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**Gonzales et al.**

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- (54) **METHODS AND SYSTEMS FOR MEDIALIZING A TURBINATE**
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- (73) Assignee: **ArthroCare Corporation**, Austin, TX (US)
- (\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 170 days.  
  
This patent is subject to a terminal disclaimer.

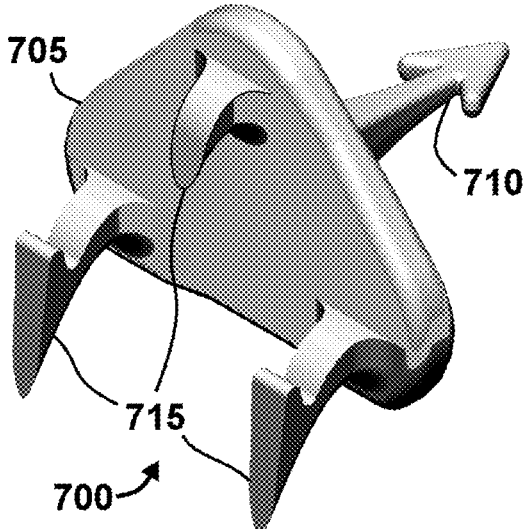
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- A61B 17/24* (2006.01)
- A61B 17/068* (2006.01)
- (52) **U.S. Cl.**  
CPC ..... *A61B 17/0401* (2013.01); *A61B 17/064* (2013.01); *A61B 17/24* (2013.01); *A61B 17/0483* (2013.01); *A61B 17/068* (2013.01); *A61B 2017/0409* (2013.01); *A61B 2017/0417* (2013.01); *A61B 2017/0461* (2013.01); *A61B 2017/0641* (2013.01); *A61B 2017/0647* (2013.01)
- (58) **Field of Classification Search**  
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See application file for complete search history.

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- (22) Filed: **Feb. 10, 2015**

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(Continued)

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- (63) Continuation of application No. 13/474,121, filed on May 17, 2012, now Pat. No. 8,979,875, which is a continuation of application No. 12/561,707, filed on Sep. 17, 2009, now Pat. No. 8,192,450.
- (60) Provisional application No. 61/097,741, filed on Sep. 17, 2008.
- (51) **Int. Cl.**  
*A61B 17/08* (2006.01)  
*A61B 17/04* (2006.01)

- Primary Examiner* — Todd J Scherbel
- (74) *Attorney, Agent, or Firm* — David A. Warmbold
- (57) **ABSTRACT**  
Methods and systems for medializing a turbinate. Exemplary embodiments comprise methods and systems for repositioning a turbinate proximal to a septum. Certain embodiments comprise an implant and a flexible member coupled to the implant. Embodiments may also comprise an insertion device to install the implant in a desired location.
- 13 Claims, 28 Drawing Sheets**



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				623/10

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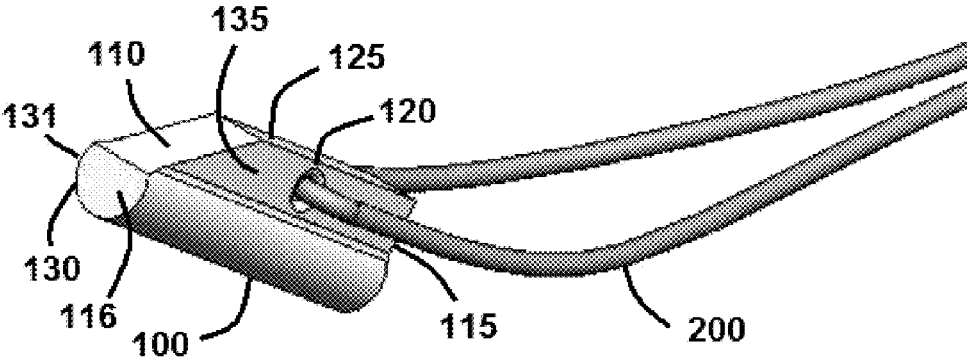


FIG. 1

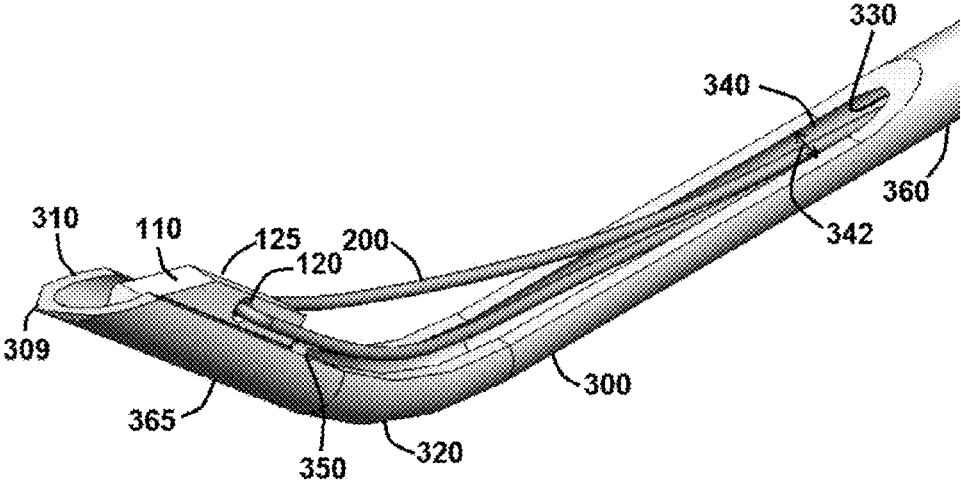


FIG. 2

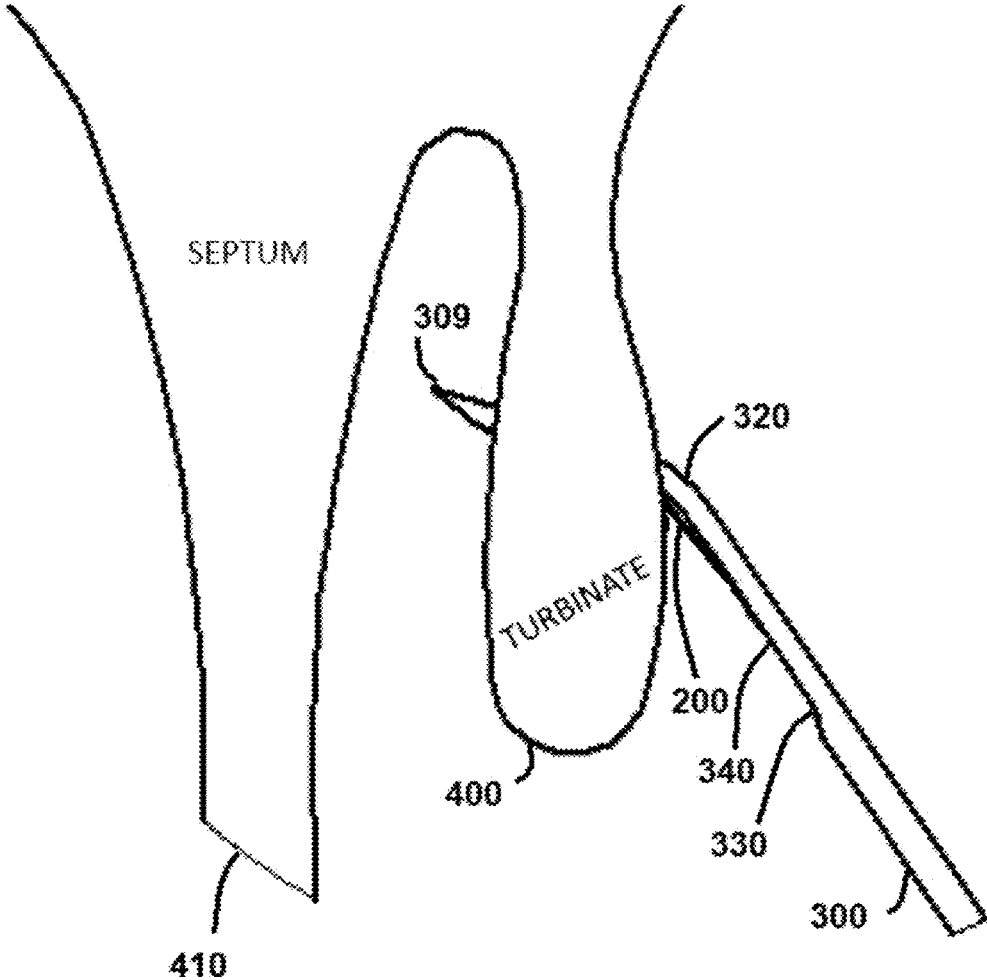


FIG. 3

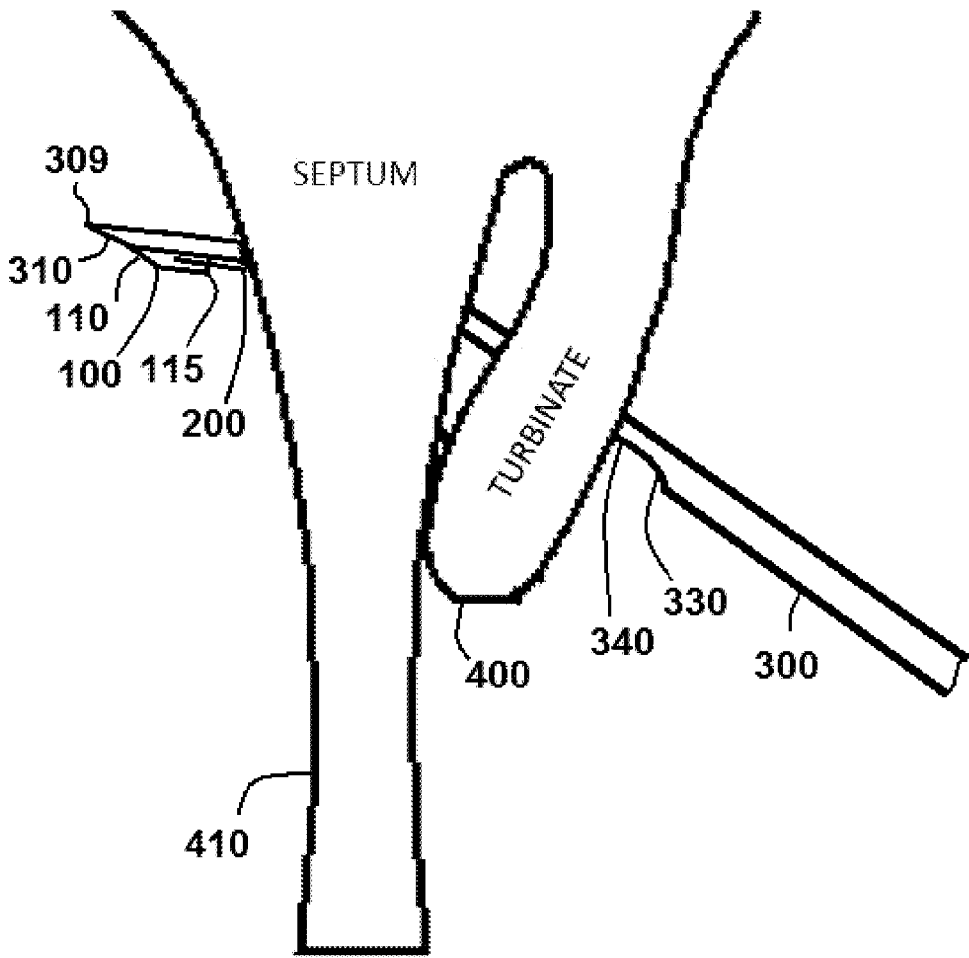


FIG. 4

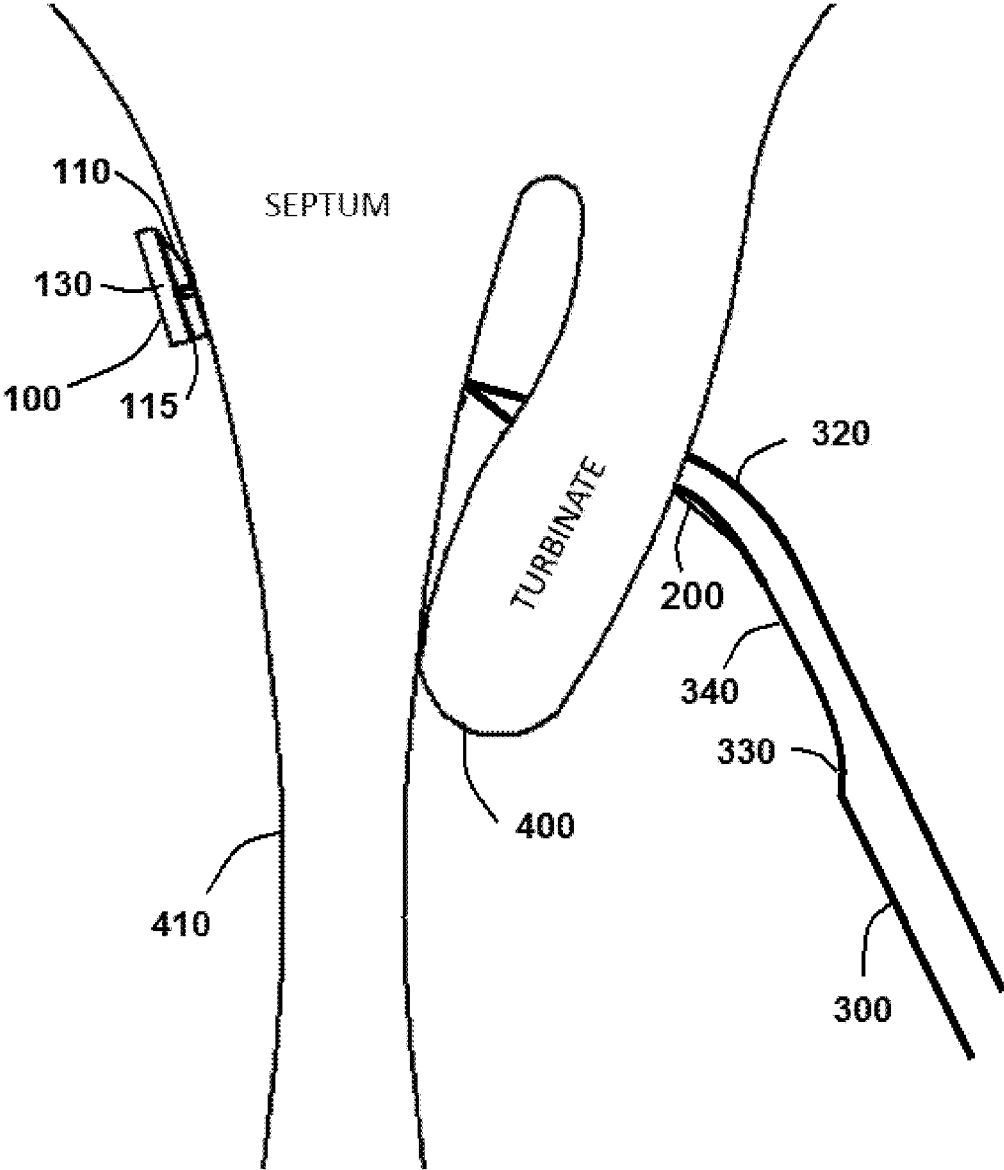
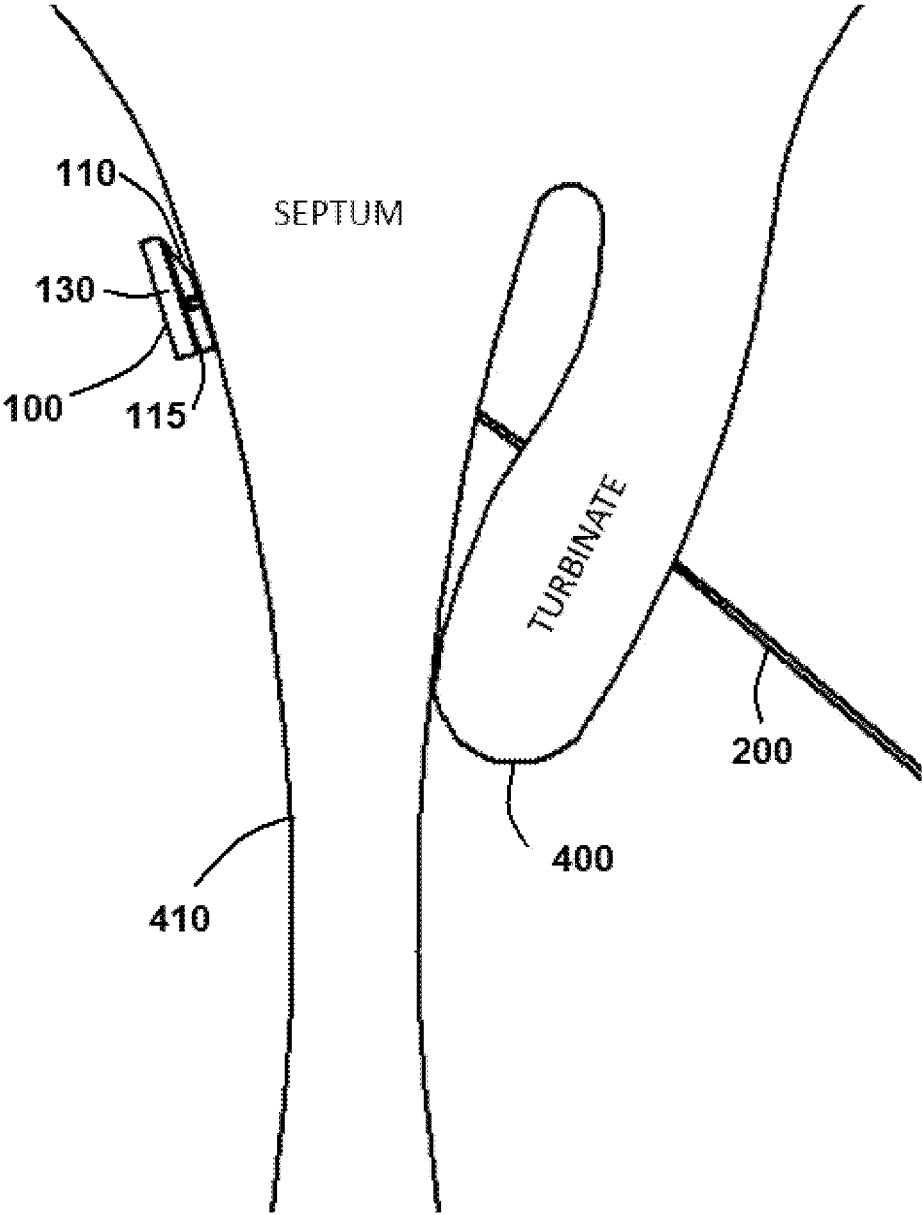


