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(71) Demandeur/Applicant:
FOCAL THERAPEUTICS, INC., US
(72) Inventeurs/Inventors:
HERMANN, GEORGE D., US;
OLSON, JONATHAN M., US;
DREWS, MICHAEL J., US;
LEBOVIC, GAIL S., US;
WILLIS, DAVID B., US
(74) Agent: BORDEN LADNER GERVAIS LLP

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(54) Title: TISSUE LOCALIZATION DEVICE AND METHOD OF USE THEREOF

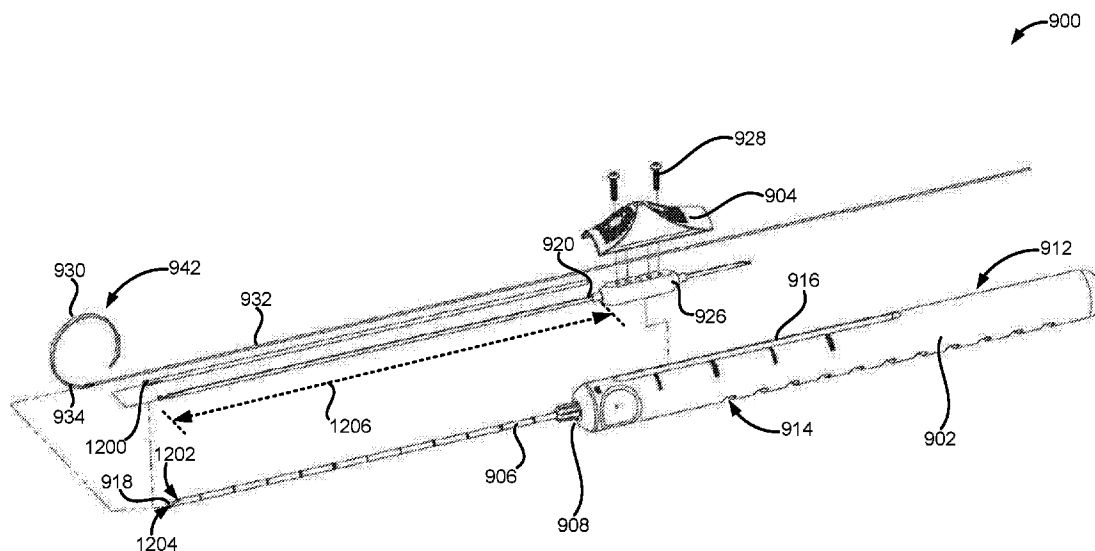


FIG. 12

(57) **Abrégé/Abstract:**

Tissue localization devices and methods of localizing tissue using tissue localization devices are disclosed. The tissue localization device can comprise a handle comprising a delivery control, a delivery needle extending out from the handle, and a localization element within the delivery needle. The localization element can be deployed out of the delivery needle or retracted back into the delivery needle when the delivery control is translated in a first direction or a second direction, respectively. The localization element can be coupled to a flexible tracking wire.

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(71) Applicant: **FOCAL THERAPEUTICS INC.** [US/US];
1010 Stewart Drive, Sunnyvale, California 94085 (US).

(72) Inventors: **HERMANN, George D.**; 13030 La Paloma
Road, Los Altos Hills, California 94022 (US). **OLSON,**
Jonathan M.; 6134 Valley Glen Drive, San Jose, Califor-
nia 95123 (US). **DREWS, Michael J.**; 3582 Arbutus Av-
enue, Palo Alto, California 94303 (US). **LEBOVIC, Gail**
S.; 4556 Biltmore Drive, Frisco, Texas 75034 (US).
WILLIS, David B.; 950 North San Antonio Road, Unit
1B, Los Altos, California 94022 (US).

(74) Agents: **XU, Daniel X.** et al.; Levine Bagade Han LLP,
2400 Geng Rd, Suite 120, Palo Alto, California 94303
(US).

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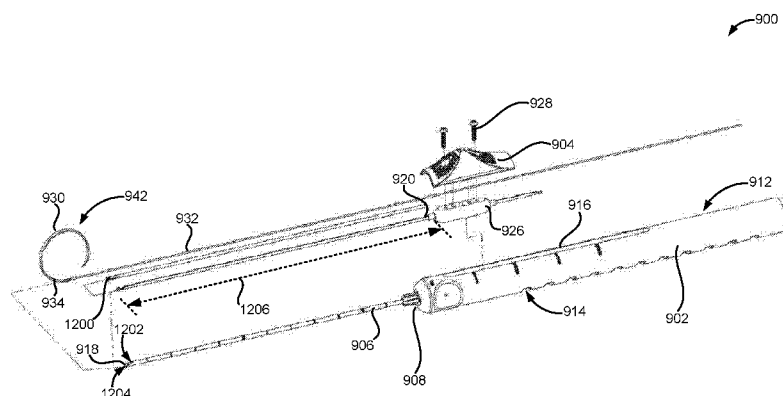


FIG. 12

(57) Abstract: Tissue localization devices and methods of localizing tissue using tissue localization devices are disclosed. The tissue localization device can comprise a handle comprising a delivery control, a delivery needle extending out from the handle, and a localization element within the delivery needle. The localization element can be deployed out of the delivery needle or retracted back into the delivery needle when the delivery control is translated in a first direction or a second direction, respectively. The localization element can be coupled to a flexible tracking wire.

1 TITLE

2 **TISSUE LOCALIZATION DEVICE AND METHOD OF USE THEREOF**

10 CROSS-REFERENCE TO RELATED APPLICATION

11 [0001] This application claims the benefit of U.S. Provisional Patent Application No.
12 62/322,729, filed April 14, 2016, and U.S. Provisional Patent Application No. 62/448,307,
13 filed January 19, 2017, which are incorporated herein by reference in their entireties.

15 FIELD OF TECHNOLOGY

16 [0002] The present disclosure relates generally to the field of tissue localization and, more
17 specifically, to a tissue localizing device for marking or bounding a suspect tissue mass.

19 BACKGROUND

20 [0003] Despite the advances made in technologies such as medical imaging to assist the
21 physician in the diagnosis and treatment of patients with possible abnormal tissue growth such
22 as cancer, it is still often necessary to physically identify abnormal tissue regions for
23 subsequent surgical removal. One disease for which this approach is a critical tool is breast
24 cancer.

25 [0004] In the detection and treatment of breast cancer, open or excisional biopsies are often
26 advisable when a suspicious tissue mass may need to be removed. In addition, lumpectomy or
27 partial mastectomy may be performed when the tissue mass is cancerous as part of breast
28 conservation therapy (BCT). One technique that is frequently employed to physically identify
29 the abnormal tissue region to be removed is called wire localization. Wire localizations often
30 require a radiologist to manually insert a wire that contains one or more hooks on its distal end
31 into the breast of the patient through a needle and then position the hook region of the wire so

1 that the end of the wire resides within or is adjacent to the suspect tissue requiring surgical
2 removal. The needle is removed and the wire is left in the tissue and the patient is then
3 transferred to the operating room, typically several hours later, to have the suspect or target
4 tissue or lesion removed by a surgeon.

5 **[0005]** However, such wires are often inaccurately placed, and once placed they are prone to
6 migration, and cannot be easily adjusted once they have exited the needle. Moreover, even if
7 the wire has been properly placed, the surgeon often cannot intraoperatively identify the tip of
8 the wire, which can result in the surgeon removing a larger portion of tissue than is necessary
9 to optimize the chances for cancer-free margins of the tissue specimen that is removed. Also,
10 if the suspect tissue mass is not found at the end of the wire, the surgeon often ends up cutting
11 or removing non-afflicted tissue without removing the lesion. In addition, after placement but
12 before the surgical procedure, the wire protrudes stiffly from the body and can become
13 dislodged or migrate to position remote from the originally demarcated region of identified
14 tissue. While the localization wire resides in the patient awaiting surgery, the wire can be
15 uncomfortable and cannot be adequately secured in a manner that would permit the patient to
16 sleep overnight without discomfort or without a high risk of dislodgement. Because of these
17 risks associated with migration and patient discomfort, the patient must proceed with the
18 surgical removal of the lesion the same day as the placement of the localization wire. In
19 addition, logistical delays between placement of the wire and eventual surgical excision can
20 exceed several hours, leading to additional discomfort and risk of migration.

21 **[0006]** Another drawback of current localization wires is the need to pass the needle and wire
22 through the lesion leading to potential transmission of cancer cells, sometimes referred to as
23 needle tract seeding.

24 **[0007]** Therefore, a solution is needed that can accurately and removably place a localization
25 or marking device into a patient to demarcate a region of tissue for subsequent surgical
26 removal. Such a solution should reliably define the border of the tissue to be removed and
27 reduce the risk of inadvertent migration, even over a period of hours or days.

28 SUMMARY

29
30 **[0008]** Tissue localization devices and methods of localizing tissue using tissue localization
31 devices are disclosed. The tissue localization device can include a delivery needle having a

1 needle lumen, a localization element slidably translatable within the needle lumen, and a liner
2 in the needle lumen. The localization element can be detachable from the delivery needle. The
3 liner can be slidably translatable relative to the needle lumen and can be located radially
4 between the needle lumen and at least part of the localization element.

5 **[0009]** The localization element can have an echogenic surface treatment. The echogenic
6 surface treatment can be a surface roughness, a pattern cut into a surface of the localization
7 element, or combinations thereof.

8 **[0010]** The tissue localization device can include a handle with a slidable delivery control and
9 a pusher element partially within the needle lumen. The delivery needle can extend from the
10 handle.

11 **[0011]** The localization element can be detachably held by the pusher element. The
12 localization element can be detachable from the pusher element in response to a translation of
13 the slidable delivery control in a first longitudinal direction. The localization element can be
14 releasable from the liner when a distal end of the pusher element is translated longitudinally
15 beyond the liner.

16 **[0012]** The slidable delivery control can have a first interface surface and a second interface
17 surface. The handle can have a proximal end and a distal end. The first interface surface can be
18 upwardly concave when viewed from the proximal end to the distal end and the second
19 interface surface can be upwardly concave when viewed from the distal end to the proximal
20 end.

21 **[0013]** The handle can have a handle dorsal side and a handle ventral side opposite the handle
22 dorsal side. The localization element can be configured to curve in a direction of the handle
23 dorsal side when deployed. The handle can have an elongate slot along the handle dorsal side.
24 The slidable delivery control can be coupled to the pusher element via a fastener extending
25 through the elongate slot.

26 **[0014]** The pusher element can have or be defined by a delivery port at a distal end of the
27 pusher element. At least part of the localization element can be detachably held within the
28 delivery port when the localization element is within the needle lumen. The pusher element
29 can have a pusher dorsal side, a pusher ventral side, and a pusher distal end. The pusher distal
30 end can be sloped and form an obtuse angle with the pusher ventral side.

1 [0015] The tissue localization device can include a spring coupled to a proximal end of the
2 liner. The spring can be configured to be at least partially compressed when the pusher element
3 is translated toward a distal end of the delivery needle relative to the liner in response to a
4 translation of the slidable delivery control in the first longitudinal direction. The tissue
5 localization device can also have a tracking wire coupled to the localization element. At least a
6 segment of the tracking wire can be configured to be coiled or tied into a loop.

7 [0016] Furthermore, the tissue localization device can include a delivery needle having a
8 needle lumen, a pusher element slidably translatable within the needle lumen, and a
9 localization element having an interlocking framework or interlocking portion. The pusher
10 element can have or be defined by a delivery port. The interlocking framework can be
11 interlockable with the delivery port when at least part of the pusher element resides within the
12 needle lumen. The interlocking framework can be releasable from the delivery port when the
13 delivery port exits the needle lumen.

14 [0017] The interlocking framework of the localization element can include an eyelet frame and
15 a shoulder portion. The eyelet frame can be detachably positioned within the delivery port
16 when the localization element is within the needle lumen.

17 [0018] Furthermore, the tissue localization device can include a handle with a slidable delivery
18 control and a delivery needle extending out from the handle. The delivery needle can have a
19 needle lumen and a pusher element slidably translatable and partially within the needle lumen.
20 The tissue localization device can also include a localization element detachably held by the
21 pusher element when in the needle lumen.

22 [0019] The pusher element can have a pusher dorsal side and a pusher ventral side. The needle
23 lumen can have a lumen dorsal surface defining an upper portion or top half of the needle
24 lumen and a lumen ventral surface defining a lower portion or bottom half of the needle
25 lumen. The pusher element can also have a pusher proximal end and a pusher distal end
26 opposite the pusher proximal end. The pusher distal end can be sloped and form an obtuse
27 angle with the pusher ventral side. The obtuse angle formed by the pusher distal end and the
28 pusher ventral side can be seen when viewed from a lateral side of the tissue localization
29 device. The pusher distal end can also form an acute angle with the pusher dorsal side when
30 viewed from the lateral side of the tissue localization device.

1 [0020] At least part of the localization element can be configured to exit the delivery needle in
2 response to a translation of the slidable delivery control in a first longitudinal direction. The
3 localization element can be configured to retract into the delivery needle in response to a
4 translation of the slidable delivery control in a second longitudinal direction opposite the first
5 longitudinal direction. The localization element can be retracted back into the delivery needle
6 after at least a part of the localization element is deployed out of the delivery needle.

7 [0021] The localization element can be constrained into a first configuration when within the
8 needle lumen. The localization element can transform into a second configuration when
9 deployed out of the delivery needle. The second configuration can be a circular shape. The
10 second configuration can also be a half-circle shape, a crescent shape, a falciform shape, or a
11 sickle-shape. The localization element can have an element distal end with one sharpened
12 element tip. The localization element can also have at least two sharpened element tips. The
13 two sharpened element tips can branch out or diverge at an angle away from one another. The
14 two sharpened element tips can also furcate or branch out. The localization element can have
15 an echogenic surface treatment. The echogenic surface treatment can be a surface roughness, a
16 pattern cut into a surface of the localization element, or combinations thereof.

17 [0022] The localization element can have a curvature plane. The entire localization element
18 can be substantially within the curvature plane. In other variations, at least part of the
19 localization element can be curved in alignment with the curvature plane and another part of
20 the localization element can curve out of the curvature plane. The localization element can
21 curve into a complete or partial helix.

22 [0023] The tissue localization device can also have a liner partially encasing the pusher
23 element. The liner can be positioned in between a portion of the pusher element and the needle
24 lumen. A portion of the localization element can be encased by the pusher element and the
25 liner. The liner can be made from a metallic material a polymer such as a polyether ether
26 ketone (PEEK), or combinations thereof. The liner can be a hollow tube. In other variations,
27 the liner can have a dorsal liner and a ventral liner. The dorsal liner can be positioned in
28 between the pusher dorsal side and the lumen dorsal surface. The ventral liner casing can be
29 positioned in between the pusher ventral side and the lumen ventral surface.

30 [0024] The tissue localization device can include a spring coupled to a proximal end of the
31 liner. The spring can be configured to be at least partially compressed when the pusher element

1 is translated toward a distal end of the delivery needle relative to the liner in response to a
2 translation of the slidable delivery control in the first longitudinal direction.

3 **[0025]** The tissue localization device can also include a tracking wire coupled to the
4 localization element. The tracking wire can be a stainless steel wire covered by a polymer
5 jacketing. The tracking wire can be a flexible wire capable of being coiled or tied into a loop.
6 At least part of the tracking wire can be covered by a polymer jacketing.

7 **[0026]** The delivery needle can have a needle dorsal side and a needle ventral side opposite the
8 needle dorsal side. The delivery needle can also have a beveled distal end. The localization
9 element can be configured to exit or be deployed out of the beveled distal end. The beveled
10 distal end can have a rounded edge along a proximal rim of the beveled distal end at a region
11 that can be referred to as a heel. The beveled distal end can also have two lateral sharpened
12 edges converging and meeting at a needle tip. The two lateral sharpened edges can be
13 contiguous with or extend out from the rounded edge.

14 **[0027]** The delivery needle can have a needle dimple proximal to the rounded edge along the
15 needle dorsal side. The needle dimple can have a dimple length and a dimple width. The
16 needle dimple can be a substantially oval-shaped dimple. The needle dimple can be a
17 concavity extending radially into the needle lumen and obstructing part of the needle lumen
18 along the dimple length.

19 **[0028]** The pusher element can have a delivery port and the localization element can be
20 detachably held within the delivery port. The delivery port can be a cutout along the pusher
21 dorsal side. The localization element can be deployed out of the delivery needle when the
22 pusher element pushes the localization element in the first longitudinal direction. The
23 localization element can be configured to automatically detach or dislodge from the pusher
24 element and the delivery needle when at least part of the delivery port is translated by the
25 delivery control out of the delivery needle. The localization element can be retracted back into
26 the delivery needle when at least a portion of the localization element is still within the
27 delivery port and the pusher element pulls the localization element in the second longitudinal
28 direction.

29 **[0029]** The delivery port can have a distal port side, a proximal port side, and a port base. The
30 distal port side can form an acute angle with the port base when viewed from the lateral side of
31 the tissue localization device.

1 [0030] The localization element can include a locator proximal end and a locator distal end
2 opposite the locator proximal end. The locator distal end can include a sharpened locator tip.
3 The locator proximal end can include an eyelet frame surrounding an aperture, a narrow
4 portion, and a shoulder portion. The eyelet frame can be detachably positioned within the
5 delivery port of the pusher element when the movement or translation of the localization
6 element is controlled by the delivery control. The localization element can be deployed out of
7 the delivery needle when the pusher element pushes the shoulder portion of the localization
8 element in the first longitudinal direction. The localization element can be retracted back into
9 the delivery needle when at least a portion of the eyelet frame is still within the delivery port
10 and the pusher element pulls on a side of the eyelet frame, namely an eyelet shoulder, in the
11 second longitudinal direction.

12 [0031] The localization element can be covered by a blue-oxide finish. The blue-oxide finish
13 can reduce friction when the localization element is translated through the needle lumen and
14 makes contact with an inner surface of the needle lumen.

15 [0032] The handle can have a handle distal end, a handle proximal end opposite the handle
16 distal end, a handle dorsal side, a handle ventral side opposite the handle dorsal side, and an
17 elongate slot defined along the handle dorsal side. The handle can also have a handle lumen.
18 At least part of the pusher element can slidably translate within the handle lumen. The delivery
19 control can be coupled to the pusher element via fasteners extending through the elongate slot.
20 In some variations, the tissue localization device can comprise a gear mechanism and the
21 translation of the pusher element can be facilitated by the gear mechanism.

22 [0033] The delivery control can include a first interface surface and a second interface surface.
23 The first interface surface can be upwardly concave when viewed from the proximal end to the
24 distal end and the second interface surface can be upwardly concave when viewed from the
25 distal end to the proximal end. The localization element can be translated in the first
26 longitudinal direction when the first interface surface is pushed in the first longitudinal
27 direction. The localization element can curve in a direction of the handle dorsal side when
28 deployed out of the delivery needle.

29 [0034] The tracking wire can be coupled to the localization element at various points along the
30 length of the localization element. The tracking wire can be coupled to the locator proximal
31 end of the localization element. The tracking wire can be coupled or tied to the eyelet frame of

1 the localization element. The tracking wire can be threaded through the aperture and tied to the
2 eyelet frame. At least part of the tracking wire can be positioned within the delivery port when
3 the eyelet frame is positioned within the delivery port. The tracking wire can be coupled to the
4 localization element at a midpoint along the length of the localization element.

5 **[0035]** The tracking wire can have a wire distal segment and a wire proximal segment opposite
6 the wire distal segment. At least part of the wire distal segment can be secured to part of
7 another segment of the wire in between the wire distal segment and the wire proximal segment
8 at an attachment site along the wire. The wire distal segment can be secured to part of another
9 segment of the wire by adhesive or spot welding. For example, the attachment site can be a
10 weld site. The segment of the wire in between the wire distal segment and the attachment site
11 can be formed as a loop. A polymer jacketing can cover or ensheath at least part of the
12 tracking wire. The polymer jacketing can also cover or ensheath the attachment site. The
13 tracking wire can comprise or be composed of stainless steel. The polymer jacketing can be a
14 heat-shrink polymer or tube wrapped around the tracking wire.

