surgical PAB procedures involve the risks present with all surgical procedures. In addition, use of surgical PAB has a number of particular disadvantages and drawbacks. Primary among these drawbacks is the inability of the surgeon performing the procedure to accurately assess, from the hemodynamic standpoint, the optimal final diameter to which the PA should be adjusted. Often, the surgeon must rely upon his or her experience in adjusting the band to achieve acceptable forward flow while decreasing the blood flow sufficiently to protect the pulmonary vasculature.

[007] It is also not uncommon for the band to migrate towards one of the pulmonary artery branches (usually the left), resulting in stenosis of the other pulmonary artery branch (usually the right). There have also been reports of hardening of the vessels around the band due to buildup of calcium deposits and scarring of the PA wall beneath the band, which can also inhibit blood flow. Flow resistance due to PAB may change over time, and additional surgeries to adjust band tightness occur in up to one third of patients. The band is typically removed in a subsequent operation, for example, when a congenital malformation is corrected in the child or infant.

[008] In addition to the classical use of PAB for treatment of congenital defects in infants and children, there has been a recent report of use of surgical PAB for left ventricle dilated cardiomyopathy (LVDCM) in infants and young children. This method includes increasing the pressure load on the right ventricle by surgically placing a band around the pulmonary artery. The increased pressure in the right ventricle caused a leftward shift of the interventricular septum and improvement of left ventricle function. It was found that the optimal degree of constriction was achieved when the RV pressure was approximately 60% to 70% of the systemic level and so that the interventricular septum slightly moved to a midline position. The success of these procedures in infants and children has been reported to be possibly due to the potential for myocyte recovery and repopulation being significantly greater for infants and young children than for adults. However, it is the position of the inventors that the geometric improvements to the failing heart due to PAB may

be responsible, at least partially, for the observed improvements in LV function, and therefore PAB for adult left ventricle heart failure may demonstrate similar improvement in LV function.

[009] The MPA is not a favorable location for positioning an implant due to its relatively large diameter (~30mm) and short length (~50mm). The full length of the MPA is not usable for an implant due to the proximity to the pulmonary valve on one end, and the bifurcation to the pulmonary branches on the other. It is estimated that the usable length of the MPA for the implant is approximately 30mm. Implantation of a short, wide device into the MPA is very difficult, and there is significant danger that the device will rotate or otherwise not be placed concentric with the MPA, in which case near complete blockage of the MPA could occur. In addition, the device may erroneously be placed either too close to the pulmonary valve or to the bifurcation. The branch pulmonary arteries are more favorable for placement of an implant due to their smaller diameter than the MPA and the longer available length for placement of an implant. When implants are placed in the branch PAs, it is required to place two implants in a bilateral fashion, in order to cause an increase in RV pressure.

[0010] Accordingly, there is a need to provide a relatively simple medical apparatus, which could be implanted in a minimally-invasive fashion, and which can allow an adjustment of blood flow through a vessel. There is also a need for gradual reduction in the diameter of the MPA or branch PAs, which is not currently feasible with the surgical PAB approaches described above. In addition, there is a need to use the medical apparatus for treatment of the mature adult population suffering from left ventricle (LV) failure.

#### SUMMARY OF THE INVENTION

[0011] The methods and apparatuses of the invention describe a medical apparatus configured to reduce a diameter of a blood vessel for treating or at least reducing the severity of a congestive failure of the heart, such as but not limited to: systolic heart failure, diastolic heart failure, left ventricle (LV) heart failure, right ventricle (RV) heart failure, congenital defects of the heart for which surgical pulmonary artery banding (PAB) is used, and any other condition which requires pulmonary artery banding (PAB).

[0012] Some embodiments of the present invention provide a new medical apparatus for deployment within an anatomical blood vessel comprising:

- a first tubular wall; and
- a second tubular wall, placed within the first tubular wall;

wherein the first and second tubular walls are firmly connected at their edges, therefore restricted to have same overall longitudinal length ( $L$ ); and  
wherein the second tubular wall is configured to be partially constricted towards its inner radial axis, while maintaining its overall longitudinal length;  
accordingly, the combination of the first and second tubular walls forms a diametrical reducer.

[0013] In some embodiments, the second tubular wall comprises plurality of section elements, wherein at least some of the sections elements are configured to allow a motion of at least some of the section elements one relative to another, when a constriction force is applied.

[0014] In some embodiments, at least some of the section elements are configured to be deformed, when a constriction force is applied.

[0015] In some embodiments, the plurality of section elements comprise strut elements and connecting elements; and wherein the connecting elements are configured to be deformed, when a constriction force is applied.

[0016] In some embodiments, at least some of the section elements are arranged in rows or rings-like configuration.

[0017] In some embodiments, the section elements' motion comprises at least one of: deformation, translation, rotation, twist, contraction, conversion and collapse.

[0018] In some embodiments, at least one of the first- and the second- tubular walls comprises binding elements at its edges, configured for the connection of the first and the second tubular walls one to another.

[0019] In some embodiments, the apparatus further comprising a constricting element configured to constrict a circumference of a portion of the second tubular wall.

[0020] In some embodiments, the constriction provides the second tubular wall with a radial neck section, configured for reduction of the effective diameter of the anatomical blood vessel.

[0021] In some embodiments, at least a portion of the second tubular wall is coated with a coating material.

[0022] In some embodiments, the constriction is provided, while the medical apparatus is within the anatomic vessel.

[0023] In some embodiments, the first and second tubular walls are concentric.

[0024] In some embodiments, material of the first and second tubular walls comprises at least one of the group consisting of: Nitinol, stainless steel, Titanium, Cobalt-Chromium alloy, Tantalum alloy, polymer, Platinum alloy and any combination thereof.

[0025] In some embodiments, the first tubular wall is made of a first material and the second tubular wall is made of a second material.

[0026] In some embodiments, the first and second tubular walls are manufactured by a laser cut process.

[0027] In some embodiments, the ratio between the medical apparatus's longitudinal length and diameter of the first tubular wall is smaller than three (3).

[0028] In some embodiments, the medical apparatus is reversibly collapsible and configured to be delivered into the anatomic vessel via a catheter.

[0029] Some embodiments of the present invention provide a new method of use of an apparatus configured for reduction of effective diameter of an anatomic vessel, the method comprising:

- providing a medical apparatus having a second tubular wall placed within a first tubular wall;
- deploying the medical apparatus within an anatomical blood vessel; and
- constricting at least a portion of the second tubular wall, thereby providing the second tubular wall with a radial neck section, while maintaining its overall longitudinal length.

[0030] In some embodiments, the step of providing comprises partially constricting the second tubular wall.

[0031] In some embodiments, the step of providing comprises at least partially coating the second tubular wall.

[0032] In some embodiments, the step of providing comprises connecting both the first- and the second- tubular walls at their edges, thereby restricting the first- and the second- tubular walls to have the same overall longitudinal length.