FIG. 5



**FIG. 6**

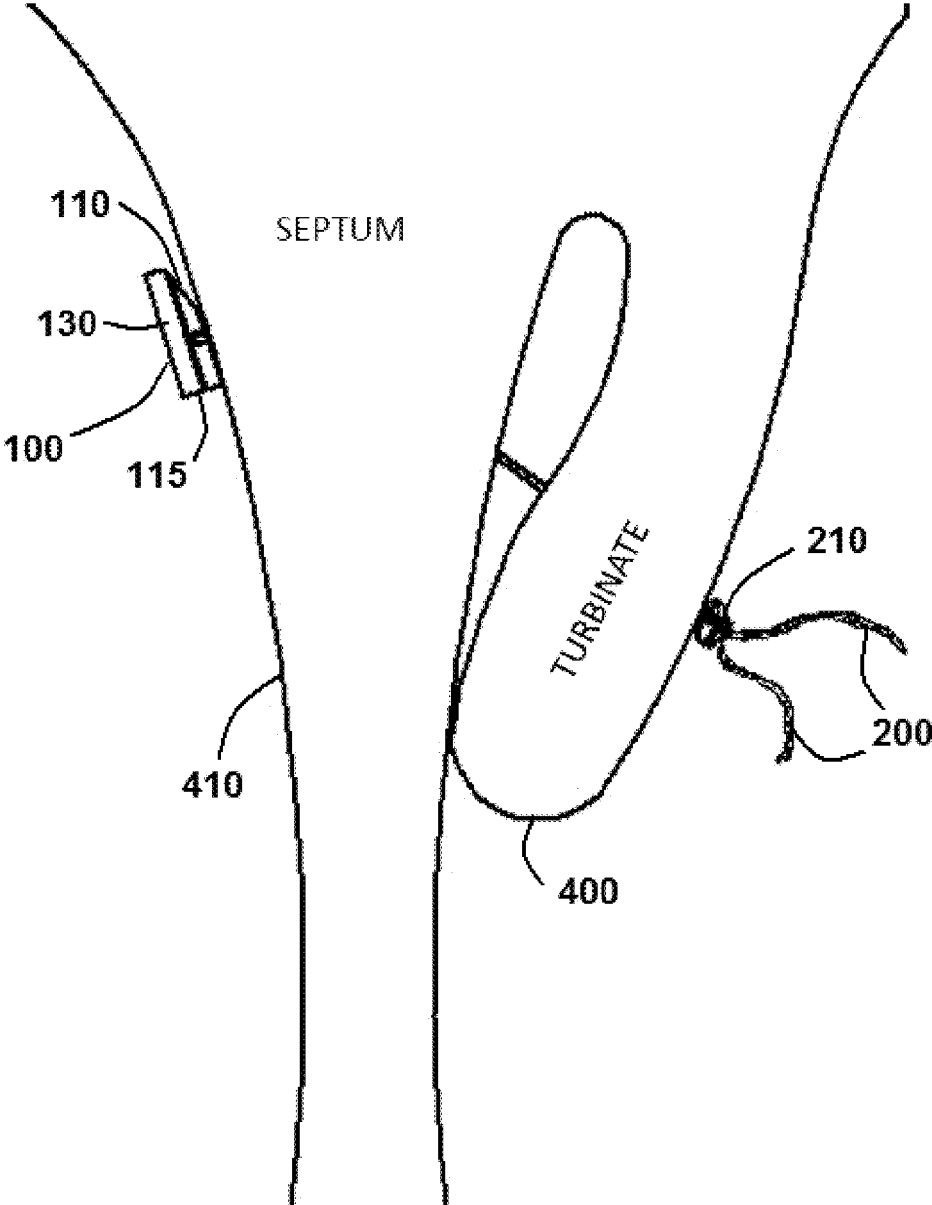


FIG. 7



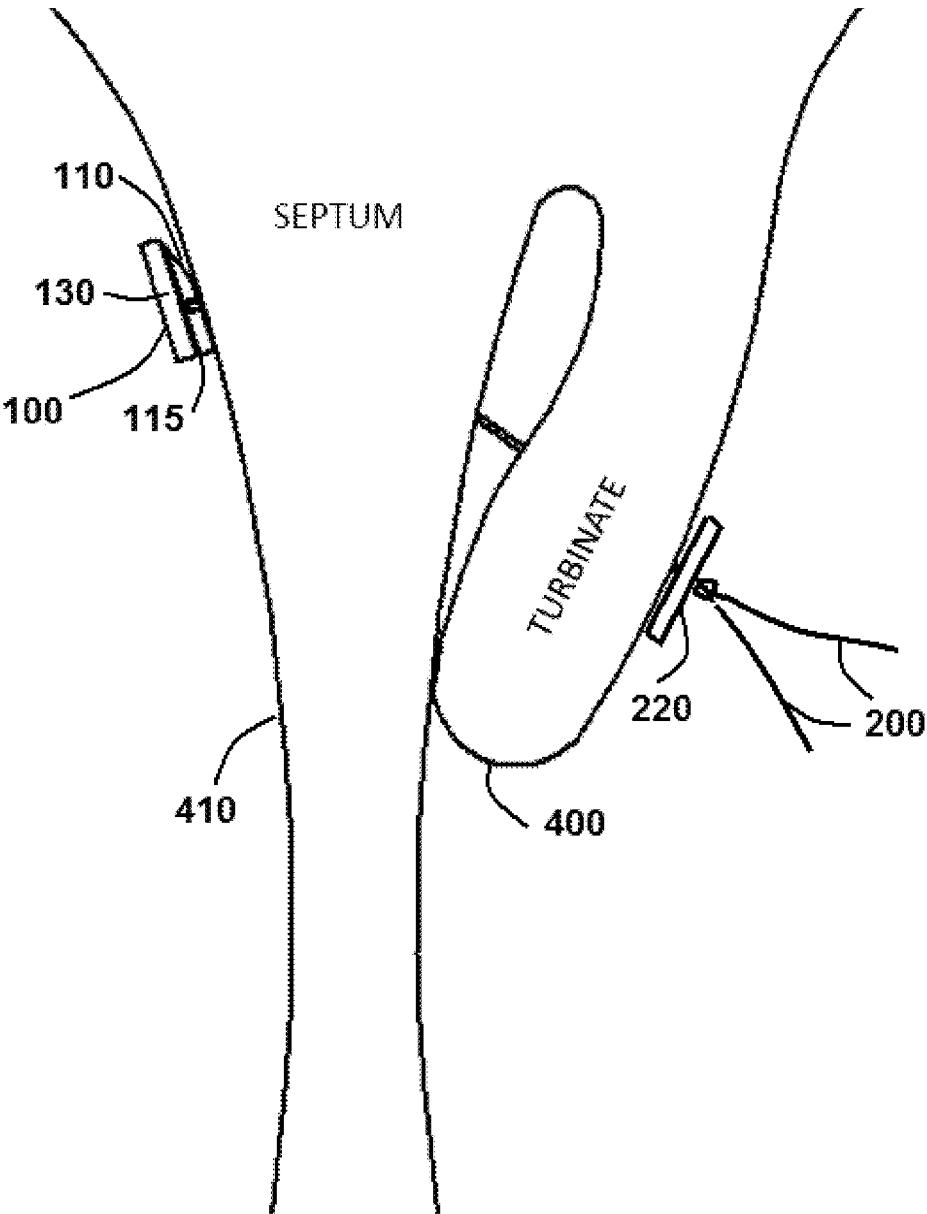


FIG. 8

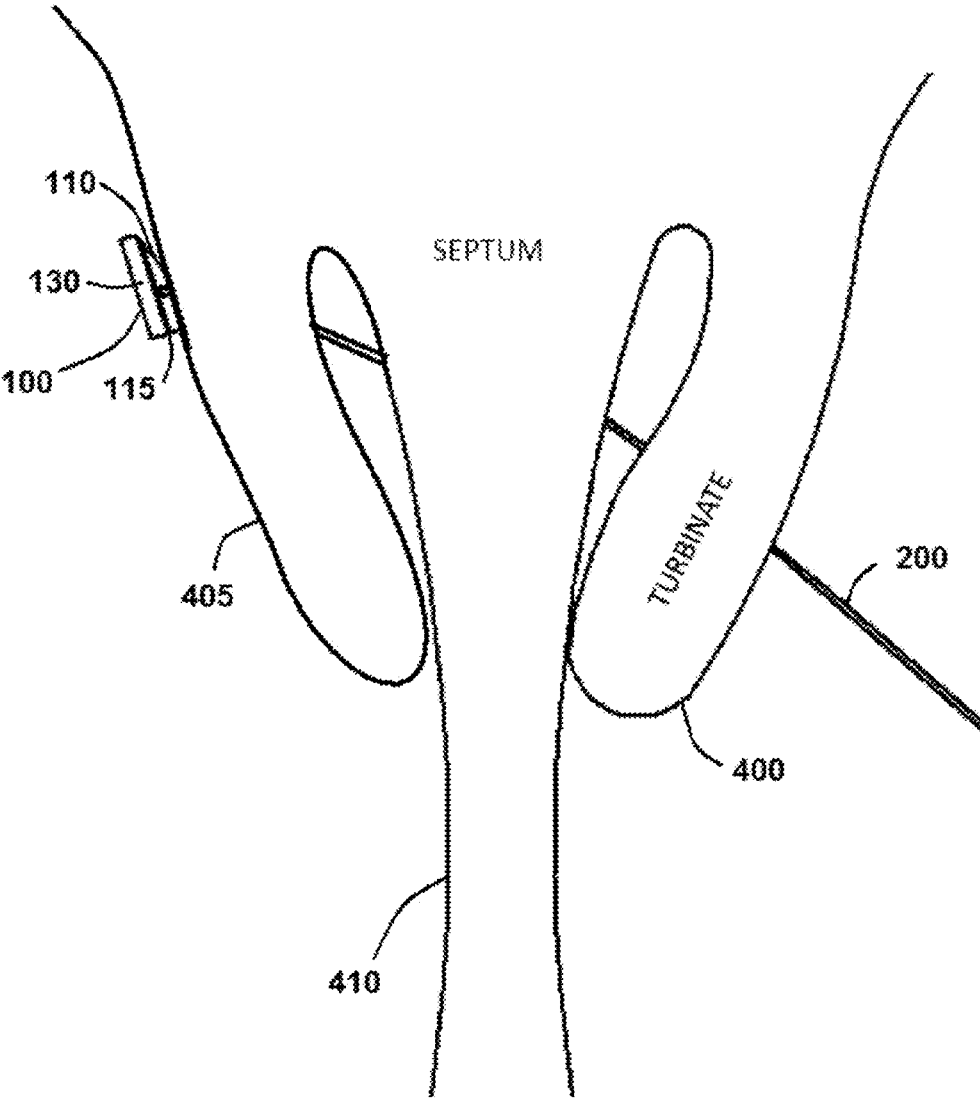


FIG. 9A

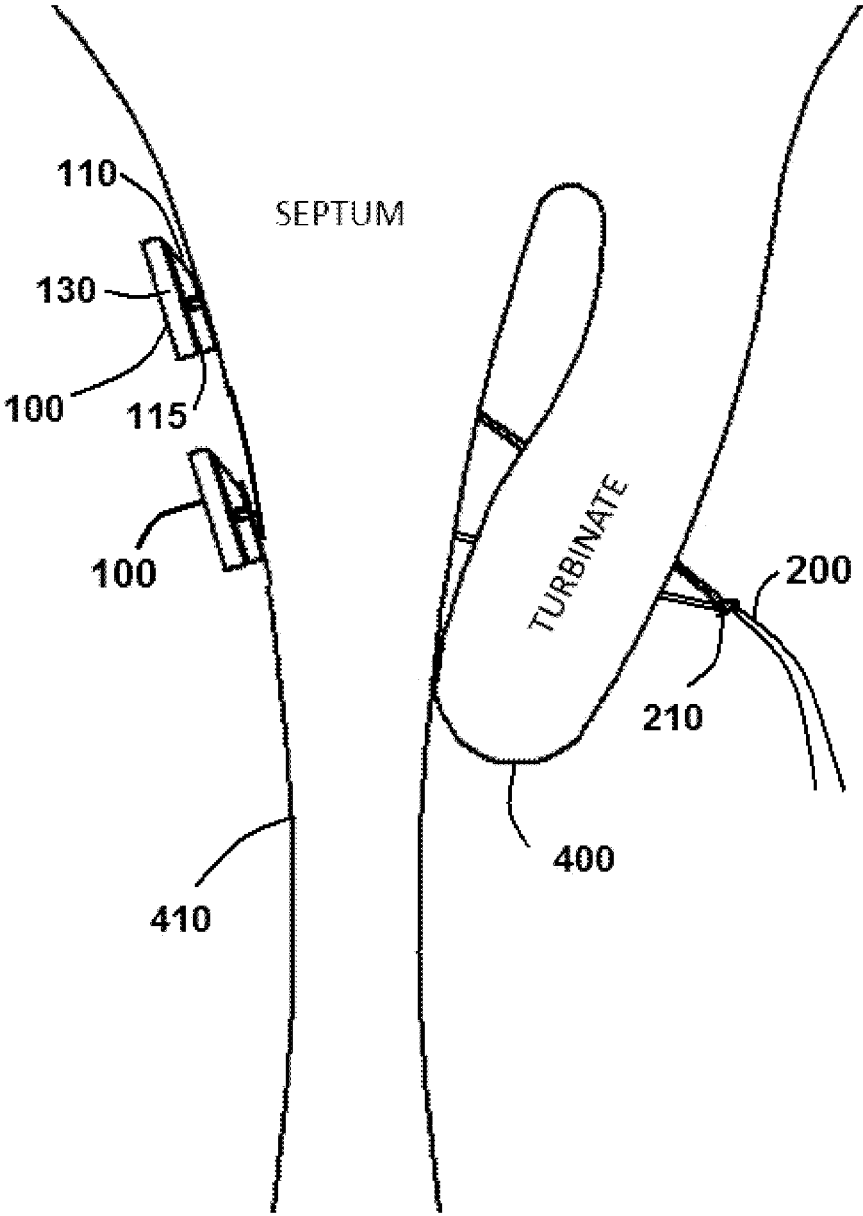


FIG. 9B

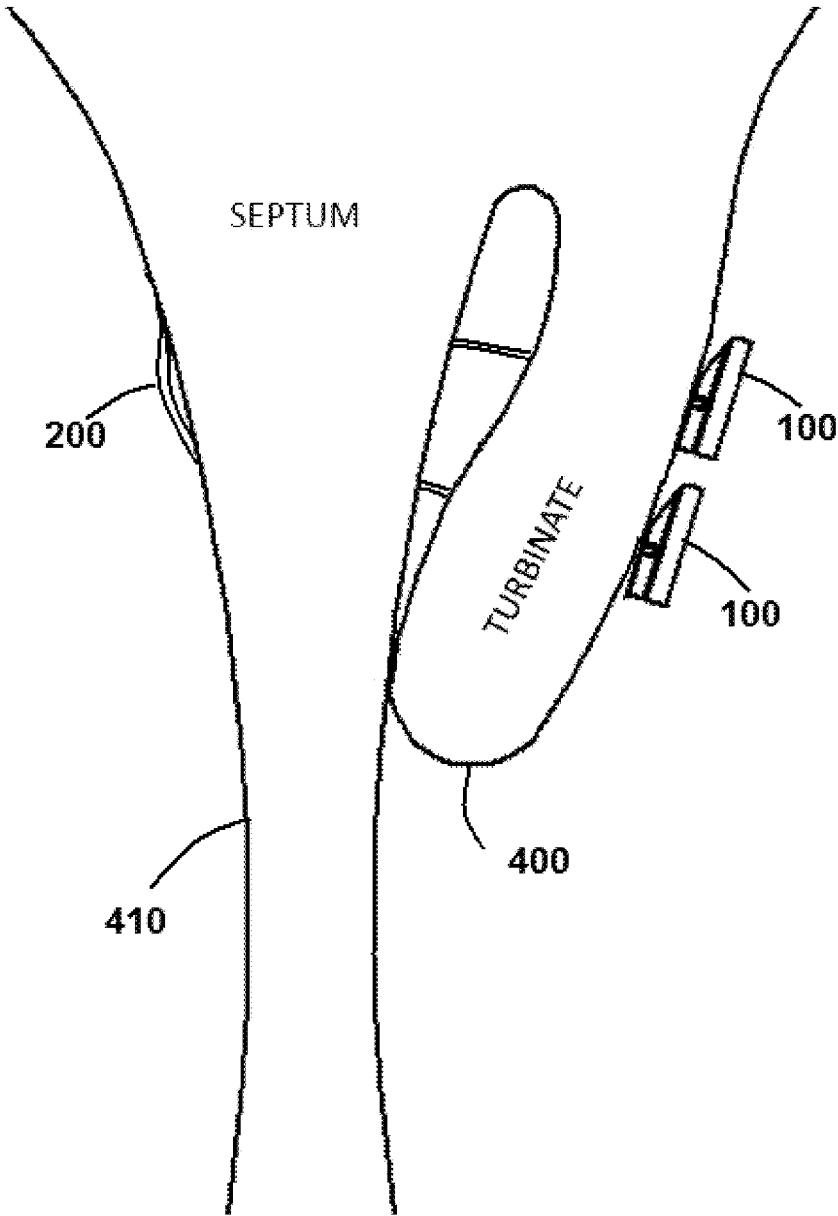


FIG. 9C

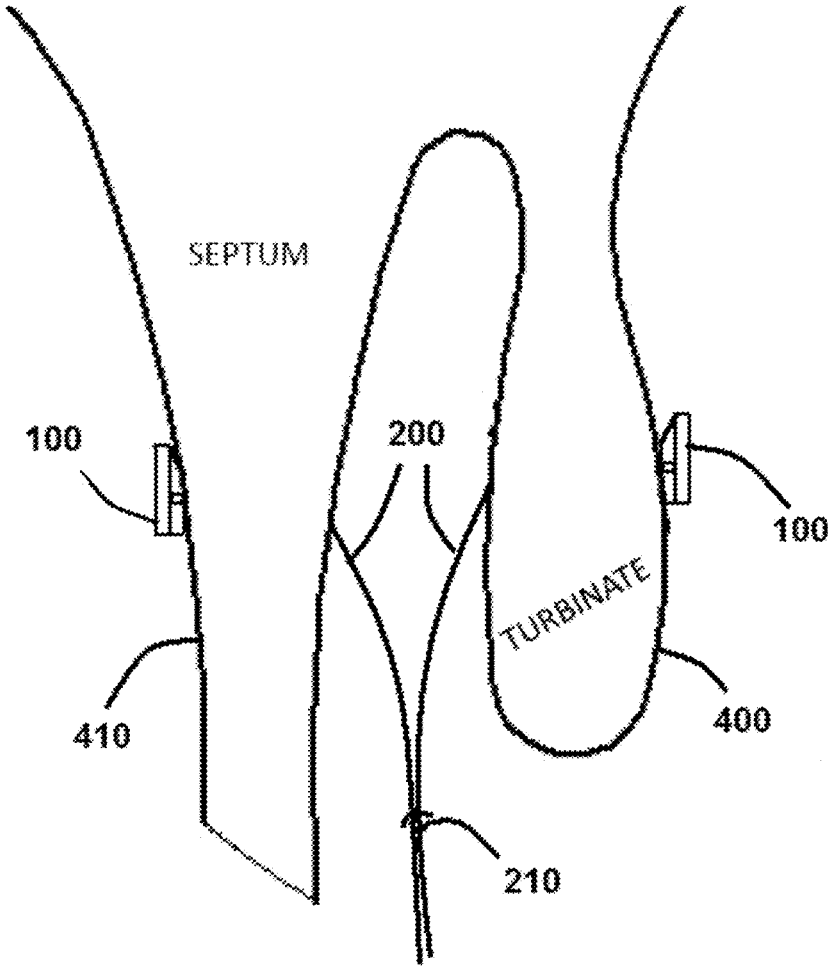


FIG. 9D

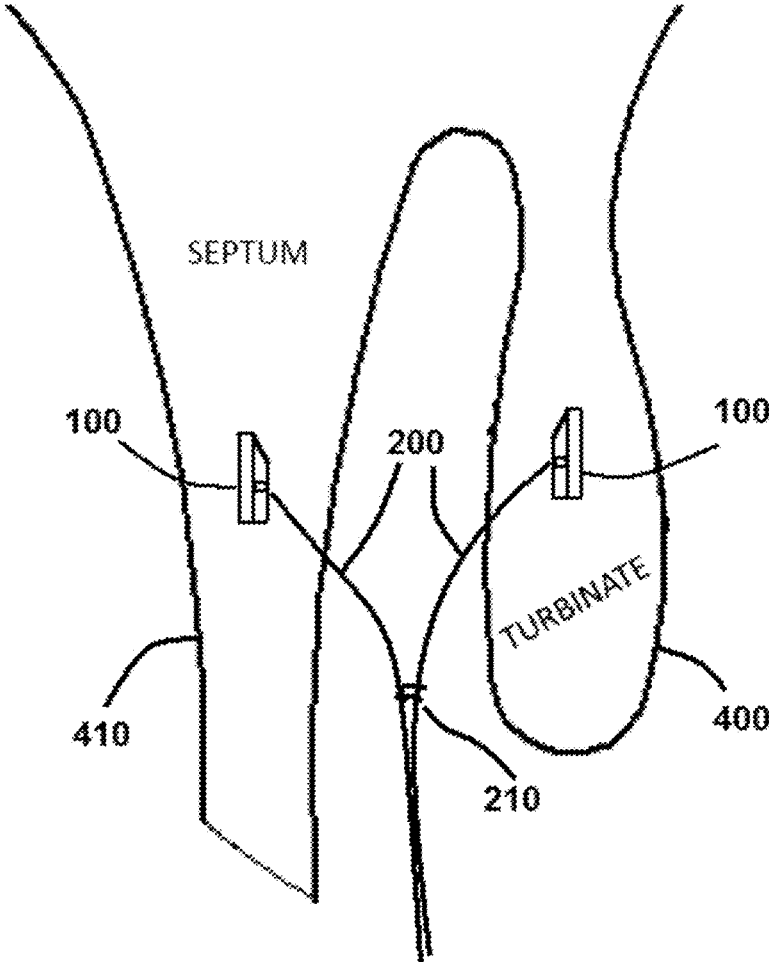


FIG. 9E

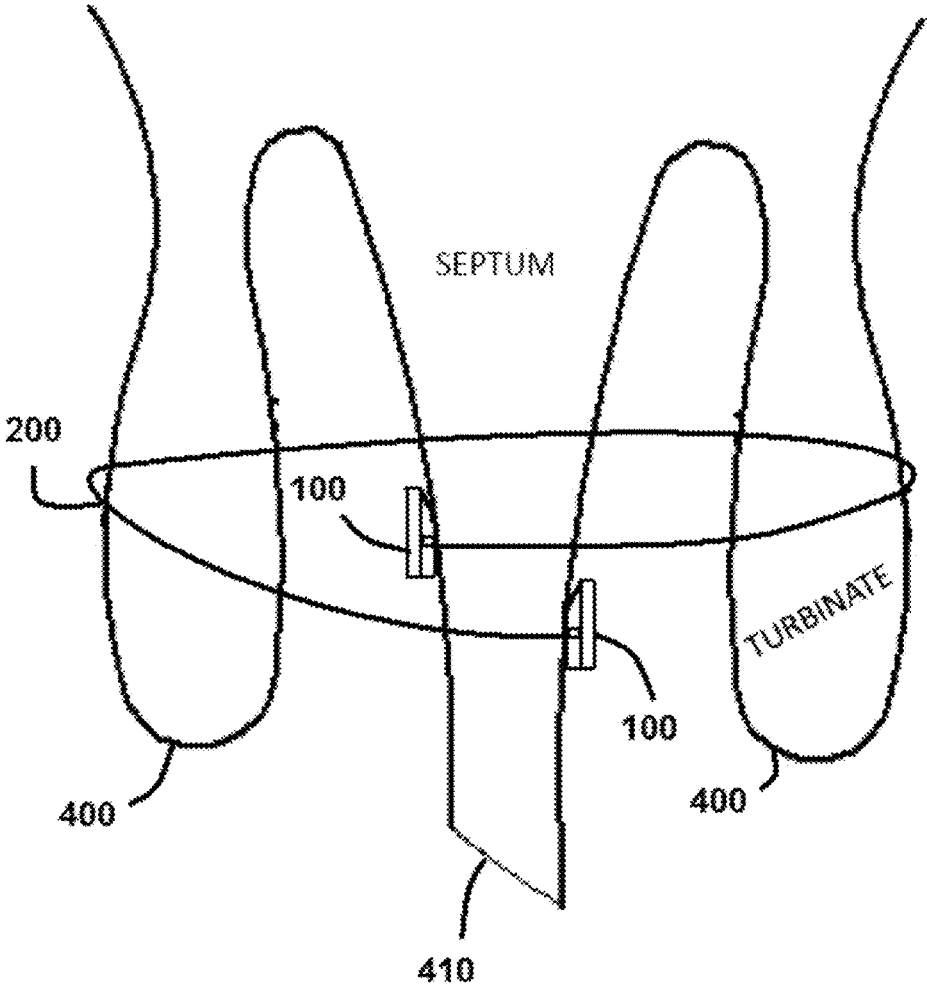


FIG. 9F

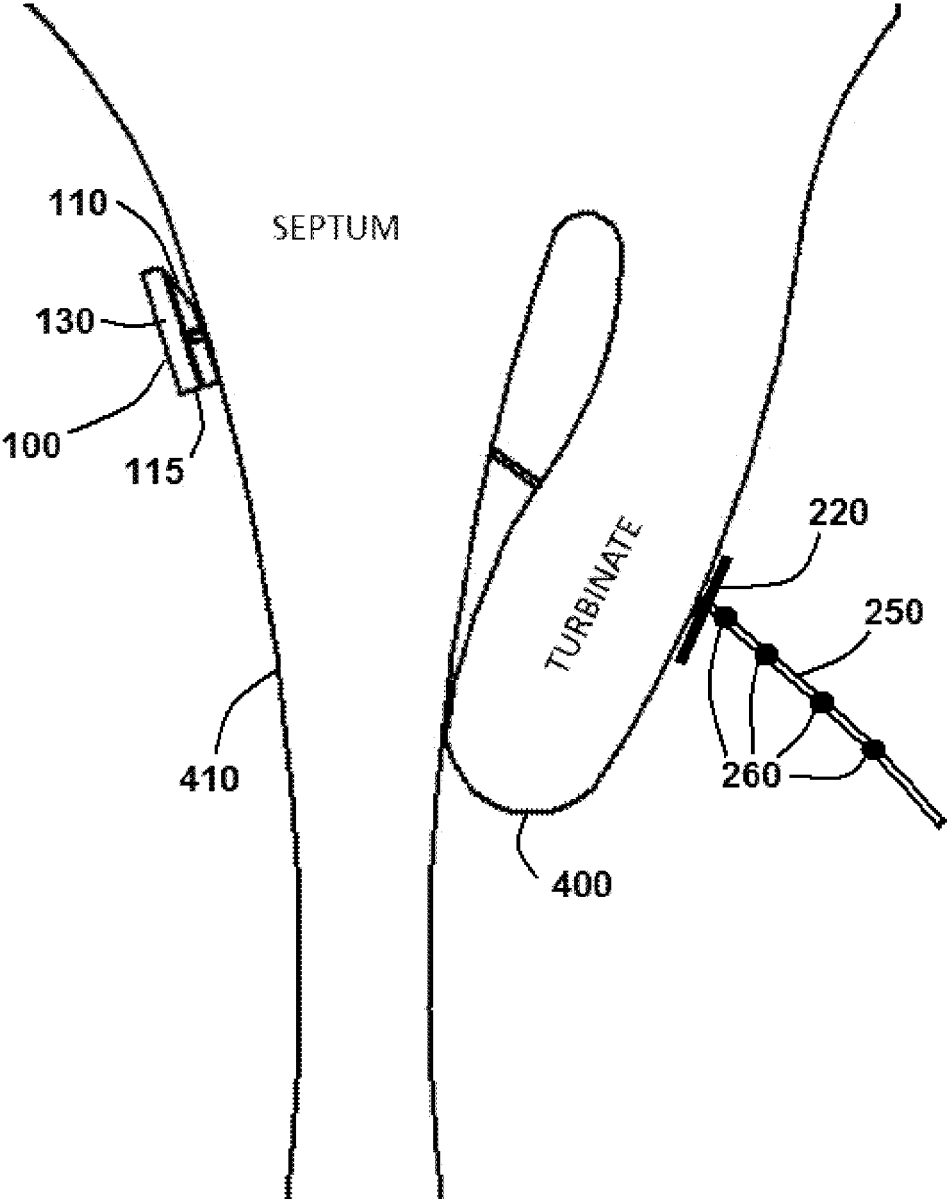


FIG. 9G



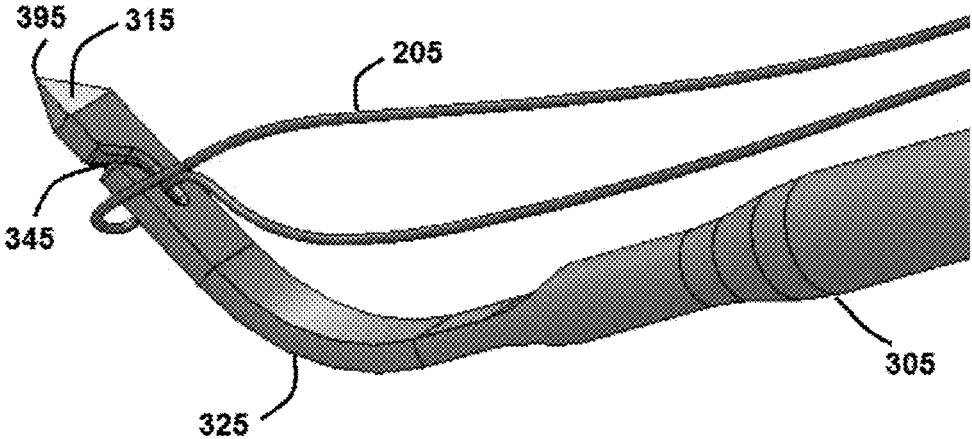


FIG. 10A

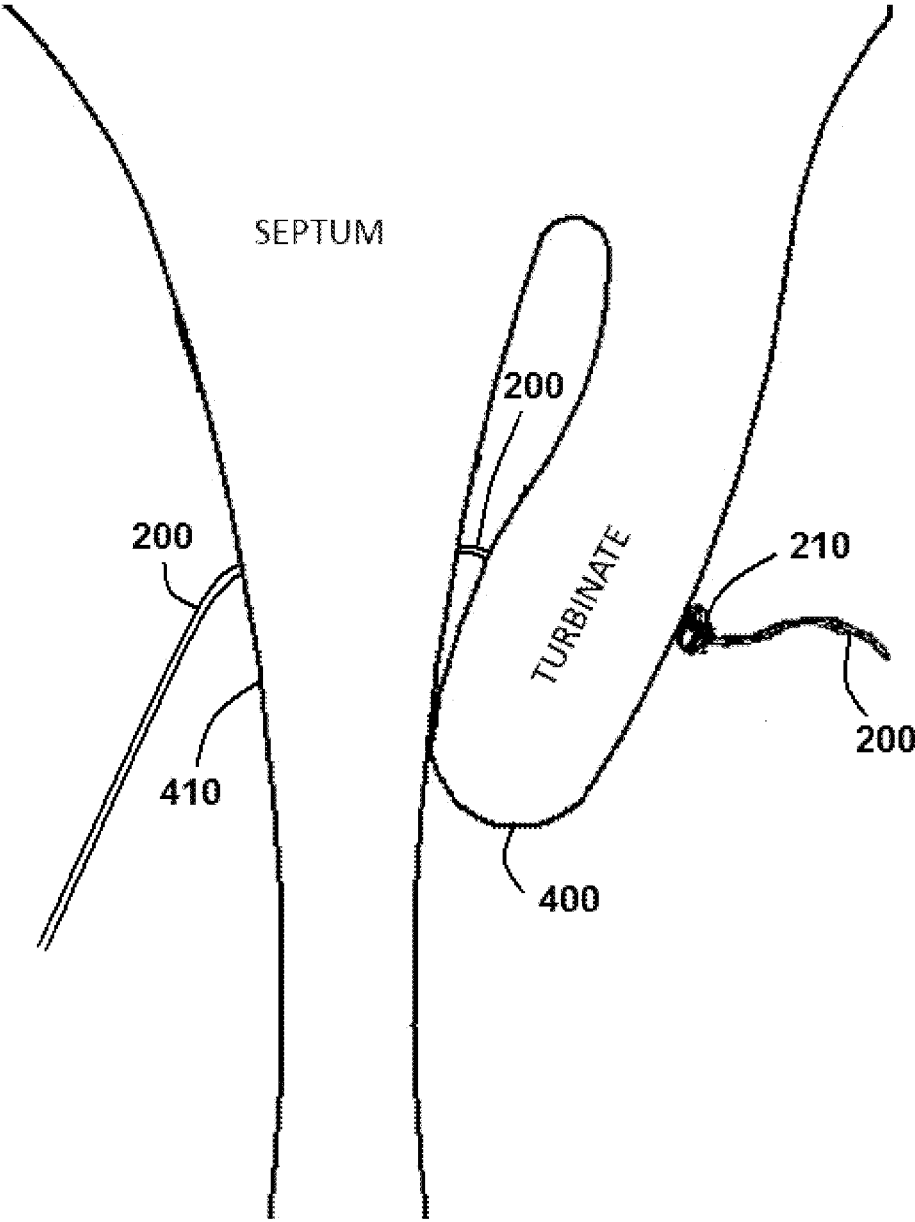


FIG. 10B

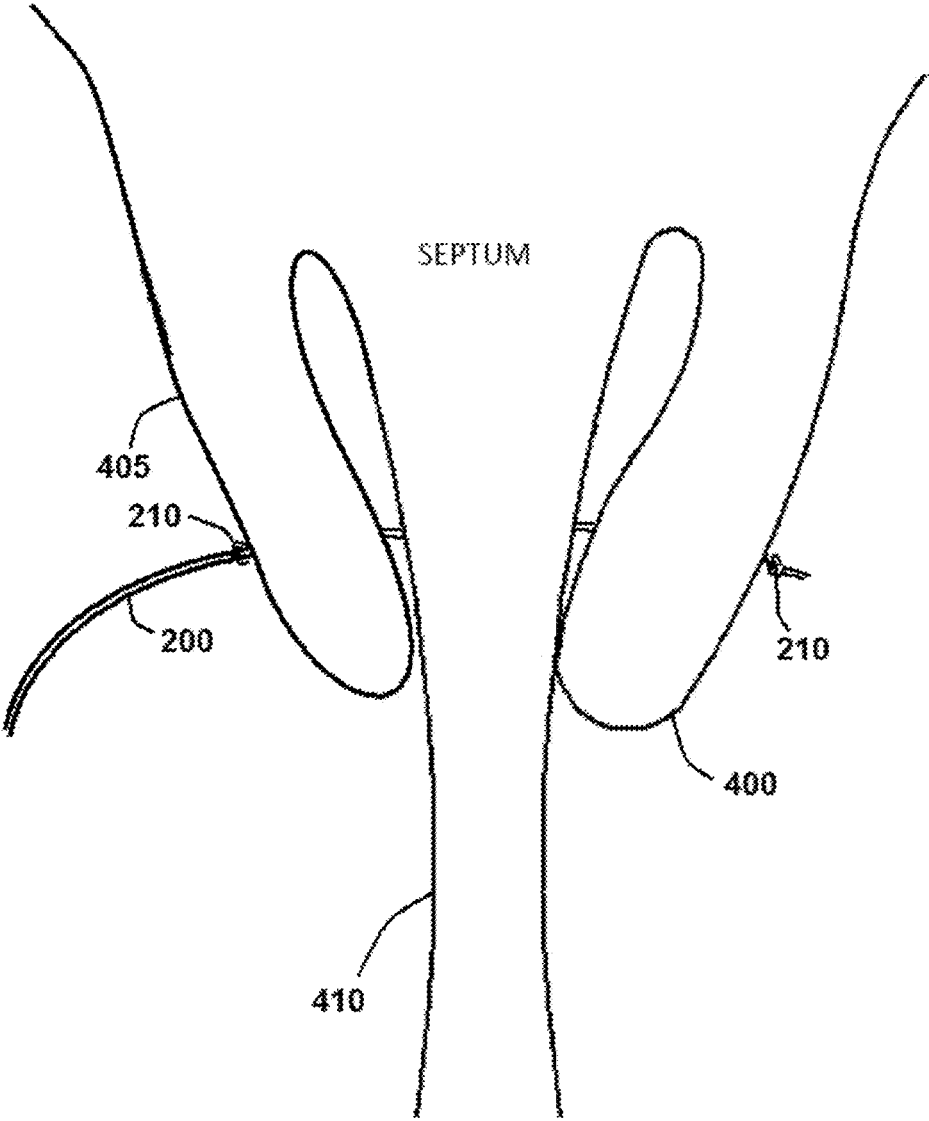


FIG. 10C

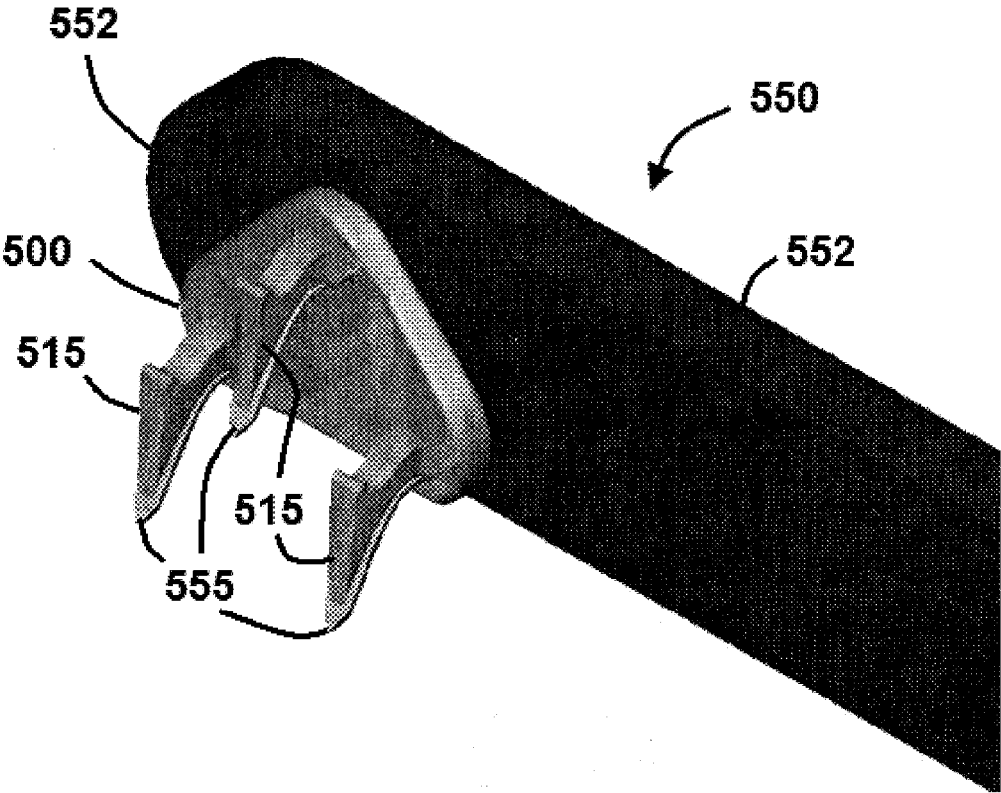


FIG. 11

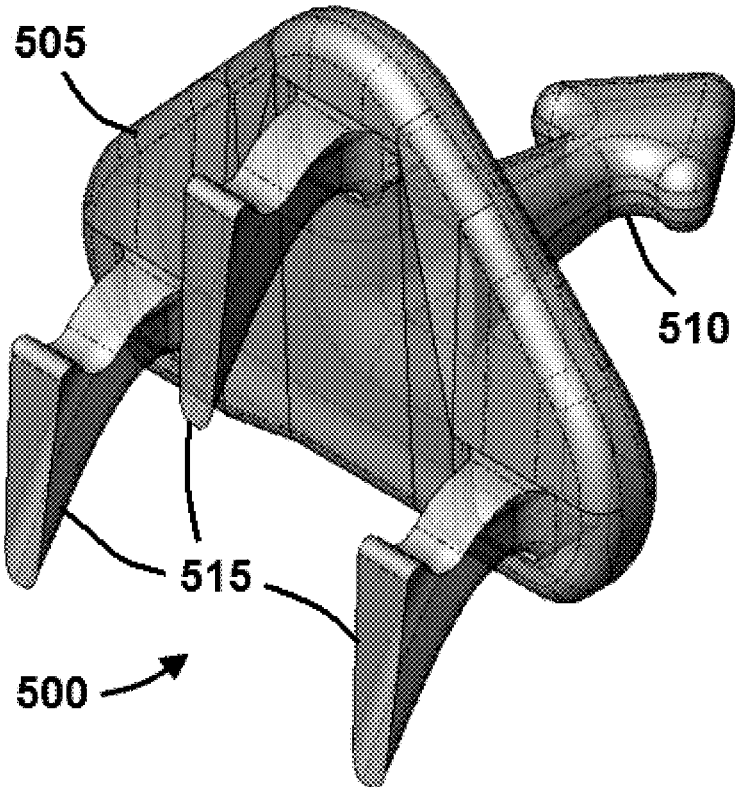


FIG. 12

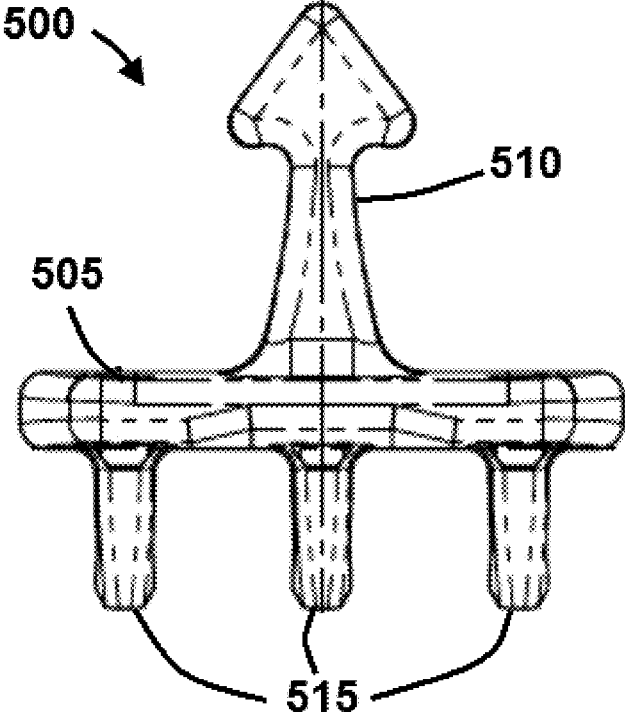


FIG. 13

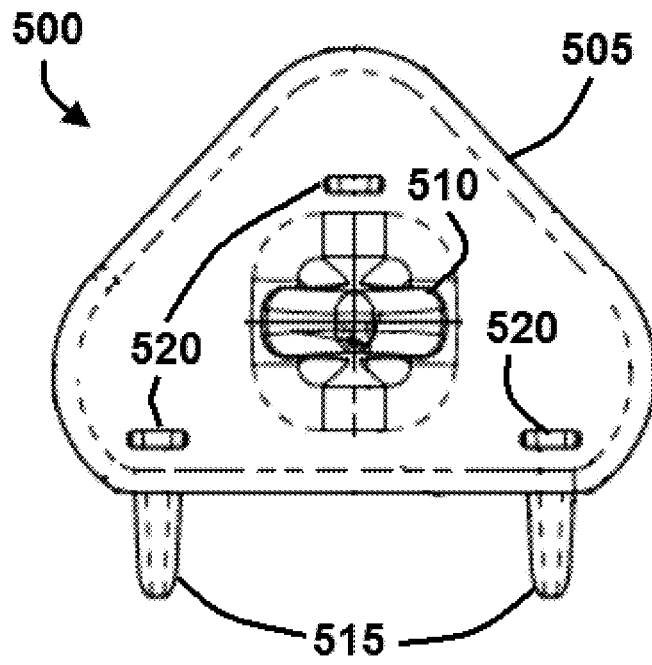


FIG. 14

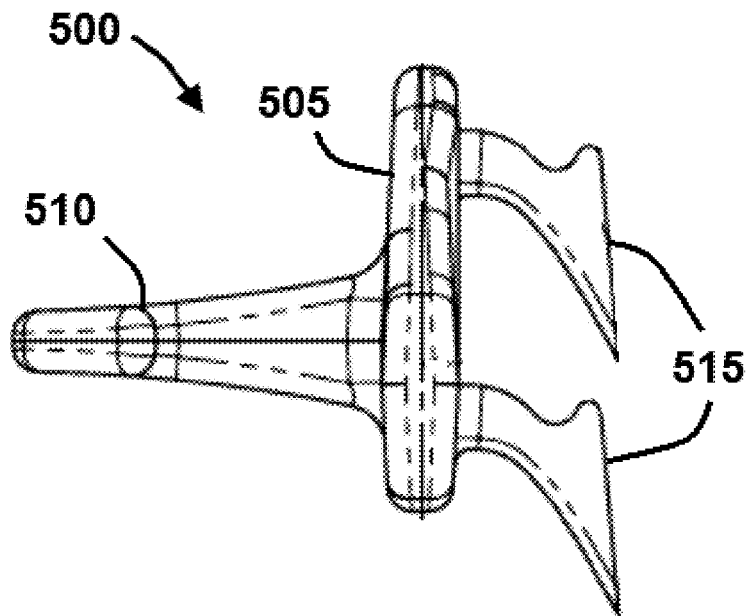


FIG. 15

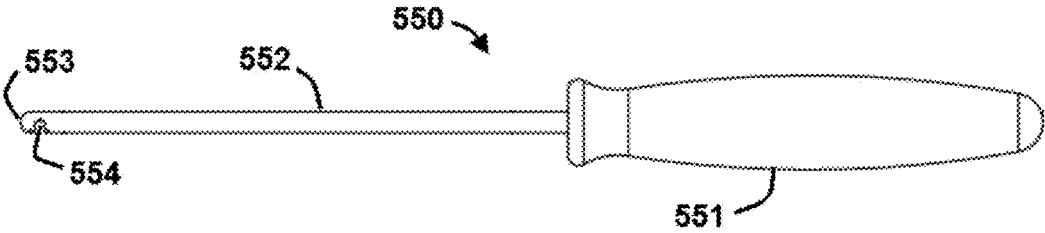


FIG. 16

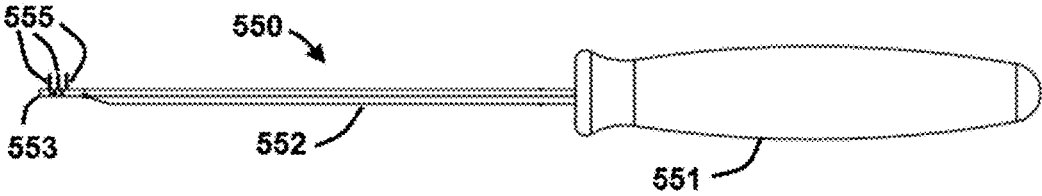


FIG. 17

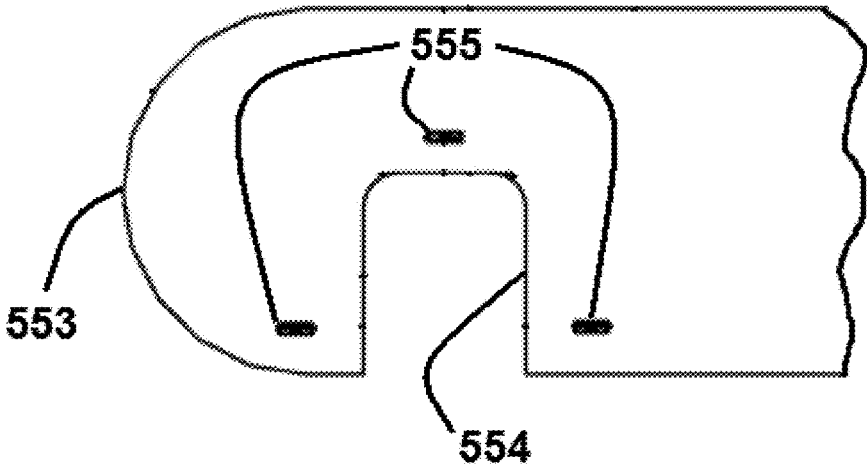


FIG. 18



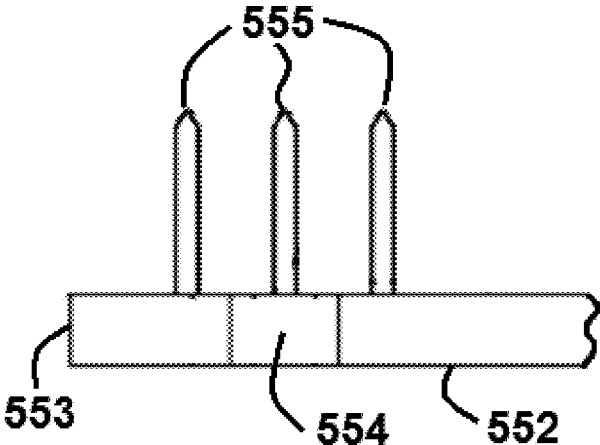


FIG. 19

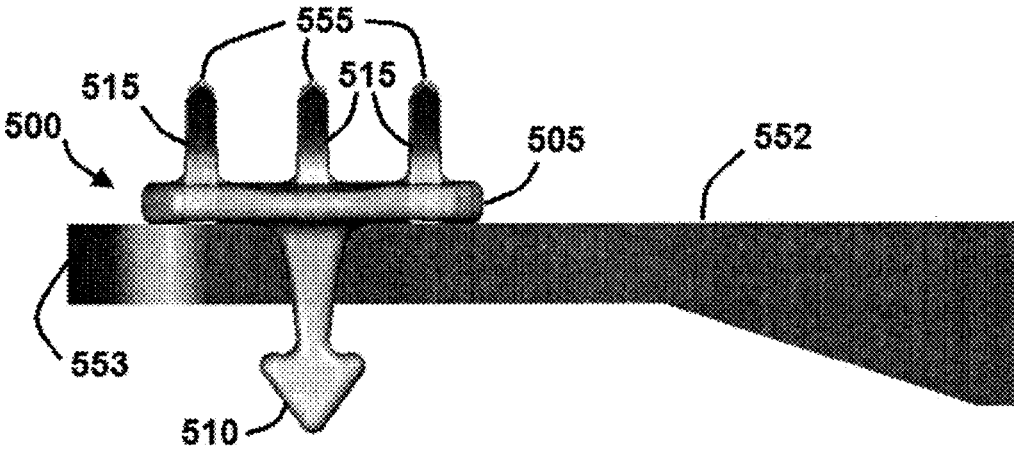


FIG. 20

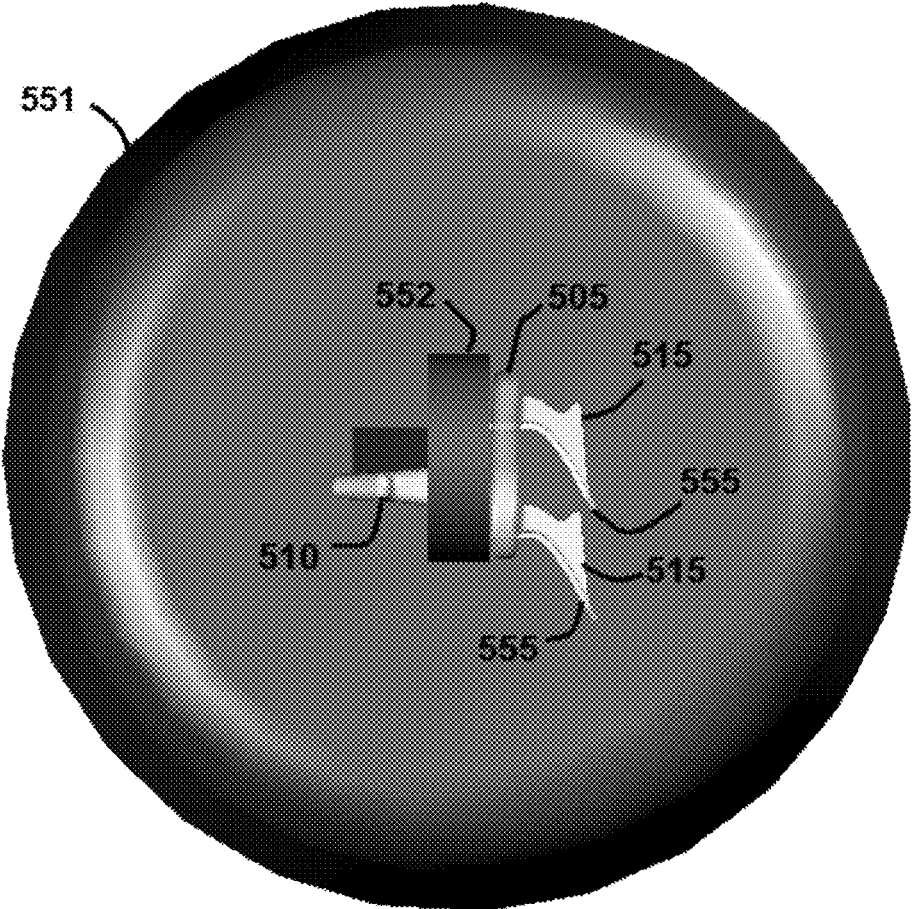


FIG. 21

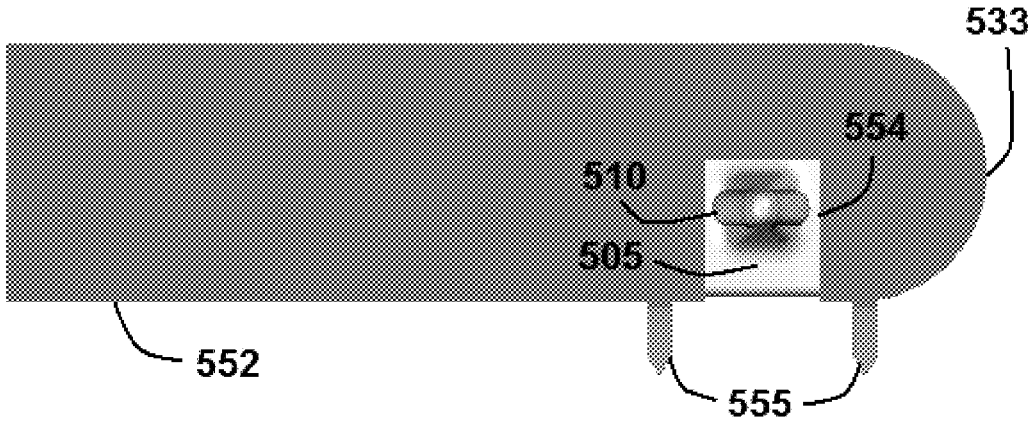


FIG. 22

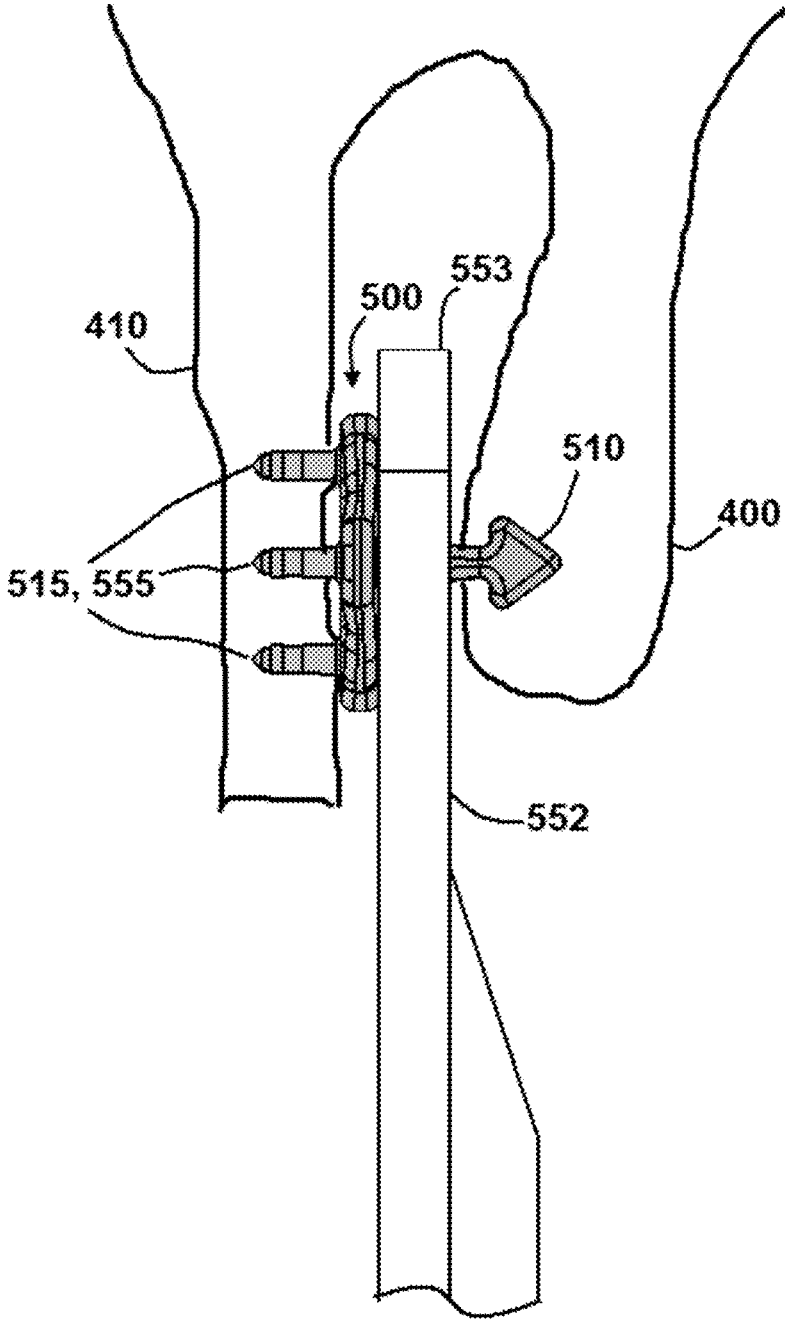


FIG. 23A

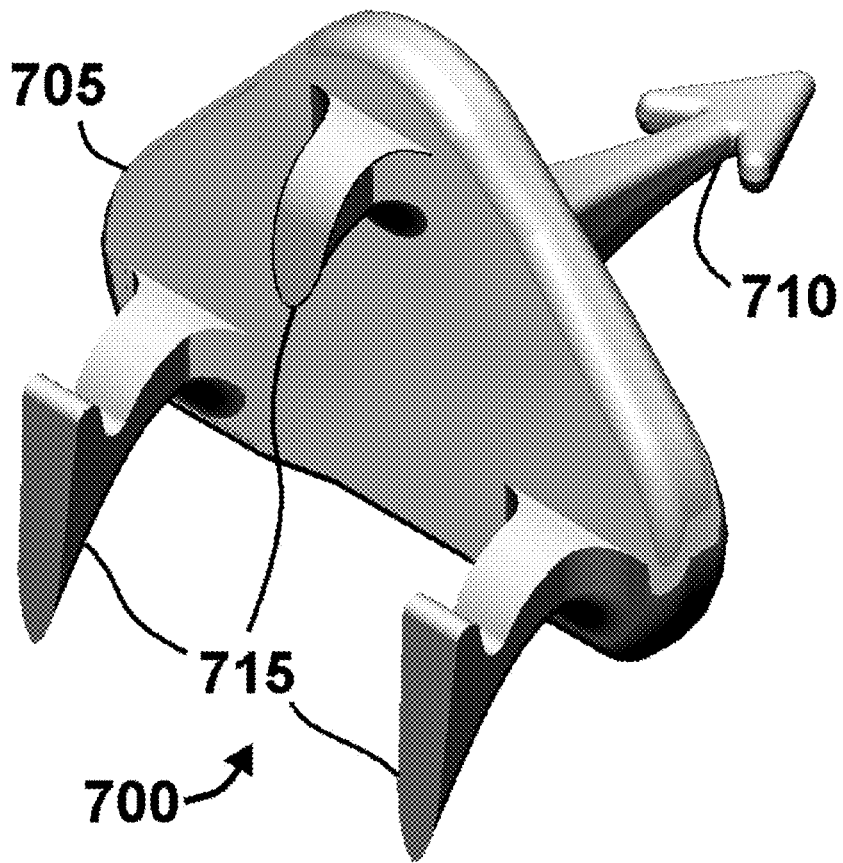


FIG. 23B

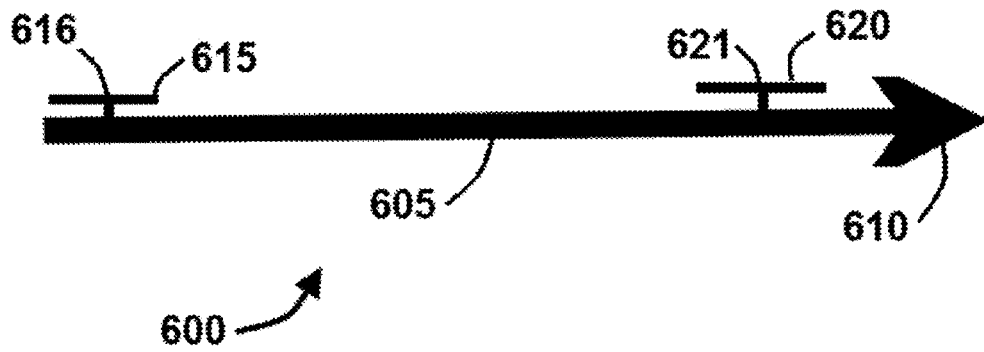


FIG. 24

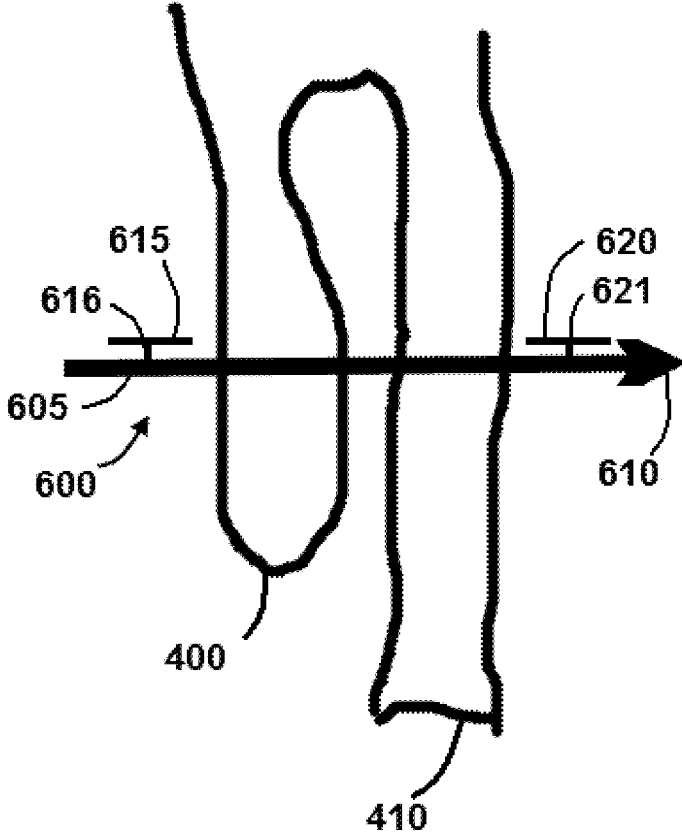


FIG. 25

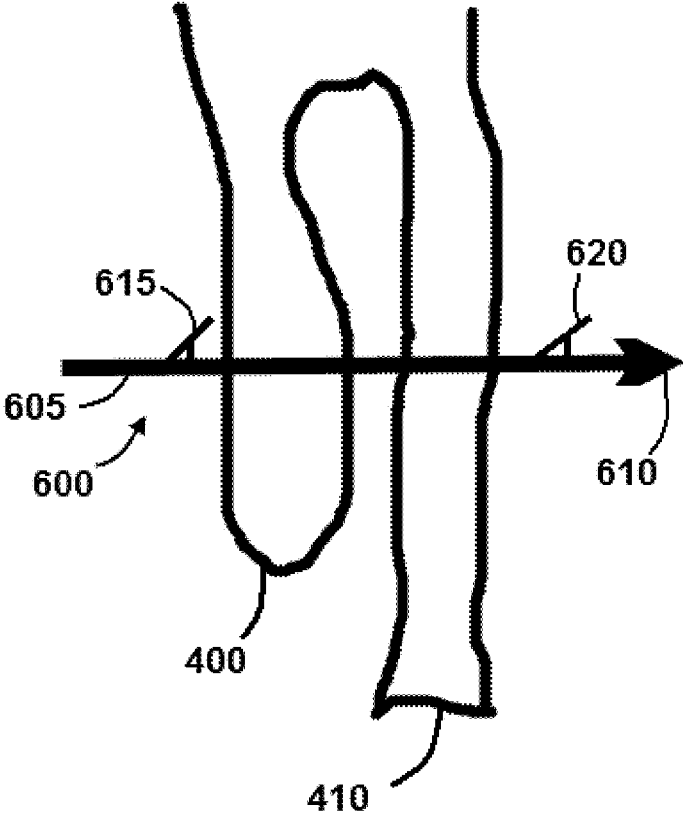


FIG. 26

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## METHODS AND SYSTEMS FOR MEDIALIZING A TURBINATE

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of currently U.S. patent application Ser. No. 13/474,121 filed May 17, 2012, which claims priority to U.S. patent application Ser. No. 12/561,707 filed Sep. 17, 2009, now U.S. Pat. No. 8,192,450 issued Jun. 5, 2012, which claims priority to U.S. Provisional Application No. 61/097,741 filed on Sep. 17, 2008. The entire text of each of the above-referenced disclosures is specifically incorporated herein by reference without disclaimer.

### BACKGROUND OF THE INVENTION

Sinusitis is a progression of inflammation, stasis, infection, and continued inflammation. Typically, the beginning of all sinus infections is either allergy or viral infection. Both of these conditions lead to swelling of the sinus and nasal mucosa that when severe enough, causes the small holes, called ostia, of the sinuses to close. Once the ostia are closed, the environment inside the sinuses becomes conducive to bacterial growth. The way this typically occurs is that once the ostia are shut, the oxygen content of the sinus drops and the fluid inside the sinus is unable to escape which leads to further inflammation. The reduced oxygen content and inflammation disrupts the ability of the cilia of the cells of the sinus to operate properly which leads to further stasis.