15 **[0036]** A method for using a tissue localization device is also disclosed. The method can
16 involve translating a localization element of the tissue localization device in a first longitudinal
17 direction through a needle lumen of a delivery needle of the tissue localization device. The
18 method can also involve deploying a localization element of the tissue localization device out
19 of the delivery needle into tissue and retracting the localization element into the needle lumen
20 after at least part of the localization element is deployed out of the delivery needle. The
21 method can further involve repositioning the tip of the delivery needle and redeploying the
22 localization element out of the delivery needle into the tissue.

23 **[0037]** The method can also include deploying the localization element out of the delivery
24 needle into a curved configuration having a first curvature plane and redeploying the
25 localization element out of the delivery needle into the curved configuration having a second
26 curvature plane. The method can further involve compressing a spring coupled to a proximal
27 end of a liner partially encasing a pusher element coupled to the slidable delivery control prior
28 to deploying the localization element out of the delivery needle.

29 **[0038]** The method can also involve advancing a needle tip of the delivery needle into the
30 tissue to an offset from a target tissue site of the tissue and positioning an ultrasound
31 transducer on the tissue. The method can further involve deploying the localization element

1 out of the delivery needle by pushing a slidable delivery control of the tissue localization
2 device in the first longitudinal direction along a handle of the tissue localization device and
3 moving the ultrasound transducer on the tissue while translating the localization element.

4 **[0039]** A method of localizing tissue using a tissue localization device is also disclosed. The
5 method can involve positioning a delivery needle of the tissue localization device adjacent to
6 or at a target tissue site and holding the handle of the tissue localization device using one hand
7 of a user. The needle tip can be positioned at an offset location adjacent to a target tissue site.
8 The offset location can be separated from the target tissue site by less than a difference
9 between a diameter of the localization element and a diameter of the target tissue site.

10 **[0040]** The user can include a surgeon, a radiologist, or another health professional. The
11 method can also involve pushing a slidable delivery control of the tissue localization device in
12 a first longitudinal direction using at least one finger of the same hand of the user. The method
13 can involve translating a localization element of the tissue localization device in the first
14 longitudinal direction through a needle lumen of the delivery needle in response to the pushing
15 of the slidable delivery control.

16 **[0041]** The method can also involve deploying the localization element out of the delivery
17 needle adjacent to or at the target tissue site. At least part of the localization element can curve
18 when deployed. The method can also involve at least partially compressing a spring coupled to
19 a proximal end of a liner partially encasing the pusher element prior to deploying the
20 localization element out of the delivery needle.

21 **[0042]** The method can further involve retracting the localization element back into the
22 delivery needle after at least part of the localization element is deployed out of the delivery
23 needle. Retracting the localization element can involve holding the handle of the tissue
24 localization device using the one hand of the user and pulling the slidable delivery control in a
25 second longitudinal direction using at least one finger of the same hand of the user. The second
26 longitudinal direction can be opposite the first longitudinal direction.

27 **[0043]** The method can further involve deploying the localization element out of the delivery
28 needle into a curved configuration having a curvature plane. The localization element can
29 radially surround at least a portion of a suspect tissue mass in the tissue of the patient such that
30 the curvature plane of the localization element intersects at least a portion of the suspect tissue
31 mass. In another variation, the localization element can be deployed adjacent or proximal to

1 the suspect tissue mass such that the curvature plane does not intersect any portion of the
2 suspect tissue mass.

3 **[0044]** The localization element can be coupled to a flexible tracking wire. At least a segment
4 of the tracking wire can extend out of the tissue of the patient while a distal end of the tracking
5 wire can be coupled to the localization element deployed within the tissue of the patient. The
6 distal end of the tracking wire can swivel or rotate relative to the localization element when the
7 localization element and the tracking wire are deployed out of the delivery needle and the
8 pusher element. The distal end of the tracking wire can swivel or rotate into a deployed
9 alignment. The deployed alignment can be a spatial positioning or alignment which is secant
10 or non-tangent with respect to a curve formed by the deployed localization element. For
11 example, the localization element can be deployed into a circular configuration and the distal
12 end of the tracking wire can be aligned secant or non-tangent to the circular configuration.

13 **[0045]** The method can further involve retracting a distal tip of the delivery needle away from
14 the target tissue site. Retracting the distal tip of the delivery needle can expose the tracking
15 wire coupled to the localization element.

16 **[0046]** The method can further involve viewing a position of the localization element in tissue
17 using an ultrasound transducer. The method can also involve moving the ultrasound transducer
18 on a tissue surface proximal to the target tissue site while deploying the localization element.

19 **[0047]** The method can involve locating a suspect tissue mass in the patient by periodically
20 pulling on the segment of a tracking wire extending outside the body of the patient. The
21 method can further involve palpating or feeling, with at least one finger of a user, an outer
22 tissue layer (e.g., a dermis) above the target tissue site while pulling on the segment of the
23 tracking wire extending outside the body of the patient. The method can further involve
24 locating a suspect tissue mass within the tissue of the patient based on a tension exhibited by
25 the tracking wire being pulled and a movement felt by the at least one finger of the user.

26 **[0048]** The method can further involve coiling the segment of the tracking wire extending out
27 of the tissue of the patient tracking wire into a loop and adhering (e.g., with Tegaderm™ or
28 other biocompatible adhesives or dressings) or otherwise securing the tracking wire extending
29 outside the body of the patient to the dermis or patient dressing of the patient.

30 **[0049]** In another variation, a tissue localization device can include a handle having a rotatable
31 delivery control, a delivery needle extending out from the handle, and a localization element

1 configured to be deployed out of the delivery needle when the delivery control is rotated in a
2 first rotational direction. The localization element can be in a first configuration when within
3 the delivery needle. The localization element can transform into a second configuration when
4 deployed out of the delivery needle. A part of the localization element can be detachably held
5 by a distal end of a pusher element configured to longitudinally translate within the delivery
6 needle. The tissue localization device can further include a tracking wire coupled to the
7 localization element.

8 **[0050]** The localization element can be retracted into the delivery needle when the rotatable
9 delivery control is rotated in a second rotational direction. The rotatable delivery control can
10 include a knob.

11 **[0051]** The handle can include an orientation arch defined along a handle dorsal side. The
12 orientation arch can have a curvature and the localization element can be configured to curve
13 in a direction matching the curvature of the orientation arch when deployed. The handle can
14 have a handle lumen. The tissue localization device can include a drive pipe within the handle
15 lumen. The drive pipe can be configured to rotate within the handle lumen in response to a
16 rotation of the rotatable delivery control. The drive pipe can have a pipe lumen surrounding a
17 car element.

18 **[0052]** The car element can be coupled to the pusher element. The car element can be
19 configured to translate longitudinally within the pipe lumen of the drive pipe in response to the
20 rotation of the drive pipe.

21 **[0053]** The tissue localization device can further include a sound-generating element. The
22 sound-generating element can be configured to produce sound when at least part of the
23 localization element exits or is deployed out of the delivery needle. The sound-generating
24 element can include a spring.

25 **[0054]** The tissue localization device can also include a tactile feedback-generating element.
26 The tactile feedback-generating element can be configured to produce tactile feedback at least
27 part of the time when the localization element exits or is being deployed out of the delivery
28 needle.

29 **[0055]** In another variation, a method of localizing tissue using a tissue localization device
30 involves positioning a delivery needle of the tissue localization device adjacent to or at a target
31 tissue site. The method can also involve rotating a rotatable delivery control of the tissue

1 localization device in a first rotational direction and translating a localization element of the
2 tissue localization device in a first longitudinal direction through a needle lumen of the
3 delivery needle in response to the rotation of the rotatable delivery control. Translating the
4 localization element in the first longitudinal direction further involves translating a pusher
5 element within a drive pipe of the tissue localization device.

6 **[0056]** The method can further involve deploying the localization element out of the delivery
7 needle adjacent to or at the target tissue site in response to the rotation of the rotatable delivery
8 control. The method can also involve retracting a distal tip of the delivery needle away from
9 the target tissue site and exposing a tracking wire coupled to the localization element while
10 retracting the distal tip of the delivery needle.

11 **[0057]** The method can further involve holding a handle of the tissue localization device using
12 one hand of a user and rotating the rotatable delivery control in the first rotational direction
13 using at least one finger of the same hand of the user.

14 **[0058]** The method can also involve retracting the localization element into the delivery needle
15 after at least part of the localization element is deployed out of the delivery needle. The
16 localization element can be retracted by holding a handle of the tissue localization device using
17 one hand of a user and rotating the rotatable delivery control in a second rotational direction
18 using at least one finger of the same hand of the user.

19 **[0059]** The method can further involve creating tactile feedback using a tactile feedback-
20 generating element of the tissue localization device when the localization element is partially
21 deployed out of a distal tip of the delivery needle. The method can also involve generating a
22 sound using a sound-generating element of the tissue localization device when the localization
23 element is partially deployed out of a distal tip of the delivery needle.

24 **[0060]** In another variation, a method for localizing tissue using a tissue localization device
25 including a delivery needle comprises advancing, using one hand, a needle tip of the delivery
26 needle of the tissue localization device into a tissue at an offset from a target tissue site of the
27 tissue. The method can further involve positioning, using another hand, an ultrasound
28 transducer proximal to the target tissue site on a tissue surface of the tissue. The method can
29 also involve deploying a localization element out of the delivery needle into the tissue. The
30 method can further involve moving the ultrasound transducer on the tissue surface while
31 deploying the localization element.

1 [0061] A tissue localization system is also disclosed. The tissue localization system can
2 include a tissue localization device configured to be held by only one hand of a user and an
3 ultrasound transducer configured to be held by only one hand of a user and moved on a surface
4 of the tissue while the localization element is deployed into the tissue. The tissue localization
5 device can include a handle with a slidable delivery control, a delivery needle extending from
6 the handle, and a pusher element coupled to the slidable delivery control. The tissue
7 localization device of the tissue localization system can also include a localization element
8 detachably held by the pusher element. The pusher element can be configured to deploy at
9 least part of the localization element from the delivery needle into a tissue in response to a
10 translation of the slidable delivery control.

11 [0062] A tracking wire to locate a marked target tissue site is also disclosed. The tracking wire
12 can include a wire having a wire distal segment and a wire proximal segment opposite the wire
13 distal segment. At least part of the wire distal segment can be secured to a part of another
14 segment of the wire in between the wire distal segment and the wire proximal segment at an
15 attachment site along the wire. The segment of the wire in between the wire distal segment and
16 the attachment site can be formed as a loop. The tracking wire can also include a polymer
17 jacketing covering at least part of the wire. The attachment site can be covered by the polymer
18 jacketing.

19 [0063] The wire can be made of stainless steel. At least a segment of the tracking wire can be
20 configured to be deployed into the tissue of a patient. At least a segment of the tracking wire in
21 between the wire distal segment and the wire proximal segment can be configured to be tied
22 into a knot around a portion of a localization element.

23 [0064] A method of preparing a tissue localization assembly is also disclosed. The method
24 can involve threading a wire distal segment of a wire through an aperture of a localization
25 element. The method can also involve securing at least part of the wire distal segment to part
26 of another segment of the wire in between the wire distal segment and the wire proximal
27 segment at an attachment site along the wire. The segment of the wire in between the wire
28 distal segment and the attachment site can form a loop. The method can further involve
29 covering at least part of the wire with a polymer jacketing.

30 [0065] The method can also involve covering the attachment site with the polymer jacketing.
31 The method can further involve inserting a segment of the wire into a lumen of a pusher

1 element of a tissue localization device. The method can also involve positioning at least a part
2 of the localization element coupled to the wire into a delivery port of the pusher element. The
3 method can further involve slidably translating the pusher element into a lumen of a delivery
4 needle of the tissue localization device.

6 BRIEF DESCRIPTION OF THE DRAWINGS

7 [0066] Fig. 1A illustrates a perspective view of a tissue localization device.

8 [0067] Fig. 1B illustrates a side view of the tissue localization device.

9 [0068] Fig. 1C is a black-and-white image of the tissue localization device.

10 [0069] Fig. 2A illustrates deployment of a localization element.

11 [0070] Fig. 2B illustrates retraction of the localization element.

12 [0071] Fig. 2C is a black-and-white image of the localization element attached to a tracking
13 wire.

14 [0072] Fig. 3A illustrates a close-up perspective view of a tip of a delivery needle during
15 deployment of the localization element.

16 [0073] Fig. 3B illustrates a close-up bottom perspective view of the tip of the delivery needle
17 during deployment of the localization element.

18 [0074] Fig. 3C illustrates a close-up perspective view of a tip of the delivery needle after
19 deployment of the localization element.

20 [0075] Fig. 3D illustrates a close-up bottom perspective view of the tip of the delivery needle
21 after deployment of the localization element.

22 [0076] Fig. 3E illustrates a close-up side view of the tracking wire being pulled out of the
23 delivery needle after deployment of the localization element.

24 [0077] Fig. 3F illustrates a close-up perspective view of the tracking wire being pulled out of
25 the delivery needle after deployment of the localization element.

26 [0078] Fig. 4A is a perspective view of a knob and handle of the tissue localization device.

27 [0079] Fig. 4B is a cutaway view illustrating a part of the interior of the tissue localization
28 device.

29 [0080] Fig. 5A is a cutaway view illustrating another part of the interior of the tissue
30 localization device.

1 [0081] Fig. 5B is a cutaway view illustrating yet another part of the interior of the tissue
2 localization device.

3 [0082] Fig. 5C is a cutaway view illustrating another part of the interior of the tissue
4 localization device.

5 [0083] Fig. 6A is a cutaway view illustrating a tactile and/or audible feedback mechanism of
6 the tissue localization device.

7 [0084] Fig. 6B is another cutaway view illustrating the tactile and/or audible feedback
8 mechanism of the tissue localization device.

9 [0085] Fig. 6C is a front cutaway view illustrating the tactile and/or audible feedback
10 mechanism of the tissue localization device.

11 [0086] Fig. 6D is a perspective cutaway view illustrating the tactile and/or audible feedback
12 mechanism of the tissue localization device.

13 [0087] Fig. 6E is a side cross-sectional view illustrating the tactile and/or audible feedback
14 mechanism of the tissue localization device.

15 [0088] Fig. 6F is a front cutaway view illustrating the tactile and/or audible feedback
16 mechanism of the tissue localization device.

17 [0089] Fig. 6G is a perspective cutaway view illustrating the tactile and/or audible feedback
18 mechanism of the tissue localization device.

19 [0090] Fig. 6H is a side cross-sectional view illustrating the tactile and/or audible feedback
20 mechanism of the tissue localization device.

21 [0091] Fig. 6I is a front cutaway view illustrating the tactile and/or audible feedback
22 mechanism of the tissue localization device.

23 [0092] Fig. 6J is a perspective cutaway view illustrating the tactile and/or audible feedback
24 mechanism of the tissue localization device.

25 [0093] Fig. 6K is a side cross-sectional view illustrating the tactile and/or audible feedback
26 mechanism of the tissue localization device.

27 [0094] Fig. 7 is an exploded view of the tissue localization device.

28 [0095] Fig. 8A illustrates a target tissue region, the localization element and the delivery
29 needle inside a patient tissue model.

30 [0096] Fig. 8B illustrates the localization element surrounding a target tissue region or mass
31 and the delivery needle exiting the patient tissue model.

1 [0097] Fig. 8C illustrates the localization element surrounding the target tissue region and a
2 distal end of the tracking wire positioned outside of the patient tissue model.

3 [0098] Fig. 9 illustrates an exploded view of another variation of the tissue localization device.

4 [0099] Figs. 10A and 10B illustrate perspective and side views, respectively, of the assembled
5 tissue localization device of Fig. 9.

6 [0100] Figs. 10C and 10D illustrate side and perspective cut-away views, respectively, of the
7 assembled tissue localization device of Fig. 9.

8 [0101] Figs. 11A and 11B illustrate top and bottom perspective views, respectively, of a
9 localization element detached from a pusher element.

10 [0102] Figs. 11C and 11D illustrate top and bottom perspective views, respectively, of a
11 localization element detachably held by a pusher element.

12 [0103] Figs. 11E and 11F illustrate top and bottom perspective views, respectively, of a
13 tracking wire rotated relative to a localization element when the localization element is
14 detached from a pusher element.

15 [0104] Fig. 12 illustrates an exploded view of another variation of the tissue localization
16 device.

17 [0105] Fig. 13A illustrates a perspective view of a localization element deployed out of a
18 delivery needle by a pusher element covered by a polymer liner.

19 [0106] Figs. 13B and 13C illustrate perspective and side views, respectively, of a localization
20 element detached from a pusher element partially separated from a polymer liner.

21 [0107] Figs. 14A and 14B illustrate a variation of a delivery needle having a needle dimple.

22 [0108] Fig. 14C illustrates a close-up of a beveled distal end of a variation of a delivery
23 needle.

24 [0109] Fig. 14D illustrates a close-up of a variation of a pusher element covered by a polymer
25 liner extending out of the beveled distal end.

26 [0110] Fig. 14E illustrates a cross-section of the delivery needle enclosing the pusher element
27 covered by the polymer liner along line A-A shown in Fig. 14D.

28 [0111] Fig. 15A illustrates a tracking wire coupled to an end of a variation of a localization
29 element.

30 [0112] Fig. 15B illustrates a tracking wire coupled to a midpoint along a length of a variation
31 of a localization element.

1 [0113] Fig. 15C illustrates a side view of a tracking wire coupled to an end of a variation of a
2 localization element.

3 [0114] Fig. 15D illustrates a perspective view of a tracking wire coupled to an end of a
4 variation of a localization element.

5 [0115] Fig. 15E illustrates a tracking wire coupled to a midpoint along a length of a variation
6 of a localization element.

7 [0116] Fig. 15F illustrates a tracking wire coupled to a point in between a midpoint and an end
8 of a variation of a localization element.

9 [0117] Fig. 16 illustrates a variation of a localization element in a partial helical configuration.

10 [0118] Fig. 17 illustrates a locator distal end of a variation of a localization element with
11 branched locator tips.

12 [0119] Fig. 18A illustrates a deployment of a localization element around a suspect tissue
13 mass.

14 [0120] Fig. 18B illustrates a halo deployment of a localization element above a suspect tissue
15 mass.

16 [0121] Fig. 18C illustrates a side view of a halo deployment of a localization element above a
17 suspect tissue mass.

18 [0122] Fig. 18D illustrates a perspective view of the halo deployment of the localization
19 element above a suspect tissue mass.

20 [0123] Fig. 18E is another perspective view of a halo deployment of a localization element
21 above a suspect tissue mass.

22 [0124] Fig. 19A illustrates a segment of a flexible tracking wire extending out from a patient's
23 tissue and coiled to reduce the excess length of the tracking wire.

24 [0125] Fig. 19B illustrates a segment of a flexible tracking wire extending out from breast
25 tissue.

26 [0126] Fig. 19C illustrates a segment of tracking wire coiled and taped to breast tissue.

27 [0127] Fig. 20A illustrates a distal end of a multi-filament tracking wire.

28 [0128] Fig. 20B illustrates a distal end of a multi-filament tracking wire having a welded end.

29 [0129] Figs. 20C-D illustrate an example cross-section of an attachment site of a multi-
30 filament tracking wire covered by a polymer jacketing.

31 [0130] Fig. 21 illustrates a variation of a method of operating the tissue localization device.

[0131] Fig. 22 illustrates another variation of a method of operating the tissue localization device.

[0132] Figs. 23A-G illustrate a variation of a method of operating the tissue localization device.

[0133] Figs. 24A-G illustrate examples of a localization element surface.

[0134] Figs. 25A-C illustrate a variation of a pusher element.

[0135] Fig. 26 illustrates a variation of a localization element including one or more barbs.

