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(54) **METHOD AND APPARATUS FOR ANCHORING IMPLANTS**

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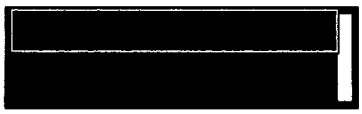
(57) **ABSTRACT**

Methods, devices and systems facilitate retention of a variety of therapeutic devices. Devices generally include an anchoring element, which has been designed to promote fibrotic ingrowth, and an anchored device, which has been designed to firmly engage the complementary region of the anchoring element. The anchoring element may be placed in a minimally invasive procedure temporally separated from the deployment of the anchored device. Once enough time has passed to ensure appropriate fixation of the anchoring element by tissue and cellular ingrowth at the site of placement, the anchored device may then be deployed during which it firmly engages the complementary region of the anchoring element. In this manner, a firm attachment to the implantation site may be made with a minimum of required hardware. Some embodiments are delivered through a delivery tube or catheter and while some embodiments may require laparoscopy or open surgery for one or more of the placement procedures. Some embodiments anchor devices within the cardiovascular tree while others may anchor devices within the gastrointestinal, peritoneal, pleural, pulmonary, urogynecologic, nasopharyngeal or dermatologic regions of the body.



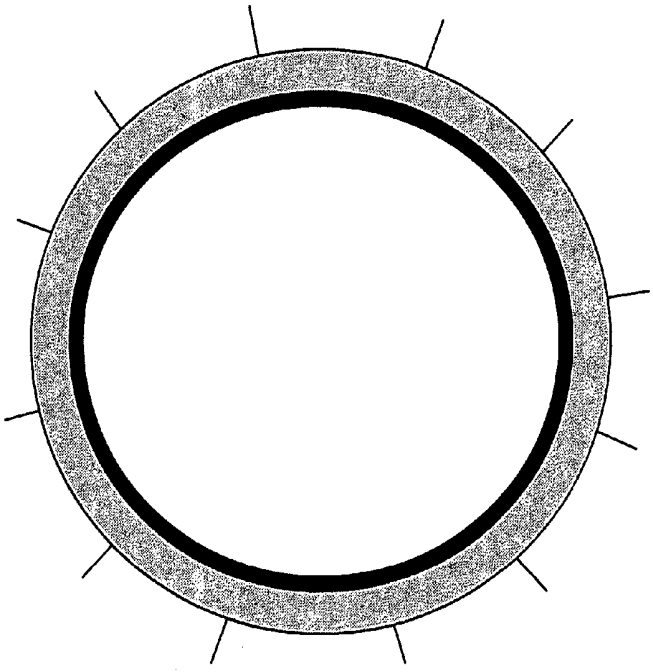
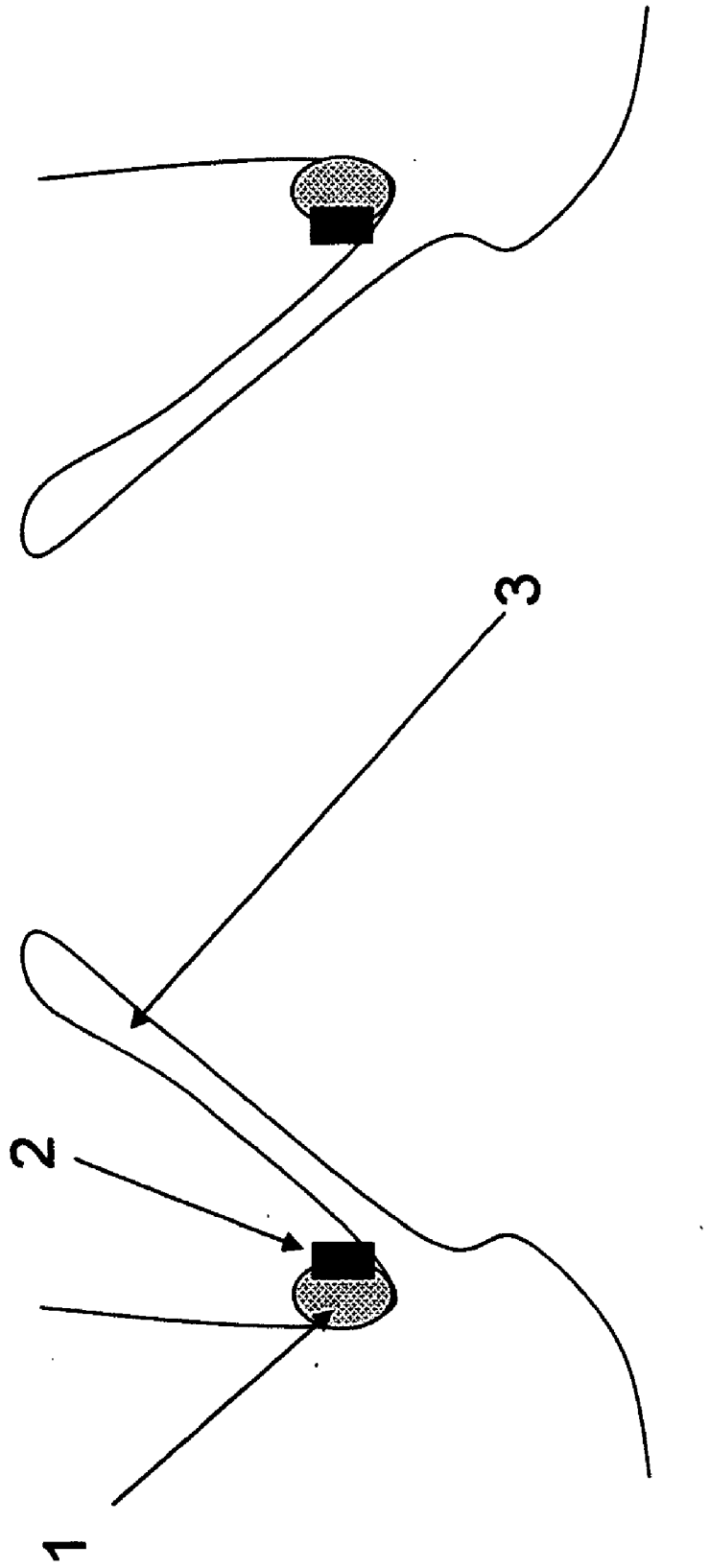