The typical patient that is seen by the otolaryngologist is started on antibiotics. Usually the antibiotic course can be as long as six weeks to eradicate the bacteria and bring the sinuses back to normal. For those patients in whom antibiotics do not relieve the problem, the primary alternative is surgery. Although sinus and nasal surgeries are now common with 500,000 to 700,000 of such surgeries being performed annually in the U.S., these surgeries are typically both destructive and permanent. Around 10% of patients who undergo sinus surgery have scarring that leads to continued sinus problems which frequently require revision surgery.

One frequent problem is postoperative adhesions. These adhesions can occur between the middle turbinate and the adjacent nasal areas. One particular problem is the adhesion of the middle turbinate to the lateral nasal wall. Some surgeons have proposed removing the lower half of the middle turbinate to avoid this problem. This procedure, however, has its own problems (e.g., crust formation, nasal hygiene issues).

Other solutions that have been suggested include placing a suture through the middle turbinate on one side of the nose, through the nasal septum, and then through the middle turbinate on the other side before the suture is tied off. Such a suture draws the middle turbinates medially and prevents the formation of adhesions between the middle turbinate and the lateral nasal wall. However, this suture is difficult and time-consuming to place and requires the puncturing of three separate structures in the nose. This can lead to discomfort for the patient, bleeding, infection, and other complications.

Another solution surgeons have proposed is the use of various packing materials and splints. The use of these materials and devices however leads to the formation of scar tissue, which is undesirable and can lead to airway obstruc-

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tion and infection. The adhesion of the middle turbinate to adjacent structures in the nose remains a problem in nasal and sinus surgery.