[0136] Fig. 27 illustrates a variation of the tissue localization device including a stainless steel liner.

[0137] Figs. 28A-B illustrate an example of a spring coupled to the stainless steel liner.

[0138] Figs. 29A-J illustrate example retraction locks.

[0139] Figs. 30A-B illustrate an example setup for using the tissue localization device during imaging.

[0140] Figs. 31A-B illustrate variations of a tissue localization wire.

[0141] Fig. 32A-B illustrate variations of using a stabilization sling.

DETAILED DESCRIPTION

[0142] Figs. 1A, 1B, and 1C illustrate that a tissue localization device 100 can include a handle 102 coupled to a delivery needle 104. The handle 102 can include a handle grip 106, a knob portion 108, and a handle nose 110. The handle grip 106 can be a portion of the handle 102 configured to be grasped or held by a user such as a surgeon, radiologist or other imaging professional. The handle grip 106 can be sized or shaped for a user to grasp the handle 102 with one hand. The handle grip 106 can be shaped as a cylinder, a tube, a rod, or combinations thereof. In other variations, the handle grip 106 can be shaped as an elongate ovoid, prism, ellipsoid, cone, or combinations thereof. The handle grip 106 can have finger grooves, holes, indentations, or combinations thereof.

[0143] The handle grip 106 can be connected to or contiguous with a knob portion 108. The knob portion 108 can be a portion of the handle 102 housing a knob 112 for controlling the tissue localization device 100. The knob portion 108 can include an orientation arch 114. The orientation arch 114 can be a curved protuberance extending out from a surface of the handle 102. The orientation arch 114 can help a user properly orient the tissue localization device 100

1 by informing the user of the deployed curvature of a localization element 116. For example,
2 the orientation arch 114 can have a half-oval or bow-shaped curvature denoting a direction
3 and/or plane of curvature of the localization element 116 when deployed.

4 **[0144]** The knob 112 can be barrel or ellipsoid-shaped component for controlling the
5 deployment or retraction of the localization element 116. The knob 112 can be a separate
6 component attached to the handle 102 at the knob portion 108. The knob 112 can be positioned
7 in proximity to the orientation arch 114. The knob 112 can have longitudinal ridges or
8 grooves. The longitudinal ridges or grooves of the knob 112 can allow a user to more easily
9 rotate the knob 112. The knob 112 can be rotated in a clockwise direction, a counterclockwise
10 direction, or combinations thereof. The knob 112 can freely rotate until the localization
11 element 116 is deployed out of the tissue localization device 100. A user can hold the handle
12 grip 106 of the handle 102 with one hand and use the fingers of the same hand to rotate the
13 knob 112 to control the deployment or retraction of the localization element 116.

14 **[0145]** The knob portion 108 can be connected to or contiguous with the handle nose 110.
15 The handle nose 110 can be a portion of the handle 102 coupled to or housing a portion of the
16 delivery needle 104. The handle nose 110 can include a nozzle or luer end 118. The luer end
17 118 can fixedly secure a packaging needle cover tube (not shown) to the handle 102. The luer
18 end 118 can be cross-shaped, conical, rectangular, frustoconical, or combinations thereof.

19 **[0146]** The handle 102, the knob 112, or combinations thereof can be fabricated from or made
20 of a polymer such as an injection molded polymer. For example, the handle 102, the knob 112,
21 or combinations thereof can be composed of or comprise acrylonitrile butadiene styrene (ABS)
22 plastic, polycarbonate, polypropylene (PP), or combinations thereof. The handle 102 can also
23 be fabricated from or include parts fabricated from glass-filled polymers, metals or metal
24 alloys such as stainless steel, or combinations thereof.

25 **[0147]** The handle 102 can have a longitudinal dimension of between 100.0 mm and 200.00
26 mm. For example, the handle 102 can have a longitudinal dimension of approximately 155.0
27 mm. When the handle grip 106 is shaped as a cylinder, the handle grip 106 can have a
28 diameter between 9.0 mm and 13.0 mm. For example, the handle grip 106 can have a diameter
29 of approximately 11.0 mm.

30 **[0148]** The delivery needle 104 can include a needle tip 120 and a needle base 122. The needle
31 tip 120 can be an end of the delivery needle 104 for puncturing the skin of a patient and

1 deploying the localization element 116. The delivery needle 104 can have a needle lumen. The
2 needle lumen can be a hollow cavity within the delivery needle 104 for storing or housing the
3 localization element 116, a tracking wire 126, a portion therein, or combinations thereof.

4 **[0149]** The needle tip 120 can have a beveled or deflected tip or point. The needle tip 120 can
5 also include a blade, a sharpened edge, or a cutting edge. For example, the needle tip 120 can
6 include a hypodermic point bevel, an intradermal point bevel, a deflected point septum, or
7 combinations thereof. The needle tip 120 can also have a bevel angle of between 15 degrees
8 and 45 degrees.

9 **[0150]** The needle base 122 can be partially housed or secured by the luer end 118, the handle
10 nose 110, other internal handle components, or combinations thereof. The delivery needle 104
11 can include one or more depth markers 124 in between the needle tip 120 and the needle base
12 122. The depth markers 124 can be markings, etchings, or surface indentations on the surface
13 of the delivery needle 104 in between the needle tip 120 and the needle base 122. The depth
14 markers 124 can assist a user, such as a surgeon, radiologist or other imaging professional, to
15 insert the delivery needle 104 into the tissue site of the patient. The depth markers 124 can be
16 separated by increments of millimeters, centimeters, inches, or combinations thereof.

17 **[0151]** The delivery needle 104 can be made of metal, a metal alloy such as stainless steel, or a
18 rigid medical grade polymer. The delivery needle 104 can have a diameter of between 0.5 mm
19 and 1.5 mm. The delivery needle 104 can have a diameter of approximately 1.0 mm.

20 **[0152]** The delivery needle 104, for example when made from a rigid medical polymer, can
21 include or be covered by a radiopaque material or coating. The radiopaque material or coating
22 can include gold or gold coating, platinum or platinum coating, tungsten or tungsten coating,
23 iridium or iridium coating, tantalum or tantalum coating, barium sulfate, rhodium, or
24 combinations thereof.

25 **[0153]** The delivery needle can have an echogenic surface such as can be generated by
26 sandblasting or beadblasting on portions of the needle, such as at the distal tip, for example, to
27 enhance visualization of the needle or portions thereof during clinical ultrasound imaging.

28 **[0154]** Figs. 1A and 1B illustrate that the localization element 116 can be curved or loop-
29 shaped when deployed. The localization element 116 can be a flexible wire or length of metal,
30 polymer, or combinations thereof combinations thereof. The localization element 116 can take
31 on an arcuate, curvilinear, or looping shape when deployed out of the delivery needle 104. The

1 localization element 116 can penetrate tissue and serve as a boundary or guidance marker for a
2 tissue mass for subsequent removal and/or analysis.

3 **[0155]** Figs. 1A and 1B also illustrate that the tissue localization device 100 can include a
4 tracking wire 126. The tracking wire 126 can be coupled or connected to the localization
5 element 116. The tracking wire 126 can be made of metal, a metal alloy such as stainless steel,
6 or a medical grade polymer, a stainless steel cable with polymer jacketing, a polymer thread, a
7 polymer tube, or combinations thereof. The tracking wire 126 can include or be covered by a
8 radiopaque material, for example, for enhanced visualization of the tracking wire 126 when
9 imaged.

10 **[0156]** The tracking wire 126 can be used to track the deployment or insertion path of the
11 delivery needle 104, the localization element 116, or combinations thereof combinations
12 thereof into the patient. The tracking wire 126, or a portion therein, can be housed within the
13 handle 102 when the localization element 116 is not deployed or not fully deployed. A
14 segment of the tracking wire 126 can also be located outside the handle 102 when the
15 localization element 116 is not deployed or not fully deployed. For example, a segment of the
16 tracking wire 126 can extend out of an end of the handle 102 proximate to the handle grip 106
17 when the localization element 116 is not deployed or not fully deployed.

18 **[0157]** Fig. 2A illustrates that the localization element 116 can have a deployment trajectory
19 200 when deployed from the delivery needle 104. The deployment trajectory 200 can include a
20 substantially two-dimensional or planar trajectory along a substantially two-dimensional plane.
21 For example, the deployment trajectory 200 can include a substantially two-dimensional
22 trajectory along a plane bisecting a longitudinal axis of the tissue localization device 100. In
23 other variations, the deployment trajectory 200 can include a three-dimensional trajectory.

24 **[0158]** The localization element 116 can follow its deployment trajectory 200 to achieve a
25 predetermined shape 202. The predetermined shape 202 can include a circular shape, an oval,
26 a spiral shape, or combinations thereof combinations thereof. In other variations, the
27 predetermined shape 202 can include a triangular shape, a rectangular shape, a trapezoidal
28 shape, or combinations thereof combinations thereof. The deployment trajectory 200 can be a
29 trajectory or path mimicking or following such a predetermined shape 202. For example, the
30 localization element 116 can have the predetermined shape 202 of a two-dimensional circle

1 and the localization element 116 can emerge from the delivery needle 104 in a circular
2 trajectory.

3 **[0159]** For example, the localization element 116 can have predetermined shape 202 of a
4 circle or loop having a diameter of between 10.0 to 40.0 mm. The localization element 116 can
5 have a predetermined shape 202 of a circle or loop having a diameter of approximately 25.0
6 mm.

7 **[0160]** Fig. 2A illustrates that the localization element 116 can be deployed from the delivery
8 needle 104 when the knob 112 is turned in a first rotational direction 204. The first rotational
9 direction 204 can include a clockwise rotational direction or a counterclockwise rotational
10 direction when viewed along the longitudinal axis of the tissue localization device 100 from
11 the handle grip 106 to the handle nose 110.

12 **[0161]** For example, the localization element 116 can exit or emerge out of the needle tip 120
13 of the delivery needle 104 when the knob 112 is turned in the first rotational direction 204.
14 The localization element 116 can exit or emerge out of the needle tip 120 in a reverse loop
15 trajectory representing the deployment trajectory 200 of the localization element 116. The
16 reverse loop trajectory can be a substantially circular trajectory curving backward toward the
17 needle base 122 of the delivery needle 104. The localization element 116 can initially curve
18 upward or in a direction toward the apex or top of the orientation arch 114 before looping
19 backwards toward the needle base 122. In other variations, the localization element 116 can
20 initially curve downward or in a direction away from the apex or top of the orientation arch
21 114 before looping backwards toward the needle base 122.

22 **[0162]** Fig. 2B illustrates that the localization element 116 can be retracted into the delivery
23 needle 104 when the knob 112 is turned in a second rotational direction 206. The second
24 rotational direction 208 can be a different rotational direction than the first rotational direction
25 204. The second rotational direction can include a counterclockwise rotational direction or a
26 clockwise rotational direction when viewed along the longitudinal axis of the tissue
27 localization device 100 from the handle grip 106 to the handle nose 110.

28 **[0163]** The localization element 116 can have a retraction trajectory 208 when retracting back
29 into the delivery needle 104. The retraction trajectory 208 can be the reverse or opposite of the
30 deployment trajectory 200. For example, when the deployment trajectory 200 is an upward
31 curving loop trajectory as shown in Fig. 2A, the retraction trajectory 208 is a downward

1 curving loop trajectory as shown in Fig. 2B. The retraction trajectory 208 can be a
2 substantially two-dimensional trajectory, a three-dimensional trajectory, or combinations
3 thereofcombinations thereof.

4 **[0164]** The localization element 116 can re-enter or retract back into the needle tip 120 of the
5 delivery needle 104 when the knob 112 is turned in the second rotational direction 208. The
6 localization element 116 can re-enter or retract back into the needle tip 120 by reversing or
7 retracing the deployment trajectory 200 of the localization element 116.

8 **[0165]** Fig. 2C illustrates that the localization element 116 can be in a circular shape
9 representing the predetermined shape 202. The localization element 116 can have a
10 predetermined shape 202 set by using shape memory techniques, heating techniques, bending
11 techniques, or combinations thereofcombinations thereof. The localization element 116 can be
12 composed of or fabricated from spring steel, a nickel-titanium alloy such as Nitinol™, a shape
13 memory polymer, stainless steel, or combinations thereofcombinations thereof.

14 **[0166]** The localization element 116 can include or be covered by a radiopaque material or
15 coating. The radiopaque material or coating can include gold or gold coating, platinum or
16 platinum coating, tungsten or tungsten coating, iridium or iridium coating, tantalum or
17 tantalum coating, barium sulfate, rhodium, hydrophilic and other lubricious coatings, or
18 combinations thereof.

19 **[0167]** Fig. 3A illustrates that the tissue localization device 100 can include a pusher element
20 or pusher element 300. The pusher element 300 can be used by the tissue localization device
21 100 to deploy the localization element 116. The pusher element 300 can be positioned inside
22 the delivery needle 104 when the localization element 116 resides in the delivery needle 104.
23 The pusher element 300 can slidably move longitudinally within the delivery needle 104. The
24 pusher element 300 can be advanced longitudinally forward or longitudinally backward
25 through the delivery needle 104 when a user turns the knob 112 in the first rotational direction
26 204 or the second rotational direction 208, respectively. The pusher element 300 can be
27 composed of or fabricated from a polymer, stainless steel, or combinations thereof.

28 **[0168]** The pusher element 300 can include a pusher tip 302. The pusher tip 302 can be a
29 portion of the pusher element 300 removeably attached to the localization element 116. The
30 pusher tip 302 can have a window 304. The window 304 can be a partial opening or cutaway
31 section along the pusher tip 302.

1 [0169] The localization element 116 can include an element base 308 and an element tip 306.
2 The element base 308 can be a portion of the localization element 116 configured to be
3 removeably attached to the pusher element 300. The element tip 306 can be an end of the
4 localization element 116 distal to the element base 308. The element tip 306 can be configured
5 to pierce or cut through patient tissue. The element tip 306 can have a beveled edge, a
6 sharpened edge, a pointed tip, or combinations thereof.

7 [0170] Fig. 3B illustrates that the element base 308 of the localization element 116 can include
8 an eyelet frame 310, a narrow portion 312, and a shoulder 314. The eyelet frame 310 can be
9 connected to the shoulder 314 by the narrow portion 312. The eyelet frame 310 can have an
10 eyelet 316. The eyelet 316 can be an opening or bore configured to receive the tracking wire
11 126. The tracking wire 126 can be threaded through the eyelet 316 and the threaded end can be
12 connected, for example by crimping via a ferrule or tied, to the remainder of the tracking wire
13 126 using a crimp sleeve, a tie, a knot, an adhesive, a coil, heat shrink polymer jacketing, or
14 combinations thereof.

15 [0171] The eyelet frame 310 can fit within the window 304 of the pusher element 300 to allow
16 the pusher element 300 to engage with the localization element 116. The portion of the pusher
17 element 300 distal to the window 304 can partially surround the narrow portion 312 of the
18 element base 308 when the eyelet frame 310 is within the window 304.

19 [0172] Fig. 3B illustrates that the pusher element 300 can advance the localization element
20 116 out of the delivery needle 104 by pushing on the shoulder 314 of the localization element
21 116. The pusher element 300 can also retract or draw the localization element 116 into the
22 delivery needle 104 by pulling on the eyelet frame 310. The pusher element 300 can retract the
23 localization element 116 back into the delivery needle 104 as long as the eyelet frame 310, the
24 narrow portion 312, or combinations thereof do not disengage from the pusher tip 302 of the
25 pusher element 300. The eyelet frame 310 can disengage from the pusher tip 302 when the
26 eyelet frame 310 is displaced out of the window 304 of the pusher element 300. The narrow
27 portion 312 can disengage from the pusher tip 302 when the narrow portion 312 and eyelet
28 frame 310 are no longer surrounded by the distal portion of the pusher element 300. When the
29 localization element resides within tissue, the shape memory of the localization element causes
30 the proximal portion of the localization element to pull away from the pusher tip 302 once the
31 narrow portion 312 and eyelet frame 310 are no longer constrained by the pusher element 300.

[0173] Figs. 3C-3F illustrate that the localization element 116 can be deployed when the pusher tip 302 of the pusher element 300 no longer engages with the element base 308. Figs. 3C and 3D also illustrate that the tracking wire 126 can be pulled through the pusher element 300, the delivery needle 104, or combinations thereof once the localization element 116 is deployed. The tracking wire 126 can be pulled through the pusher element 300, the delivery needle 104, or combinations thereof when the user retracts the delivery needle 104 out of the patient after the localization element 116 is deployed. The entire length of the tracking wire 126 can be pulled through the handle 102, the delivery needle 104, the pusher element 300, or combinations thereof once the user has fully retracted the delivery needle 104 out of the patient.

[0174] Fig. 4A illustrates that the tissue localization device 100 can be controlled by the knob 112. A user can rotate the knob 112 in the first rotational direction 204 to advance the localization element 116 toward the needle tip 120 or out of the delivery needle 104. A user can also rotate the knob 112 in the second rotational direction 208 to retract the localization element 116 back into the needle tip 120 or further into the delivery needle 104. The localization element 116 can be advanced or retracted when the pusher tip 302 of the pusher element 300 pushes or pulls, respectively, on the element base 308 of the localization element 116.

[0175] Fig. 4B illustrates that the tissue localization device 100 can have a drive pipe 400 positioned within the handle 102. The drive pipe 400 can extend from the handle grip 106 to the handle nose 110. The drive pipe 400 can rotate within the handle grip 106. A portion of the drive pipe 400 along the knob portion 108 can be surrounded or defined by an inner barrel 402. The inner barrel 402 can be configured to interact with the knob 112 to allow the knob 112 to rotate the drive pipe 400.

[0176] For example, a user can rotate the knob 112 in a first rotational direction 204 to rotate the drive pipe 400 in the same first rotational direction 204. Also, for example, the user can rotate the knob 112 in a second rotational direction 208 to rotate the drive pipe 400 in the same second rotational direction 208.

[0177] The drive pipe 400 can be fabricated from or made of a polymer such as an injection molded polymer. For example, the drive pipe 400 can be composed of or comprise acrylonitrile butadiene styrene (ABS) plastic, polycarbonate, polypropylene (PP), or

combinations thereof. The drive pipe 400 can also be fabricated from or include parts fabricated from metals or metal alloys such as stainless steel.

[0178] Fig. 5A illustrates that the drive pipe 400 can have a pipe lumen 500. The pipe lumen 500 can be the interior or inside surface of the drive pipe 400. Fig. 5A also illustrates that the tissue localization device 100 can have a car 502 residing inside the pipe lumen 500. The car 502 can be a component of the tissue localization device 100 configured to maneuver (e.g., push or pull) the pusher element 300. The car 502 can be shaped as an elliptic cylinder having a trivial height dimension. For example, the car 502 can be shaped as an elliptic cylinder having a height dimension of between 1.0 mm and 4.5 mm. In other variations, the car 502 can be shaped as a flattened rectangle, an oval disc, a circular disc, or combinations thereof.

[0179] The car 502 can be within a car track 510. The car track 510 can be an elongate channel segment having a surface and walls that support the car 502 as the car 502 slides along the central, longitudinal axis of the handle. The car track 510 can be part of a rod or shaft having a concavity or depression along a longitudinal length of the rod or shaft. The car 502, or a portion therein, can fit within the concavity or depression of the car track 510. The car track 510 can be coupled to the delivery needle 104. In other variations, the car track 510 can be separate from the delivery needle 104. The car track 510 can reside or be disposed in the pipe lumen 500. The car track 510 can remain stationary as the drive pipe 400 rotates.

[0180] The pusher element 300 can be attached to the car 502. The pusher element 300 can be fixedly attached to the car 502 via adhesives, interference fit, screws, or combinations thereof. The pusher element 300 can be attached to the car 502 by being threaded or molded through the body of the car 502. The pusher element 300 can be attached to a car front portion 504. The car front portion 504 can be an end or segment of the car 502 proximal to the handle nose 110. The pusher element 300 can be attached to, contiguous with, or extend out from the car front portion 504.