Figure 1



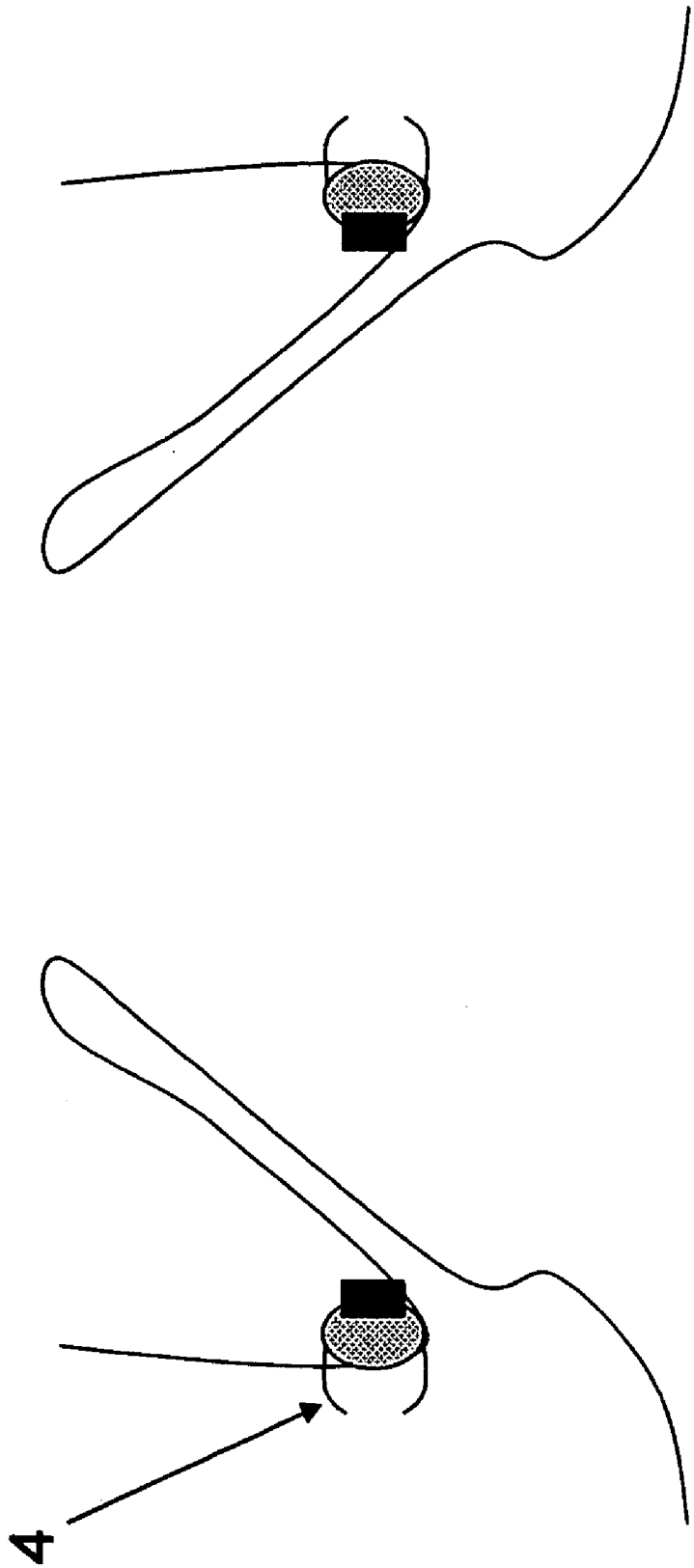


Figure 2

Figure 3

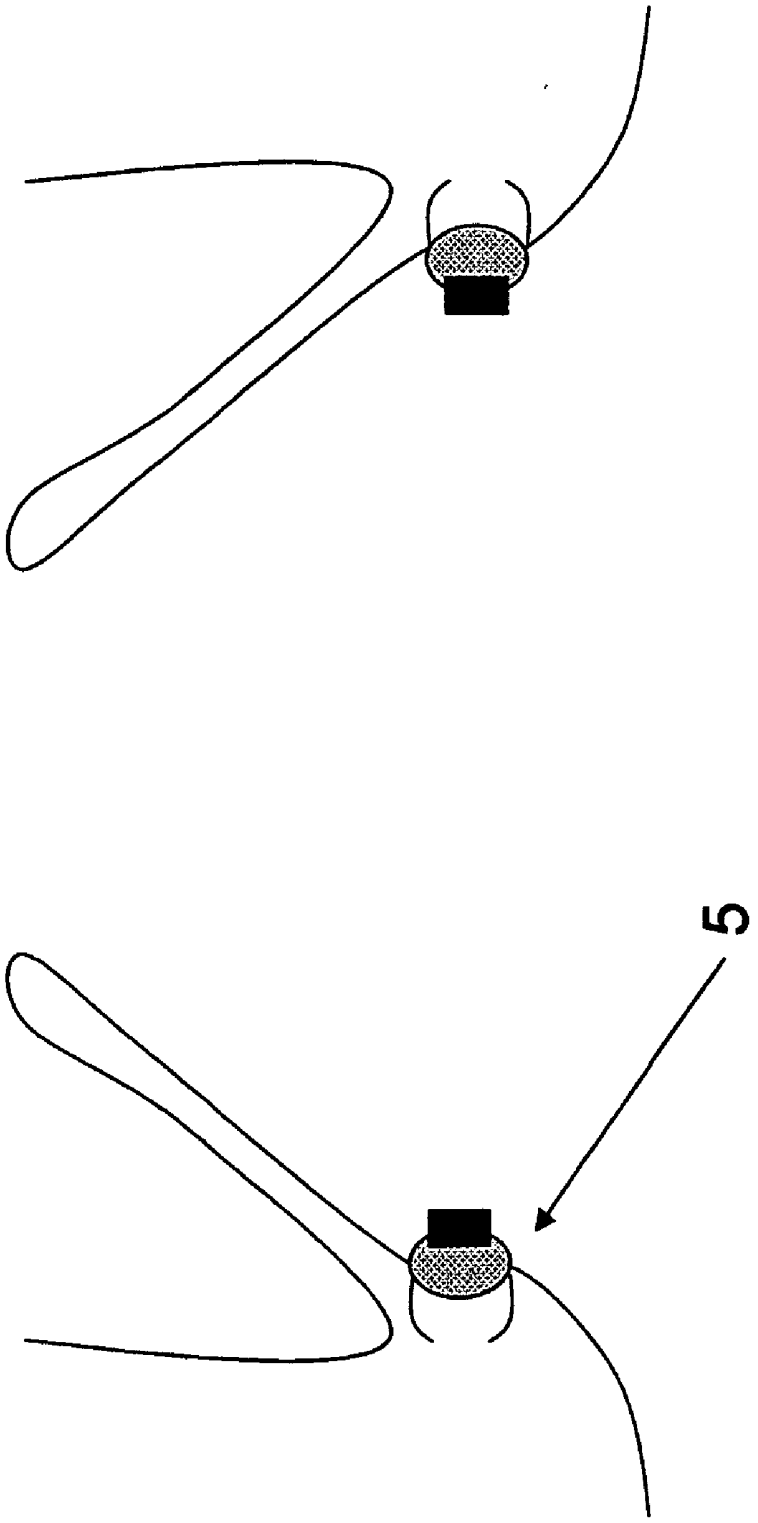
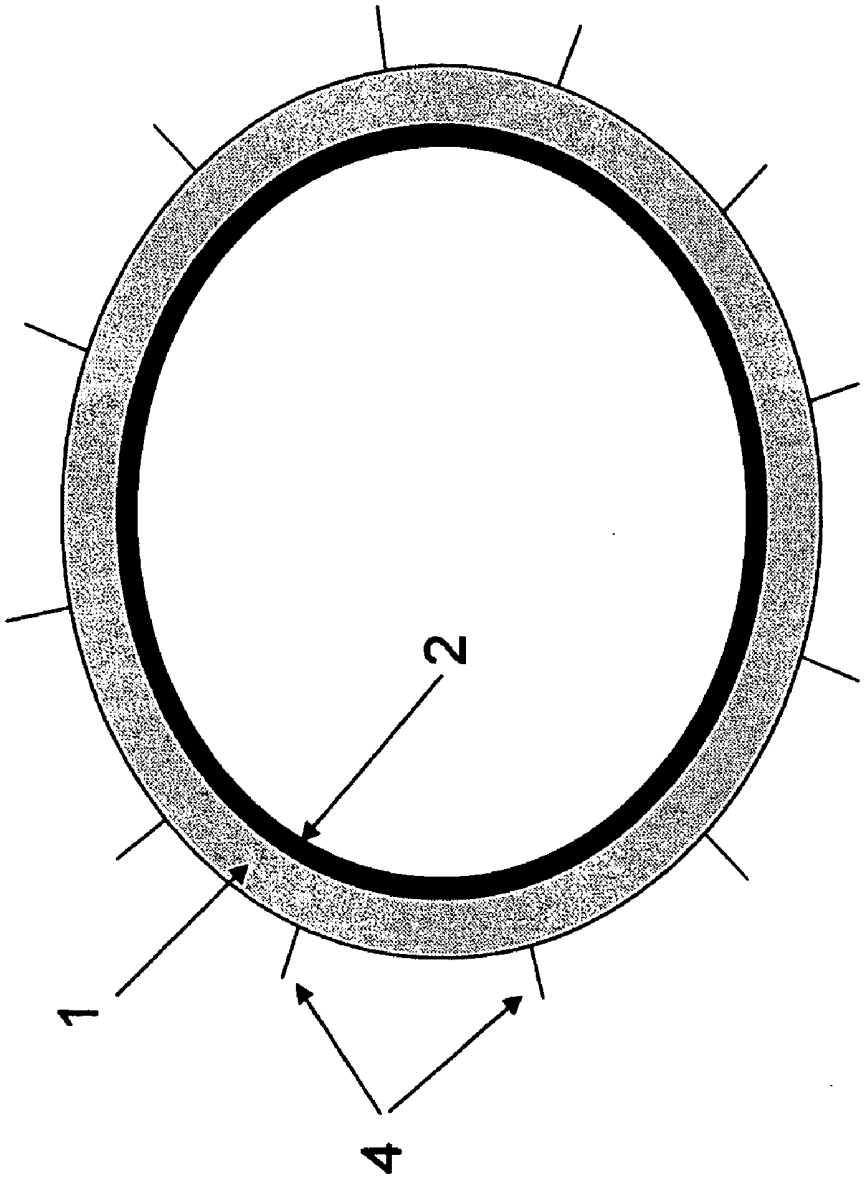