[0033] In some embodiments, the step of deploying comprises delivering the medical apparatus into an anatomical blood vessel via a catheter.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0034] The subject matter regarded as the invention is particularly pointed out and distinctly claimed in the concluding portion of the specification. The invention, however, both as to organization and method of operation, together with objects, features, and advantages thereof, may be understood by reference to the following detailed description when read with the accompanying drawings in which:

[0035] **Fig. 1** conceptually depicts a stent like medical apparatus having first and second tubular walls, according to some embodiments of the invention;

[0036] **Figs. 2A** and **2B** conceptually depict a flattened image and picture image of a second tubular wall, respectively, according to some embodiments of the invention;

[0037] **Fig. 3** conceptually depicts a first tubular wall, according to some embodiments of the invention;

[0038] **Fig. 4** conceptually depicts a stent like medical apparatus, in a constricted configuration, according to some embodiments of the invention;

[0039] **Fig. 5A** conceptually depicts a medical apparatus crimped within a delivery system, according to some embodiments of the invention;

[0040] **Fig. 5B** conceptually illustrates a crimped second tubular wall, according to some embodiments of the invention;

[0041] **Figs. 6A** and **6B** conceptually illustrate a non-limiting schematic example for a second tubular wall, according to some embodiments of the invention;

[0042] **Figs. 6C** and **6D** conceptually illustrate non-limiting flattened schematic examples for second tubular walls, according to some embodiments of the invention;

[0043] **Fig. 7** conceptually depicts a stent like medical apparatus having a first tubular wall and a second coated tubular wall, according to some embodiments of the invention; and

[0044] **Fig. 8** conceptually demonstrates a method of use of an apparatus configured for a reduction of an effective diameter of an anatomic vessel, according to some embodiments of the invention.

[0045] It will be appreciated that for simplicity and clarity of illustration, elements shown in the figures have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference numerals may be repeated among the figures to indicate corresponding or analogous elements.



## DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0046] The following description is provided, alongside all chapters of the present invention, so that to enable any person skilled in the art to make use of the invention and sets forth the best modes contemplated by the inventor of carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide a medical apparatus configured to reduce a diameter of a blood vessel for treating or at least reducing the severity of a congestive failure of the heart, such as but not limited to: systolic heart failure, diastolic heart failure, left ventricle (LV) heart failure, right ventricle (RV) heart failure, congenital defects of the heart for which surgical pulmonary artery banding (PAB) is used, and any other condition which requires pulmonary artery banding (PAB).

[0047] As used herein, in one embodiment, the term “about”, refers to a deviance of between 0.0001-5% from the indicated number or range of numbers. In one embodiment, the term “about”, refers to a deviance of between 1 - 10% from the indicated number or range of numbers. In one embodiment, the term “about”, refers to a deviance of up to 25% from the indicated number or range of numbers.

[0048] According to some embodiments, the term “a” or “one” or “an” refers to at least one.

[0049] According to some embodiments the present invention provides a stent like medical apparatus for deployment within an anatomical blood vessel, as demonstrated at least in **Fig. 1**, which is configured to reduce the effective diameter of an anatomical blood vessel.

[0050] According to some embodiments, the medical apparatus **100** comprises:

- a first tubular wall **110** (also noted as outer tubular wall); and
- a second tubular wall **120** (also noted as inner tubular wall), placed within the first tubular wall;

wherein the first- and second- tubular walls are firmly connected (one to another) at their proximal- and distal- edges **131,132**, therefore restricted to have same overall longitudinal length (*L*); and

wherein the second tubular wall is configured to be partially constricted **121** towards its inner radial axis, while maintaining its overall longitudinal length;

it is therefore that the combination of the first and second tubular walls forms a diametrical reducer.

[0051] According to some embodiments, the constriction process may be applied after the deployment of the apparatus within an anatomical blood vessel.

[0052] According to some embodiments, the constriction is provided while the medical apparatus is

within the anatomic vessel. According to some embodiments, the constriction provides the second tubular wall with a radial neck section, configured for reduction of the effective diameter of the anatomical blood vessel. According to some embodiments, at least a portion of the second tubular wall is coated with a coating material, as further demonstrated in Fig. 7, **760**.

[0053] According to some embodiments, in addition to the coating of the second tubular wall, two bands of coating on the proximal and distal ends of the first tubular wall can be applied, configured to create a fluid seal with the coating of the second tubular wall, as further demonstrated in Fig. 7, **770**.

[0054] The coating material can be selected, for a non-limiting example, from: silicone elastomers, urethane containing polymers (such as polyurethane, silicone-polyurethane, polycarbonate urethanes, and silicone polycarbonate urethanes), PTFE (polytetrafluoroethylene), ePTFE (expanded PTFE), PLA (including PLGA, PLLA), xenograft or allograft tissue (such as pericardial tissue).

[0055] According to some embodiments, the second tubular wall comprises a plurality of section elements, wherein at least some of the section elements are configured to allow a motion of at least some of the section elements one relative to another, when a constriction force is applied.

[0056] Reference is now made to **Figs. 2A** and **2B**, which schematically demonstrate a second tubular wall, according to some embodiments of the invention. **Fig. 2A** illustrates a flattened second tubular wall, shown after the process of laser cutting, according to some embodiments of the invention. **Fig. 2B** depicts a picture of a second tubular wall after constriction due to a constriction force ( $F$ ), according to some embodiments of the invention.

[0057] As shown in both **Figs. 2A** and **2B** the second tubular wall **220** comprises, according to some embodiments, a plurality of connected section elements **221**, **222**, wherein at least some of the section elements are configured to be deformed when a force, for example a constriction force ( $F$ ), is applied thereon. The deformed section elements allow a motion of some of the section elements one relative to another, therefore configured to allow a constriction of at least a part of the second tubular wall. Consequently, the deformed section elements allow the second tubular wall to expand its path length ( $L_p$ ), during the radial constriction, while maintaining its overall longitudinal length ( $L$ ).

[0058] According to some embodiments the plurality of section elements can all have a similar shape and/or configuration. According to other embodiments the plurality of section elements can have a variety of shapes and/or configurations.

[0059] According to some embodiments, the plurality of section elements can comprise strut elements **221** and connecting elements **222**, as demonstrated in **Figs. 2A** and **2B**. The connecting elements are configured to be deformed when a constriction force ( $F$ ) is applied, and thereby configured to allow an increase in the distance between the strut elements rows/rings. The deformation of the connecting elements consequently allows the constriction of at least a part of the second tubular wall, with an increased path length ( $L_p$ ), while maintaining its overall longitudinal length ( $L$ ). According to some embodiments, the strut elements **222** can also be deformed by the constricting force, however in a much smaller deformation extent than of the connecting elements.

[0060] In the examples of **Figs. 2A** and **2B**, the increased distance between the strut elements is enabled by twisting of rows/rings of strut elements, one relative to the other via the connecting elements, as demonstrated by the marked arrows in the flattened schematic illustration in **Fig. 2A**. In other embodiments, and as demonstrated in **Figs. 6C** and **6D**, the increased distance between the strut elements is enabled by extension of the connecting elements **622,632**.

[0061] According to some embodiments, at least some of the section elements are arranged in rows or rings-like configuration **223**. The rings **223** are configured to move one relative to another, during the constriction.

[0062] According to some embodiments, the motion of the section elements comprises at least one of: translation, deformation, rotation, twist, contraction, conversion and collapse.