[0181] The car 502 can include a car tooth 506. The car tooth 506 can be a projection or protuberance extending out of the car 502. The car tooth 506 can extend out vertically in a direction perpendicular to a longitudinal axis of the tissue localization device 100. The car tooth 506 can also extend out in the direction of the apex or top of the orientation arch 114. The car tooth 506 can be shaped as a cube or a trapezoid. The car tooth 506 can have rounded

or beveled edges or corners. In other variations, the car tooth 506 can be ovoid, half-spherical, conical, frustoconical, or combinations thereof.

[0182] Figs. 5A and 5B illustrate that the pipe lumen 500 can include a spiral channel that extends radially inward from the surface of the pipe lumen into the inner surface of the drive pipe 400. Solid material between the spiral channels is shown for example as region 508.

[0183] As the knob is turned in one rotational direction, it causes the spiral channel to advance the car, thereby advancing the pusher tube, thereby causing the localization element 116 to advance from within the delivery needle 104. When the knob is manually turned in the opposite rotational direction, the process is reversed, causing the localization element 116 to retract within the delivery needle 104.

[0184] Fig. 5C illustrates that the car 502 can be propelled by the drive pipe 400 until the car 502 reaches the end of the pipe lumen 500 at the handle nose 110 portion of the handle 102. The car 502 can come to a stop when the car tooth 506 is passed to an end gear 514. The end gear 514 can be the protruding gear 508 closest to the nozzle end 118. The end gear 514 can be the last protruding gear 508 in the pipe lumen 500 before the end of the pipe lumen 500.

[0185] The car 502 can come to a stop or be prevented from moving when the car front portion 504 makes contact with or pushes against a car stop 512. The car stop 512 can be a stationary raised edge or protruding surface feature at the end of the pipe lumen 500 proximal to the luer end 118. In other variations, the car stop 512 can be a separate stationary component of the tissue localization device 100 coupled to the nozzle end 118.

[0186] The drive pipe 400, the knob 112, or combinations thereof can be prevented from rotating further in the first rotational direction 204 when the car 502 reaches the car stop 512. The drive pipe 400, the knob 112, or combinations thereof can be prevented from rotating in the first rotational direction 204 when the end gear 514 pushes against the car tooth 506 of the stopped car 502. The car tooth 506 of the stopped car 502 can block the further angular rotation of the end gear 514.

[0187] The drive pipe 400 can be rotated in the second rotational direction 208 to push the car 502 away from the car stop 512 and toward the opposite end of the pipe lumen 500. When the drive pipe 400 is rotated in the second rotational direction 208, the end gear 514 can also rotate in the second rotational direction 208 and apply a force to the car tooth 506 in the direction of handle grip 106.

1 **[0188]** Figs. 6A and 6B illustrate that the tissue localization device 100 can include a
2 rotational alert 600, such as a tactile feedback or sound-generating alert. The rotational alert
3 600 can be configured to generate an audible and/or tactile signal or indication to a user of the
4 tissue localization device 100 that the localization element 116 is about to deploy and detach
5 and no longer instantly retractable. The signal or indication can include tactile clicking or
6 vibration, audible clicking noises, tapping sensations and/or noises, grinding sensations and/or
7 noises, increased rotational resistance, squealing, scraping, scratching, or combinations
8 thereof. The rotational alert 600 can include a rod, a pin, a hook, a spring, or combinations
9 thereof protruding from the car front portion 504.

10 **[0189]** The drive pipe 400 can include a grooved section 602. The grooved section 602 can be
11 a portion of the drive pipe 400 having longitudinal grooves 604 around a circumference of the
12 pipe lumen 500. The rotational alert 600 can interact with the longitudinal grooves 604 to
13 generate the audible and/or tactile signal. The rotational alert 600 can interact with the
14 longitudinal grooves 604 when the car 502 enters the grooved section 602. The grooved
15 section 602 can be in the vicinity of the car stop 512. The rotational alert 600 can interact with
16 the longitudinal grooves 604 as the pipe lumen 500 rotates in the first rotational direction 204,
17 the second rotational direction 208, or combinations thereof. The pipe lumen 500 can rotate the
18 longitudinal grooves 604 in the first rotational direction 204, the second rotational direction
19 208, or combinations thereof. The rotational alert 600 can tap or drag against the longitudinal
20 grooves 604 to generate the detectable audible and/or tactile signal.

21 **[0190]** The rotational alert 600 can generate the audible and/or tactile signal to inform the user
22 that the car 502 has pushed the pusher tip 302 of the pusher element 300 out of the delivery
23 needle 104. The audible and/or tactile signal can also indicate that the element base 308 of the
24 localization element 116 can soon become dislodged or separated from the pusher tip 302 of
25 the pusher element 300.

26 **[0191]** The grooved section 602 can be a portion of the drive pipe 400 in the handle nose 110
27 of the handle 102. The rotational alert 600 can generate the audible and/or tactile signal until
28 the car reaches the car stop 512.

29 **[0192]** Figs. 6C, 6D, and 6E illustrate that the rotational alert 600 can have a rotational alert
30 tip 606. The rotational alert tip 606 can be an end of the rotational alert 600 distal to the car
31 front portion 504. The rotational alert tip 606 can be a curved or coiled tip of an elongate rod

1 representing the body of the rotational alert 600. Figs. 6C, 6D, and 6E illustrate that the
2 rotational alert 600, the rotational alert tip 606, or combinations thereof can proceed down the
3 pipe lumen 500 without generating any noticeable audible and/or tactile alert signals or noises
4 as the car 502 is pushed through the pipe lumen 500 toward the handle nose 110.

5 **[0193]** Figs. 6F, 6G, and 6H illustrate that the rotational alert tip 606 can be positioned within
6 a longitudinal groove 604 when the rotational alert 600 enters the grooved section 602 of the
7 drive pipe 400. The grooves section 602 can have longitudinal ridges 608 separated by
8 longitudinal grooves 604. The longitudinal ridges 608 can protrude radially inward toward the
9 center of the pipe lumen 500.

10 **[0194]** The rotational alert 600 can generate an audible and/or tactile signal or feedback when
11 the drive pipe 400 is rotated in either the first rotational direction 204 or the second rotational
12 direction 208 when the rotational alert tip 606 is in the grooved section 602. The rotational
13 alert 600 can generate the audible and/or tactile signal or feedback as the rotational alert tip
14 606 makes contact with the longitudinal ridges 608, the longitudinal grooves 604, or
15 combinations thereof as the drive pipe 400 is rotated.

16 **[0195]** Figs. 6I, 6J, and 6K illustrate that the rotational alert tip 606 can be deflected by the
17 longitudinal ridges 608 when the drive pipe 400 is rotated in either the first rotational direction
18 204 or the second rotational direction 208. The rotational alert tip 606 can be deflected when
19 the rotational alert 600 is pushed radially inward by the longitudinal ridges 608. For example,
20 when the rotational alert 600 is a rod having a curved or hooked end representing the rotational
21 alert tip 606, the curved or hooked end can be deflected by the longitudinal ridges 608 as the
22 drive pipe 400 is rotated by the knob 112. In this example, the rod and the curved or hooked
23 end can be pushed radially inward when the curved or hooked end is deflected by the
24 longitudinal ridges 608.

25 **[0196]** Fig. 7 illustrates that the drive pipe 400 can be positioned within the handle 102 when
26 the tissue localization device 100 is in an assembled state. The car track 510 can be coupled to
27 the delivery needle 104 and both the car track 510 and the delivery needle 104 can be
28 positioned within the drive pipe 400 when the tissue localization device 100 is in the
29 assembled state. The car 502 can be fixedly attached to the pusher element 300. The pusher
30 element 300 can be threaded through the delivery needle 104 and can be positioned in the
31 delivery needle 104 when the tissue localization device 100 is in the assembled state. The

1 localization element 116 can be coupled to the tracking wire 126. The tracking wire 126 can be
2 threaded through the pusher element 300 before the pusher element 300 is inserted into the
3 delivery needle 104. The localization element 116 can be removably attached to the pusher tip
4 302 of the pusher element 300. The localization element 116 can also be pressed into a
5 straightened configuration to be inserted into the delivery needle 104.

6 **[0197]** Fig. 8A illustrates that the localization element 116 can surround a target tissue 700,
7 for example having or being a target tissue mass, when deployed in a patient tissue model. The
8 localization element 116 can cut through the patient's tissue, such as a breast tissue or lung
9 tissue, as the pusher element 300 and the car 502 are pushed longitudinally through the pipe
10 lumen 500. The localization element 116 can curve into the predetermined shape 202 to
11 surround and mark the target tissue 700. The predetermined shape 202 can be a circular shape.
12 The localization element 116 can be deployed from the tissue localization device 100 when the
13 eyelet frame 310 of the localization element 116 is dislodged or otherwise becomes separated
14 from the window 304 of the pusher element 300. In addition, the localization element 116 can
15 be deployed when the narrow portion 312 of the localization element 116, the shoulder 314, or
16 combinations thereof is separated from the pusher tip 302 of the pusher element 300.

17 **[0198]** The user can complete the deployment of the localization element 116 by retracting the
18 delivery needle 104, the pusher element 300, or combinations thereof completely out of the
19 patient's tissue site. The localization element 116 can become anchored in the implantation site
20 of the patient's tissue as the localization element 116 is separated from the rest of the tissue
21 localization device 100.

22 **[0199]** Fig. 8B illustrates that the end of the tracking wire 126 coupled to the localization
23 element 116 can remain in the patient's tissue prior to removal of the delivery needle 104 from
24 the tissue site. The tracking wire 126 can serve as a path or trail for informing a surgeon of the
25 path taken by the delivery needle 104 into the patient's appendage. The tracking wire 126 can
26 also serve as a path or trail for indicating the location of the target tissue region delineated by
27 the curved localization element 116.

28 **[0200]** Fig. 8C illustrates that the end of the tracking wire 126 not attached or coupled to the
29 localization element 116 can emerge from the patient's skin after the delivery needle is
30 removed. This exposed segment of the tracking wire 126 can be allowed to extend from the
31 patient and because the wire 126 is flexible, the wire 126 can comfortably reside on the

1 patient's skin (with or without coiling it) and secured by, for example, adhesive dressing to the
2 patient's skin. For example, the exposed segment of the tracking wire 126 can be taped by
3 surgical tape to the patient's appendage. The exposed segment of the tracking wire 126 can
4 also be coiled, folded, twisted, or cut before or after being taped to the patient's skin or
5 dressing. The flexible nature of the tracking wire 126 enables the patient to be comfortable
6 while the localization element remains in situ, with minimal risk of dislodgement of the
7 localization element. This feature allows for logistic flexibility in planning for the surgical
8 removal of the localized tissue (e.g. place the localization element on one day and remove the
9 tissue specimen and localization element on a subsequent day).

10 **[0201]** Although not shown in the figures, it is anticipated by this disclosure that multiple
11 localization elements 116 can be used to mark or surround the suspect tissue mass in three
12 dimensions.

13 **[0202]** Fig. 9 illustrates that the tissue localization device 900 can have a handle 902 with a
14 slidable delivery control 904 and a delivery needle 906 extending out from the handle 902. The
15 handle 902 can be shaped as a cylinder, a tube, a rod, an elongate ovoid, an ellipsoid, a cone,
16 or combinations thereof. The handle 902 can comprise finger grooves, holes, indentations, or
17 combinations thereof. The handle 902 can be sized or shaped such that a user can grasp the
18 handle 902 with one hand. The handle 902 can comprise or be composed of acrylonitrile
19 butadiene styrene (ABS) plastic, polycarbonate, polypropylene (PP), or other suitable
20 polymers, or combinations thereof. The handle 902 can also comprise components fabricated
21 from metals or metal alloys such as stainless steel.

22 **[0203]** The handle 902 can have a handle distal end 908, a handle proximal end 910 opposite
23 the handle distal end 908, a handle dorsal side 912, a handle ventral side 914 opposite the
24 handle dorsal side 912, and an elongate slot 916 defined along the handle dorsal side 912.

25 **[0204]** The handle distal end 908 can include a nozzle or luer end. The luer end can fixedly
26 secure a packaging needle cover (not shown in Fig. 9) to protect the delivery needle 906.

27 **[0205]** The delivery needle 906 can also have a needle lumen 918 and a pusher element 920
28 slidably translatable within the needle lumen 918. The delivery needle 906 can comprise or be
29 composed of a metal, metal alloy, or a rigid medical grade polymer. When the delivery needle
30 906 is made of a polymer, the delivery needle 906 can be covered with a radiopaque material

1 or coating. The pusher element 920 can have a pusher distal end 922 and a pusher proximal
2 end 924 opposite the pusher distal end 922.

3 **[0206]** The pusher element 920 can have a pusher plug 926 affixed near the pusher proximal
4 end 924. The pusher plug 926 can be affixed to a stationary position along the pusher element
5 920. The pusher plug 926 can have a number of threaded bores or holes defined along a dorsal
6 surface of the pusher plug 926. The delivery control 904 can be connected to the pusher
7 element 920 via fasteners 928 screwed into the threaded bores or holes of the pusher plug 926.
8 At least a portion of each of the fasteners 928 can extend through the elongate slot 916 when
9 the delivery control 904 is coupled to the pusher element 920. In other variations, the delivery
10 control 904 can be connected to the pusher plug 926 via adhesives, an interference or locking
11 fit, clips, clasps, snap buttons, wire connectors, insert molding, or combinations thereof. The
12 elongate slot 916 can act as a track or guiding lane for the longitudinal translation of the
13 delivery control 904. The delivery control 904 can be pushed toward the handle distal end 908
14 or pulled toward the handle proximal end 910 to translate the pusher element 920 within the
15 needle lumen 918.

16 **[0207]** The positioning or orientation of the delivery control 904 relative to the handle 902 can
17 indicate the deployment orientation of the localization element 930 relative to the handle 902.
18 For example, the localization element 930 can deploy toward a side of the tissue localization
19 device 900 on which the delivery control 904 is disposed. Alternatively, the localization
20 element 930 can deploy toward an opposite side of the tissue localization device 900 from the
21 delivery control 904, or the delivery control 904 can have arrows pointing toward a direction
22 of the localization element's deployment.

23 **[0208]** The tissue localization device 900 can also include a localization element 930 and a
24 flexible tracking wire 932 coupled to the localization element 930. The tracking wire 932 can
25 have a wire distal segment 934 including a wire distal end 936 and a wire proximal segment
26 938 including a wire proximal end 940.

27 **[0209]** The localization element 930 can be curled or curved into a deployed configuration 942
28 when unconstrained by or deployed from the delivery needle 906. The localization element
29 930 can be pressed or formed into a flat or unfurled configuration when positioned within the
30 needle lumen 918 of the delivery needle 906. The localization element 930 can be initially
31 positioned within the needle lumen 918 when the tissue localization device 900 is in the

1 assembled state. The localization element 930 can slidably translate within the needle lumen
2 918. As will be discussed in the following sections, the localization element 930 can be
3 detachably held by or can detachably interlock with the pusher element 920 when the
4 localization element 930 is within the needle lumen 918.

5 **[0210]** Fig. 9 also illustrates that the handle 902 can have a number of deployment stage
6 markers 944. The deployment stage markers 944 can be graphics, etchings, or indents along
7 the outside surface of the handle 902. The deployment stage markers 944 can inform a user of
8 the extent of the deployment of the localization element 930 based on a position of the delivery
9 control 904 relative to the deployment stage markers 944. The deployment stage markers 944
10 can include a starting marker 946, an initial deployment marker 948, a halfway deployment
11 marker 950, and a deployed marker 952.

12 **[0211]** The starting marker 946 can be a marker most proximal to the handle proximal end
13 910. The localization element 930 can be completely within the needle lumen 918 when the
14 delivery control 904 is positioned behind the starting marker 946. The initial deployment
15 marker 948 can be positioned distal to the starting marker 946. At least a portion of the
16 localization element 930 can be located outside of the needle lumen 918 when the delivery
17 control 904 is positioned in between the starting marker 946 and the initial deployment marker
18 948. The halfway deployment marker 950 can be positioned distal to the initial deployment
19 marker 948. At least half of the length of the localization element 930 can be located outside of
20 the needle lumen 918 when the delivery control 904 is positioned in between the initial
21 deployment marker 948 and the halfway deployment marker 950. The halfway deployment
22 marker 950 can also indicate the point at which the localization element 930 can still be
23 retracted back into the delivery needle 906. The deployed marker 952 can be the marker
24 closest to the handle distal end 908. The localization element 930 can be fully laterally
25 deployed when the delivery control 904 is positioned in between the halfway deployment
26 marker 950 and the deployed marker 952. The deployed marker 952 can also indicate the point
27 at which the localization element 930 can no longer be retracted back into the delivery needle
28 906.

29 **[0212]** Fig. 9 also illustrates that the delivery needle 906 can have a number of needle depth
30 markers 954. The needle depth markers 954 can be located in between the needle tip and the
31 needle base. The needle depth markers 954 can be markings, etchings, or surface indentations

1 on the surface of the delivery needle 906. The needle depth markers 954 can assist a user, such
2 as a surgeon, radiologist or other imaging professional, to insert the delivery needle 906 into
3 the tissue of a patient. The needle depth markers 954 can be separated by increments of
4 millimeters, centimeters, inches, or combinations thereof.

5 **[0213]** Fig. 10A illustrates that the delivery control 904 can include a substantially triangular
6 component having a first interface surface 1000 and a second interface surface 1002. The first
7 interface surface 1000 and the second interface surface 1002 can be sloped or raised. The first
8 interface surface 1000 can be upwardly concave when viewed from the handle proximal end
9 910 to the handle distal end 908. The second interface surface 1002 can be upwardly concave
10 when viewed from the handle distal end 908 to the handle proximal end 910. In other
11 variations, the first interface surface 1000 and the second interface surface 1002 can be any
12 shape or orientation needed to advance or retract the delivery control 904 with one hand of a
13 user.

14 **[0214]** A method of operating the tissue localization device 900 can involve a user holding the
15 handle 902 of the tissue localization device 900 using one hand of the user. The method can
16 also involve the user pushing the first interface surface 1000 of the delivery control 904 in a
17 first longitudinal direction 1004 with at least one finger of the same hand holding the handle
18 902. All references to finger in this disclosure can include one or more digit fingers, a thumb, a
19 part of a finger, or any combinations thereof. The first longitudinal direction 1004 can be a
20 forward direction. For example, the delivery control 904 can be pushed in the first longitudinal
21 direction 1004 from the starting marker 946 to the initial deployment marker 948, the halfway
22 deployment marker 950, or the deployed marker 952. The localization element 930 can be
23 translated through the needle lumen 918 in response to the pushing or withdrawing of the
24 delivery control 904.

25 **[0215]** In cases where the delivery control 904 is not pushed to the deployed marker 952 or
26 beyond, the method can further involve the user pulling or otherwise applying force to the
27 second interface surface 1002 in the second longitudinal direction 1006. The second
28 longitudinal direction 1006 can be a backward direction opposite the first longitudinal
29 direction 1004. The localization element 930 can be retracted back into the delivery needle 906
30 or further into the delivery needle 906 in response to the pulling of the delivery control 904.

[0216] The user can pull or otherwise apply force to the second interface surface 1002 with at least one finger of the same hand holding the handle 902. In this manner, the tissue localization device 900 can be operated entirely with one hand of the user. This feature is important because, in many cases, the other hand of the user is simultaneously being used to position an ultrasound transducer, thereby enabling the user to position the delivery needle 906 and control the deployment and retraction of the localization element 930 via the handle 902 under simultaneous ultrasound guidance.