Figure 4



Figures 5A-B

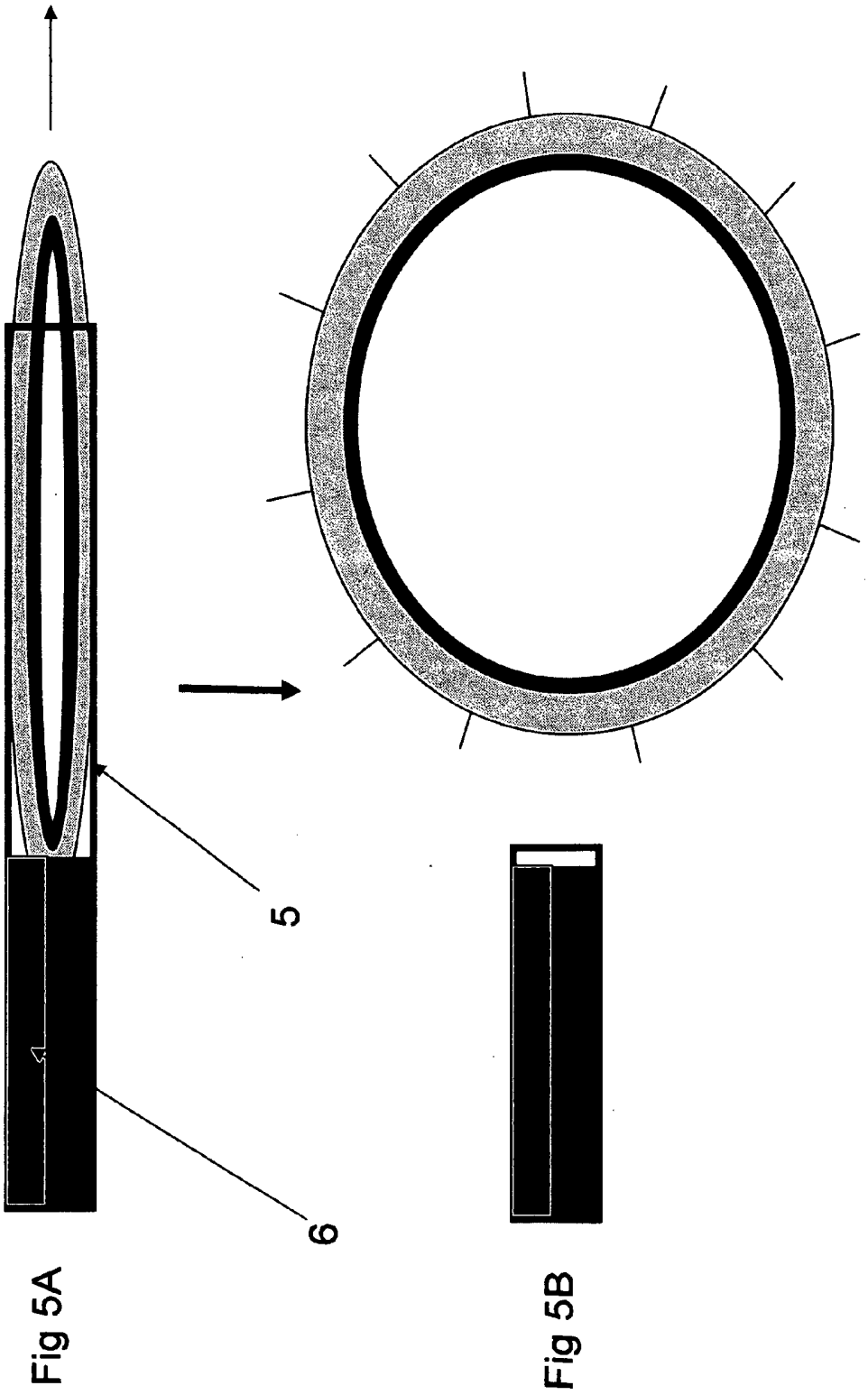


Fig 5A

Fig 5B

Figure 6A-B

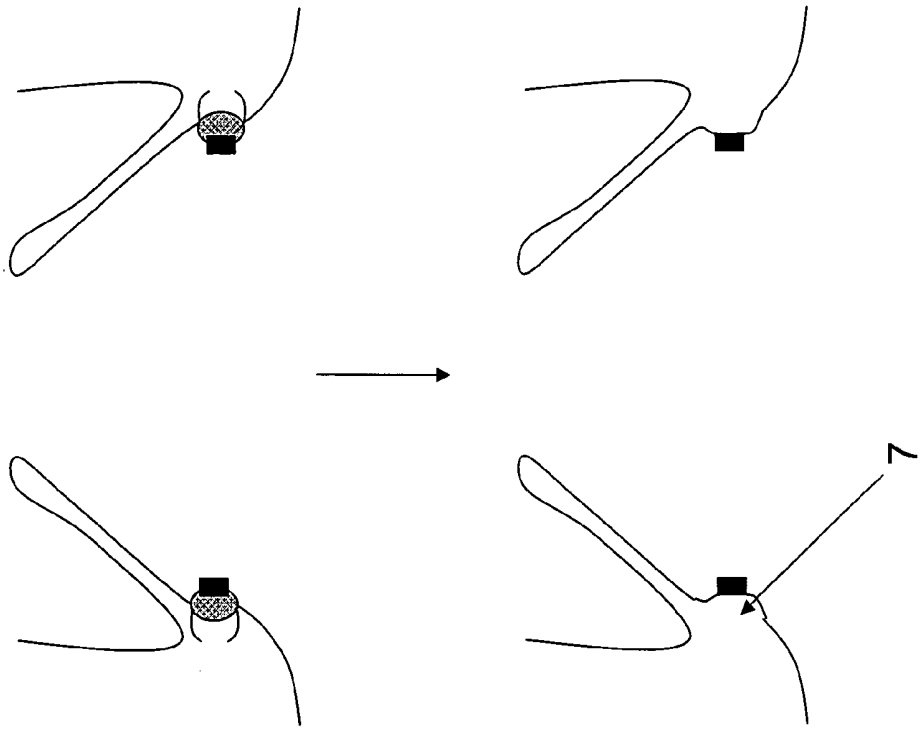


Fig 6A

Fig 6B