[0063] According to some embodiments, at least one of the first and the second tubular walls comprises binding elements **224,314** at its edges, configured for the connection of the first and the second tubular walls one to another. According to some embodiments, the connection can be by a suture, adhesion, welding, mechanical connection, or any other means of connection.

[0064] Reference is now made to **Fig. 3**, which demonstrates a first tubular wall, according to some embodiments of the invention. The first tubular wall **310** as demonstrated comprises binding elements **314** at its edges, configured for the connection of the first and the second tubular walls one to another. According to some embodiments the first tubular wall further comprises at least one grip element **340** (and **740**, **Fig. 7**), at least at one edge thereof. The grip element is configured to be pulled and thereby assist in loading the medical apparatus, for its insertion into a delivery system, as further demonstrated in **Fig. 5A**, and/or for re-sheathing of the apparatus into the delivery system during the process of deployment into the target vessel.

[0065] Reference is now made to **Fig. 4**, which demonstrates a medical apparatus **400** comprising

the first tubular wall **410** and the second tubular wall **420** bound together at both their proximal and distal ends via their binding elements **414,424**, and where the medical apparatus is shown in a partially constricted configuration. According to some embodiments, the apparatus further comprises a constricting element **430** configured to constrict a circumference of a portion of the second tubular wall **420**.

[0066] According to some embodiments the constriction of the second tubular wall can be provided before- and/or after- the deployment of the apparatus within the vessel; therefore, can be provided with an initial constricted state and/or constricted in real time to a final constricted state, respectively.

[0067] Reference is now made to **Figs. 5A** and **5B**, which demonstrate a stent-like medical apparatus **500**, according to some embodiments of the invention. As demonstrated the stent-like medical apparatus is configured for a reversible collapse and therefore configured to be delivered into the anatomic vessel via a catheter tube. **Fig. 5A** demonstrates the collapsed/crimped apparatus **500** within the delivery catheter **550**, whereas **Fig. 5B** demonstrates only the collapsed second tubular wall **520**, within the delivery catheter **550**, which is hidden by the first tubular wall at Fig. 5A. According to some embodiments, the overall longitudinal length ( $L_c$ ) of the collapsed/crimped apparatus is larger than the overall longitudinal length ( $L$ ) of the non-collapsed apparatus, ( $L_c > L$ ).

[0068] According to some embodiments, the overall longitudinal lengths of first and second tubular walls are the same whether in a crimped configuration (in a delivery catheter), a deployed configuration (in a vessel), or a constricted configuration (having an hourglass shape).

[0069] According to some embodiments, at least one of the outer and inner tubular walls is made of a collapsible memory shape material, therefore self-expanding material. According to some embodiments, at least one of the outer and inner tubular walls is manufactured by laser cut process.

[0070] According to some embodiments, the ratio  $N$  ( $N = L / D_{out}$ ) between the medical apparatus's **100** longitudinal length ( $L$ ), as demonstrated in Fig. 1, and the diameter of the outer tubular wall ( $D_{out}$ ) is smaller than a predetermined numeral selected from the group consisting of: 3, 2.5, 2, 1.5, 1, 0.5, 0.3 and any ratio within their range. According to a preferred embodiment,  $N$  is smaller than 1.5.

[0071] According to some embodiments, the first and second tubular walls are concentric. According to some embodiments, the medical apparatus is axisymmetric.

[0072] According to some embodiments, the material of the outer and inner tubular walls comprises at least one from the group consisting of: Nitinol, stainless steel, Titanium, Cobalt-Chromium alloy, Tantalum alloy, polymer (ePTFE, PU, etc.), Platinum alloy and any combination thereof.

[0073] According to some embodiments, the outer tubular wall is made of a first material and the inner tubular wall is made of a second material. According to some embodiments, the outer and inner tubular walls are made of the same material.

[0074] Reference is now made to **Figs. 6A** and **6B**, which demonstrate a non-limiting schematic example for a second tubular wall **620** before (Fig. 6A) and after (Fig. 6B) its constriction. In this non-limiting example, the overall initial longitudinal length of the second tubular wall is  $26mm$  and its initial diameter before its constriction is  $15mm$ . After a partial constriction of the second tubular wall, by applying a circumference constriction force ( $F$ ) its minimal diameter is  $10mm$ , while its overall longitudinal length is kept  $26mm$ , such that the path length ( $L_p$ ) of the second tubular wall has increased without an increase in its overall length ( $L$ ).

[0075] Reference is now made to **Figs. 6C** and **6D**, which schematically demonstrate two different non-limiting flattened schematic examples for second tubular walls, according to some embodiments of the invention. As shown, the second tubular wall **625,635** comprises, according to some embodiments, a plurality of strut elements **621,631** and a plurality of connecting elements **622,632**. When a constriction force ( $F$ ) is applied, at least some of the connecting elements are configured to be deformed and cause an increase in the distance between the strut elements rows/rings, therefore allowing a constriction of at least a part of the second tubular wall, with an increased path length, while maintaining its overall longitudinal length. The rows or rings-like configurations **623,633** are also demonstrated.

[0076] Reference is now made to **Fig. 7**, which conceptually depicts a stent like medical apparatus **700** having a first tubular wall and a second coated tubular wall. According to some embodiments of the invention the medical apparatus **700** comprises:

- a first tubular wall **710** (also noted as outer tubular wall); and
- a second tubular wall **720** (also noted as inner tubular wall), placed within the first tubular wall;

wherein the first- and second- tubular walls are firmly connected at their proximal and distal edges **714,724**, therefore restricted to have same overall longitudinal length; and

wherein the second tubular wall is configured to be partially constricted **730** towards its inner radial axis, while maintaining its overall longitudinal length;

it is therefore that the combination of the first and second tubular walls forms a diametrical reducer.

[0077] **Fig. 7** further demonstrates that at least a portion of the second tubular wall **720** is coated with a coating material **760**, for example by an ePTFE, such that the flow through the vessel will be guided

through the second tubular wall. **Fig. 7** further demonstrates that in addition to the coating of the second tubular wall, the proximal and distal ends of the first tubular wall can be coated **770**, according to some embodiments of the invention, to create a fluid seal with the coating of the second tubular wall.

[0078] Reference is now made to **Fig. 8**, which conceptually demonstrates a method of use of an apparatus configured for a reduction of an effective diameter of an anatomic vessel, according to any of the above-mentioned embodiments. The method **800** comprising:

- providing **810** a medical apparatus having a second tubular wall placed within a first tubular wall;
- deploying **820** the medical apparatus within an anatomical blood vessel; and
- constricting **830** at least a portion of the second tubular wall, thereby providing the second tubular wall with a radial neck section, while maintaining its overall longitudinal length.

[0079] According to some embodiments, the step of providing further comprises partially constricting **811** the second tubular wall to an initial constricted state, which may be further constricted. According to some embodiments, the initial constriction is provided via a heating process; for example, by heat treatment of the Nitinol of the second tubular wall to maintain a specific shape; for example, to have a shape of an hourglass.

[0080] According to some embodiments, the step of providing further comprises at least partially coating **812** the second tubular wall.