[0217] Fig. 10B illustrates that the localization element 930 can be curled into a deployed configuration 942 when the delivery control 904 is translated to the deployed marker 952. Figs. 10A and 10B also illustrate that at least a segment of the tracking wire 932, such as the wire proximal end 940, can extend out of the handle proximal end 910 when the delivery control 904 is translated to the deployed marker 952. More of the tracking wire 932 can extend out of the handle proximal end 910 as the delivery control 904 is pulled in the second longitudinal direction 1006 toward the handle proximal end 910. The tracking wire 932 can be housed within a lumen of the pusher element 920 when the localization element 930 is detachably held by or detachably interlocks with the pusher element 920.

[0218] Fig. 10C illustrates that the handle 902 can have a handle lumen 1008. The pusher plug 926 and at least a segment of the pusher element 920 can be housed within the handle lumen 1008. The pusher plug 926 and the pusher element 920 can also translate longitudinally within the handle lumen 1008.

[0219] Fig. 10C also illustrates that the handle 902 can have a handle length 1010. For example, the handle length 1010 can be between approximately 12.0 cm and 20.0 cm. The handle length 1010 can be approximately 16.0 cm. Fig. 10C further illustrates that the delivery needle 906 can have a needle length 1012. For example, the needle length 1012 can be between approximately 10.0 cm and 15.0 cm. The needle length 1012 can be approximately 12.0 cm. Fig. 10C also illustrates that the pusher element 920 can have a pusher length 1014. For example, the pusher length 1014 can be between approximately 16.0 cm to 20.0 cm. The pusher length 1014 can be approximately 17.5 cm. Fig. 10C further illustrates that the tracking wire 932 can have a wire length 1016. For example, the wire length 1016 can be between approximately 20.0 cm and 30.0 cm. The wire length 1016 can also be greater than 30.0 cm depending on the location of a target tissue site.

[0220] Fig. 10D illustrates that the fasteners 928 can extend into a portion of the delivery control 904 to connect the delivery control 904 to the pusher plug 926 and the pusher element 920. Fig. 10D also illustrates that the elongate slot 916 can provide clearance for the fasteners 928 as the delivery control 904, the pusher plug 926, and the pusher element 920 translate longitudinally in the first longitudinal direction 1004 or the second longitudinal direction 1006. Fig. 10D further illustrates that connecting the delivery control 904 to the pusher element 920 via the pusher plug 926 prevents the pusher element 920 from being translated (e.g., pushed or pulled) entirely out of the handle lumen 1008 or the needle lumen 918. In some variations, the tissue localization device 900 can comprise a gear mechanism and the translation of the pusher element 920 can be facilitated by the gear mechanism.

[0221] Figs. 11A and 11B illustrate that the localization element 930 can have a locator proximal end 1100 and a locator distal end 1102. The locator distal end 1102 can have a sharpened locator tip 1104 for piercing through tissue. The locator proximal end 1100 can include an eyelet frame 1106 surrounding an aperture 1108, a narrow portion 1110, and a shoulder portion 1112. The eyelet frame 1106 can be connected to the shoulder portion 1112 by the narrow portion 1110. The aperture 1108 can be positioned substantially in the middle of the eyelet frame 1106. The aperture 1108 can be an opening, hole, or bore configured to receive the tracking wire 932.

[0222] Figs. 11A and 11B also illustrate that the pusher element 920 can have a pusher dorsal side 1114 and a pusher ventral side 1116 opposite the pusher dorsal side 1114. A delivery port 1118 can be defined along the pusher dorsal side 1114 proximal to the pusher distal end 922. The delivery port 1118 can be a cutout along the pusher dorsal side 1114. The eyelet frame 1106 of the localization element 930 can be detachably positioned within the delivery port 1118 of the pusher element 920 when the localization element 930 is within the needle lumen 918. The eyelet frame 1106, shoulder portion 1112, and narrow portion 1110 of the localization element 930 are collectively referred to herein as an interlocking framework, which allows the localization element 930 to releasably interlock with the pusher element 920. The movement or translation of the localization element 930 can be controlled by the delivery control 904 when the interlocking framework is positioned within or interlocked with the delivery port 1118. In particular, the interlocking of the localization element 930 and the pusher element 920 by the interlocking framework allows longitudinal translation of the

1 delivery control 904 to slide the localization element 930 in both a distal and proximal
2 direction within the delivery needle 906, both pushing the localization element 930 out of the
3 delivery needle 906 and retracting it into the delivery needle 906.

4 **[0223]** The localization element 930 can be deployed out of the delivery needle 906 when the
5 pusher distal end 922 pushes the shoulder portion 1112 of the localization element 930 in the
6 first longitudinal direction 1004 out of the delivery needle 906. The interlocking framework of
7 the localization element 930 can release from the delivery port 1118 of the pusher element 920
8 when the delivery port 1118 exits the lumen of the delivery needle 906. The localization
9 element 930 can curl into a substantially circular deployed configuration 942 when deployed.
10 The localization element 930 can curl or curve in a direction of the handle dorsal side 912
11 when deployed out of the delivery needle 906.

12 **[0224]** The localization element 930 can comprise or be composed of a metal, a metal alloy, a
13 polymer, or combinations thereof. In some variations, the localization element 930 can
14 comprise or be composed of a shape-memory material. For example, the localization element
15 930 can comprise or be composed of a shape memory metal alloy such as Nitinol[™]. The
16 localization element 930 can penetrate tissue and serve as a boundary or guidance marker for a
17 tissue mass for subsequent removal and/or analysis.

18 **[0225]** The localization element 930 can be processed or finished so as to reduce the sliding
19 friction between the localization element 930 and the inner surface of the needle lumen 918.
20 For example, the localization element 930 can be electro-polished or mechanically polished.
21 The localization element 930 can also be covered by a blue-oxide finish. The localization
22 element 930 can be covered by the blue-oxide finish by heat treating the localization element
23 930 in a salt bath.

24 **[0226]** The localization element 930 can be a flexible length of metal or wire, a flexible length
25 of polymer, a flexible length of shape-memory material, or combinations thereof. The
26 localization element 930 can take on an arcuate, curvilinear, or looping shape when deployed
27 out of the delivery needle 906.1

28 **[0227]** The pusher distal end 922 can be sloped and form an obtuse angle with the pusher
29 ventral side 1116. The obtuse angle formed by the pusher distal end 922 and the pusher ventral
30 side 1116 can be seen when viewed from a lateral side of the tissue localization device 900.
31 The sloped design of the pusher distal end 922 can allow the pusher element 920 to more

effectively push the shoulder portion 1112 of the localization element 930 in the first longitudinal direction 1004 without the shoulder portion 1112 curling upwards toward the top of the needle lumen 918. This can reduce sliding friction between the localization element 930 and the needle 918 as the localization element 930 is translated through the needle lumen 918. The pusher distal end 922 can also form an acute angle with the pusher dorsal side 1114 when viewed from the lateral side of the tissue localization device 900.

[0228] As previously discussed, the movement or translation of the localization element 930 can be controlled by the delivery control 904 when the eyelet frame 1106 is positioned within the delivery port 1118. The delivery port 1118 can have a distal port side 1120, a proximal port side 1122, and a port base 1124. The distal port side 1120 can form an acute angle with the port base 1124 when viewed from the lateral side of the tissue localization device 900.

[0229] The localization element 930 can be retracted back into the delivery needle 906 even after at least a portion of the localization element 930, such as the locator distal end 1102, has exited the needle lumen 918. The localization element 930 can be retracted back into the delivery needle 906 when the distal port side 1120 of the pusher element 920 pulls on an eyelet shoulder 1113 in the second longitudinal direction 1006. The pusher element 920 can be pulled in the second longitudinal direction 1006, for example, when a user applies a force to the second interface surface 1002 of the delivery control 904 in the second longitudinal direction 1006.

[0230] The pusher element 920 can have a pusher lumen 1126. The narrow portion 1110 of the localization element 930 can be positioned within a segment of the pusher lumen 1126 when the eyelet frame 1106 is positioned within the delivery port 1118.

[0231] Figs. 11A and 11B also illustrate that the tracking wire 932 can be coupled to the locator proximal end 1100 of the localization element 930. The tracking wire 932 can be coupled or tied to the eyelet frame 1106 of the localization element 930. The wire distal end 936 of the tracking wire 932 can be threaded through the aperture 1108 such that a loop 1128 forms around the eyelet frame 1106. The wire distal end 936 can then be secured to another segment of the tracking wire 932 at an attachment site 1130. For example, the wire distal end 936 can be secured to an attachment site 1130 along the wire distal segment 934. More specifically, the wire distal end 936 can be welded or adhered with adhesive to another segment of the tracking wire 932 at a site serving as the attachment site 1130. In other

1 variations, the wire distal end 936 can be tied to another segment of the tracking wire 932 or
2 crimped to another segment of the tracking wire 932 using a ferrule.

3 **[0232]** The tracking wire 932 can comprise or be composed of a metal or metal alloy such as
4 stainless steel. The tracking wire 932 can comprise or be composed of a cable for flexibility,
5 tensile strength, and low-profile. For example, the cable can be a 19-filament metal wire cable.
6 In other variations, the tracking wire 932 can comprise or be composed of a braided cable such
7 as a high-tensile strength braided suture used in such applications as orthopedic surgery.

8 **[0233]** A polymer jacketing 1132 can cover or ensheath at least part of the tracking wire 932.
9 The polymer jacketing 1132 can also cover or ensheath the attachment site 1130. The polymer
10 jacketing 1132 can be a heat-shrink polymer or tube wrapped around the tracking wire 932. At
11 least part of the tracking wire 932 can be positioned within the pusher lumen 1126, the needle
12 lumen 918, and the handle lumen 1008 when the localization element 930 is detachably held
13 by or detachably interlocks with the pusher element 920. By jacketing the side-by-side
14 portions of the tracking wire 932, the tracking wire 932 behaves as one filament, making it
15 easier for the clinician to handle the tracking wire 932 for example during coiling or
16 subsequently during surgical specimen removal.

17 **[0234]** Once the localization element 930 has detached from the pusher element 920, the
18 tracking wire 932 can exit the pusher lumen 1126 and the needle lumen 918 as the delivery
19 needle 906 is retracted away from the deployed localization element 930. For example, the
20 localization element 930 can be deployed out of the delivery needle 906 within the tissue of a
21 patient. In this example, an operator of the tissue localization device 900 can slowly retract the
22 delivery needle 906 out of the tissue of the patient. As the delivery needle 906 is retracted out
23 of the patient, more of the tracking wire 932 can be exposed. As will be discussed in the
24 following sections, at least a segment of the tracking wire 932 can remain within the tissue of
25 the patient after the delivery needle 906 is removed from the patient.

26 **[0235]** Figs. 11C and 11D illustrate that the movement or translation of the localization
27 element 930 can be controlled by the delivery control 904 when the eyelet frame 1106 is
28 positioned within the delivery port 1118. The localization element 930 can automatically
29 detach or be dislodged from the pusher element 920 and the delivery needle 906 when at least
30 part of the eyelet frame 1106 held by the delivery port 1118 is translated by the delivery
31 control 904 out of the delivery needle 906. For example, the localization element 930 can

1 automatically separate, detach, or dislodge from the pusher element 920 when the eyelet frame
2 1106 is pushed out of the needle lumen 918 and the localization element 930 no longer
3 constrained by the interior surface of the needle lumen 918. The localization element 930 can
4 be considered detached from the pusher element 920 when the eyelet frame 1106 is no longer
5 positioned within the delivery port 1118. The rotational orientation of the pusher element 920
6 as shown in Fig 11D can improve automatic detachment of the localization element 930 from
7 the pusher element 920. This orientation facilitates the localization element 930 to move freely
8 away from the pusher element 920 due to the inherent direction of motion imparted by the
9 shape memory of the localization element. This orientation allows for automatic separation
10 from the interlocking connection between the pusher element 920 and localization element 930
11 once the interlocking framework of the localization element 930 is no longer constrained by
12 the bore of the delivery needle 906.

13 **[0236]** The localization element 930 can be retracted back into the delivery needle 906 when
14 at least a portion of the eyelet frame 1106 is still positioned within the delivery port 1118.

15 **[0237]** Figs. 11E and 11F illustrate that the tracking wire 932 coupled to the locator proximal
16 end 1100 can swivel or rotate relative to the localization element 930 when the localization
17 element 930 is detached from the rest of the tissue localization device 900. For example, the
18 loop 1128 formed by the wire distal segment 934 can swivel or rotate relative to the eyelet
19 frame 1106.

20 **[0238]** Figs. 11E and 11F illustrate that the spatial alignment of the tracking wire 932 can
21 initially be positioned essentially tangential to a curvature of the deployed localization element
22 930. For example, the localization element 930 can curl into a circular shape when in the
23 deployed configuration 942 and the tracking wire 932 can initially be aligned tangent to the
24 circular-shaped localization element 930. Figs. 11E and 11F also illustrate that the loop 1128
25 formed by the tracking wire 932 can subsequently swivel or rotate with respect to the eyelet
26 frame 1106 typically due to movement of the proximal end of the localization element 930 as
27 it becomes unconstrained by the needle lumen 918. Once the loop 1128 swivels or rotates, the
28 spatial alignment of the tracking wire 932 relative to the localization element 930 can change.
29 For example, at least a segment of the tracking wire 932 can be aligned as a secant or in a non-
30 tangential orientation relative to the circular-shaped localization element 930 once the loop
31 1128 formed by the wire distal segment 934 swivels or rotates.

1 [0239] The tracking wire 932 can automatically change its spatial alignment relative to the
2 localization element 930 once the localization element 930 is detached from the rest of the
3 delivery system of the tissue localization device 900. For example, when the tracking wire 932
4 is aligned tangential to the curled localization element 930, the localization element 930 can be
5 more susceptible to inadvertent displacement within the tissue of the patient when the tracking
6 wire 932 is pulled or when the patient moves. Changing the spatial alignment of the tracking
7 wire 932 relative to the localization element 930 can make the deployed localization element
8 930 more difficult to displace within the tissue of the patient by pulling on the tracking wire
9 932 or when the patient moves. In addition, changing the alignment of the tracking wire 932
10 relative to the localization element 930 from a tangential alignment to a secant or non-
11 tangential alignment can reduce the risk that the localization element 930 inadvertently retracts
12 out of the tissue of the patient when the tracking wire 932 is being pulled by the patient or a
13 health professional or when a patient moves.

14 [0240] Fig. 12 illustrates that the tissue localization device 900 can include a polymer liner
15 1200. The polymer liner 1200 can radially ensheath or surround at least a portion of the pusher
16 element 920, and can be slidably translatable in the delivery needle 906. The polymer liner
17 1200 can prevent metal-on-metal contact between the outer surface of the pusher element 920
18 and at least a portion of the localization element 930 as well as the surface of the needle lumen
19 918 as the pusher element 920 is translated through the needle lumen 918. The liner 1200 can
20 also move along with the pusher element 920 as the pusher element travels through the
21 delivery needle lumen thereby preventing metal from sliding against metal for the portion of
22 the localization element 930 that is ensheathed by the liner 1200. The polymer liner 1200 can
23 be interposed or pressed between an outer surface of the pusher element 920 and the surface of
24 the needle lumen 918 or a portion of the localization element 930 or tracking wire 932 and the
25 surface of the needle lumen 918 in order to reduce the static and/or dynamic frictional forces
26 acted upon by the pusher element 920, the localization element 930 or tracking wire 932 as the
27 pusher element 920 travels through the needle lumen 918.

28 [0241] The needle lumen 918 can have a lumen dorsal surface 1202 and a lumen ventral
29 surface 1204. The lumen dorsal surface 1202 can refer to an upper portion or top half of the
30 needle lumen 918. The lumen ventral surface 1204 can refer to a lower portion or bottom half
31 of the needle lumen 918. The polymer liner 1200 can completely encircle or surround the

1 pusher element 920 such that no contact is made between the external surface of the pusher
2 element 920 and the needle lumen 918 as the pusher element 920 is translated longitudinally
3 through the needle lumen 918. In another variation, the polymer liner 1200 can cover the
4 pusher dorsal side 1114 and prevent the pusher dorsal side 1114 from contacting the lumen
5 dorsal surface 1202 as the pusher element 920 is translated longitudinally through the needle
6 lumen 918. The polymer liner 1200 can cover the pusher ventral side 1116 and prevent the
7 pusher ventral side 1116 from contacting the lumen ventral surface 1204 as the pusher element
8 920 is translated longitudinally through the needle lumen 918.

9 **[0242]** The polymer liner 1200 can comprise or be fabricated from polyether ether ketone
10 (PEEK). In other variations, the polymer liner 1200 can comprise or be fabricated from any
11 polymer or polymer blend (e.g., a fluoropolymer) capable of facilitating the longitudinal
12 translation of the pusher element 920 through the needle lumen 918.

13 **[0243]** The polymer liner 1200 can have a liner length 1206 substantially equivalent to the
14 needle length 1012. In other variations, the needle length 1012 can be greater than the liner
15 length 1206.

16 **[0244]** Figs. 13A to 13C illustrate that the polymer liner 1200 can include a dorsal liner 1300
17 and a ventral liner 1302. The dorsal liner 1300 and the ventral liner 1302 can combine to
18 radially ensheath or surround the pusher element 920. The polymer liner 1200 can have a liner
19 distal segment 1304. The liner distal segment 1304 can extend from the pusher distal end 922
20 to the proximal port side 1122.

21 **[0245]** Fig. 13B illustrates that the dorsal liner 1300 can separate from the ventral liner 1302
22 when the liner distal segment 1304 is pushed or deployed out of the needle lumen 918. The
23 dorsal liner 1300 can separate from the ventral liner 1302 by curling away from the ventral
24 liner 1302. The dorsal liner 1300 can separate from the ventral liner 1302 when the
25 localization element 930 detaches from the pusher element 920. For example, because of the
26 force acted upon the liner by the shape memory of the localization element, the eyelet frame
27 1106 can separate the dorsal liner 1300 from the ventral liner 1302 at the liner distal segment
28 1304 as the eyelet frame 1106 detaches or is physically displaced from the delivery port 1118.

29 **[0246]** The dorsal liner 1300 can act as an additional safeguard against the inadvertent
30 detachment of the localization element 930 from the pusher element 920 when the localization
31 element 930 is being translated through the needle lumen 918. For example, the dorsal liner

1300 along with the port base 1124 of the pusher element 920 can act as an additional layer of material to hold the eyelet frame 1106 within the delivery port 1118 when the localization element 930 is within the needle lumen 918 or in motion through the needle lumen 918.

[0247] The polymer liner 1200 including the dorsal liner 1300 and the ventral liner 1302 can be, attached, in part, to the pusher element 920. For example, the polymer liner 1200 can be attached to the pusher element 920 by UV cured adhesives. The polymer liner 1200 can be mechanically fitted to the pusher element 920 by methods such as crimping within the pusher plug 926.

[0248] The dorsal liner 1300 can once again join with the ventral liner 1302 to radially ensheath or surround the pusher element 920 when the pusher element 920 is translated in the second longitudinal direction 1006 back into the needle lumen 918. For example, the dorsal liner 1300 can once again join with the ventral liner 1302 when the localization element 930, along with the pusher element 920, is retracted back into the needle lumen 918. Also, for example, the dorsal liner 1300 can again join with the ventral liner 1302 when the localization element 930 is completely deployed out of the delivery needle 906 and the empty pusher element 920 is retracted back into the needle lumen 918.

[0249] Figs. 14A and 14B illustrate that the delivery needle 906 can have a beveled distal end 1400 and a needle dimple 1402. The beveled distal end 1400 can be defined by a rounded edge 1404 along a proximal rim 1406 of the beveled distal end 1400 and two lateral sharpened edges 1408 converging into a needle tip 1410.

[0250] The rounded edge 1404 can be positioned proximal to the two lateral sharpened edges 1408 and the needle tip 1410. The two lateral sharpened edges 1408 and the needle tip 1410 can be configured to pierce through the dermis and into the underlying tissue of the patient. The proximal rim 1406 of the beveled distal end 1400 can be the portion of the beveled distal end 1400 not included as part of the two lateral sharpened edges 1408 and the needle tip 1401. The rounded edge 1404 can be a surface feature of the proximal rim 1406 formed by smoothing or rounding out the edges of the proximal rim 1406. The rounded edge 1404 can have a radius. The rounded edge 1404 can reduce the mechanical trauma to the localization element 930 caused by an otherwise sharp-edged beveled distal end 1400.