Given this serious and common complication of sinus surgery, there remains a need in the art for preventing the formation of adhesions between the middle turbinate and adjacent nasal structures, particularly the lateral nasal wall. The desired solution preferably limits or eliminates the complications of the other proposals which have been used including infection, scar tissue formation, adhesions, bleeding, and patient discomfort.

### SUMMARY OF THE INVENTION

Embodiments of the present disclosure provide methods and systems for reducing the adhesions formed in a patient's nasal cavity following a sinus or nasal procedure. In particular, embodiments reduce the formation of adhesions between the lateral nasal wall and the middle turbinate by directing the middle turbinate toward the nasal septum. This system pulls the middle turbinate medially to avoid the formation of adhesions which may lead to further complications after sinus or nasal surgery. The relocation of the middle turbinate toward the nasal septum may be temporary or permanent. This system may also be used prior to surgery to pull the middle turbinate away from the uncinate process to provide improved visualization of the lateral nasal cavity during surgery.

Certain embodiments may include a method of medializing a turbinate, the method comprising: coupling a flexible member to an implant; coupling the implant to an insertion device; inserting a portion of the insertion device into a nasal cavity on a first side of a septum; piercing the septum with the insertion device; directing the implant through the septum such that the implant is located on a second side of the septum; removing the insertion device from the nasal cavity; leaving the implant on the second side of the septum; and using the flexible member to secure a turbinate in a location proximal to the septum. In specific embodiments, coupling the implant to the insertion device may comprise inserting the implant in a channel in the insertion device. In particular embodiments, coupling the implant to the insertion device may comprise placing the implant against a stop in the channel. Certain embodiments may further comprise penetrating the turbinate with the insertion device. In specific embodiments piercing the septum with the insertion device may include engaging a tapered end of the insertion device with the septum. In specific embodiments, piercing the septum with the insertion device may further comprise aligning a tapered surface of the implant with the tapered end of the insertion device. In certain embodiments, the flexible member may be a suture. In particular embodiments, using the flexible member to secure the