Figure 7A-B

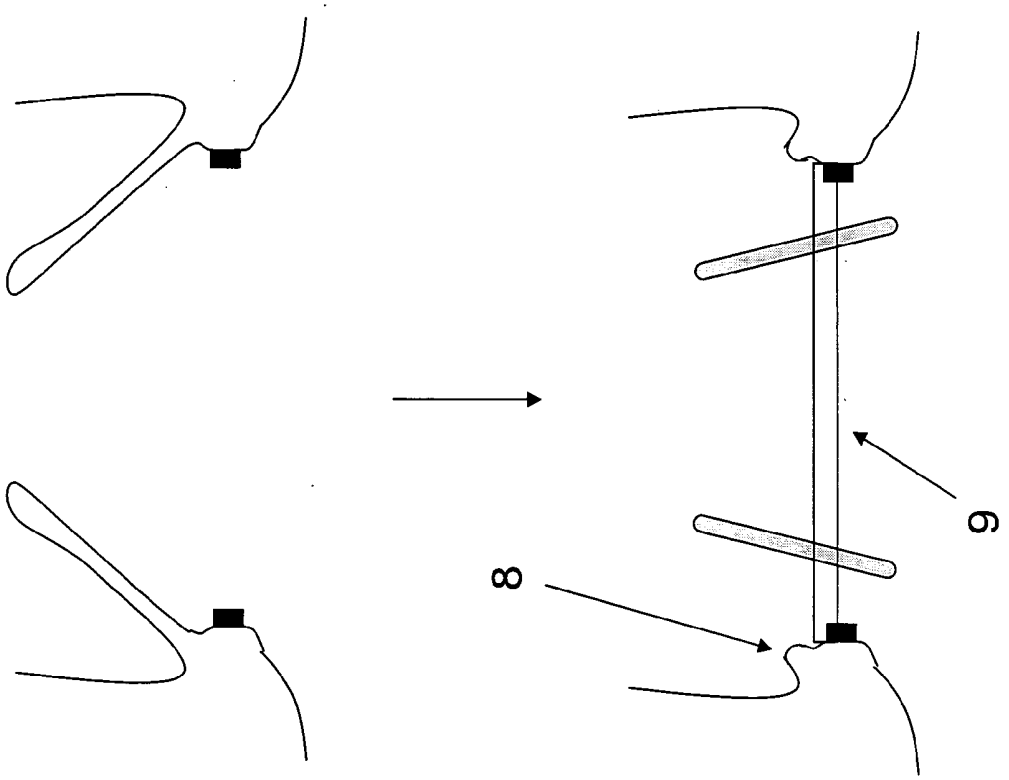


Fig 7A

Fig 7B

Figure 8A-B

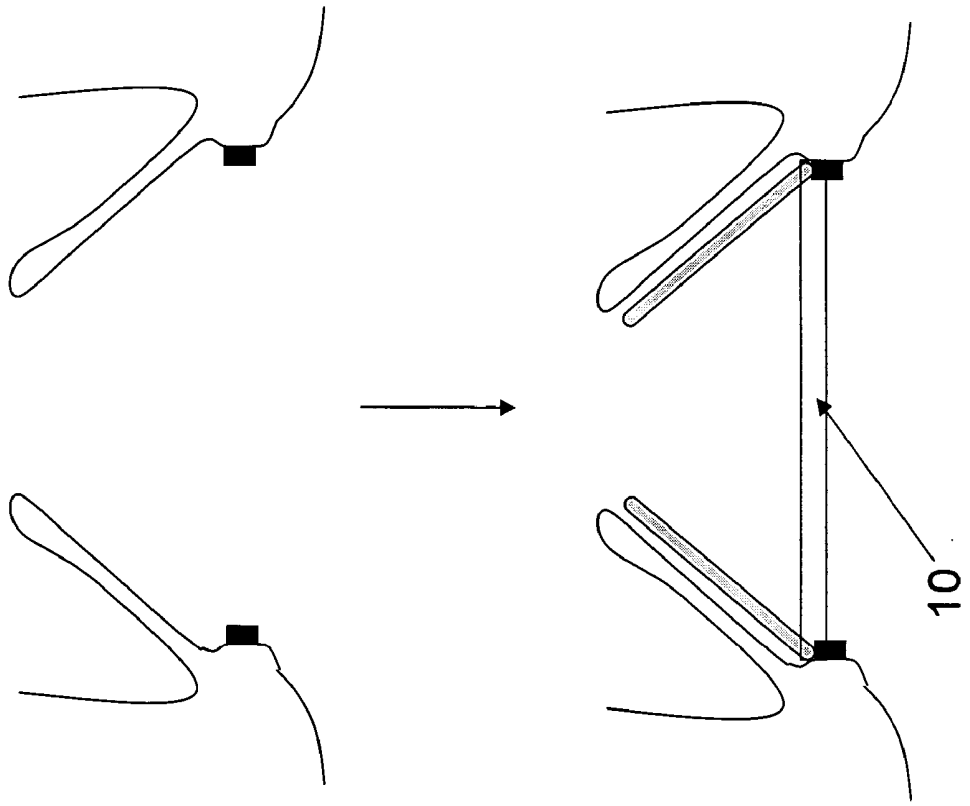
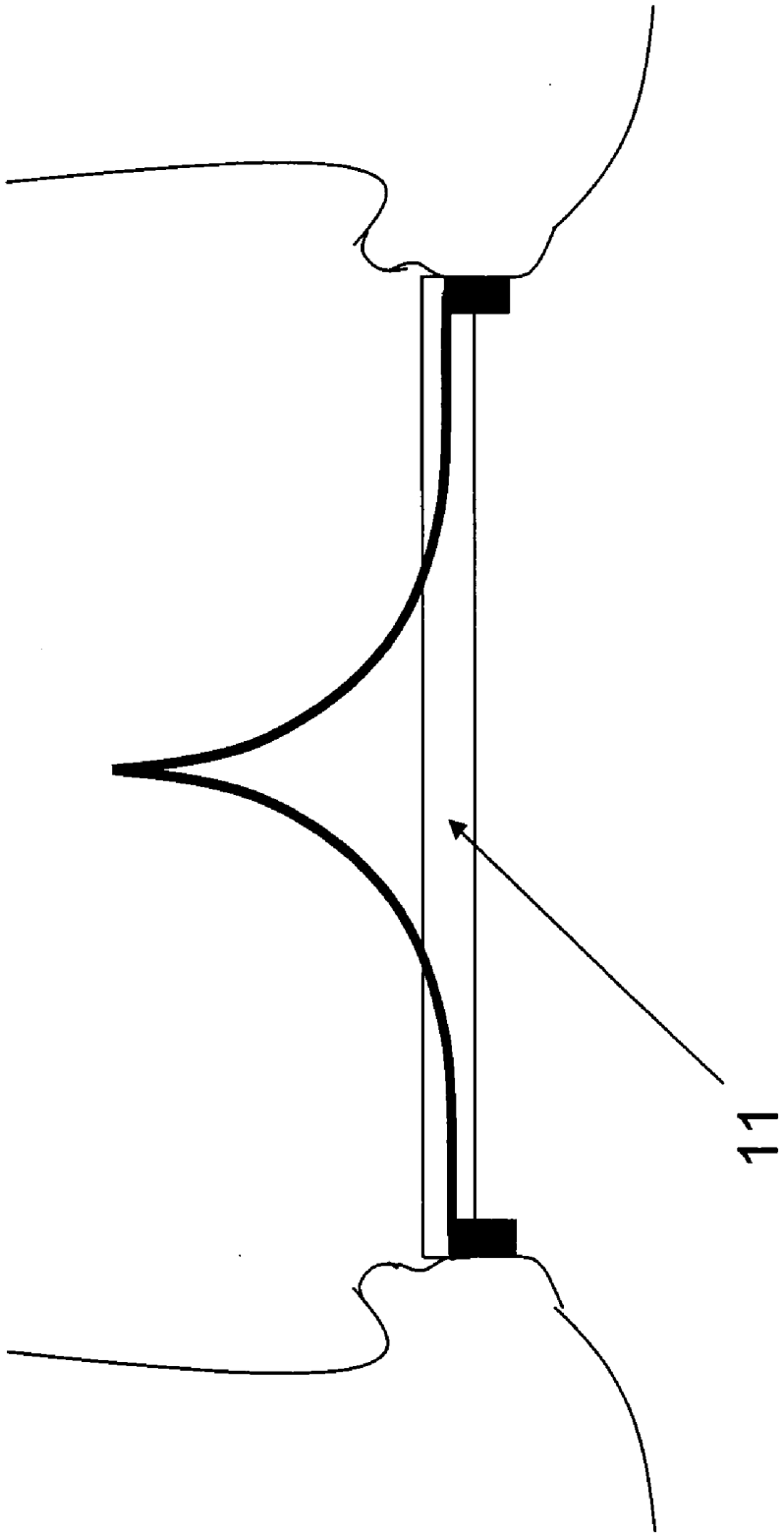