[0251] The delivery needle 906 can have a needle dorsal side 1412 and a needle ventral side 1414 opposite the needle dorsal side 1412. The needle dimple 1402 can be a concavity, divot,

1 or flattened region along the needle dorsal side 1412. The needle dimple 1402 can be shaped
2 as a half-ellipsoid. In other variations, the needle dimple 1402 can be oval or oblong-shaped.
3 The needle dimple 1402 can be proximal to the rounded edge 1404 of the beveled distal end
4 1400.

5 **[0252]** Fig. 14C illustrates that the needle dimple 1402 can have a dimple length 1418. For
6 example, the dimple length 1418 can be between approximately 0.5 mm and 1.5 mm.

7 **[0253]** Fig. 14D illustrates that the pusher element 920 covered by the polymer liner 1200 can
8 translate longitudinally out of the beveled distal end 1400 having the needle dimple 1402. The
9 pusher element 920 can be an elongate half-cylinder having a hollow interior. The needle
10 dimple 1402 can allow the pusher element 920 to more easily exit the beveled distal end 1400
11 of the delivery needle 906.

12 **[0254]** Fig. 14E illustrates that the needle lumen 918 can have a lumen diameter 1416. For
13 example, the lumen diameter 1416 can be between approximately 0.8 mm and 1.3 mm. Fig.
14 14E also illustrates that the needle dimple 1402 can have a dimple width 1420. The dimple
15 width 1420 can be between approximately 0.5 mm and 1.1 mm. The dimple width 1420 can be
16 less than the lumen diameter 1416 such that the pusher element 920 can translate past the
17 section of the delivery needle 906 defined by the needle dimple 1402 without being obstructed
18 by the needle dimple 1402.

19 **[0255]** When the dimple width 1420 is less than the lumen diameter 1416, the lateral sides of
20 the pusher element 920 can be unobstructed by the needle dimple 1402 as the pusher element
21 902 moves through the needle lumen 918. The needle dimple 1402 can allow the localization
22 element 930 to more easily exit the beveled distal end 1400 of the delivery needle 906. For
23 example, the needle dimple 1402 can reduce the likelihood of the eyelet frame 1106 from
24 being inadvertently detached from the delivery port 1118 when the localization element 930 is
25 being deployed out of the delivery needle 906.

26 **[0256]** For example, the indentation of the needle dimple 1402 on the needle lumen 918 of the
27 delivery needle 906 causes the localization element 930 to be pushed away from the beveled
28 distal end 1400 of the delivery needle 906 as it is retracted or advanced. This reduces the
29 friction and/or abrasion of the localization element 930 against the beveled distal end 1400 of
30 the delivery needle 906.

1 [0257] The needle dimple 1402 can allow the localization element 930 to be retracted into or
2 deployed out of the beveled distal end 1400 of the delivery needle 906 when at least part of the
3 localization element 930 has been deployed out of the delivery needle 906. As another
4 example, the needle dimple 1402 can ensure the delivery port 1118 holds the eyelet frame
5 1106 by pushing the eyelet frame 1106 further into the delivery port 1118 when the pusher
6 element 920 is being retracted into the needle lumen 918.

7 [0258] Fig. 14E also illustrates that the polymer liner 1200 can have a liner inner diameter
8 1422 and a liner outer diameter 1424. The liner inner diameter 1422 can be between
9 approximately 0.90 mm and 1.10 mm. For example, the liner inner diameter 1422 can be
10 approximately 1.10 mm. The liner outer diameter 1424 can be between approximately 1.00
11 mm and 1.20 mm. For example, the liner outer diameter 1424 can be approximately 1.14 mm.

12 [0259] Fig. 15A illustrates that the tracking wire 932 can be coupled to the localization
13 element 930 at the locator proximal end 1100. For example, the tracking wire 932 can be
14 looped around the eyelet frame 1106 of the localization element 930. As shown in Fig. 15A,
15 the localization element 930 can have a substantially circular deployed configuration 942. The
16 deployed configuration 942 can be a predetermined shape or configuration of the localization
17 element 930. For example, the deployed configuration 942 can be a shape memory
18 configuration obtained by heat setting the localization element 930 during its manufacturing
19 process. The localization element 930 can automatically transform into its deployed
20 configuration 942 when deployed or detached from the rest of the tissue localization device
21 900.

22 [0260] Fig. 15B illustrates that the localization element 930 can have a locator length 1500.
23 For example, when the localization element 930 is formed into a substantially circular
24 deployed configuration 942, the locator length 1500 can be a perimeter length. Fig. 15B
25 illustrates that the tracking wire 932 can be coupled to the localization element 930 at a
26 midpoint 1502 along the locator length 1500. For example, the localization element 930 can
27 have an aperture or notch defined at the midpoint 1502 and the tracking wire 932 can be
28 looped through the aperture or notch and tied to the localization element 930 at the midpoint
29 1502.

30 [0261] The tracking wire 932 can be coupled to the localization element 930 at a point in
31 between the midpoint 1502 and the locator proximal end 1100 or in between the midpoint

1 1502 and the locator distal end 1102. The tracking wire 932 can be coupled to the midpoint
2 1502 or another point along the length of the localization element 930 other than the locator
3 proximal end 1100 to prevent the tracking wire 932 from inadvertently displacing or retracting
4 the localization element 930 when the localization element 930 is deployed within the tissue of
5 a patient. For example, the tracking wire 932 can inadvertently displace or retract the
6 localization element 930 when a user pulls on the tracking wire 932 or the patient moves after
7 the localization element 930 is deployed within the tissue of the patient.

8 **[0262]** Figs. 15C and 15D illustrate that the localization element 930 having a sickle or
9 falciform-shaped deployed configuration 942. The sickle or falciform shape can be a partial
10 circular shape or crescent shape. As shown in Fig. 15C, the tracking wire 932 can be coupled
11 to the sickle or falciform-shaped localization element 930 at the locator proximal end 1100.

12 **[0263]** Fig. 15E illustrates that the tracking wire 932 can be coupled to the localization
13 element 930 having the sickle or falciform-shaped deployed configuration 942 at a midpoint
14 1502 along the curved locator length 1500 of the localization element 930. The different
15 deployed shapes of the localization element 930 can allow the tissue localization device 900 to
16 localize or demarcate tissue masses of different sizes and shapes.

17 **[0264]** Fig. 15F illustrates that the tracking wire 932 can be coupled to the localization
18 element 930 at an attachment point 1504 along the locator length 1500 in between the
19 midpoint 1502 and the locator proximal end 1100. For example, the attachment point 1504 can
20 be located at a point one-quarter the locator length 1500. The localization element 930 can
21 have an aperture or notch defined at the attachment point 1504 and the tracking wire 932 can
22 be looped through the aperture or notch and tied to the localization element 930 at the
23 attachment point 1504.

24 **[0265]** Fig. 16 illustrates that the localization element 930 can have a curvature plane 1600
25 when in the deployed configuration 942. The curvature plane 1600 can be a two dimensional
26 plane used to orient the localization element 930. For example, in the variations of the
27 localization element 930 shown in Figs. 11A to 11F, the entire localization element 930 can be
28 curved substantially in alignment with the curvature plane 1600. Fig. 16 illustrates that at least
29 part of the localization element 930 can be curved in alignment with the curvature plane 1600
30 and another part of the localization element 930 can be curved or otherwise oriented out of the
31 curvature plane 1600.

1 [0266] For example, the locator proximal end 1100 can be curved in alignment with the
2 curvature plane 1600 and the locator distal end 1102 can be curved out of the curvature plane
3 1600. As shown in Fig. 16, the localization element 930 can have a full or partial helical shape
4 when in the deployed configuration 942. A part of the localization element 930 can curve out
5 of the curvature plane 1600 to localize or demarcate a suspect tissue mass in the patient's body
6 in three-dimensions.

7 [0267] Fig. 17 illustrates that the localization element 930 can have a branched distal segment
8 1700. As shown in Fig. 17, the branched distal segment 1700 can be an instance of the locator
9 distal end 1102 having two or more sharpened locator tips 1104. For example, when the
10 branched distal segment 1700 has two sharpened locator tips 1104, the two sharpened locator
11 tips 1104 can diverge at an angle away from one another. The branched distal segment 1700 of
12 the localization element 930 can allow the localization element 930 to more securely anchor
13 into the tissue of the patient, and also can more fully delineate the tissue site in three
14 dimensions.

15 [0268] Fig. 18A illustrates that the localization element 930 deployed into the tissue 1800 of a
16 patient can encircle or radially surround at least part of a suspect tissue mass 1802. For
17 example, the tissue 1800 can include breast tissue or lung tissue. The suspect tissue mass 1802
18 can include a tumor or other cancerous cells, necrotic tissue, lymph nodes, scar-tissue, target
19 tissue, fibro adenoma, calcifications, otherwise diseased tissue, or combinations thereof.

20 [0269] Fig. 18A illustrates that the localization element 930 in the deployed configuration 942
21 can be curved or curled in alignment with a curvature plane 1600. The localization element
22 930 can encircle or radially surround at least part of the suspect tissue mass 1802 when the
23 curvature plane 1600 intersects at least part of the suspect tissue mass 1802. The deployed
24 localization element 930 can serve as a boundary or guide for identifying and demarcating the
25 location or boundary (e.g. the posterior margin) of the suspect tissue mass 1802 for further
26 analysis or excision.

27 [0270] Figs. 18B-18E illustrate that the localization element 930 can be deployed adjacent to
28 or abutting the suspect tissue mass 1802. For example, the localization element 930 can be
29 deployed above or proximal to the suspect tissue mass 1802 such that the localization element
30 930 forms a type of halo adjacent the suspect tissue mass 1802. This deployment can be
31 referred to as a halo deployment. The localization element 930 can be deployed at one or more

locations adjacent to or abutting the suspect tissue mass 1802 such that the curvature plane 1600 formed by the localization element 930 does not intersect at least a portion of the suspect tissue mass 1802. By deploying the localization element 930 above or away from the suspect tissue mass 1802, the user can ensure that the localization element 930 does not puncture, pierce, or otherwise disturb the suspect tissue mass 1802 or other tissue structures nearby (e.g., nerves, blood vessels, etc.).

[0271] Figs. 18A, 18B, and 18D illustrate that at least a segment of the tracking wire 932 can extend out of the tissue 1800 of the patient while the wire distal end 936 coupled to the localization element 930 is deployed within the tissue 1800 of the patient. The tracking wire 932 can serve as a path or trail informing a surgeon of the path taken by the delivery needle 906 into the patient's tissue 1800. The tracking wire 932 may also serve as an intraoperative guide to the location of the localization element 930.

[0272] A method of locating the suspect tissue mass 1802 using the deployed localization element 930 and the tracking wire 932 can involve periodically pulling on the segment of the tracking wire 932 extending outside of the tissue 1800 of the patient. For example, a surgeon responsible for excising a suspect tissue mass 1802 can pull or tug on the segment of the tracking wire extending outside the tissue 1800 of the patient. The method can further involve palpating or feeling, with at least one finger of a user, an outer tissue layer (e.g., a skin or dermis) above or proximal to a target tissue site while pulling on the segment of the tracking wire 932 extending outside the tissue 1800 of the patient. The method can also involve locating the suspect tissue mass 1802 within the tissue 1800 of the patient based on a tension exhibited by the tracking wire 932 being pulled and the movement felt by the finger of the user on the outside tissue layer.

[0273] If electrocautery is used during surgical dissection, several attributes of the localization element 930 can reduce the risk of damage to the localization element 930 and tracking wire 932 from inadvertent arcing of electrocautery during surgical dissection. Inadvertent passage of current to the tracking wire 932 can be reduced because the polymer jacketing 1132 of the tracking wire serves as an electrical insulator. Also, because of the ribbon-like and hence relatively large surface area the localization element 930, it may be less prone to inadvertent electrocautery damage than a localization wire with a smaller surface area, as the larger surface area is inherently more electrically dissipative.

[0274] Figs. 19A-19C illustrate that the tracking wire 932 can be flexible enough to be easily wound into a coiled segment 1900. The tracking wire 932 is extremely flexible, having a flexibility comparable to surgical suture or household sewing thread. For example, the segment of the tracking wire 932 extending outside the tissue 1800 of the patient (see Fig. 19B) can be easily wound into the coiled segment 1900 and can be taped (e.g., with Tegaderm™ or other biocompatible adhesives, bandages, or dressings) to the skin of the patient (see Fig. 19C). Coiling the tracking wire 932 can reduce the length of the excess segment of the tracking wire 932 extending out of the patient's tissue and can ensure that the excess segment of the tracking wire 932 will not interfere with the patient while wearing normal clothing or dressing or will not prevent the patient from sleeping normally.

[0275] The secure retention properties of the localization element 932 within the tissue site, combined with the suture-like flexibility of the tracking wire can enable a breast patient to go home after placement of the localization element. Prior to this device, current localization wires are too prone to movement and are too stiff to allow the patient to return to home with localization wire in place. This attribute is important because this enables the localization procedure to be de-coupled from the surgical tissue removal procedure (e.g. lumpectomy). This has valuable clinical scheduling implications because with the use of this device, the surgeon no longer has to rely on the localization element to be placed the day of the scheduled surgical excision (e.g. lumpectomy), eliminating delays and operating room scheduling uncertainties, which can be costly to the healthcare system.

[0276] Fig. 20A illustrates that the tracking wire 932 can be fabricated from a cable that is composed of a number of filaments 2000. For example, the cable of the tracking wire 932 can comprise or be composed of a multi-filament (e.g., 19-filament) wire, where each filament is composed of stainless steel, tungsten, or other material. In other variations, the tracking wire 932 can comprise or be composed of between seven and 31 filaments 2000. Each of the filaments 2000 can have a filament diameter. In some variations, the filament diameter can be between approximately 0.025 mm and 0.035 mm. For example, the filament diameter can be approximately 0.030 mm. The tracking wire 132 can also have a wire diameter, the wire diameter can be between approximately 0.150 mm and 0.155 mm. For example, the wire diameter can be approximately 0.152 mm. The cable can alternatively be comprised of polymer fibers which can have an even greater strand count (e.g., up to 100 polymer strands),

1 and can have a different diameter. For example, the wire diameter can alternatively be between
2 approximately 0.125mm and 0.255mm.

3 **[0277]** Fig. 20B illustrates that a distal end of the tracking wire 932 can have a welded tip
4 2002 to capture and join together the plurality of filament ends. Fig. 20C illustrates that a
5 polymer jacketing 1132 can ensheath or otherwise surround the attachment site 1130 of the
6 tracking wire 932. The polymer jacketing 1132 can be made of heat-shrinkable material and
7 can thus conform more closely to the underlying cables of the tracking wire 932. Fig. 20C
8 illustrates a cross-section of the tracking wire 932 prior to the polymer jacketing 1132
9 undergoing the heat-shrinking process, and Fig. 20D is a cross-section illustrating the polymer
10 jacketing 1132 conforming to the tracking wire 932 after undergoing heat-shrinking. The
11 attachment site 1130 can be a site or segment along the tracking wire 923 where one segment
12 of the tracking wire 932 is attached to another segment of the tracking wire 932. For example,
13 the wire distal end 936 can be threaded through the aperture 1108 within the eyelet frame 1106
14 and looped back to align with a more proximal segment of the tracking wire 932. The wire
15 distal end 936 can then be welded to the more proximal segment of the tracking wire 932 and
16 the weld site can be referred to as the attachment site 1130.

17 **[0278]** The polymer jacketing 1132 may surround a portion of the tracking wire 932 in
18 proximity to the attachment site 1130 between the tracking wire 932 and the localization
19 element 930, or the polymer jacketing 1132 may extend a length of the tracking wire 932. The
20 polymer jacketing 1132 can also be used to identify lengths of the tracking wire 932. For
21 example, an additional layer of the polymer jacketing 1132 can be disposed around an
22 approximately 3cm long portion of the tracking wire 932 at a distal end of the wire 932. The
23 additional layer of jacketing 1132 can change the feel of the wire 932 to a surgeon using the
24 tracking wire 932 to locate a target tissue site, identifying to the surgeon when he/she is
25 approaching the distal end of the tracking wire 932. Additional layers of the jacketing 1132
26 may alternatively be disposed at other locations along the tracking wire 932, such as every
27 2cm along its length. Alternatively, one or more metallic ferrules (e.g. stainless steel,
28 tantalum) may be placed at one or more locations along the length of the tracking wire 932
29 (e.g. beneath the polymer jacketing) to signify various levels of proximity to the localization
30 element 930. Other depth marking methods may include printing or the use of different
31 colored polymer segments.

1 [0279] The polymer jacketing 1132 can be composed of one or more polymers, such as
2 polyolefin, polyvinyl chloride (PVC), or a thermoplastic elastomer (e.g., PEBAX[™]). By
3 enclosing at least a portion of the tracking wire 932 in a polymer jacketing 1132, wear and risk
4 of damage to the tracking wire 932 may be reduced. In addition, the polymer jacketing 1132
5 may also reduce snagging or fraying of the tracking wire 932.

6 [0280] Fig. 21 illustrates a method 2100 of operating the tissue localization device 900. The
7 method 2100 can involve removing the tissue localization device 900 from a sterile package in
8 operation 2102. The method 2100 can also involve removing a needle protector covering the
9 delivery needle 906 in operation 2104. The method 2100 can further involve holding the
10 handle 902 of the tissue localization device 900 with one hand and advancing the delivery
11 needle 906, under ultrasonic or radiologic guidance, into the tissue of the patient until the
12 distal end 1400 of the delivery needle 906 is adjacent to a suspect tissue mass (or other target
13 tissue site) 1802 in operation 2106. The method 2100 can further involve translating or
14 pushing the delivery control 904 of the tissue localization device 900 in a first longitudinal
15 direction 1004 using at least one finger of the same hand holding the handle 902 in operation
16 2108.

17 [0281] The method 2100 can further involve translating the localization element 930 of the
18 tissue localization device 900 out of the delivery needle 906 in response to the translation of
19 the delivery control 904 in operation 2110. The localization element 930 can be deployed out
20 of the distal end 1400 of the delivery needle 906 when a delivery port 1118 of a pusher
21 element 920 holding the localization element 930 is advanced out of the needle lumen 918. If
22 the localization element 930 is not deployed in a desired path, the localization element 930 can
23 be retracted into the needle lumen after at least part of the localization element 930 is deployed
24 out of the delivery needle 906. The delivery needle 906 can subsequently be repositioned. For
25 example, the delivery needle 906 can be rotated about a longitudinal axis of the delivery
26 needle 906 (e.g., to achieve a desired deployment path for the localization element 930), and
27 the localization element 930 can be redeployed out of the delivery needle 906 into the tissue.

28 [0282] The method 2100 can further involve surrounding, encircling, or otherwise identifying
29 the suspect tissue mass 1802 using the deployed localization element 930 in operation 2112.
30 The localization element 930 can form into the deployed configuration 942 around the suspect
31 tissue mass 1802 or above the suspect tissue mass 1802. The localization element 930 can

1 automatically disengage or detach from the pusher element 920 when the delivery port 1118 of
2 the pusher element 920 is advanced out of the needle lumen 918.