turbinate in a location proximal to the septum may comprise tying a knot in the flexible member. In certain embodiments, using the flexible member to secure the turbinate in a location proximal to the septum may comprise engaging the turbinate with a retainer secured to the flexible member. In particular embodiments, the retainer may be secured to the flexible member with a knot. In certain embodiments, the retainer may be secured to the flexible member with a projection on the flexible member.

Particular embodiments may include an implant configured for insertion into a tissue in a nasal cavity. The implant may comprise: a first end; a second end; a base portion and an upper portion, wherein the base portion is configured to be retained in a channel of an insertion device; and a tapered

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surface proximal to the first end. In certain embodiments, the base portion may have a cross-section that is semicircular. In particular embodiments, the base portion may be wider than the upper portion. In certain embodiments, the second end may not be configured to pierce tissue. In specific embodiments, the second end may be substantially perpendicular to an axis extending from the first end to the second end. Certain embodiments may also comprise an aperture. In certain embodiments, the aperture is in the upper portion.

Specific embodiments may comprise an insertion device configured to install an implant into a tissue in a nasal cavity. The insertion device may comprise: an elongate body having an angled portion and a handle portion; a tapered first end proximal to the angled portion; a curved portion between the angled portion and the handle portion; a channel in the angled portion; and a stop in the channel. In certain embodiments, the channel may be configured to receive the implant of claim 12. In specific embodiments, the stop may be positioned such that the tapered surface of the implant may be substantially aligned with the tapered first end of the insertion device when the implant is installed in the channel and engaged with the stop of the insertion device.

Particular embodiments may comprise an implant configured to medialize a turbinate to a septum. The implant may comprise: a main body comprising a top, a bottom, a first side, and a second side; a first barb extending from the first side; a second barb extending from the second side; and a first aperture extending through the main body, where the first aperture is proximal to the first barb. It is understood that labeling a