Fig 8A

Fig 8B

Figure 9



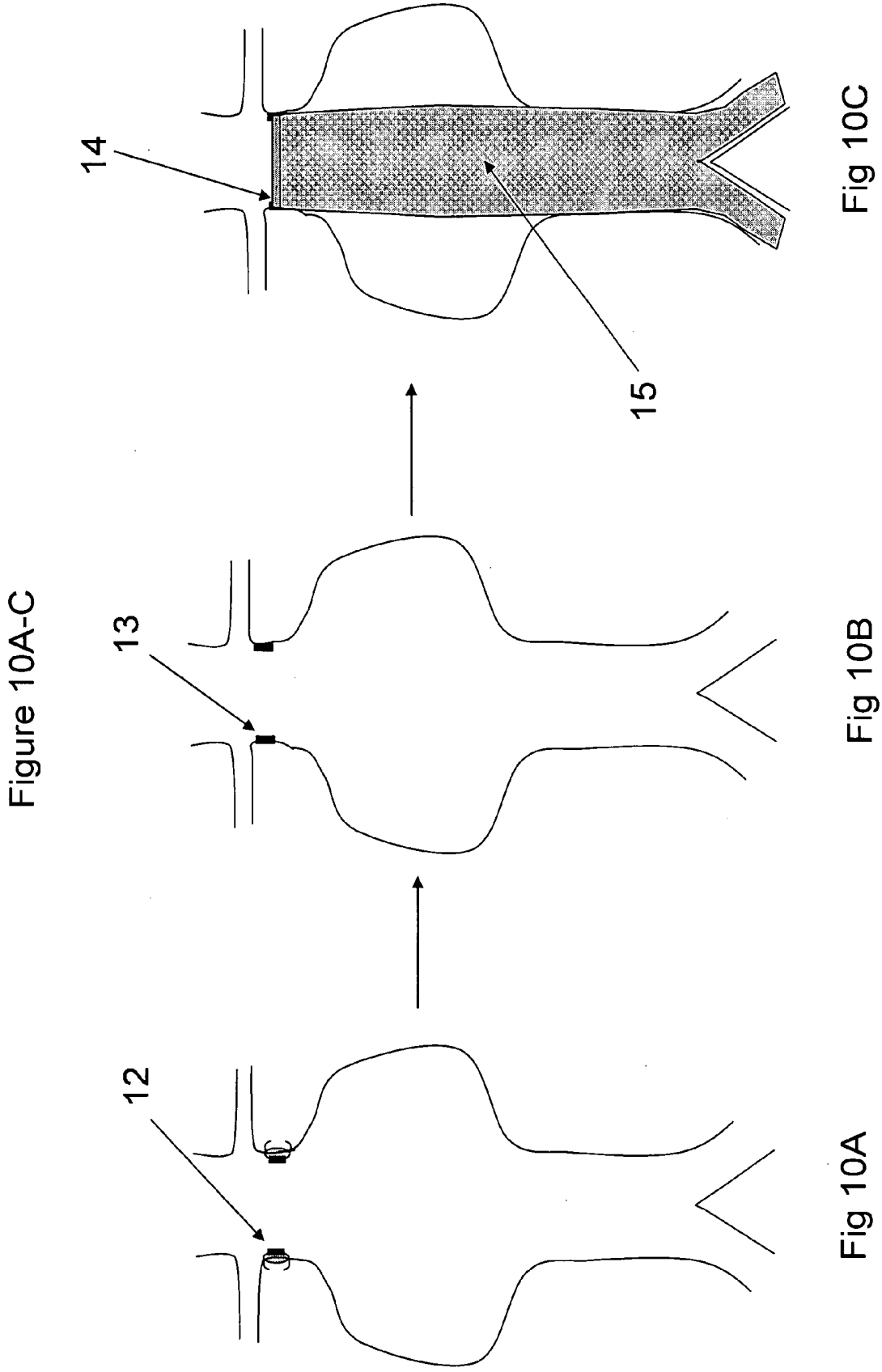


Figure 10A-C

Fig 10C

Fig 10B

Fig 10A

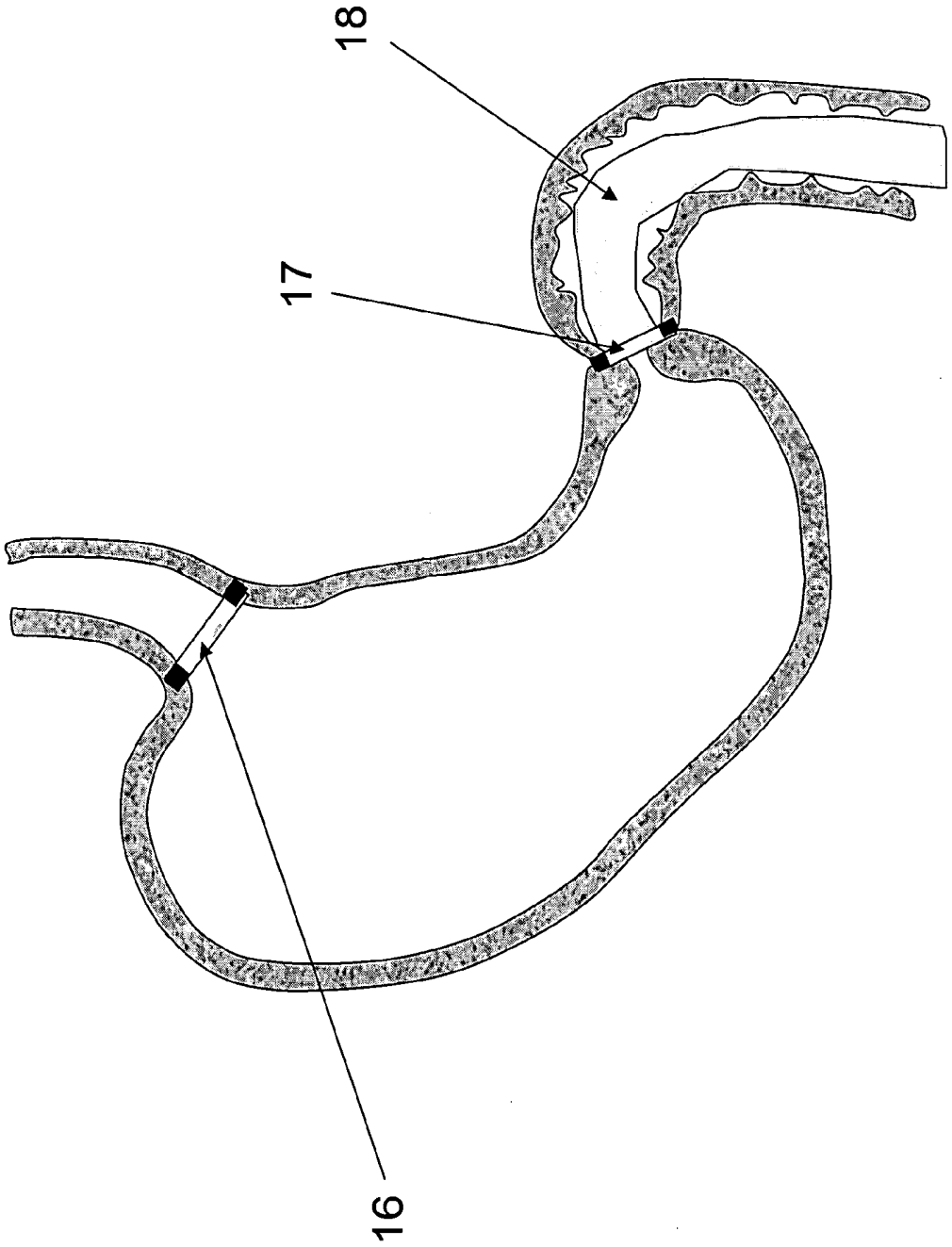


Figure 11

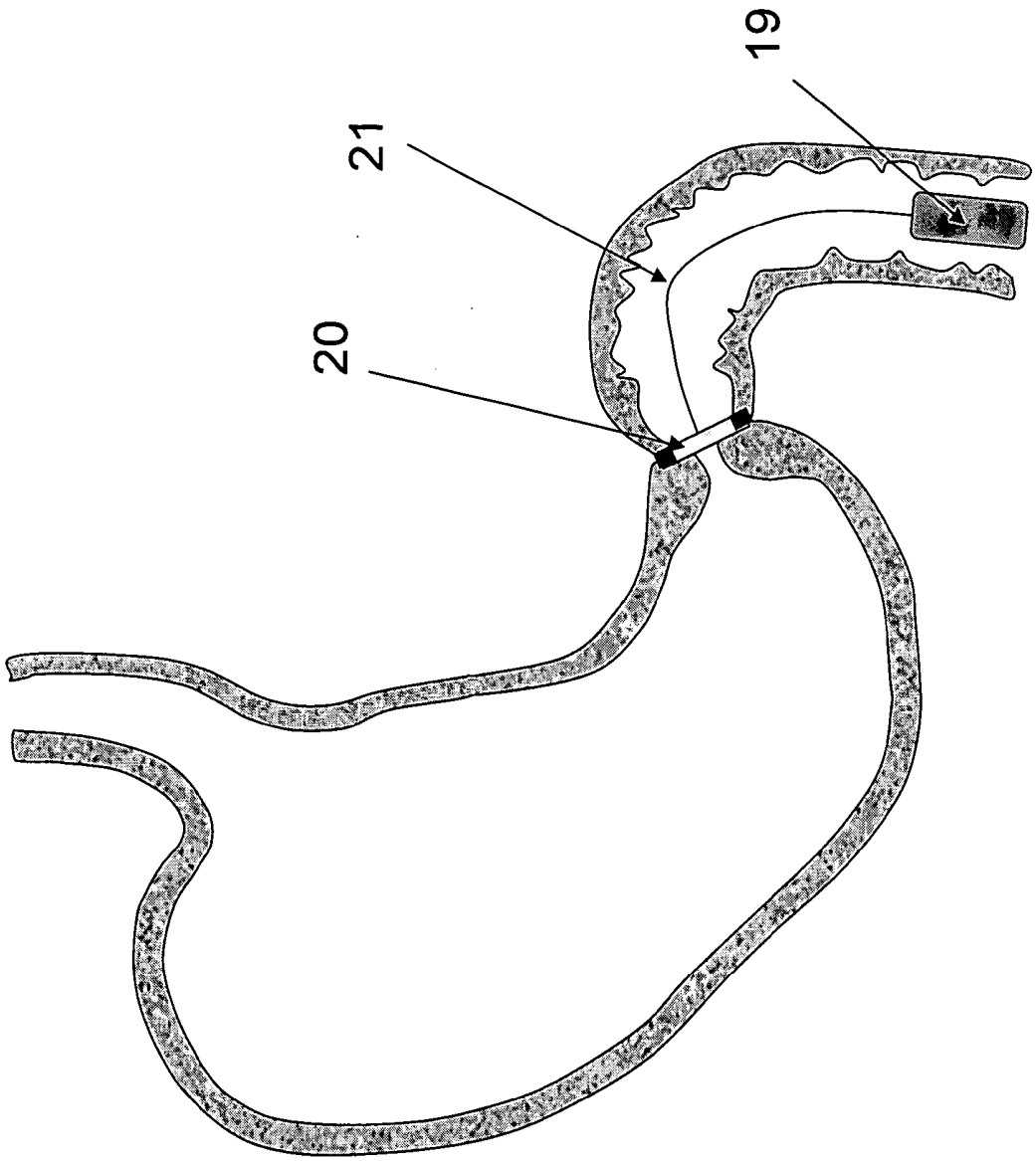


Figure 12

METHOD AND APPARATUS FOR ANCHORING IMPLANTS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application Ser. No. 60/613,205, filed Sep. 27, 2004. The relevant disclosure of the application cited in this paragraph is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to the field of medical devices, in particular therapeutic vascular intervention devices requiring anchoring.

[0003] In the last few decades, therapeutic intervention in the cardiovascular arena has seen major advances in the reducing the invasiveness of life-saving procedures. In fact, coronary artery bypass has been surpassed, now, by coronary stenting in most patients with two or fewer lesions. Continuing this trend, several cardiovascular stents and valves have been designed to facilitate minimally invasive placement, frequently through the use of percutaneous catheter technologies.

[0004] While successful in several arenas, the minimally invasive placement of cardiovascular devices in areas of high flow or high stress has been relatively unsuccessful. This is due, in large part, to the migration of the devices after they have been placed but before they developed a firm attachment to the wall of the lumen. These issues are currently being seen in several percutaneous aortic valve technologies.

[0005] In an effort to combat the migration issue, several devices such as those found in Anduiza U.S. Pat. No. 6,875,231 and Anderson's U.S. Pat. Nos. 6,186,614, 5,840,081 and 5,411,552 are incorporating larger and larger support structures which span larger and larger sections of the lumen, causing issues related to side-branch obstruction and the requirement for anticoagulation. These devices also require a large degree of external pressure in the lumen which they are anchored to be able to withstand the large migration-producing forces they face immediately post-implantation. Furthermore, these issues are also prevalent in percutaneous aortic aneurysm repair.

[0006] The current state of the art, then, would benefit from a minimally invasive method to firmly anchor cardiovascular and other types of devices in a low-profile, reversible manner using a minimum of hardware. The current invention provides this advance with a two-component procedure in which an anchoring element and an anchored device are placed in separate procedures. This two-part procedure allows for the anchoring element to be placed with enough lead time to allow for cellular ingrowth and firm anchoring prior to placement of the anchored device. Thus, before the device is attached, the physician will be able to visualize exactly where the device will be placed and the device will remain firmly in place once placed. After the anchoring element has been firmly embedded in the vascular wall, the anchored device (stent, valve, etc.) can be inserted and firmly attached to the anchoring element. The insertion of the device can also be accompanied by other interventions, ie native valve debridement. The present invention overcomes the limitations of the prior art by allowing for low-profile insertion into the lumen with a decreased risk of migration due to the presence of extensive tissue-ingrowth prior to exposing the anchored device to the migration-producing forces it will face immediately post-implantation.

SUMMARY OF THE INVENTION