[0081] According to some embodiments, the step of providing further comprises connecting **813** both the first- and the second- tubular walls at their edges, thereby restricting the first- and the second-tubular walls to have the same overall longitudinal length.

[0082] According to some embodiments, the step of deploying comprises delivering **821** the medical apparatus into an anatomical blood vessel via a catheter, wherein the medical apparatus is provided in a crimped configuration, which is configured to expand back, once deployed out of the delivering catheter.

[0083] According to some embodiments, a therapeutic result for the use of a medical apparatus as mentioned above, for patients with LV heart failure, can be at least one of the group consisting of:

- an increase in the left ventricle ejection fraction (LVEF);

- a decrease in the left ventricle end diastolic pressure (LVEDP);
- improvement in the clinical symptoms of heart failure; and
- any combination thereof.

[0084] While certain features of the invention have been illustrated and described herein, many modifications, substitutions, changes, and equivalents will now occur to those of ordinary skill in the art. It is, therefore, to be understood that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.

**CLAIMS**

1. A medical apparatus for deployment within an anatomical blood vessel comprising:
  - a first tubular wall; and
  - a second tubular wall, placed within the first tubular wall;wherein the first and second tubular walls are firmly connected at their edges, therefore restricted to have same overall longitudinal length ( $L$ ); and  
wherein the second tubular wall is configured to be partially constricted towards its inner radial axis, while maintaining its overall longitudinal length;  
the combination of the first and second tubular walls forms a diametrical reducer.
2. The medical apparatus of claim 1, wherein the second tubular wall comprises plurality of section elements, wherein at least some of the sections elements are configured to allow a motion of at least some of the section elements one relative to another, when a constriction force is applied.
3. The medical apparatus of claim 2, wherein at least some of the section elements are configured to be deformed, when a constriction force is applied.
4. The medical apparatus of claim 2, wherein the plurality of section elements comprise strut elements and connecting elements; and wherein the connecting elements are configured to be deformed, when a constriction force is applied.
5. The medical apparatus of any one of claims 2 to 4, wherein at least some of the section elements are arranged in rows or rings-like configuration.
6. The medical apparatus of any one of claims 2 to 5, wherein the section elements' motion comprises at least one of: deformation, translation, rotation, twist, contraction, conversion and collapse.
7. The medical apparatus of any one of claims 1 to 6, wherein at least one of the first- and the second- tubular walls comprises binding elements at its edges, configured for the connection of the first and the second tubular walls one to another.
8. The medical apparatus of any one of claims 1 to 7, further comprising a constricting element configured to constrict a circumference of a portion of the second tubular wall.
9. The medical apparatus of any one of claims 1 to 8, wherein the constriction provides the second tubular wall with a radial neck section, configured for reduction of the effective diameter of the anatomical blood vessel.



10. The medical apparatus of any one of claims 1 to 9, wherein at least a portion of the second tubular wall is coated with a coating material.
11. The medical apparatus of any one of claims 1 to 10, wherein the constriction is provided, while the medical apparatus is within the anatomic vessel.
12. The medical apparatus of any one of claims 1 to 11, wherein the first and second tubular walls are concentric.
13. The medical apparatus of any one of claims 1 to 12, wherein material of the first and second tubular walls comprises at least one of the group consisting of: Nitinol, stainless steel, Titanium, Cobalt-Chromium alloy, Tantalum alloy, polymer, Platinum alloy and any combination thereof.
14. The medical apparatus of any one of claims 1 to 13, wherein the first tubular wall is made of a first material and the second tubular wall is made of a second material.
15. The medical apparatus of any one of claims 1 to 14, wherein the first and second tubular walls are manufactured by a laser cut process.
16. The medical apparatus of any one of claims 1 to 15, wherein the ratio between the medical apparatus's longitudinal length and diameter of the first tubular wall is smaller than three (3).
17. The medical apparatus of any one of claims 1 to 16, wherein the medical apparatus is reversibly collapsible and configured to be delivered into the anatomic vessel via a catheter.
18. A method of use of an apparatus configured for reduction of effective diameter of an anatomic vessel, the method comprising:
  - providing a medical apparatus having a second tubular wall placed within a first tubular wall;
  - deploying the medical apparatus within an anatomical blood vessel; and
  - constricting at least a portion of the second tubular wall, thereby providing the second tubular wall with a radial neck section, while maintaining its overall longitudinal length.
19. The method of claim 18, wherein the step of providing comprises partially constricting the second tubular wall.

20. The method of any one of claims 18 to 19, wherein the step of providing comprises at least partially coating the second tubular wall.
21. The method of any one of claims 18 to 20, wherein the step of providing comprises connecting both the first- and the second- tubular walls at their edges, thereby restricting the first- and the second- tubular walls to have the same overall longitudinal length.
22. The method of any one of claims 18 to 21, wherein the step of deploying comprises delivering the medical apparatus into an anatomical blood vessel via a catheter.