surface the “top” or “bottom” is for reference purposes only, and is not intended to limit the implant to any specific orientation, for example, during use. In specific embodiments, the first barb may be curved downward towards the bottom of the main body as the first barb extends from the first side of the main body. In particular embodiments, the first aperture may be below first barb. Certain embodiments may further comprise a third barb and a fourth barb, each extending from the first side. Specific embodiments may further comprise a second aperture proximal to the third barb, and a third aperture proximal to the fourth barb. In particular embodiments, the first barb may be shorter than the third barb and the fourth barb.

In certain embodiments, the second barb extends perpendicular from the second side. In particular embodiments, the main body of the implant is triangular-shaped and the top of the body is located at an intersection of the first side and the second side. In specific embodiments, the first barb is configured to penetrate mucosa of a nasal septum. In certain embodiments the second barb is configured to penetrate a turbinate.

Certain embodiments may also comprise a kit for medializing a turbinate to a septum. In specific embodiments, the kit may comprise an implant having: a main body comprising a top, a bottom, a first side, and a second side; a first barb extending from the first side; a second barb extending from the second side; and a first aperture extending through the main body, wherein the first aperture is proximal to the first barb. The kit may also comprise an insertion device comprising a handle portion, a shaft, a distal end, and a first projection proximal to the distal end. In specific embodiments, the first projection may be configured to extend through the first aperture when the implant is coupled to the insertion device. In certain embodiments, the implant may comprise a second aperture proximal to a third barb and a third aperture proximal to a fourth barb. In specific embodiments, the insertion device may comprise a second projection configured to extend through the second aperture and a

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third projection configured to extend through the third aperture when the implant is coupled to the insertion device. In certain embodiments, the first, second and third projections are flexible. In particular embodiments, the insertion device may comprise a recessed portion configured to engage the implant when the implant is coupled to the insertion device.