[0007] As mentioned above, the current invention consists of two components, an anchoring element and the anchored device. When used in combination, the two components provide for the firm, minimally invasive anchoring of cardiovascular technologies. The anchoring element, itself, has three main functions: 1) to adhere to the vascular lumen, 2) to encourage fibrotic ingrowth, and 3) to provide a firm attachment site for the anchored device. The anchoring element has been designed to adhere to the lumen of the vessel using standard technologies including staples, clips, pins, stents, etc, made from standard materials, nitinol, stainless steel, etc., to provide for a firm attachment. The anchoring element, in the preferred embodiment, is coated with, or fabricated from, materials designed to encourage cellular ingrowth, such as loose weave dacron, polyester, etc, such that with adequate passage of time the element will become firmly embedded in the vessel wall. While this is the preferred embodiment, the present invention doesn't necessarily require this second feature as the benefit of reduction in invasiveness and precision in placement found with this two part procedure make the invention an advance in the field in and of themselves. The cellular ingrowth, though, is anticipated to be beneficial, though, and is considered preferable. The third component of the anchoring element provides for firm attachment of the anchored device. In its preferred embodiment this attachment mechanism is a reversible mechanical locking mechanism in the medial aspect of the anchoring element. This mechanism, though, could also consist of attraction by magnetism, chemical bonding, interference fit, etc.

[0008] The anchored device can consist of any implanted device requiring firm anchoring. The anchored device consists of the device body, whether it be a mitral valve, aortic valve, aortic aneurysm stent, gastrointestinal stent, etc., which firmly engages the anchoring element. In the case of a lengthy device, such as an aortic aneurysm stent or duodenal sleeve, multiple attachment rings may be placed on the device and multiple anchoring elements may be placed prior to deployment of the device. In this way both the proximal and distal aspects of the device can be firmly anchored once the device is deployed. Optionally, the proximal aspect of the device may be the only portion of the device which attaches to the anchoring element and the distal portion of the device, which requires less mechanical strength, may simply use standard anchoring mechanisms, such as staples, clips, pins, stents.

[0009] In its preferred embodiment, then, the anchoring element is placed at the desired site and is then given at least a week to allow for cellular ingrowth, after which the patient then has the device placed. The device then, is held firmly in place using natural cellular and fibrotic reactions thus reducing the requirement for complex and extensive anchoring hardware. The device placement and anchoring element placement, while separate procedures, may be less invasive than any single procedure due to the drastic reduction in required hardware for each procedure. The anchored device

addresses a number of the critical issues limiting deployment of existing technologies. Specifically, the anchored device will facilitate precise, secure positioning of the implant without the need for excessive pressures on the wall of the lumen or overly aggressive, but ineffective, anchoring mechanisms at the time of placement of the anchored device. One such example includes the use of an anchoring element placed in the vicinity of the pyloric sphincter, either on the sphincter itself or adjacent to the sphincter in the duodenum or the stomach, then allowing time for tissue ingrowth prior to placement of the complementary anchored device, ie gastric or duodenal electrical stimulator, duodenal sleeve, pyloric sphincter restrictor, etc. This mechanism will allow for the placement of gastrointestinal, as well as other, technologies using much less hardware and with a decreased risk of perforation or migration of the anchored device.