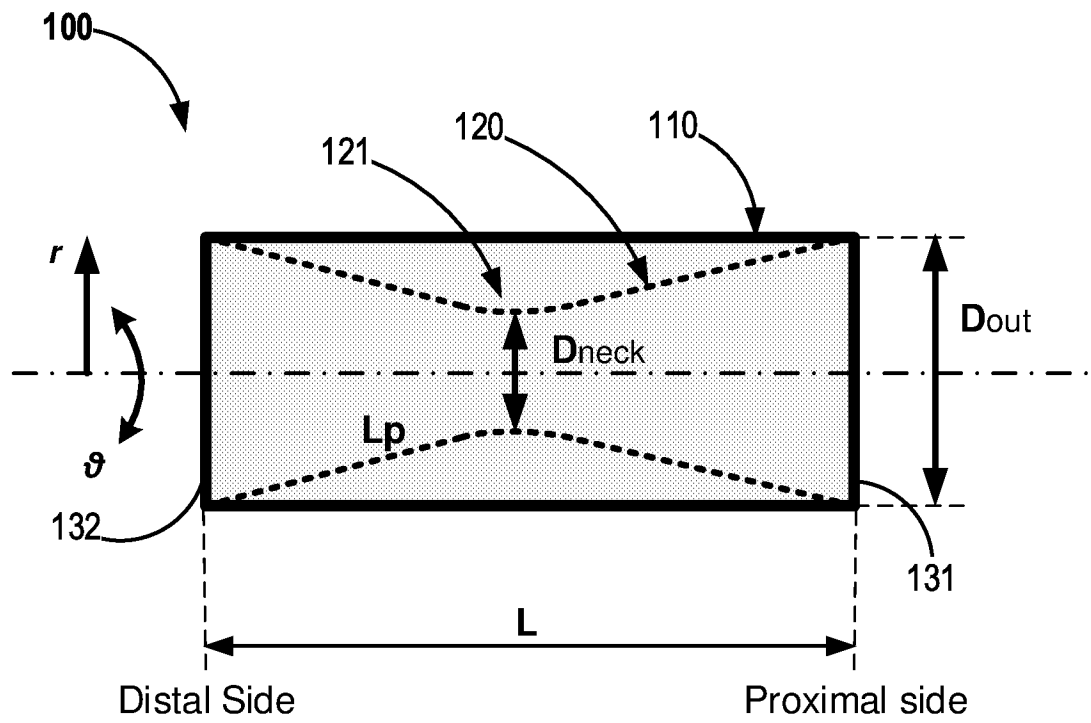


Fig. 1

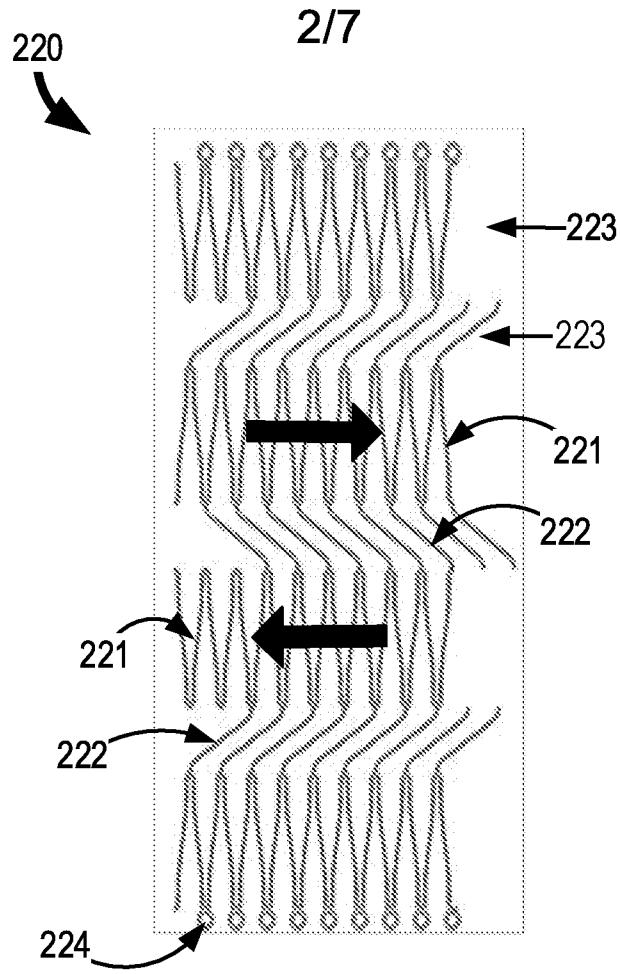


Fig. 2A

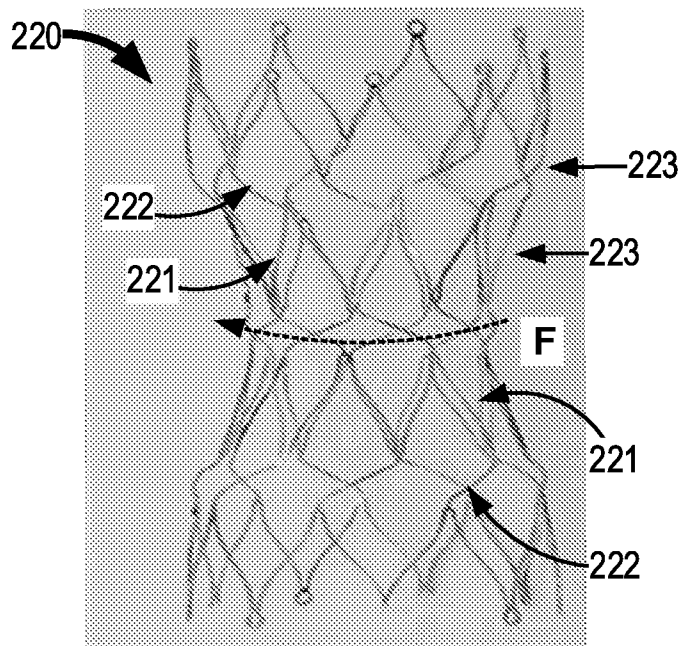
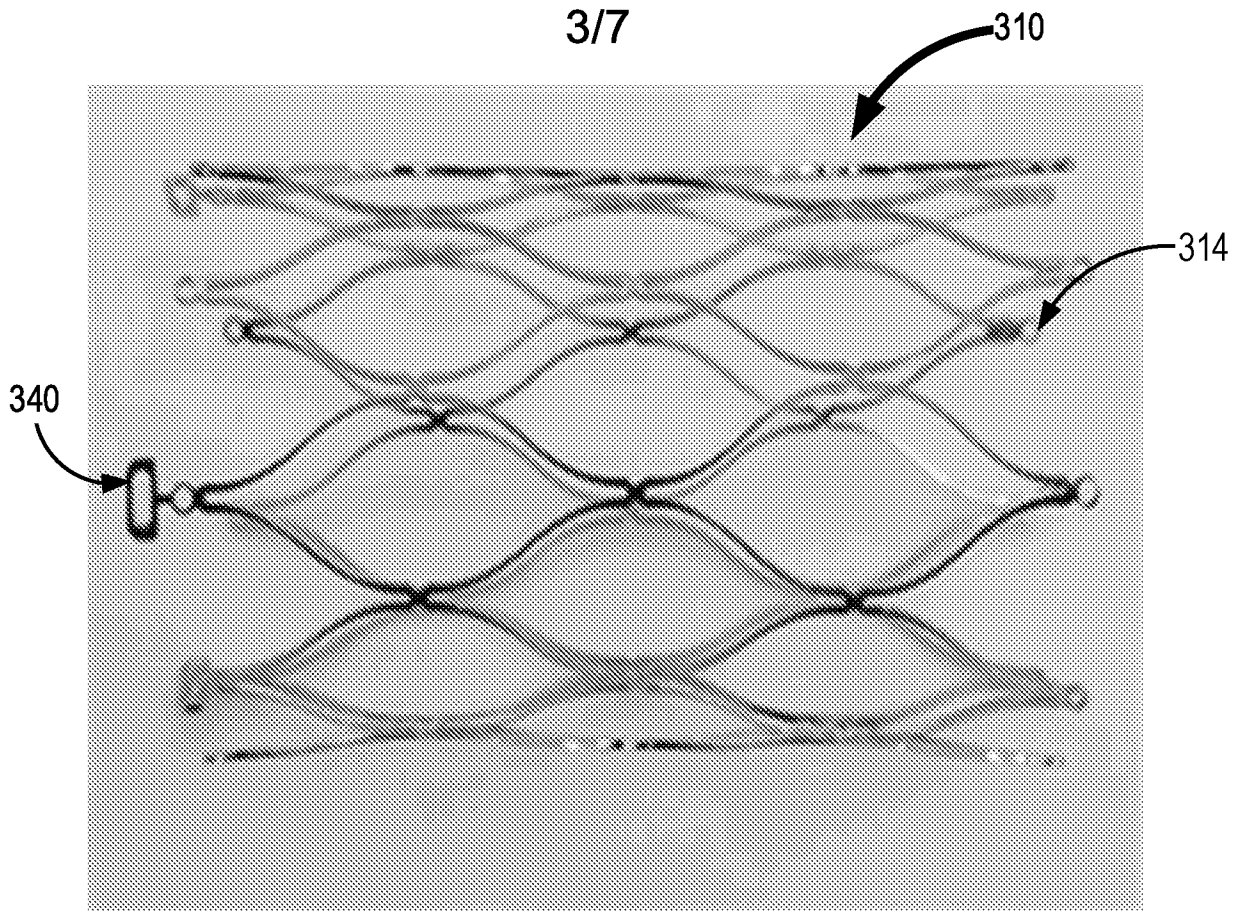