Certain embodiments comprise a method of medializing a turbinate, where the method comprises: providing an implant according to a previously-described embodiment; providing an insertion device comprising a handle portion, a shaft, a distal end, and a first projection proximal to the distal end; inserting the first projection of the insertion device through a first aperture of the implant; inserting the implant and the distal end of the insertion device into a nasal cavity between a turbinate and a septum; inserting a first barb of the implant into the septum; inserting a second barb of the implant into the turbinate; removing the first projection from the first aperture; and removing the insertion device from the nasal cavity.

In certain embodiments, removing the first projection from the first aperture may comprise rotating the insertion device about a longitudinal axis of the shaft of the insertion device. In particular embodiment, the implant may further comprise a third and fourth barb extending from the first side of the implant, and the third and fourth barb may be inserted into the septum. In certain embodiments, the implant may further comprise a second aperture proximal to the third barb and comprise a third aperture proximal to the fourth barb. In specific embodiments, the insertion device may comprise a second and third projection, and the second projection may be inserted into the second aperture, and the third projection may be inserted into the third aperture when the first projection is inserted into the first aperture. In particular embodiments, the insertion device may comprise a recessed portion proximal to the distal end. In specific embodiments, the method of claim 36 wherein the recessed portion is configured so that the second barb extends through the recessed portion when the first projection of the insertion device is inserted through the first aperture of the implant.

Certain embodiments may comprise an implant configured to secure a turbinate. The implant may comprise: an elongate body comprising a first end and a second; a tapered surface proximal to the first end; a first locking member proximal to the first end; and a second locking member proximal to the second end. In specific embodiments, the first and second locking members may each comprise a pivot. In particular embodiments, the first and second locking members may be configured to be placed in a first position that is aligned with the elongate body and a second position that is not aligned with the elongate body.

As used herein, the terms “a” and “an” are defined as one or more unless this disclosure explicitly requires otherwise.

The term “substantially” and its variations are defined as being largely but not necessarily wholly what is specified as understood by one of ordinary skill in the art, and in one non-limiting embodiment the term “substantially” refers to ranges within 10%, preferably within 5%, more preferably within 1%, and most preferably within 0.5% of what is specified.

The terms “comprise” (and any form of comprise, such as “comprises” and “comprising”), “have” (and any form of have, such as “has” and “having”), “include” (and any form of include, such as “includes” and “including”) and “contain” (and any form of contain, such as “contains” and “containing”) are open-ended linking verbs. As a result, a method or device that “comprises,” “has,” “includes” or



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“contains” one or more steps or elements possesses those one or more steps or elements, but is not limited to possessing only those one or more elements. Likewise, a step of a method or an element of a device that “comprises,” “has,” “includes” or “contains” one or more features possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

The term “coupled,” as used herein, is defined as connected, although not necessarily directly, and not necessarily mechanically.

Other objects, features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples, while indicating specific embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will be apparent to those skilled in the art from this detailed description.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings form part of the present specification and are included to further demonstrate certain aspects of the invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of example embodiments presented here. The drawings are not to scale, and certain distances or spacings may be exaggerated to provide clarity. The drawings are examples only. They do not limit the claims.

FIG. 1 is a perspective view of an implant coupled to a flexible member according to an exemplary embodiment of the present disclosure.

FIG. 2 is a perspective view of the implant and flexible member of FIG. 1 coupled to an insertion device.

FIG. 3 is a side view of the insertion device of FIG. 2 during a method of installation.

FIG. 4 is a side view of the insertion device of FIG. 2 during a method of installation.

FIG. 5 is a side view of the insertion device of FIG. 2 during a method of installation.

FIG. 6 is a side view of the implant and flexible member of FIG. 1 during a method of installation.

FIG. 7 is a side view of the implant and flexible member of FIG. 1 during a method of installation.

FIG. 8 is a side view of the implant and flexible member of FIG. 1 and a retainer during a method of installation.

FIG. 9A is a side view of the implant and flexible member of FIG. 1 during a method of installation.

FIG. 9B is a side view of first turbinate medializing system during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 9C is a side view of second turbinate medializing system during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 9D is a side view of third turbinate medializing system during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 9E is a side view of fourth turbinate medializing system during a method of installation according to an exemplary embodiment of the present disclosure.

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FIG. 9F is a side view of fifth turbinate medializing system during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 9G is a side view of sixth turbinate medializing system during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 10A is a perspective view of an insertion device and flexible member according to an exemplary embodiment of the present disclosure.

FIG. 10B is a side view of a flexible member during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 10C is a side view of a flexible member during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 11 is a perspective view of an implant and an insertion device according to an exemplary embodiment of the present disclosure.

FIG. 12 is a perspective view of the implant of FIG. 11.

FIG. 13 is a top view of the implant of FIG. 11.

FIG. 14 is a back view of the implant of FIG. 11.

FIG. 15 is a side view of the implant of FIG. 11.

FIG. 16 is a front view of the insertion device of FIG. 11.

FIG. 17 is a top view of the insertion device of FIG. 11.

FIG. 18 is a detailed view of a portion of the insertion device of FIG. 11.

FIG. 19 is a detailed view of a portion of the insertion device of FIG. 11.

FIG. 20 is a detailed view of a portion of the implant and insertion device of FIG. 11.

FIG. 21 is an end view of a portion of the implant and insertion device of FIG. 11.

FIG. 22 is a detailed view of a portion of the implant and insertion device of FIG. 11.

FIG. 23A is a partial section view of a portion of the implant and insertion device of FIG. 11 during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 23B is a perspective view of a another embodiment of an implant.

FIG. 24 is a side view of an implant according to an exemplary embodiment of the present disclosure.

FIG. 25 is a partial section view of the implant of FIG. 24 during a method of installation according to an exemplary embodiment of the present disclosure.

FIG. 26 is a partial section view of the implant of FIG. 24 during a method of installation according to an exemplary embodiment of the present disclosure.

#### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Embodiments of the present disclosure comprise a method and system for medializing one or more turbinates in a nasal cavity. Specific embodiments comprise a method and system for displacing a middle turbinate towards a septum and holding the middle turbinate proximal to the septum. Referring initially to FIGS. 1-8, an implant 100 is coupled to a flexible member or suture 200 and an insertion device 300. In this embodiment, implant 100 comprises a tapered surface 110 proximal to a leading end 116, and a trailing end 115 that is substantially perpendicular to an axis extending between leading end 116 and trailing end 115. In the illustrated embodiment, implant 100 comprises a lateral surface 125 and an aperture 120, through which suture 200 passes. Implant 100 can be inserted into insertion device 300 so that tapered surface 110 is generally aligned with a

tapered surface 310 proximal to an end 309 of insertion device 300. In the embodiment shown, insertion device 300 comprises an angled portion 365 that is angled with respect to a handle portion 360 that can be gripped by a user during installation of implant 100 with insertion device 300. Insertion device 300 may also have a curved portion 320 between angled portion 365 and handle portion 360. In the embodiment shown, insertion device 300 comprises a hollow portion 330 that allows suture 200 to pass through insertion device 300.

A portion of the external wall of insertion device 300 may be removed to reveal a groove or channel 340 formed in insertion device 300. Channel 340 can be configured to receive implant 100 prior to an installation of implant 100. In the embodiment shown, implant 100 has a cross-section with a variable width such that a base portion 130 is wider than upper portion 135. For example, base portion 130 has a semi-circular shape that is configured to fit within channel 340. As used herein, the term "base portion" includes the portion of implant 100 that is retained by channel 340. In this embodiment, base portion 130 has a shape that is more than half a circle and has a widest portion 131 that is wider than opening 342 in groove. Implant 100 can be inserted into the open end 309 of insertion device 300, but will not fall laterally out of channel 340 because widest portion 131 is wider than opening 342. Implant 100 can therefore enter and exit channel 340 via the opening at end 309 of insertion device 300. A stop 350 in channel 340 can be used to prevent implant 100 from moving farther away from end 309.

When implant 100 is inserted into channel 340 and placed against stop 350, tapered surface 110 is generally aligned with tapered surface 310 so that they are in approximately the same plane. As shown in FIGS. 3 and 4, insertion device 300 (with implant 100 installed) can be used to penetrate a turbinate 400 (such as the middle turbinate) and a septum 410. Tapered surfaces 110 and 310 can pierce turbinate 400 and septum 410 as insertion device 300 is directed towards septum 410. As shown in FIG. 4, insertion device 300 can pierce septum 410 sufficiently for implant 100 to be placed on the side of septum 410 opposite of turbinate 400. When implant 100 is so positioned, insertion device 300 can be withdrawn. As shown in FIGS. 2-5, the portion of insertion device 300 that penetrates turbinate 400 and septum 410 (e.g., the portion comprising channel 340) has a smaller cross-section than the remainder of insertion device 300. This configuration allows insertion device 300 to more easily penetrate turbinate 400 and septum 410 and minimizes the trauma cause to turbinate 400 and septum 410.

Trailing end 115 of implant 100 (e.g., the end of implant 100 that is opposite of leading end 116 and tapered surface 110) is configured so that it will not pass through septum 410 (or another tissue through which it has been inserted) when insertion device 300 is retracted. As insertion device 300 is withdrawn or retracted from the position shown in FIG. 4, trailing end 115 will engage septum 410. As insertion device 300 is further retracted, trailing end 115 will stay engaged with septum 410 and implant 100 will slide within channel 340 towards end 309. When insertion device 300 is withdrawn enough so that end 309 passes back through septum 410, implant 100 will not pass through septum 410 (e.g., trailing edge 115 is not configured to penetrate septum 410, and implant 100 is allowed to freely slide towards end 309 when trailing edge 115 engages septum 410).

As shown in FIG. 5, implant 100 will remain on one side of septum 410 while end 309 is withdrawn to the opposite side of septum 410. Suture 200 will remain coupled to implant 100 and insertion device 300. Suture 200 can pass

through an aperture (not visible in the figures) created in turbinate 400 and septum 410 by insertion device 300. As tension is placed on suture 200, implant 100 will rotate so that aperture 120 is proximal to septum 410. In the embodiment shown, lateral surface 125 is placed against septum 410. Lateral surface 125 is configured so that it is larger than the aperture created in septum 410 by insertion device 300. With implant 100 in the position shown in FIG. 5, implant 100 is even less likely to pass back through septum 410 while insertion device 300 is being removed. As shown in FIG. 6, insertion device 300 can be removed so that suture 200 is withdrawn from channel 340 and hollow portion 330 of insertion device 300. Turbinate 400 can be directed towards septum 410 and a knot 210 can be tied in suture 200 to secure turbinate 400 in a position so that it is proximal to septum 410, as shown in FIG. 7. In certain embodiments, knot 210 may be tied in suture 200 prior to the placement of implant 100 and configured to slide into the position shown in FIG. 7 prior to securing knot 210 into place. As shown in FIG. 8A, in still other embodiments, a retainer 220 may be used to retain turbinate in the desired position. Retainer 220 may be secured via a knot similar to knot 210, or in any other manner known to those skilled in the art.

Referring now to FIG. 9A, in certain embodiments, implant 100 may be installed in a manner to capture a turbinate 405 on the side opposite of septum 410 from turbinate 400. Insertion device 300 may be used to pierce turbinate 400, septum 410, and turbinate 405 in order to place implant in the position shown in FIG. 9A. The other steps in the process to secure turbinate 405 are equivalent to those described above for turbinate 400. For example, a knot or retainer may be used to secure turbinate 400 in the position shown in FIG. 9A. The tension on suture 200 between implant 100 and the knot or retainer will also cause turbinate 405 to be deflected towards septum 410.

As shown in FIGS. 9B-9E, more than one implant 100 may be used to secure one (or more) turbinates. In the embodiment shown in FIG. 9B, a pair of implants 100 are inserted through septum 410. A suture 200 is coupled to each implant, and a knot 210 is tied in suture 200 on the opposite side of turbinate 400 from septum 410. Knot 210 may be a sliding knot that allows it to be positioned so that turbinate 400 is held in the desired location. Suture 200 may be coupled to implants 100 before implants 100 are inserted through septum 410, or may be coupled to implants 100 after they are installed in the desired location. In certain embodiments, suture 200 may not comprise knot 210, but may instead be a fixed length that is used to secure turbinate 400. Suture 200 may extend through turbinate 400 or may extend around turbinate 400. Suture 200 may also comprise a unitary piece of material that is coupled to each implant 100, or may comprise separate pieces of material coupled to each implant 100.

Referring now to FIG. 9C, an embodiment is shown that is similar to that depicted in FIG. 9B. However, in this embodiment, implants 100 are positioned proximal to turbinate 400 rather than septum 410. In the embodiment shown, suture 200 is a unitary piece that is coupled to implants 100. It is understood that other embodiments may comprise a knot similar to knot 210 shown in FIG. 9B.

As shown in FIG. 9D, one implant 100 may be installed through septum 410, while a second implant 100 may be installed through turbinate 400. Suture 200 is coupled to each implant 100, and a knot 210 (or other locking device) can be used to couple the portions of suture 200 that extend to each implant 100. In certain embodiments, knot 210 may

be a sliding knot that allows knot **210** to be moved to different locations to secure turbinate **400** in the desired position.

Referring now to FIG. 9E, another embodiment is similar to that shown in FIG. 9D. In this embodiment, however, implants **100** are installed in turbinate **400** and septum **410**, rather than pushed through turbinate **400** and septum **410**. It is understood that any of the embodiments disclosed herein may be modified so that the implant is installed in turbinate **400** and/or septum **410**.

Referring now to FIG. 9F, another embodiment comprises a pair of implants **100** inserted through opposing sides of septum **410**. A first implant **100** is installed through septum **410** from the left side of septum **410** to the right side of septum **410** (as shown in FIG. 9F). In addition, a second implant **100** is installed from the right side of septum **410** to the left side of septum **410**. Implants **100** are coupled via a suture **200** that extends around (or through) turbinates **400** such that turbinates **400** are secured proximal to septum **410**.

As shown in FIG. 9G, another embodiment may comprise an implant **100** coupled to a flexible member **250**. In this embodiment, implant **100** and a portion of flexible member **250** are inserted through turbinate **400** and septum **410**. Flexible member **250** comprises a series of projections **260** configured to hold retainer **220** in a desired position. Retainer **220** is configured so that it can be forced past a projection **260** and toward implant **100** during the installation process. Retainer **220** is also configured so that it will not move past a projection **260** in the direction away from implant **100** after it is installed in the desired location. Projections **260** are spaced along flexible member **250** so that retainer **220** can be placed in any number of positions to position turbinate **400** proximal to septum **410**.

In still other embodiments, an implant may not be used to secure a turbinate proximal to the septum. Instead, a flexible member or suture may be inserted through the turbinate and septum and a knot can be tied in the suture. Referring now to FIG. 10A, an insertion device **305** comprises a curved portion **325** and a pointed or tapered surface **315** proximal to an end **395**. Insertion device **305** further comprises a retaining channel or slot **345** configured to retain a suture **205**. Insertion device **305** can be used to pierce a turbinate and septum (not shown) in a manner similar to that described above in the discussion of insertion device **300**. However, rather than inserting an implant through the turbinate and septum, insertion device **305** inserts suture **205** through the turbinate and septum. Retaining slot **345** can be configured so that suture **205** is retained as insertion device **305** is pushed through tissue such as the turbinate or septum. Retaining slot **345** can also be configured so that as insertion device **305** is withdrawn back through tissue, suture **205** will become disengaged from retaining slot **345**.