[0010] The device will provide the following advances over the current state of the art: (1) Facilitation of self-seating and avoidance of coronary ostia or other sensitive regions; (2) Elimination of the frequent complication of migration and inadequate sizing with the anchoring of a device with a known diameter to native tissue; (3) Incorporation of radiographic contrast into part one of the anchored device will facilitate localization of the coronary ostia prior to placing the valve and also facilitate exact positioning/orientation of the implant. This feature will also facilitate visualization of real-time fluoroscopic landmarks during placement of the implant; (4) Encouragement of native tissue ingrowth into the anchoring element with the embedding of elements in the anchor material that would encourage cellular ingrowth (especially important in the setting of a potentially calcified aorta). This last feature will allow for a greatly decreased footprint of the overall device and use of much less hardware in anchoring the device.

[0011] While the preferred embodiment has been described as an anchoring element to anchor devices within a lumen, the anchoring element may also consist of a ring, a tube, a socket, a port, a catheter, a patch or any other fastener allowing for firm engagement of the complementary region of the anchored device. The mechanism for firm engagement may be an interference fit, locking, screw-type or magnetically coupled device, but is not limited to these options as an firm engagement mechanism will suffice.

[0012] Also, while the anchored device, in the preferred embodiment, has been described as a cardiovascular device, the anchored device may consist of one or more of several devices including, but not limited to: prosthetic aortic, tricuspid or mitral heart valves, abdominal aortic aneurysm stents, coronary stents, gastrointestinal stents, gastrointestinal devices anchored in the esophagus, stomach or duodenum, gastrointestinal devices anchored within the gastrointestinal lumen, urologic devices anchored within the bladder, peritoneal devices anchored within the peritoneum, pulmonary devices anchored within the pulmonary tree, nasopharyngeal devices anchored within the nasopharynx, orthopedic devices anchored into bone and/or dermatologic devices anchored into the skin or subcutaneous tissues.

[0013] The competitive advantages of the present invention include: Firm anchoring of device with reduced migration risk, exact placement of device, and reduced invasiveness due to reduction in hardware requirements and overall footprint of the implanted device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1**—Longitudinal section of the anchoring element deployed in the supravalvular position with interference fit and without clips, staples, etc.

[0015] **FIG. 2**—Longitudinal section of the anchoring element deployed in the supravalvular position with clips, staples, etc

[0016] **FIG. 3**—Longitudinal section of the anchoring element deployed in the subvalvular position with clips, staples, etc

[0017] **FIG. 4**—Aerial cross-section view of the anchoring element's entire circumference with clips

[0018] **FIG. 5**—Possible deployment mechanism for anchoring element

[0019] **FIG. 6A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position (**FIG. 6A**) with clips illustrating fibrotic ingrowth (**FIG. 6B**).

[0020] **FIG. 7A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position illustrating fibrotic ingrowth (**FIG. 7A**) and subsequent device deployment and attachment to the anchoring element with debridement of the native valve (**FIG. 7B**)

[0021] **FIG. 8A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position illustrating fibrotic ingrowth (**FIG. 8A**) and subsequent device deployment and attachment to the anchoring element without debridement of the native valve (**FIG. 8B**)

[0022] **FIG. 9A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position illustrating fibrotic ingrowth (**FIG. 8A**) and subsequent deployment of porcine valve to the anchoring element with debridement of the native valve (**FIG. 8B**)

[0023] **FIG. 10A**-C—Longitudinal section of the anchoring element deployed with clips in the abdominal aorta (**FIG. 10A**) illustrating fibrotic ingrowth (**FIG. 10B**) and subsequent deployment of abdominal aortic aneurysm stent to anchoring element (**FIG. 10C**)

[0024] **FIG. 11**—Cross-section of the gastrointestinal tract anchoring embodiment illustrating anchoring of a lower esophageal ring and a pyloric ring to which a intestinal sleeve is attached

[0025] **FIG. 12**—Cross-section of the gastrointestinal tract anchoring embodiment wherein an electrical stimulator for the treatment of obesity is shown attached to a pyloric anchoring element

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] **FIG. 1**—This illustration represents the deployed anchoring element placed in the aortic valve region. As can be seen from the illustration, the anchoring element consists solely of a material to promote fibrotic ingrowth **1** and the attachment ring **2** designed to engage the aortic valve device. In this case, the device is deployed above the native aortic valve **3**.

[0027] **FIG. 2**—This illustration represents the deployed anchoring element again placed in the aortic valve region

but this time with clips to secure the anchoring element to the aorta. As can be seen from the illustration, the anchoring element consists of a material to promote fibrotic ingrowth **1**, the attachment ring **2** designed to engage the aortic valve device and clips, staples, etc **4** for the attachment of the anchoring element to the aortic tissues. In this case, the device is deployed above the native aortic valve.

[**0028**] **FIG. 3**—This illustration represents the deployed anchoring element again placed in the aortic valve region but this time with clips to secure the anchoring element. As can be seen from the illustration, the anchoring element consists of a material to promote fibrotic ingrowth **1**, the attachment ring **2** designed to engage the aortic valve device and clips, staples, etc **4** for the attachment of the anchoring element to the aortic tissues. In this case, the device is deployed below the native aortic valve.

[**0029**] **FIG. 4**—Is an aerial cross-section view of the anchoring element's entire circumference with clips. In this view the entire circumference of the fibrotic ingrowth anchoring element **1** and the device attachment ring **2** can be visualized as can the clips **4** to secure the device to native tissues. In this case the anchoring element is attached with clips, but it could be attached with a expanding stent, staples, sutures, glues or other attachment modalities.

[**0030**] **FIG. 5**—Is a view of a possible deployment mechanism for the anchoring element. In this case the anchoring element is placed inside of an insertion tube or catheter **5** and placed in the region where deployment is desired. A plunger **6** is then used to expel the device into its proper position. This is but one of many possible deployment mechanisms with the optimal embodiment being a deployment mechanism that allows for reversible circumferential deployment in a consistent manner.

[**0031**] **FIG. 6A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position (**FIG. 6A**) with clips illustrating fibrotic ingrowth (**FIG. 6B**). In this case, the subvalvular clips hold the anchoring element in place until the cellular and fibrotic ingrowth can provide for firm permanent attachment **7**.

[**0032**] **FIG. 7A**-B—In this longitudinal section of the anchoring element deployed in the subvalvular position fibrotic ingrowth (**FIG. 7A**) and subsequent device deployment to the anchoring element with debridement of the native valve (**FIG. 7B**) are illustrated. Once the anchoring element has been firmly anchored by fibrotic ingrowth, the new aortic valve **9** may be placed with or without removal of the existing native valve **8**.

[**0033**] **FIG. 8A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position illustrating fibrotic ingrowth (**FIG. 8A**) and subsequent device deployment to anchoring element without debridement of the native valve (**FIG. 8B**). Here the aortic valve device **10** is placed without removal of the native valve.

[**0034**] **FIG. 9A**-B—Longitudinal section of the anchoring element deployed in the subvalvular position illustrating fibrotic ingrowth (**FIG. 8A**) and subsequent deployment of porcine valve **11** to anchoring element with debridement of the native valve (**FIG. 8B**)

[**0035**] **FIG. 10A**-C—Longitudinal section of the anchoring element deployed with clips in the abdominal aorta **12** (**FIG. 10A**) illustrating fibrotic ingrowth **13** (**FIG. 10B**) and subsequent deployment of abdominal aortic aneurysm stent **15** to the anchoring element **14** (**FIG. 10C**). In this case the anchoring element has been deployed just below the renal arteries and just above the neck of the aneurysm. As can be seen in this case, this invention allows for much more precise placement of abdominal aortic stents in much tighter regions than would otherwise be possible with existing longer stent-based devices.