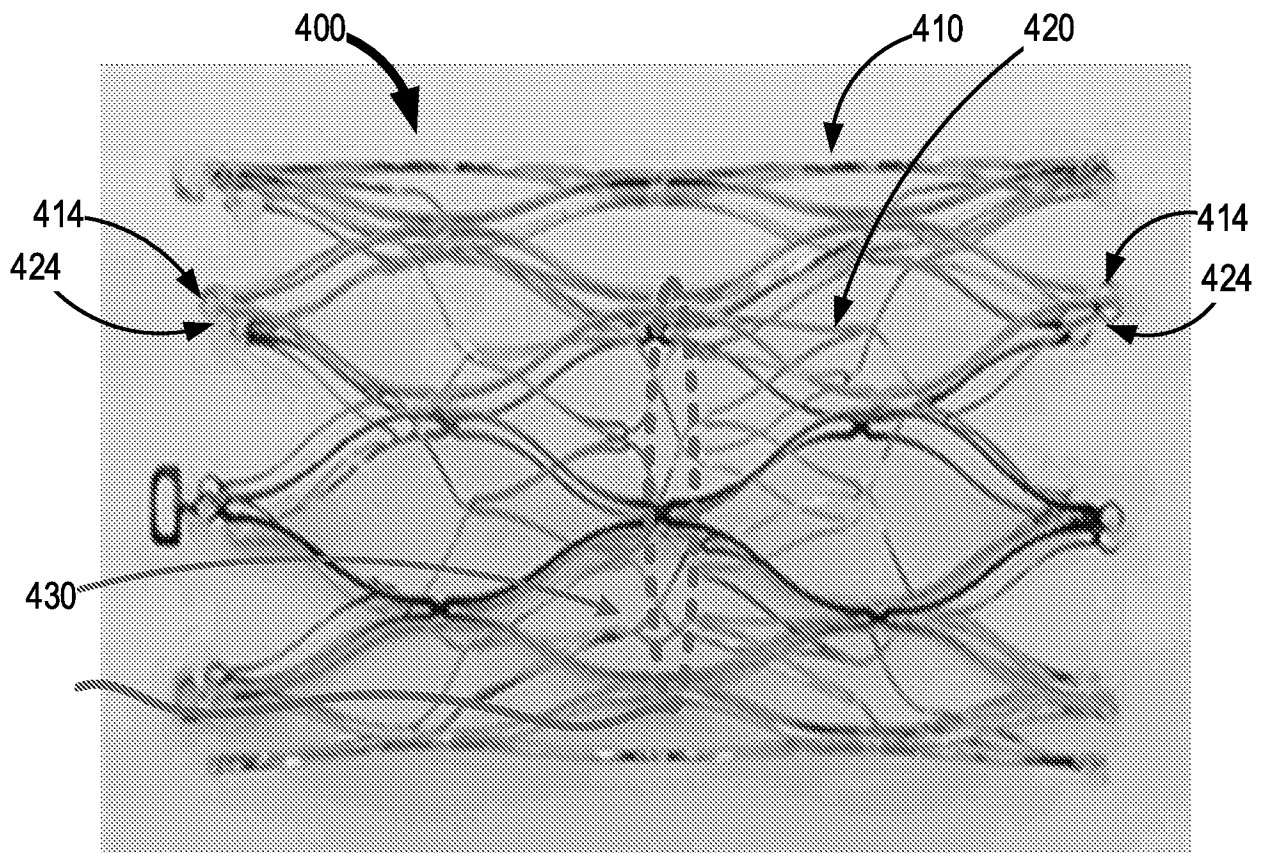
Fig. 2B



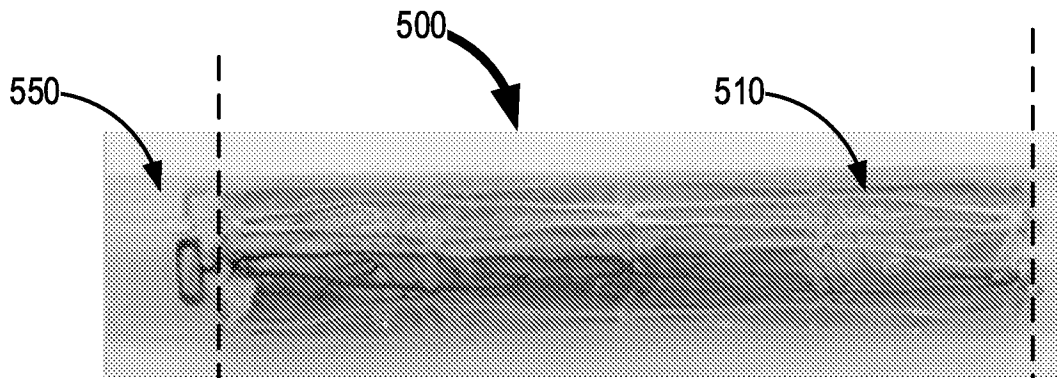
Distal Side

**Fig. 3**

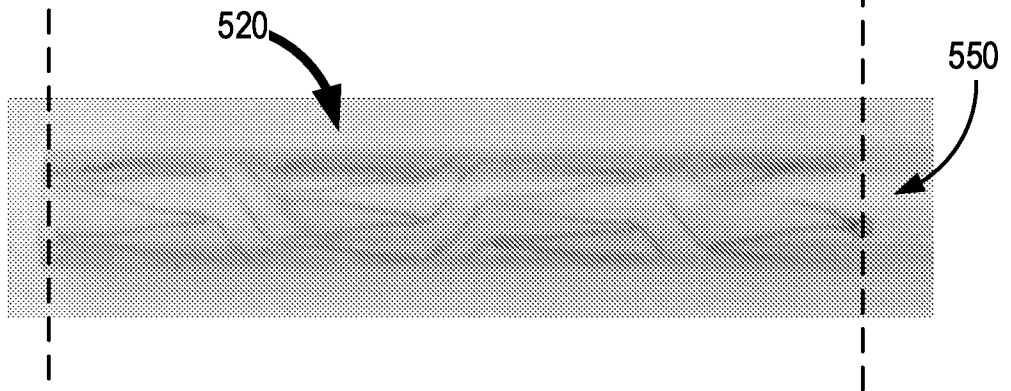
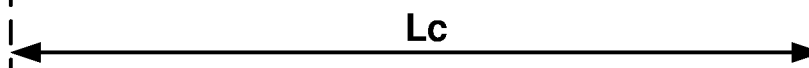
Proximal side