3 **[0283]** The method 2100 can further involve retracting the beveled distal end 1400 of the
4 delivery needle 906 away from the suspect tissue mass 1802 and exposing the tracking wire
5 932 coupled to the localization element 930 in operation 2114. The method 2100 can also
6 involve coiling and/or cutting the segment of the tracking wire 932 extending out of the tissue
7 of the patient and securing (e.g., using Tegaderm™ or another biocompatible adhesive or
8 dressing) the coiled or cut segment of the tracking wire 932 directly or indirectly to the skin or
9 patient dressing of the patient in operation 2116. By doing so, the tracking wire 932 extending
10 out of the body of the patient can be secured closer to the body of the patient (e.g., flush with
11 the skin surface) such that the tracking wire 932 is not inadvertently pulled or displaced. At
12 this point, the patient can be sent home from the procedure and asked to return the following
13 day to surgically excise the localized tissue mass 1802 from the patient, or the suspect tissue
14 mass 1802 can be excised the same day. The same facility which placed the localization
15 element 930 into the body of the patient can perform the excision procedure such as the
16 lumpectomy.

17 **[0284]** Fig. 22 illustrates a method 2200 for using a tissue localization device to localize
18 tissue. The method 2200 is described with respect to Figs. 23A-G.

19 **[0285]** The method 2200 can include holding the tissue localization device in one hand while
20 holding an ultrasound transducer in another hand (2202). For example, Fig. 23A shows a user
21 holding the tissue localization device 900 in a first (e.g., right) hand 2304 while holding an
22 ultrasound transducer 2302 in a second (e.g., left) hand 2306. The method 2200 is described
23 with respect to use of the tissue localization device 900, the user may alternatively hold the
24 tissue localization device 100 in the first hand 2304. The tissue localization device 900 and
25 ultrasound transducer 2302 can each be operable with a single hand of the user, and sized to fit
26 within a single hand of the user. Thus, the user can concurrently operate both the tissue
27 localization device 900 and the ultrasound transducer 2302.

28 **[0286]** The method 2200 can include advancing, using one hand, a needle tip 2312 of the
29 delivery needle 906 into a tissue 2300 at an offset from a target tissue site 2318 in step 2204.
30 The target tissue site can include a suspect tissue mass such as a tumor or lesion, a volume of
31 tissue immediately surrounding a suspect tissue mass, or any other volume of the tissue 2300.

To reduce a distance the needle 906 travels through the tissue 2300, the needle 906 can be advanced at an angle 2320 from a base of the tissue 2300. For example, if the tissue 2300 is breast tissue of a patient, the needle 906 can be advanced at an angle 2320 from a chest plane of the patient. The angle 2320 may depend on a size of the tissue 2300, a size of the localization element 930, a size of the target tissue site 2318, orientation of the tissue localization device 900 with respect to the tissue, or other factors. For example, the angle 2320 is small enough that the localization element 930 when deployed will not pass through a surface of the tissue 2300, but large enough to reduce, where possible, the distance the needle 906 travels through the tissue 2300.

[0287] The needle tip 2312 can be advanced into the tissue 2300 until positioned in a plane intersecting the target tissue site, a plane proximal to the target tissue site, or a plane distal to the target tissue site, while offset from the target tissue site 2318. The offset can be a threshold distance from an edge of the target tissue site such that the localization element 930 when deployed does not intersect the target tissue site. As shown for example in Fig. 23B, the needle tip 2312 is offset from the target tissue site 2318 by a distance 2314. The offset can be toward a side of the target tissue site 2318 distal to the user of the tissue localization device 900. For example, if the patient is lying on her back while the method 2200 is performed, the needle tip 2312 can be offset toward the patient's dorsal side relative to the target tissue site 2318.

[0288] The offset from the target tissue site can be limited based on a diameter of the localization element 930 when deployed and a size of the target tissue site 2318. For example, the distance 2314 is less than a difference between a diameter of the localization element and a diameter of the target tissue site, enabling the localization element 930 when deployed to radially surround at least part of the target tissue site without intersecting the target tissue site. Alternatively, the needle tip 2312 may be offset from the target tissue site 2318 in a plane proximal or distal to the target tissue site 2318. For example, the needle tip 2312 may be offset proximal to the target tissue site 2318 such that the localization element is deployed as illustrated in Fig. 18B, in which a curvature plane formed by the deployed localization device 930 does not intersect the target tissue site 2318. The user can use the slidable delivery control 904 to determine an expected direction of curvature of the localization element 930. For example, the localization element 930 may curve toward a side of the tissue localization device 900 on which the slidable delivery control 904 is disposed. The slidable delivery control 904

1 can alternatively identify the expected direction of curvature of the localization element 930 in
2 other ways.

3 **[0289]** The method 2200 can further include positioning, using another hand, the ultrasound
4 transducer 2302 proximal to the target tissue site on a surface of the tissue (2206). For
5 example, referring again to Fig. 23B, the ultrasound transducer 2302 is positioned on a surface
6 2316 of the tissue 2300, proximal to the target tissue site 2318. The ultrasound transducer 2302
7 can be positioned on the tissue surface 2316 while the tissue localization device 900 is inserted
8 into the tissue 2300.

9 **[0290]** The method 2200 can further include deploying the localization element 930 out of the
10 delivery needle 906 into the tissue (2208). The localization element 930 can be deployed by
11 pushing a slidable delivery control 904 in a first longitudinal direction along the tissue
12 localization device 900. For example, in Fig. 23C, the slidable delivery control 904 is pushed
13 in a first longitudinal direction 2320 along the tissue localization device 900 (e.g., toward a
14 distal end of the tissue localization device 900) to deploy the localization element 930 from the
15 delivery needle 906. In other variations, the localization element 930 can be deployed in other
16 ways, such as by turning a knob in a first rotational direction. While the localization element
17 930 is being deployed, the ultrasound transducer 2302 can be used to view a position of the
18 localization device 930 in the tissue and verify that the localization device 930 is deployed to
19 surround or otherwise identify the target tissue site 2318 without intersecting the target tissue
20 site.

21 **[0291]** The method 2200 can further include moving the ultrasound transducer 2302 on the
22 tissue surface while deploying the localization element 930 in step 2210. The ultrasound
23 transducer 2302 can be moved on the tissue surface 2316 in a number of different ways,
24 including translation across the surface (e.g., while remaining perpendicular to the surface) and
25 rotation around axes of the ultrasound transducer (e.g., yaw, pitch, or roll rotation). Fig. 23D
26 illustrates an example of the ultrasound transducer 2302 moved on the surface 2316 of the
27 tissue 2300 in a pitch rotation 2322 around a transverse axis of the ultrasound transducer 2302,
28 concurrently with the deployment of the localization element 930. Fig. 23E is a schematic
29 illustrating a side view of the pitch rotation 2322 shown in Fig. 23D. By moving the
30 ultrasound transducer 2302 in the pitch rotation 2322, the position of the localization element
31 930 can be better visualized, for example if the localization element 930 passes out of an

1 image window detectable by the ultrasound transducer 2302, or if the target tissue site 2318
2 partially or fully obscures the localization element 930 from detection by the original position
3 of the ultrasound transducer 2302. Other movements of the ultrasound transducer 2302 may
4 similarly improve visualization of the localization element 930 as the element is deployed.

5 **[0292]** The localization element 930 can continue to be deployed out of the delivery needle
6 906, while the ultrasound transducer 2302 is moved as desired, until the localization element
7 930 has been completely deployed from the delivery needle 906. Fig. 23F illustrates an
8 example of the localization element 930 deployed to at least partially surround the target tissue
9 site 2318. During deployment of the localization element 930, the localization element 930 can
10 be retracted into the delivery needle 906 if, for example, the user desires to change the position
11 of the localization element 930 in the tissue. The localization element 930 can be retracted by
12 moving the slidable delivery control 904 in a second longitudinal direction opposite the first
13 longitudinal direction 2320 (e.g., toward a proximal end of the tissue localization device 900).
14 The localization element 930 may in other variations be retracted by other mechanisms, such
15 as by turning a knob in a second rotational direction opposite the first rotational direction.
16 Retracting the localization element 930 can allow the user to adjust a starting position or
17 direction of curvature of the localization element 930 in the tissue 2300. For example, if the
18 user determines the localization element 930 is deploying along a curvature path different from
19 a desired path, the user can retract the localization element 930 into the delivery needle 906,
20 rotate the tissue localization device 900 around a longitudinal axis, and begin redeploying the
21 localization element 930. The user can alternatively change a position of the needle tip in the
22 tissue 2300. When fully deployed from the delivery needle 906, the localization element 930
23 may automatically disengage or detach from the tissue localization device 900.

24 **[0293]** The method 2200 can further include, in step 2212, removing the delivery needle 906
25 from the tissue 2300 and exposing the tracking wire 932 coupled to the localization element
26 930. Fig. 23G illustrates the tracking wire 932 extending out of the tissue 2300 after the
27 delivery needle 906 is removed from the tissue 2300. The tracking wire 932 can be coiled or
28 cut and secured to the body of the patient.

29 **[0294]** Figs. 24A-G illustrate several variations of the localization element 930. As illustrated
30 in Fig. 24A, the localization element 930 may have a surface 2410 that is substantially smooth.
31 For example, the surface 2410 may be polished by electrochemical, electrolytic, or mechanical

1 polishing. In other variations, the localization element surface 2410 may include an echogenic
2 surface treatment, or a surface roughness to increase the echogenicity of the localization
3 element 930 for improved visualization under ultrasound. Fig. 24B illustrates a surface
4 roughness 2412 achieved by abrasive blasting of the localization element 930, such as
5 sandblasting or bead blasting. Figs. 24C-F illustrate various example patterns 2414 cut into the
6 localization element surface 2410 by laser cutting, laser etching, or other surface cutting
7 mechanism. Figs. 24C-E illustrate that the patterns 2414 can be cut into an exterior surface of
8 the localization element 930, while Fig. 24F illustrates that a pattern can be cut into a side of
9 the localization element 930. Patterns or other echogenic surface treatments may alternatively
10 be applied to an interior surface of the localization element 930, or can be applied to a
11 combination of the exterior, side edge, and interior surfaces of the localization element 930.

12 **[0295]** Other patterns than those shown in Figs. 24C-E may alternatively be cut into the
13 localization element surface 2410, and random lines, dots, or other shapes can be used instead
14 of patterned cuts. For example, a grid of dots may alternatively be cut into the localization
15 element surface 2410. The patterns or shapes may be cut to a depth between 0% and
16 approximately 25% of a thickness of the localization element 930. Each cut into the
17 localization element surface 2410 can be at least as deep into the surface 2410 as it is wide, or
18 can have a depth that is greater than its width. The width of each cut can be, for example,
19 approximately 0.001 to 0.006 inches. The patterns 2414 or random lines, dots, or other
20 structures may alternatively protrude from the localization element surface 2410.

21 **[0296]** As illustrated for example in Fig. 24G, one or more holes 2416 can be created through
22 the localization element 930 (e.g., radially from the interior surface to the exterior surface of
23 the localization element 930). The one or more holes 2416 can be created (e.g. drilled or laser
24 cut) near a distal tip of the localization element 930, as illustrated in the example of Fig. 24G,
25 or can be created at other locations along the localization element 930.

26 **[0297]** As described above with respect to Figs. 11A-B, the tissue localization device 900 can
27 include a pusher element 920 that, in addition to deploying the localization element 930 from
28 the tissue localization device 900, can retract the localization element 930 into the tissue
29 localization device 900. Figs. 25A-B illustrate that the tissue localization device 900 can
30 include a pusher element 2520 configured to deploy the localization element 930 from the
31 tissue localization device 900 but not retract the localization element 930. Fig. 25C illustrates a

1 cross-section of a non-retractable pusher element 2520 shown in Figs. 25A and 25B while
2 inside the delivery needle 906. As shown in Fig. 25C, the distal terminal end of the pusher
3 element 2520 can abut, contact and push against a proximal terminal end 2530 of the
4 localization element 930. Sliding the slidable delivery control 904 toward a distal end of the
5 tissue localization device 900 (e.g., toward the left side of Fig. 25C) can cause the pusher
6 element 2520 to push on the proximal end 2530 of the localization element 930, thereby
7 deploying the localization element 930 from the delivery needle 906. However, sliding the
8 slidable delivery control 904 toward a proximal end of the tissue localization device 900 (e.g.,
9 toward the right side of Fig. 25C) can retract the pusher element 2520 away from the proximal
10 end 2530 of the localization element 930 until the pusher element 2520 is no longer in contact
11 with the localization element 930, without applying force to the localization element 930
12 sufficient to retract the localization element 930 into the tissue localization device 900. The
13 shape of the face of the distal terminal end of the pusher element 2520 can be the inverse of
14 the shape of the face of the proximal terminal end 2530 of the localization element 930. For
15 example, the respective faces can be perpendicular to the respective longitudinal axes, as
16 shown in Fig. 25C.

17 **[0298]** Fig. 26 illustrates that the localization element 930 can include one or more barbs 2610
18 protruding from the localization element 930. The barbs 2610 can limit retractability of the
19 localization element 930, or can help secure the localization element 930 in tissue. The barbs
20 2610 can protrude from some portion or an entire length of the localization element 930. For
21 example, the localization element 930 can include barbs 2610 near a proximal end 2530 of the
22 localization element 930, within an angle 2612 of the proximal end 2530. The angle 2612 may
23 be any percentage of the deployed configuration of the localization element 930. The angle
24 2612 can be between approximately 10% and 25% of the circumference of the deployed
25 configuration of the localization element 930. Alternatively, the angle 2612 can be up to 100%
26 of the deployed configuration of the localization element 930. Although Fig. 26 illustrates the
27 barbs 2610 protruding from an exterior surface of the localization element 930, the barbs can
28 additionally or alternatively protrude from a side edge or interior surface of the localization
29 element 930.

30 **[0299]** The barbs 2610 shown in Fig. 26 can provide resistance against retraction of the
31 localization element 930 after one or more of the barbs 2610 have entered the tissue of a

1 patient. For example, the localization element 930 may be retractable while a distal portion is
2 deployed into the tissue of a patient and the proximal end remains inside the delivery needle
3 906 of the tissue localization device 900. However, the localization element 930 may not be
4 retractable, or may have limited retractability, after a portion of the localization element 930
5 including a barb 2610 has been deployed into the tissue.

6 **[0300]** As shown in Fig. 12, the tissue localization device 900 can include a polymer liner
7 1200 encasing or surrounding at least a portion of the pusher element 920. Fig. 27 illustrates
8 that the tissue localization device 900 can include a stainless steel liner 2700. Other aspects of
9 the tissue localization device 900 can be similar to aspects described with respect to Figs. 9
10 and 12. The stainless steel liner 2700 can be radially between at least part of the localization
11 element 930 and a needle lumen of the delivery needle 906. For example, the stainless steel
12 liner 2700 can be a substantially cylindrical tube having a hollow lumen, and can radially
13 surround at least a portion of the localization element 930. The stainless steel liner 2700
14 optionally can also radially surround at least a portion of the pusher element 920. The delivery
15 needle 906 of the tissue localization device 900 in turn can radially at least part of the stainless
16 steel liner 2700 and the pusher element 920.

17 **[0301]** The stainless steel liner 2700 can completely encircle or radially surround the pusher
18 element 920 such that no contact is made between the external surface of the pusher element
19 920 and the delivery needle 906 as the pusher element 920 is translated longitudinally through
20 the delivery needle 906. In another variation, the liner 2700 can cover a dorsal side of the
21 pusher element 920 or localization element 930 to limit the pusher dorsal side or localization
22 element dorsal side from contacting an inner dorsal surface of the delivery needle 906 as the
23 pusher element 920 and localization element 930 are translated longitudinally. The liner 2700
24 can cover a ventral side of the pusher element 920 or localization element 930 to limit the
25 pusher ventral side or localization element ventral side from contacting an inner ventral
26 surface of the delivery needle 906 as the pusher element 920 and localization element 930 are
27 translated longitudinally.

28 **[0302]** The stainless steel liner 2700 can be slidably translatable within the delivery needle
29 906. The stainless steel liner 2700 and pusher element 920 can be coupled to the slidable
30 delivery control 904, such that translation of the slidable delivery control 904 in a first
31 longitudinal direction (e.g., toward a distal end of the delivery needle 906) causes the stainless

1 steel liner 2700 and localization element 930 to translate toward the distal end of the delivery
2 needle 906. The liner 2700 can accommodate release of the localization element 930 from the
3 pusher element 920. For example, the localization element 930 can be releasable from the liner
4 when a distal end of the pusher element 920 is translated longitudinally beyond the liner. The
5 liner 2700 can have a wall thickness of approximately 0.002 to 0.004 inches.

6 **[0303]** The tissue localization device 900 can further include a spring 2710. The spring 2710
7 can be coupled to a proximal end of the stainless steel liner 2700, and a distal end 2712 of the
8 spring 2710 can push or pull the liner 2700 to slide longitudinally through the delivery needle
9 906 in response to longitudinal translation of the slidable delivery control 904. The spring
10 2710 is configured to compress in response to distal translation of the slidable delivery control
11 904 when a distal end 2712 of the spring 2710 contacts a distal end 2714 of the tissue
12 localization device handle 902. While the spring 2710 compresses, the spring 2710 stops
13 translation of the stainless steel liner 2700 and enables the pusher element 906 to translate
14 relative to the liner 2700. Thus, while the spring 2710 is uncompressed, the pusher element
15 920 and stainless steel liner 2700 can be configured to translate together toward a distal end of
16 the delivery needle 906 in response to a distal translation of the slidable delivery control 904.
17 However, while the spring 2710 is at least partially compressed, the pusher element 920 can be
18 configured to translate toward the distal end of the delivery needle 906, relative to the liner
19 2700, in response to the distal translation of the slidable delivery control 904.

20 **[0304]** Fig. 28A illustrates an example of the stainless steel liner 2700 and spring 2710 prior to
21 compression of the spring 2710, while Fig. 28B illustrates partial compression of the spring
22 2710 allowing translation of the pusher element 920 relative to the liner 2700. As shown in
23 Fig. 28A, the spring 2710 may be short enough to not contact the handle distal end 2714
24 through a portion of a range of motion of the slidable delivery control 904. Sliding the slidable
25 delivery control 904 during that portion of the range of motion may therefore also move the
26 spring 2710 and liner 2700 through the handle 902 and needle 906. Fig. 28B illustrates the
27 distal end 2712 of the spring 2710 in contact with the distal end 2714 of the tissue localization
28 device handle 902. The handle distal end 2714 can have a smaller diameter than the spring
29 2710 to stop translation of the spring distal end 2712. Alternatively, the handle 902 may
30 include a block or other mechanism at the handle distal end 2714 to prevent translation of the
31 spring distal end 2712 toward a distal end of the tissue localization device 900. When the

1 spring distal end 2712 contacts the handle distal end 2714, further distal translation of the
2 slidable delivery control 904 can compress the spring 2710.

3 **[0305]** Because the stainless steel liner 2700 is coupled to the spring 2710, the liner 2700 may
4 not translate through the delivery needle 906 while the spring 2710 is at least partially
5 compressed. However, distal translation of the slidable delivery control 904 may continue to
6 push the pusher element 920 toward the distal end of the delivery needle 906, even after the
7 spring 2710 has started to compress. Accordingly, the pusher element 920 can be translated
8 relative to the liner 2700 while the spring 2710 is at least partially compressed. As shown in
9 Fig. 28B, a portion of the pusher element 920 is pushed out of the liner 2700, exposing a distal
10 end 2716 of the pusher element 920. For example, the relative translation of the pusher
11 element 920 with respect to the liner 2700 can expose a connection point 2802 at which the
12 localization element 930 (not shown in Fig. 28B) can connect to the pusher element 920.
13 Exposing the connection point 2802 enables the localization element 930 to release from the
14 pusher element 920.