[**0036**] **FIG. 11**—Cross-section of the gastrointestinal tract anchoring embodiment illustrating anchoring of a lower esophageal ring **16** and a pyloric ring **17** to which a intestinal sleeve is attached **18**. These are but two of the possible embodiments of the gastrointestinal devices that can be anchored using this technology with other possibilities including, but not limited to: an intestinal sleeve, an electrical stimulator designed to alter transit or treat obesity, for an artificial rectum, a gastric pouch for the treatment of obesity and a flow restrictor for gastrointestinal transit.

[**0037**] **FIG. 12**—Cross-section of the gastrointestinal tract anchoring embodiment wherein an electrical stimulator for the treatment of obesity **19** is shown anchored to the pyloric anchoring element **20**, in this case via an optional conducting tether **21**. The anchoring element may be in the pyloric, cardiac or fundic regions of the stomach or may be attached to the esophagus or intestine. The tether may not be used in the instance where the stimulator is low-enough profile that it will not overly impede flow through the gastrointestinal tract and cause a bowel obstruction. The anchoring element may consist of the ring illustrated, but may also consist of any configuration of ingrowth encouraging material (including stapling, suturing, etc, at a single, non-circumferential site) deployed in any region of the stomach, esophagus or intestine. In the preferred embodiment, the anchoring element is deployed in a non-mucosal region of the stomach, esophagus and/or intestine in order to avoid erosion, ulceration and/or rupture.

We claim:

1. A multi-component implant anchoring device consisting of:

An anchoring element and

An anchored device, wherein

Said anchoring element and anchored device may be inserted separately and may form firm attachments to each other upon deployment within the body and wherein

Said anchoring element may incorporate a material or fabric to encourage cellular ingrowth and wherein

Said anchoring element may be inserted a period of time prior to the insertion of the anchored device to allow for fibrotic or cellular ingrowth to firmly secure the element in place and wherein

Said anchored device may contain at least one complementary attachment site for the anchoring element allowing for firm attachment upon implantation and wherein

Said anchored device may consist of one or more of the following devices: prosthetic aortic, tricuspid or mitral heart valves, abdominal aortic aneurysm stents, coro-

nary stents, gastrointestinal stents, electrical gastric stimulators, electrical intestinal stimulators, gastrointestinal devices anchored in the esophagus, stomach, intestine or rectum, urogynecologic devices anchored within the bladder, uterus, fallopian tubes or vagina, peritoneal devices anchored within the peritoneum, pulmonary devices anchored within the pulmonary tree, nasopharyngeal devices anchored within the nasopharynx, orthopedic devices anchored into bone and/or dermatologic devices anchored into skin.

2. A multi-component implant anchoring device consisting of:

An anchoring element and

An anchored device, wherein

Said anchoring element and anchored device may be inserted separately and may form firm attachments to each other during deployment inside the body

3. The device of claim 2 in which said anchoring element may contain support elements to provide for firm attachment to the surrounding tissues at the site of implantation wherein said support elements may consist of pins, staples, clips, stents, sutures, etc.

4. The device of claim 2 in which said anchoring element may incorporate a material or fabric to encourage cellular ingrowth

5. The device of claim 4 in which said fabric may be a Dacron, polyester, Gore-Tex, PTFE or other ingrowth encouraging material

6. The device of claim 2 in which said anchored device may contain at least one complementary attachment site for the anchoring element

7. The device of claim 6 in which said anchoring ring may provide for firm attachment of said anchored device through the use of screwing, mechanical locking, magnetic attraction, chemical bonding, or interference fitting.

8. The device of claim 6 in which said anchoring ring may provide for firm attachment to said anchored device through the use of pins, staples, clips, stents, or sutures.

9. The device of claim 2 in which said anchoring element and said anchored device can each be collapsed to a size sufficient to allow for minimally invasive, catheter-based delivery

10. The device of claim 2 in which radiographic contrast is incorporated into said anchored device to facilitate localization of anatomic landmarks (such as the coronary ostia) prior to placing said anchored device and also facilitate exact positioning/orientation of the implant.

11. The device of claim 2 in which said anchored device encourages native tissue ingrowth into the anchor with the embedding of elements in the anchor material that would encourage cellular ingrowth.

12. The device of claim 2 in which the anchored device eliminates the frequent complication of migration and inadequate sizing with the anchoring of a device with a known diameter to native tissue.

13. The device of claim 2 wherein said anchored device may consist of, but is not limited to, one or more of the following devices: prosthetic aortic, tricuspid or mitral heart valves, abdominal aortic aneurysm stents, coronary stents, gastrointestinal stents, gastrointestinal devices anchored in the esophagus, stomach or duodenum, gastrointestinal devices anchored within the gastrointestinal lumen, urogynecologic devices anchored within the bladder, uterus, fallopian tubes or vagina, peritoneal devices anchored within the peritoneum, pulmonary devices anchored within the pulmonary tree, nasopharyngeal devices anchored within the nasopharynx, orthopedic devices anchored into bone and/or dermatologic devices anchored into skin.

14. A method of anchoring an implanted device including:

Placement of an anchoring element, followed by

Deployment of the anchored device wherein

Said anchoring element may firmly engage said anchored device

15. The method of claim 14 in which at least a portion of said anchoring element may encourage native tissue ingrowth and/or cellular ingrowth.

16. The method of claim 14 in which said anchoring element may consist of a ring, a tube, a socket, a port, a catheter, a patch or any other fastener allowing for firm engagement of the complementary region of the anchored device.

17. The method of claim 14 in which said anchoring element may contain support elements, such as pins, staples, clips, stents, sutures, etc., to provide for firm attachment to the surrounding tissues at the site of implantation prior to said native tissue ingrowth and/or cellular ingrowth

18. The method of claim 15 in which at least three days, at least a week, at least a month and/or at least three months may be allowed to pass between the placement of said anchoring element and the deployment of said anchored device

19. The method of claim 14 in which said anchoring ring may provide for firm attachment to said anchored device through the use of screwing, mechanical locking, magnetic attraction, chemical bonding, interference fitting, suturing, stapling, or clipping.

20. The method of claim 14 wherein said anchored device may consist of one or more of several devices including: prosthetic aortic, tricuspid or mitral heart valves, abdominal aortic aneurysm stents, coronary stents, gastrointestinal stents, electrical gastric stimulators, electrical intestinal stimulators, gastrointestinal devices anchored in the esophagus, stomach or duodenum, gastrointestinal devices anchored within the gastrointestinal lumen, urogynecologic devices anchored within the bladder, uterus, fallopian tubes or vagina, peritoneal devices anchored within the peritoneum, pulmonary devices anchored within the pulmonary tree, nasopharyngeal devices anchored within the nasopharynx, orthopedic devices anchored into bone and/or dermatologic devices anchored into skin.

* * * * *

专利名称(译)	用于锚定植入物的方法和设备		
公开(公告)号	US20060069400A1	公开(公告)日	2006-03-30
申请号	US11/234802	申请日	2005-09-26
[标]申请(专利权)人(译)	THERANOVA		
申请(专利权)人(译)	THERANOVA，LLC		
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外部链接	Espacenet USPTO		

摘要(译)

方法，装置和系统有助于保留各种治疗装置。装置通常包括锚定元件和锚定装置，锚定元件设计用于促进纤维化向内生长，锚定装置设计成牢固地接合锚定元件的互补区域。锚定元件可以放置在与锚定装置的展开暂时分离的微创手术中。一旦经过足够的时间以确保锚定元件通过放置位置处的组织和细胞向内生长的适当固定，然后可以展开锚固装置，在锚固装置期间锚固装置牢固地接合锚固元件的互补区域。以这种方式，可以用最少的所需硬件进行与植入部位的牢固连接。一些实施方案通过输送管或导管递送，而一些实施方案可能需要腹腔镜检查或开放手术用于一个或多个放置程序。一些实施方案将装置锚定在心血管树内，而其他实施方案可将装置锚定在身体的胃肠道，腹膜，胸膜，肺，泌尿生殖，鼻咽或皮肤病区域内。