**Fig. 4**



**Fig. 5A**



**Fig. 5B**

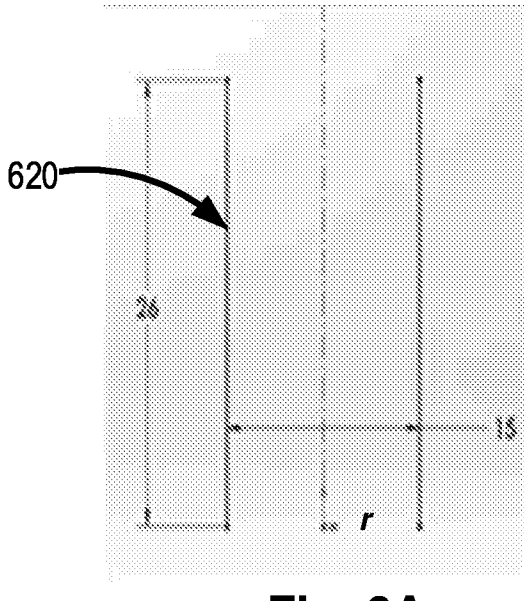


Fig. 6A

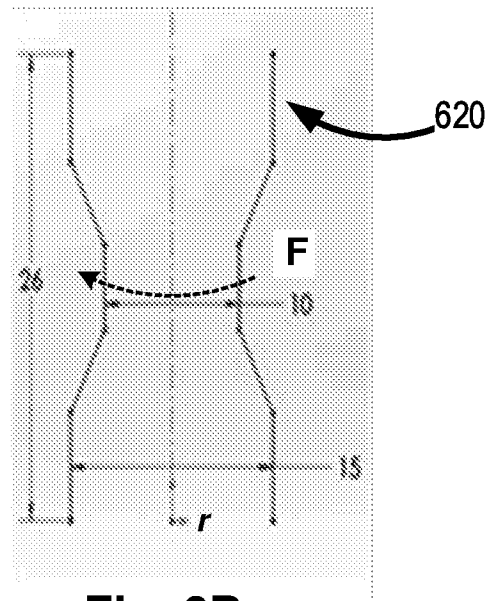


Fig. 6B

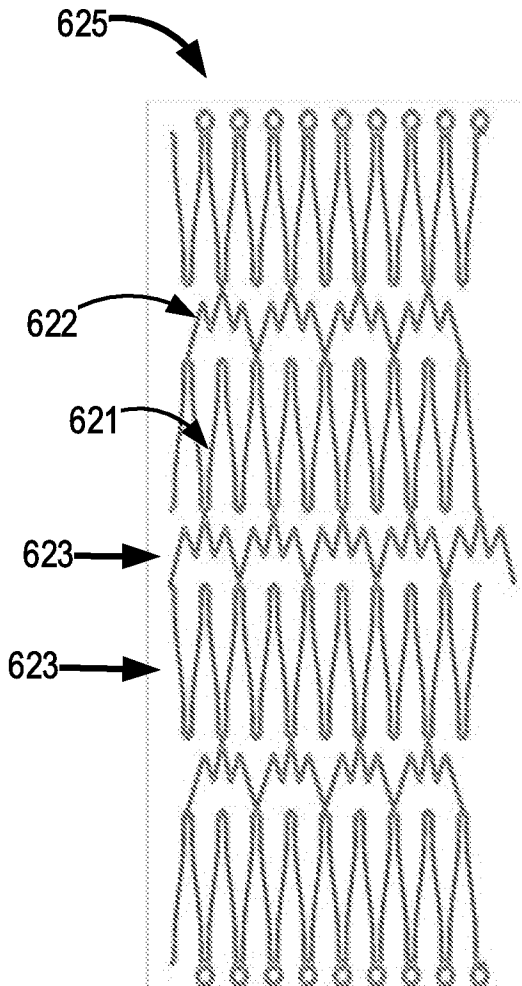


Fig. 6C

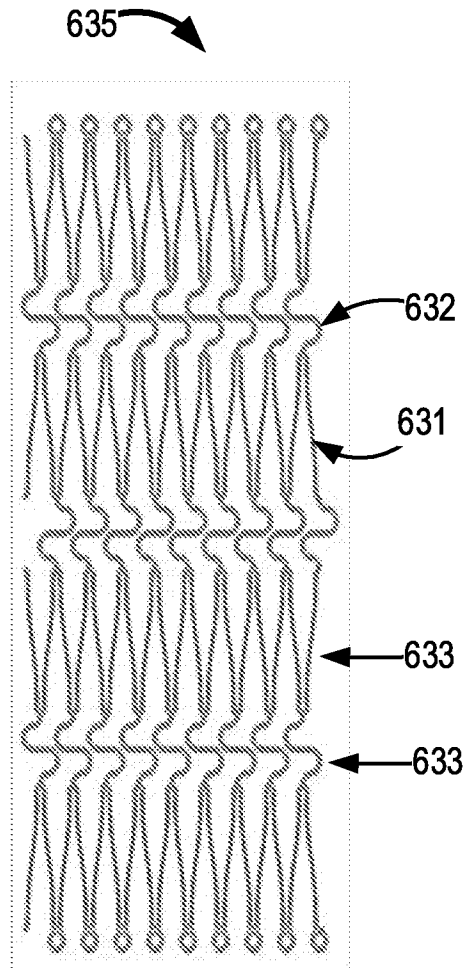


Fig. 6D

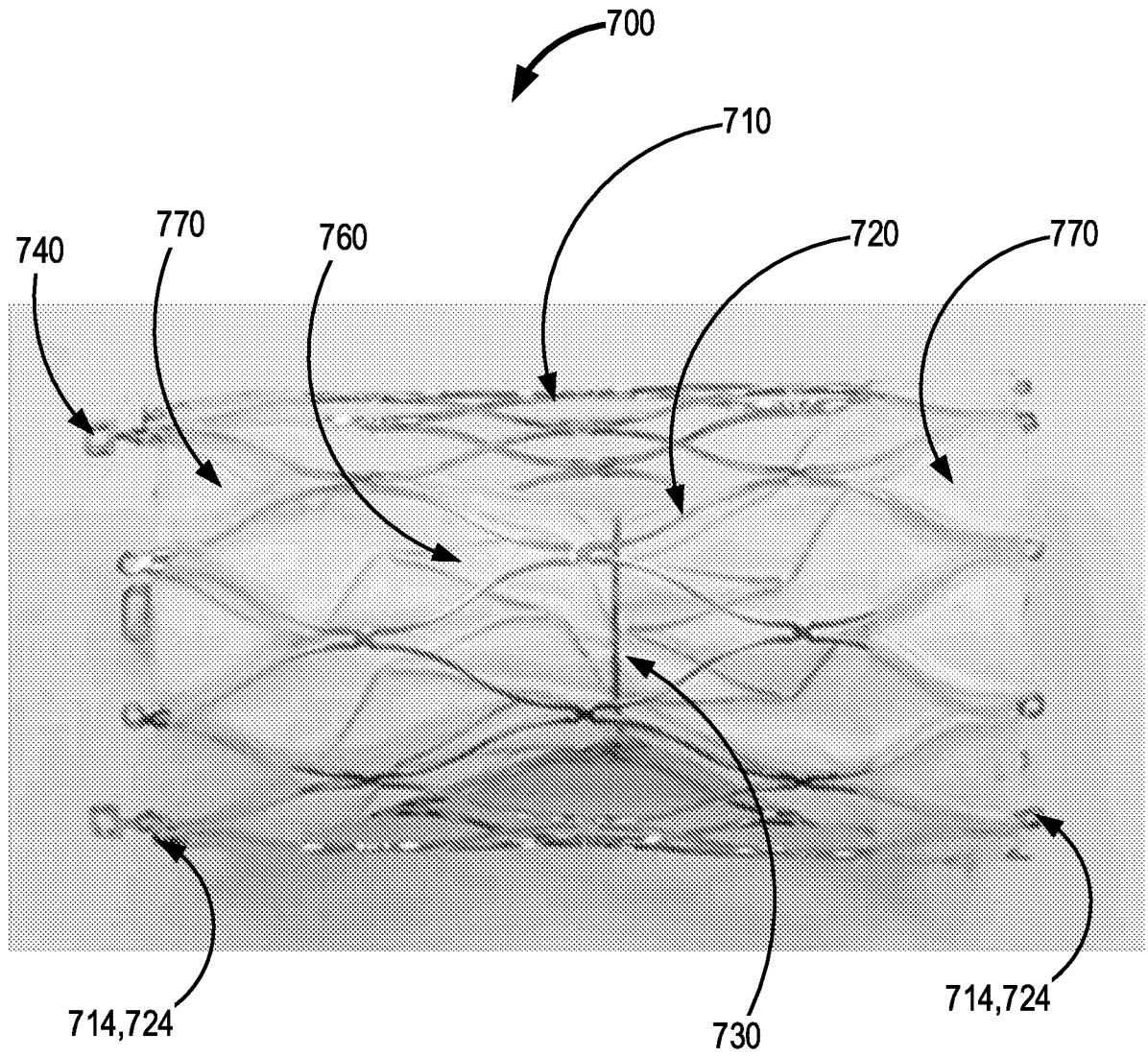


Fig. 7



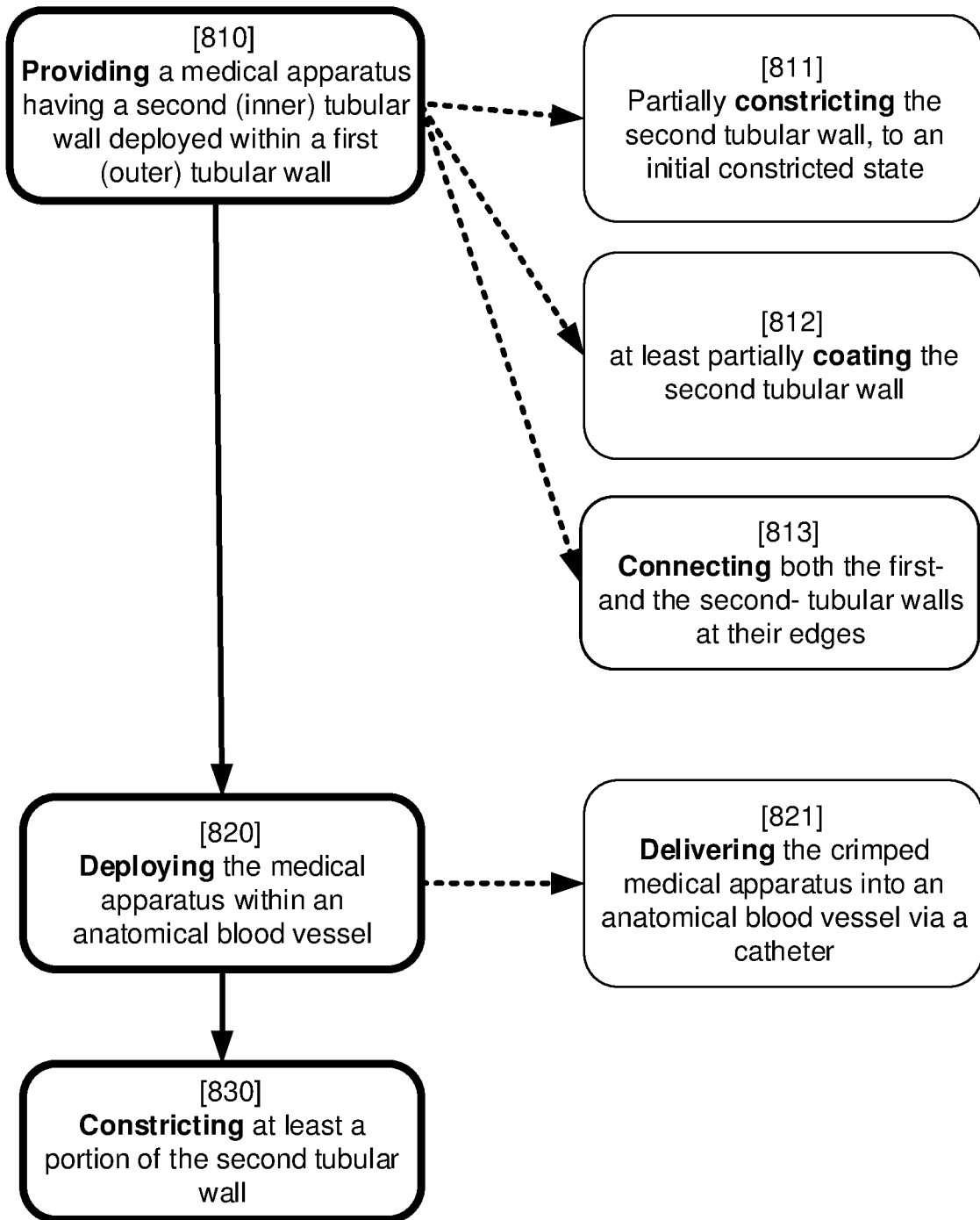


Fig. 8

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2018/050604

A. CLASSIFICATION OF SUBJECT MATTER IPC (2018.01) A61B 17/12, A61F 2/06, A61F 2/07, A61F 2/90		
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) IPC (2018.01) A61B, A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Databases consulted: Esp@cenet, Google Patents, Derwent Innovation Search terms used: inner, internal, first, tub, sheath, sleeve, layer, outer, external, second, stent, blood, flow, reducer		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013178750 A1 VOLCANO CORP. 11 Jul 2013 (2013/07/11) para.[0104], [0172], [0173], [0176], [0178]-[0180], [0196]; fig. 14a, 14b, 15a, 15b, 16	1,4,5,7-21
Y		2,3,6,22
X	US 2017042551 A1 THE BRAIN PROT COMPANY PTY LTD 16 Feb 2017 (2017/02/16) para.[0046], [0049], [0054]; fig. 3A, 3B, 4B, 5-7, 8A	1,9,12,13
Y		22
Y	EP 1870057 A1 MOREL 26 Dec 2007 (2007/12/26) * the whole document *	2,3,6
A	US 2013096580 A1 COHN et al. 18 Apr 2013 (2013/04/18) * the whole document *	1-22
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 17 Sep 2018		Date of mailing of the international search report 20 Sep 2018
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Facsimile No. 972-2-5651616		Authorized officer AHARONY Meytal  Telephone No. 972-2-5657820

**INTERNATIONAL SEARCH REPORT**  
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