One or more knots (not shown) can be tied in suture **205** to secure the turbinate proximal to the septum. In certain embodiments, more than one knot can be tied in suture **205** after it has been inserted through the turbinate and septum. For example, as shown in FIG. 10B knot **210** can be tied in the portion of suture **205** that is on the side of turbinate **400** opposite of septum **410**. Another knot or securement device (not shown) can be located in the portion of suture **205** that is on the side of the septum **410** that is opposite of turbinate **400**. Therefore, suture **205** can be used to secure the turbinate proximal to the septum. In certain embodiments, a knot can be tied in a portion of suture **205** prior to the insertion of suture **205** through the turbinate and/or septum. For example, a knot can be tied in a portion of suture **205** that is distal from retaining slot **345** prior to insertion of suture

**205**. After insertion device **305** has been used to insert suture **205** through the turbinate and septum, another knot can be tied in suture **205** (or a retainer similar to retainer **220**) can be used to secure turbinate **400** to septum **410**. In the embodiment shown in FIG. 10C, suture **200** has been passed through both turbinates **400** and septum **410**. A knot **210** (or other retaining device) can be located on suture **200** as shown in order to secure turbinates **400** proximal to septum **410**.

In another embodiment, an implant can be installed between the mucosa and septum of a patient. Referring now to FIGS. 11-23A an insertion device **550** may be used to install an implant **500** between a turbinate **400** and a septum **410** (shown in FIG. 23). In this embodiment, implant **500** comprises a main body **505**, a turbinate projection or barb **510**, three septum projections or barbs **515**, and three apertures **520**. Apertures **520** are located just below the portion where barbs **515** are coupled to main body **505**, and apertures **520** extend through main body **505**. It is understood that in other embodiments, the number and location of the barbs and apertures may be varied from the embodiment shown.

Referring specifically now to FIGS. 16-19, insertion device **550** comprises a handle portion **551** and a shaft **552** with a distal end **553**. Proximal to distal end **553** is a relief or recessed portion **554** and a plurality of projections or needles **555**. It is understood that the term "needle" as used herein encompasses any sharp object configured to pierce tissue. Implant **500** and insertion device **550** are configured such that turbinate barb **510** will fit within relief portion **554** and needles **555** will extend through apertures **520** when implant **500** is coupled to insertion device **550**. As shown in the embodiment of FIGS. 11 and 21, septum barbs **515** curve downward and deflect needles **555**, which are flexible enough to elastically deform to the position shown in FIGS. 11 and 21. In other embodiments, needles **555** may be curved prior to engagement with septum barbs **515**. In the end view of FIG. 21, it is possible to see that septum barbs **515** extend from one side of shaft **552**, while turbinate barb **510** extends from the other side of shaft **552**. Referring now to FIG. 22, turbinate barb **510** extends through relief portion **554**. The lower portions of a pair of needles **555** are also visible in FIG. 22.

During installation according to one specific embodiment, a user may grasp the handle portion **551** of insertion device **550** and place distal end **553** and implant **500** into a patient's nasal cavity and between the turbinate and septum. As shown in FIG. 23, the user may then identify the adjacent nasal septal mucosa that is in proximity to the most anterior aspect of the turbinate **400** and place septum barbs **515** into the mucosa of the nasal septum **410**, allowing turbinate barb **510** to be perpendicular to the anterior aspect of the turbinate **400**. Needles **555** extend beyond the ends of septum barbs **515** and can lead septal barbs **515** into septum **410**. After securing implant **500** in the septal mucosa, a user may push turbinate **400** medially until turbinate barb **510** pierces turbinate **400**. The user may utilize a freer or other flat instrument (not shown) to push turbinate **400** medially. After turbinate **400** has been secured to turbinate barb **510**, a user can remove insertion device **550** by rotating insertion device about its longitudinal axis. In the position shown in FIG. 23A, a user can rotate insertion device so that the top portion of shaft **552** is directed towards the right. This movement allows needles **555** to be withdrawn from septum **410**, while leaving septal barbs **515** coupled to septum **410**. Relief **554** provides clearance for turbinate barb **510** as shaft **552** is rotated. When needles **555** have been withdrawn from

septum **410**, insertion device **550** can be moved so that turbinate barb **510** is no longer located within recess **554**. Insertion device **550** can then be withdrawn from the nasal cavity, leaving implant **500** in place.

In specific embodiments, implant **500** is configured to medialize the middle turbinate for one week allowing healing of the lateral nasal wall to take place. In specific exemplary embodiments, implant **500** may be comprised of a resorbable polylactide-co-glycolide biomaterial and may have the following approximate dimensions: 6.2 mm long, 4.7 mm wide and 7 mm thick. In certain embodiments, implant **500** can be configured to degrade within approximately 2-6 months.

Referring now to FIG. **23B**, another embodiment of an implant **700** is similar to the previously-described implant **500**. This embodiment comprises a main body **700**, a turbinate projection or barb **710**, three septum projections or barbs **715**, and three apertures (not visible in the view shown in FIG. **23B**). This embodiment may also be installed using insertion device **550** in a manner similar to that described above for implant **500**.

However, in this embodiment, the upper central septal barb **715** is slightly shorter than the other septal barbs **715** (e.g., the upper central barb **715** does not extend as far away from main body **700** as do the other septal barbs **715**). During installation, the upper central septal barb **715** will not engage the tissue at the same time as the other two septal barbs **715**. In certain embodiments, this can make it easier to install implant **700** into the desired tissue.

Referring now to FIGS. **24-26**, another embodiment of an implant **600** configured to medialize a turbinate to a septum comprises an elongate main body **605**, a tapered end surface **610**, and a pair of pivoting or locking members **615**, **620** coupled to main body **605** via pivots **616**, **621**. It is understood that FIGS. **24-26** are not to scale and that locking members **615**, **620** may be closer to main body **605** than shown in the figures. Certain dimensions of implant **600** may be altered in the figures to provide clarity.

In this embodiment, locking members **615** and **620** are initially positioned to be aligned with main body **605**. With implant **600** in this configuration, it can penetrate turbinate **400** and septum **410**. In this embodiment, implant **600** penetrates both turbinate **400** and septum **410** far enough so that locking member **620** is on the side of septum **410** that is opposite of turbinate **400**. When implant **600** is so positioned, locking members **615** and **620** can be rotated into the position shown in FIG. **26**. When locking members **615** and **620** are positioned as shown in FIG. **26**, turbinate **400** can be held proximal to septum **410**. It is understood that while rotating locking members are shown in this embodiment, other configurations for locking members may be used in other embodiments. For example, locking members that extend in length or extend from the main body of the implant may also be used.

Exemplary embodiments of implants described above can be made of any biocompatible material. In certain embodiments, the implant is made of a biodegradable material. In specific embodiments, the material is a biodegradable polymer. In certain embodiments, the material is a co-polymer. In certain embodiments, the polymer is a polyester, polyanhydride, polyamide, polycarbonates, polycarbamate, polyacrylate, polymethacrylate, polystyrene, polyurea, polyether, or polyamine. In certain embodiments, the polymer is a polyester such as poly(glycolide-co-lactide) (PLGA), polyglycolic acid, poly- $\beta$ -hydroxybutyrate, and polyacrylic acid ester. In certain embodiments, the implant is made of PLGA. In certain particular embodiments, the

implant is made of 65% D,L-lactide and 35% glycolide co-polymer. The polymer selected can be formable and able to degrade in-vivo without producing toxic side products. Biodegradable polymers known in the art are useful in embodiments of this invention.

Any of the inventive devices can be made of any biocompatible material. Preferably, the device is made of a biodegradable material. In certain embodiments, the material is a biodegradable polymer. The material may be synthetic (e.g., polyesters, polyanhydrides) or natural (e.g., proteins, rubber, polysaccharides). In certain embodiments, the material is a homopolymer. In certain embodiments, the material is a co-polymer. In still other embodiments, the material is a block polymer. In other embodiments, the material is a branched polymer. In other embodiments, the material is a cross-linked polymer. In certain embodiments, the polymer is a polyester, polyurethane, polyvinyl chloride, polyalkylene (e.g., polyethylene), polyolefin, polyanhydride, polyamide, polycarbonate, polycarbamate, polyacrylate, polymethacrylate, polystyrene, polyurea, polyether, polyphosphazene, poly(ortho esters), polycarbonate, polyfumarate, polyarylate, polystyrene, or polyamine. In certain embodiments, the polymer is polylactide, polyglycolide, polycaprolactone, polydioxanone, polytrimethylene carbonate, and co-polymers thereof. Polymers that have been used in producing biodegradable implants and are useful in preparing the inventive devices include alpha-polyhydroxy acids; polyglycolide (PGA); copolymers of polyglycolide such as glycolide/L-lactide copolymers (PGA/PLLA), glycolide/D,L-lactide copolymers (PGA/PDLLA), and glycolide/trimethylene carbonate copolymers (PGA/TMC); polylactides (PLA); stereocopolymers of PLA such as poly-L-lactide (PLLA), poly-D,L-lactide (PDLA), L-lactide/D, L-lactide copolymers; copolymers of PLA such as lactide/tetramethylglycolide copolymers, lactide/trimethylene carbonate copolymers, lactide/.delta.-valerolactone copolymers, lactide .epsilon.-caprolactone copolymers, polydepsi-peptides, PLA/polyethylene oxide copolymers, unsymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones; polyhydroxyalkanoate polymers including poly-beta-hydroxybutyrate (PHBA), PHBA/beta-hydroxyvalerate copolymers (PHBA/HVA), and poly-beta-hydroxypropionate (PHPA); poly-p-dioxanone (PDS); poly-.delta.-valerolactone; poly-r-caprolactone; methylmethacrylate-N-vinyl pyrrolidone copolymers; polyesteramides; polyesters of oxalic acid; polydihydropyrans; polyalkyl-2-cyanoacrylates; polyurethanes (PU); polyvinyl alcohol (PVA); polypeptides; poly-beta-maleic acid (PMLA); poly(trimethylene carbonate); poly(ethylene oxide) (PEO); poly(.beta.-hydroxyvalerate) (PHVA); poly(ortho esters); tyrosine-derived polycarbonates; and poly-beta-alkanoic acids. In certain embodiments, the polymer is a polyester such as poly(glycolide-co-lactide) (PLGA), poly(lactide), poly(glycolide), poly(D,L-lactide-co-glycolide), poly(L-lactide-co-glycolide), poly-.beta.-hydroxybutyrate, and polyacrylic acid ester. In certain embodiments, the device is made of PLGA. In certain embodiments, the device is made of 85% D,L-lactide and 15% glycolide co-polymer. In certain embodiments, the device is made of 50% D,L-lactide and 50% glycolide co-polymer. In certain embodiments, the device is made of 65% D,L-lactide and 35% glycolide co-polymer. In certain embodiments, the device is made of 75% D,L-lactide and 25% glycolide co-polymer. In certain embodiments, the device is made of 85% L-lactide and 15% glycolide co-polymer. In certain embodiments, the device is made of 50% L-lactide and 50% glycolide co-polymer. In certain embodiments, the device is made of 65% L-lactide

and 35% glycolide co-polymer. In certain embodiments, the device is made of 75% L-lactide and 25% glycolide co-polymer. In certain embodiments, the device is made of poly(caprolactone). In certain embodiments, the device is made of Pebax, Polyimide, Braided Polyimide, Nylon, PVC, Hytreil, HDPE, or PEEK. In certain embodiments, the device is made of a fluoropolymer such as PTFE, PFA, FEP, and EPTFE. In certain embodiments, the device is made of latex. In other embodiments, the device is made of silicone. The polymer typically has a molecular weight sufficient to be shaped by molding or extrusion. The device is typically made of a material that is bioabsorbed after the device is not longer needed. For example, the device may degrade after 1 week, 2 weeks, 3 weeks, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months, 9 months, 1 year, 1.5 years, 2 years, 3 years, etc. The polymer used to make the device may be selected based on its degradation profile. The polymer can be selected as is known to the art to have a desired degradation period. For an implant of this invention, the degradation period is preferably up to about 2 years, or between about 3 weeks and about 1 year, or between about 6 weeks and about 3 months. As would be appreciated by one of skill in this art, the composition of the device may be varied to achieve the desired lifetime in vivo of the wafer.

Certain embodiments of the turbinate medializer include features such as hooks and barbs which need to be rigid and stiff enough to pierce and penetrate the mucosal or similar tissue. To function properly for the weeks after implantation, these hooks and barbs need to retain sufficient strength to approximate the body of the MTM close to the septum and turbinate. Furthermore, these features also need to be strong and somewhat elastic so that they do not easily fracture during the process of implantation. To achieve that property, the medializer may be composed of a crystalline or amorphous polymer combined with an elastomeric polymer. For example, a highly crystalline polylactide may be blended with a polyhydroxybutarate; specifically 80-97% PLLA and 20-3% PHA. Similarly, adding caprolactone or trimethyl carbonate may be added to the crystalline polymer to make it more elastic. Elasticity of the construct is achieved through the addition of the caprolactone or trimethyl carbonate to a lactide or glycolide monomer since the caprolactone and trimethyl carbonate have relatively low melting temperatures, i.e.  $-60^{\circ}$  C. for caprolactone.

All of the devices, systems and/or methods disclosed and claimed herein can be made and executed without undue experimentation in light of the present disclosure. While the devices, systems and methods of this invention have been described in terms of particular embodiments, it will be apparent to those of skill in the art that variations may be applied to the devices, systems and/or methods in the steps or in the sequence of steps of the method described herein without departing from the concept, spirit and scope of the invention. All such similar substitutes and modifications apparent to those skilled in the art are deemed to be within the spirit, scope and concept of the invention as defined by the appended claims.

The invention claimed is:

1. An implant configured to medialize a turbinate to a septum, the implant comprising:
  - a main body comprising a first surface and a second surface on an opposite side of the main body than the first surface, wherein at least one first curved barb extends from an inferior portion of the first surface and at least one second curved barb extends from a superior portion of the first surface;
    - wherein the at least one second barb is shorter than the at least one first barb; and wherein the at least one first barb and at least one second barb are configured so that during implant installation, the inferior portion and thereby the at least one first barb engages and penetrates the mucosa of a nasal septum wherein penetration is defined along a curve defined by the at least one first curved barb, so as to rotate the implant so that the at least one second barb engages and penetrate the nasal septum; and
    - a third barb extending from the second surface, wherein the third barb comprises a shaft terminating in an arrowhead shaped member with a tip which is configured to pierce a turbinate.
2. The implant of claim 1, wherein the third barb extends from the approximate center of the second surface.
3. The implant of claim 1, wherein the at least one first and second barbs are adapted to be inserted before the third barb pierces the turbinate.
4. The implant of claim 1, wherein the third barb extends perpendicularly from the second surface.
5. The implant of claim 1 wherein the at least one first barb comprises at least two first barbs, extending from the inferior portion of the first surface and wherein both barbs are similar in length and curvature.
6. The implant of claim 1 wherein the first surface comprises a continuous planar triangular surface.
7. The implant of claim 6, wherein the at least one first barb extends from the first surface adjacent an inferior vertex of the triangular surface and the at least one second barb extends from the first surface adjacent a superior vertex of the triangular surface.
8. The implant of claim 1, wherein all of the barbs on the first surface curve towards the inferior portion of the first surface.
9. The implant of claim 1 wherein the implant is configured to temporarily medialize a turbinate.
10. The implant of claim 1, wherein the implant is configured to be selectively engageable with an insertion instrument.
11. The implant of claim 10, wherein the insertion instrument is configured so as to rotate the implant.
12. The implant of claim 10 wherein the insertion instrument is configured to engage the implant so that the at least one first barb engages and penetrates the mucosa of a nasal septum.
13. The implant of claim 10 wherein the insertion instrument is configured to engage and push the turbinate so that the arrowhead shaped member pierces a turbinate.

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