15 **[0306]** The liner 2700 can enclose at least a connection point 2802 between the pusher element
16 920 and the localization element 930. Enclosing the connection point 2802 and at least part of
17 the localization element 930 within the liner 2700 can reduce friction between the connection
18 point 2802, localization element 930, and delivery needle 906. In particular, spring force in the
19 localization element 930, which can be configured to deploy from the delivery needle 906 in a
20 curved configuration, can push the proximal end of the localization element 930 against an
21 inner surface of the delivery needle 906. The connection point 2802 may have irregularly
22 shaped surfaces that can further increase friction against the delivery needle 906. By enclosing
23 at least the proximal end of the localization element 930 and the connection point 2802 within
24 the stainless steel liner 2700, the spring force can push the proximal end against the liner 2700
25 rather than the inner surface of the delivery needle 906. Accordingly, the inner surface of the
26 delivery needle 906 can be protected from potential damage from the localization element 930
27 and pusher element 920 sliding against the inner surface of the delivery needle 906, and
28 friction resisting the deployment of the localization element 930 can be reduced. The liner
29 2700 may enclose more of the localization element 930 than the proximal end; for example,
30 the liner 2700 may enclose up to the entire localization element 930 before deployment.

1 [0307] A length of the spring 2710 is based on an amount of the localization element 930
2 enclosed in the stainless steel liner 2700. In particular, the difference between the compressed
3 and uncompressed lengths of the spring 2710 can be at least the length of the localization
4 element 930 and connection point 2802 with the pusher element 920 that are enclosed within
5 the liner 2700. Alternatively, in variations using the pusher element 2520 described with
6 respect to Figs. 25A-C instead of the pusher element 920, the difference between the
7 compressed and uncompressed lengths of the spring may be more or less than the length of the
8 localization element 930 enclosed in the liner 2700.

9 [0308] The tissue localization device 900 can include a retraction lock that prevents or limits
10 retraction of the pusher element 920 into the stainless steel liner 2700 after the localization
11 element 930 has been fully deployed. Limiting retraction of the pusher element 920 can
12 improve the safety of the tissue localization device 900 after deployment of the localization
13 element 930. For example, tissue of the patient may be pinched between the pusher element
14 920 and the liner 2700 or delivery needle 906 as the pusher element 920 is retracted;
15 preventing or limiting the retraction can reduce the likelihood of pinching the tissue of the
16 patient. Furthermore, since the pusher element 920 may extend beyond an end of the delivery
17 needle 906 after complete deployment of the localization element 930, as shown for example
18 in Fig. 28B, the pusher element 920 can additionally or alternatively shield the tip of the
19 delivery needle 906 to reduce a likelihood of the user of the tissue localization device 900
20 injuring themselves or others with the exposed sharp needle tip after the tip is withdrawn from
21 the tissue.

22 [0309] Figs. 29A-J illustrate that the retraction lock can limit retraction of the pusher element
23 920. Figs. 29A and 29B are top-view cross-sections of the tissue localization device handle
24 902 and the pusher plug 926. As described above with respect to Fig. 9, the pusher plug 926
25 can be coupled to the slidable delivery control 904 and pusher element 920, and can transfer
26 longitudinal motion of the slidable delivery control 904 to the pusher element 920. Referring
27 to the example of Figs. 29A-B, the pusher plug 926 can include one or more spring-loaded
28 pins 2912 that can be compressed inside the lumen of the handle 902 (as shown in Fig. 29A)
29 and, as shown in Fig. 29B, can translate or pop into holes 2910 when the pusher plug 926
30 reaches a designated position in the handle 902. For example, the holes 2910 can be placed
31 such that the pins 2912 can pop into the holes 2910 when the localization element 930 is fully

1 deployed and has separated from the pusher element 920. The holes 2910 can be placed such
2 that the pins 2912 pop into the holes when the slidable delivery control 904 is pushed beyond
3 the point at which the localization element 930 separates from the pusher element 920. The
4 spring-loaded pins 2912 may have limited lateral movement, limiting a longitudinal distance
5 the slidable delivery control 904 can be moved after the pins 2912 have locked into the holes
6 2910. The spring-loaded pins 2912 may be compressible to slide back into the handle 902
7 lumen after locking into the holes 2910, permitting translation of the slidable delivery control
8 and retraction of the pusher element 920.

9 **[0310]** Figs. 29C-F are top-view cross-sections of another example of a retraction lock. In the
10 example of Figs. 29C-F, one or more teeth 2916 can be coupled to the pusher plug 926 and
11 one or more locks 2914 can be disposed on an inner surface of the handle 902 lumen. The
12 locks 2914 can be spring-loaded or hinged to permit free movement of the teeth 2916 and
13 pusher plug 926 in a distal direction (e.g., toward the left of Fig. 29C). Figs. 29D and E
14 illustrate progressive rotation of the locks 2914 to permit movement of the teeth 2916 in the
15 distal direction. After the teeth 2916 have moved to a distal side of the teeth 2916, as shown in
16 Fig. 29F, the locks 2914 may rotate back to an initial position to prevent or limit movement of
17 the pusher plug 926 toward the proximal end of the tissue localization device 900 (e.g., toward
18 the right of Fig. 29D). The locks 2914 may be positioned in the handle 902 such that the teeth
19 2916 are distal to the locks 2914 at or beyond the point the localization element 930 is fully
20 deployed. Alternative variations of the teeth 2916 can lock into holes when the pusher plug
21 926 is translated forward to a designated position in the tissue localization device handle 902.
22 The one or more teeth 2916 when locked in the holes can limit proximal translation of the
23 slidable delivery control 904.

24 **[0311]** Figs. 29G-J illustrate a method for using a retraction lock 2920. Fig. 29G is a
25 transverse cross-section of the tissue localization device handle 902 including the retraction
26 lock 2920, and Fig. 29H is a side view of the tissue localization device 900 including the
27 retraction lock 2920. The retraction lock 2920 can be a structure external to the handle 902 and
28 coupled to the handle 902 or the slidable delivery control 904. The retraction lock 2920 can be
29 fabricated from metal (e.g., as a wireform) or fabricated as a polymer (e.g., via molding). The
30 retraction lock 2920 can have one or more arms 2922 configured to lock a position of the
31 slidable delivery control 904 when or after the localization element 930 has been deployed into

1 tissue. The retraction lock 2920 can be rotatably coupled to the slidable delivery control 904
2 and/or the arms 2922 can be elastically deformable from a biased unlocked configuration
3 shown in Figures 29G and 29H to a relaxed or unbiased locked configuration shown in Figures
4 29I and 29J. The arms 2922 can elastically pop and/or rotate into a locked configuration, as
5 shown by arrows 2925. The arms 2922 can slide along an exterior of the handle 902 during
6 longitudinal motion of the slidable delivery control 902, and rotate to lock into the handle 902
7 or pusher plug 926 through holes 2924 in the handle 902. Fig. 29I is a transverse cross-section
8 illustrating the arms 2922 that can be locked into the holes 2924 to lock motion of the slidable
9 delivery control 904, while Fig. 29J is a side view of the tissue localization device 900 with the
10 arms 2922 that can be locked into the holes 2924. The retraction lock 2920 can be spring
11 loaded such that the arms 2922 can automatically pop into the holes 2924, or the retraction
12 lock 2920 can be configured to be manually clamped into the holes 2924 by a user of the
13 device 900.

14 **[0312]** As described above, the tissue localization device 900 can be used with an ultrasound
15 transducer. The user can operate the tissue localization device 900 with one hand and the
16 ultrasound transducer with the other hand, using the ultrasound transducer to monitor
17 deployment of the localization element 930 into tissue.

18 **[0313]** A user may use x-ray to confirm the desired deployment of the localization element
19 930. An example use of the tissue localization device 900 under x-ray monitoring is shown in
20 Figs. 30A-B. Fig. 30A illustrates a top view of a mammographic x-ray setup, which include a
21 bucky 3010 and a support platform 3020. Fig. 30B illustrates a side view of the setup shown in
22 Fig. 30A.

23 **[0314]** Referring to Figs. 30A-B, the bucky 3010 can support tissue 2300 for x-ray imaging.
24 The bucky 3010 can be placed on an opposite side of the tissue 2300 from an x-ray tube
25 delivering x-rays to the tissue 2300. For example, in Fig. 30A, the bucky 3010 is below the
26 tissue 2300, which can be placed below an x-ray tube (not shown). The bucky 3010 may
27 alternatively be aligned in a vertical direction, such that the tissue 2300 is placed horizontally
28 between an x-ray tube and the bucky 3010 for imaging.

29 **[0315]** The support platform 3020 can couple to the bucky 3010 and support the tissue
30 localization device 900. The support platform 3020 can clamp to the bucky 3010, adhere to an
31 adhesive on the bucky 3010, lock into brackets in the bucky 3010, or otherwise removably

couple to the bucky 3010. Alternatively, the support platform 3020 can be integrated with the bucky 3010. In some variations, the support platform 3020 may be adjustable to accommodate different tissue sizes or different angles of entry into the tissue. For example, the support platform 3020 may be hinged to tilt the tissue localization device 900 at an angle from a horizontal plane of the bucky 3010 or to swivel within the horizontal plane. The support platform 3020 may additionally or alternatively have an adjustable height to adjust a distance between the needle of the tissue localization device 900 and the bucky 3010. The platform 3020 may further include supports to maintain a position of the tissue localization device 900. For example, the platform 3020 may include straps to strap the tissue localization device 900 to the platform 3020 or protruding structures placed at sides and ends of the tissue localization device 900 to reduce a likelihood of the device 900 rolling or sliding on the platform 3020.

[0316] As shown in Figs. 30A-B, a user (e.g., a radiologist) may guide a patient until the patient is positioned with tissue of interest 2300 placed between the bucky 3010 and an x-ray tube. After initial x-ray imaging of the tissue 2300 to identify a target tissue site in the tissue 2300, the user may guide the needle of the tissue localization device 900 into the tissue 2300 and deploy the localization element 930 into the tissue. To ensure correct positioning of the localization element 930 in the tissue, the user may repeat x-ray imaging of the tissue 2300 before, during, or after deployment of the localization element 930. The user may leave the patient's side during imaging to reduce the user's exposure to the x-rays. The support platform 3020 can therefore support the tissue localization device 900 in the user's absence, maintaining the positioning of the device and localization element 930 during imaging and improving comfort for the patient. After the localization element 930 has been deployed to the user's satisfaction, the user can withdraw the tissue localization device 900 from the tissue 2300 and expose the tracking wire 932, as described above.

[0317] Figs. 31A-B illustrate that a tissue localization wire 3100 can be used to localize tissue without (as shown) or with the localization element 930 and tracking wire 932. The tissue localization wire 3100 can be deployed from a handle / pusher / slidable delivery control based needle system similar to that described by the tissue localization device 100 or 900, or can be configured to be advanced manually directly through a delivery needle (e.g., without use of the pusher element 920 and/or slidable delivery control 904).

1 **[0318]** The tissue localization wire 3100 can include a localization element 3130 and a
2 tracking wire 3132. The localization element 3130 can be a flexible wire or length of metal,
3 polymer, or combinations thereof. The localization element 3130 can be configured to take on
4 an arcuate or curvilinear configuration when deployed into tissue, an example of which is
5 shown in Fig. 31A. Alternatively, the localization element 3130 can be configured to take on a
6 linear or bent configuration when deployed, as shown for example in Fig. 31B. The
7 localization element 3130 can alternatively take on different shapes. The localization element
8 3130 is stiff enough to pierce into tissue of a patient and maintain a relative position in the
9 tissue as the patient moves, but flexible enough to collapse, prior to deployment, into a
10 delivery needle (e.g., the delivery needle 906 of the tissue localization device 900).

11 **[0319]** The highly flexible suture-like tracking wire 3132 can be coupled to the localization
12 element 3130 and configured to aid deployment of the tracking wire 3132 from a delivery
13 needle. For example, if the tissue localization wire 3100 is configured for manual deployment
14 from a delivery needle, the tracking wire 3132 can be configured to push the localization
15 element 3130 out of the delivery needle when the tracking wire 3132 is pushed. After the
16 localization element 3130 has been deployed into tissue of a patient, at least a portion of the
17 tracking wire 3132 may extend from the tissue to serve as a path or trail guiding a surgeon to
18 the target tissue site. The exposed portion of the tracking wire 3132 is flexible enough to be
19 able to be configured to be wrapped or tied and secured to the surface of the skin by, for
20 example, adhesive dressing. For example, the exposed portion of the tracking wire 3132 may
21 be wrapped into a circle approximately 1-5cm in diameter and taped by surgical tape to the
22 patient.

23 **[0320]** The tracking wire 3132 can be a flexible wire including one or more multi-strand
24 filaments encased in a polymer jacketing, such as the polymer jacketing 1132. However, the
25 tracking wire 3132 can alternatively include any metal, metal alloy, polymer, or combinations
26 thereof, and can be a single-stranded wire, a multi-stranded wire, a coil spring similar to
27 flexible guidewires used in cardiovascular applications, encased in a jacketing, or not encased
28 in a jacketing, or polymer (e.g. fluoropolymer) coated. The tracking wire 3132 can have a
29 substantially circular cross-section, or can have cross-sections of other shapes (e.g., square).
30 The tracking wire 3132 can have sufficient column strength to facilitate deployment (e.g., by
31 pushing) of the localization element 3130 out the end of a delivery needle, but possess

sufficient flexibility to be easily coiled without yielding so that it may be comfortably secured to tissue surface of a patient. The tracking wire 3132 may be between approximately 0.010 and 0.025 inches in diameter. When the tracking wire 3132 is configured to be pushed by hand through a delivery needle, the tracking wire 3132 may have a sufficiently large diameter and/or be sufficiently column strength to prevent buckling or “S”ing within the needle lumen. The tracking wire may be longer or shorter than shown in Figs. 31A-B.

[0321] It can be difficult to perform wire localization procedures or other ultrasound guided breast procedures because the tissue is particularly mobile or unstable, as in the instance of a fatty-replaced breast. The instability and mobility of the fatty tissue can make it challenging for even a skilled clinician to place an ultrasound-guided needle to the desired location. The mere act of mildly pressing an ultrasound on the skin near the target tissue can cause the target tissue to move out of the field of view of the ultrasound transducer. The forces involved in placing and advancing a needle through this tissue can cause additional unwanted mobility of the tissue, further compromising ultrasound visualization.

[0322] Fig. 32A illustrates a tissue stabilization device, such as a securement or stabilization sling 3200 for stabilizing tissue to be penetrated by the tissue localization device 900 or 100 and imaged by an ultrasound probe. The sling 3200 can stabilize breast tissue and provide support for such tissue as the delivery needle 906 of the tissue localization device 900 or 100 or other ultrasound-guided devices (e.g., percutaneous biopsy, fine needle aspiration, and percutaneous marker devices) The sling 3200 can stabilize the mobile tissue and allow for needle penetration as well as positioning of the ultrasound probe for realtime ultrasound guidance

[0323] The sling 3200 can comprise a polymeric material, a fabric, or combinations thereof. The sling 3200 can comprise an iodophor-impregnated layer or coating (e.g., 3M™ Ioban™ incise drapes or coverings), for example to cover the skin and minimize the risk of surgical site infection.. The sling 3200 can comprise an anti-microbial layer that does not contain iodine, for example, for patients who have an iodine allergy. The anti-microbial layer can comprise silver nanoparticles. The sling 3200 (or other stabilization devices herein described) can be used to support mobile tissue such as, but not limited to, breast tissue (as stated above), abdominal tissue, leg tissue, upper arm tissue, buttock tissue, or scrotal tissue. The sling 3200 can comprise one or more biocompatible adhesive-backed layers that adhere to the skin to

1 provide an appropriate ultrasound interface and a grip on the skin to maintain traction on the
2 tissue to decrease tissue mobility.

3 **[0324]** The sling 3200 can deliver a support pressure 3202 against the breast surface. The
4 support pressure 3200 can have a directional component toward the medial direction of the
5 wearer of the sling. The tissue localization device 900 or 100 can be inserted, as shown by
6 arrow 3204, into the breast not through and medial to the sling (as shown) or through the sling.
7 The insertion direction of the tissue localization device can have a directional component
8 toward the lateral side of the wearer of the sling. The support pressure 3200 can prevent or
9 minimize breast motion or deformation during the insertion and other use of the tissue
10 localization device 900 or 100 in the breast.

11 **[0325]** Figure 32B illustrates that a patch 3206 can be placed on the breast, for example at the
12 site of insertion of the tissue localization device 900 or 100 through the skin. The patch 3206
13 can be placed on the breast before insertion of the tissue localization device 3200 through the
14 patch 3206 and the breast skin. The patch 3206 can be above or below the sling 3200. The
15 patch 3206 can be attached to the sling 3200. The patch 3206 can be made from the same or
16 different material as the sling 3200. The patch 3206 can have one or more iodophor-
17 impregnated layers or coating (e.g., 3M™ Ioban™ incise drapes or coverings), for example to
18 cover the skin and minimize the risk of surgical site infection.

19 **[0326]** The tissue stabilization devices can be comprised of a clamshell type device, with one
20 side of the clamshell having a rigid surface and the other side of the clamshell comprised of a
21 yoke (e.g. two prongs) that suspend a segment of flexible adhesive polymer sheeting such as
22 Ioban™ between the two prongs. The hinge of the clamshell may be spring loaded to “close”
23 the clamshell and/or may have a releaseable ratcheting mechanism to hold the clamshell closed
24 around the breast tissue at an adjustable (e.g., by further ratcheting or release of the
25 ratchet) level of compression. The clamshell can be closed around the breast. The interior
26 surface of the rigid side of the clamshell can contact the patient’s breast and form a stable
27 platform against which the breast can be further stabilized by the opposing side of the
28 clamshell. The opposing surface of the clamshell may be comprised of an adhesive-backed
29 polymer sheeting whose inner surface is pressed against the breast so that the breast tissue can
30 be mildly compressed between the clamshell device. The clamshell can be applied to the breast
31 in a number of directions (e.g. cranio-caudal, medial-lateral, etc.) as desired by the clinician.

1 The rigid clamshell can be configured to have a pad (e.g. foam) to aid in comfort during
2 compression. After the clamshell has been applied to the breast, an ultrasound probe and
3 needle may be placed into or onto either the exposed skin or the adhesive film region of the
4 stabilization device.

5 **[0327]** The two opposing sides can be not hinged as in the clamshell configuration described
6 above. For example, the two roughly parallel surfaces can be advanced towards each via one
7 or more ratchet or screw-feed mechanisms until the desired level of compression around the
8 breast is achieved. As with the previously described clamshell device, one compression surface
9 can be relatively rigid while the opposing compression surface can be comprised of flexible
10 film suspended by the prongs of a yoke. The rigid side need not be a flat plane but can also be
11 curved (e.g. slightly concave) to provide additional comfort and stabilization. In use, the two
12 opposing sides can be brought together around the breast in the desired orientation and the
13 breast tissue is thus stabilized for use in an ultrasound guided percutaneous procedure. At the
14 end of the procedure the stabilization device can be released and the film removed.

15 **[0328]** The film region need not comprise the entire compression surface. Both sides can be
16 rigid and there can be window regions within the compression surfaces. The window regions
17 may or may not contain film sheeting depending on the size of the window. In some instances
18 windows in the compression surfaces will not be needed (e.g., in some large breasted patients)
19 and the skin can be sufficiently accessed in areas where there are not compression surfaces.
20 Both compression sides can be comprised of the film yoke to optimize accessibility of the
21 breast to the needle or ultrasound probe.

22 **[0329]** Each of the individual variations described and illustrated herein has discrete
23 components and features which may be readily separated from or combined with the features
24 of any of the other variations. Modifications may be made to adapt a particular situation,
25 material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or
26 scope of the disclosure.

27 **[0330]** Methods recited herein may be carried out in any order of the recited events that is
28 logically possible, as well as the recited order of events. Moreover, additional elements of the
29 method or operations may be provided or elements of the method or operations may be
30 eliminated to achieve the desired result.

1 [0331] Furthermore, where a range of values is provided, every intervening value between the
2 upper and lower limit of that range and any other stated or intervening value in that stated
3 range is encompassed within the disclosure. Also, any optional feature of the inventive
4 variations described may be set forth and claimed independently, or in combination with any
5 one or more of the features described herein.

6 [0332] All existing subject matter mentioned herein (e.g., publications, patents, patent
7 applications and hardware) is incorporated by reference herein in its entirety except insofar as
8 the subject matter may conflict with that of the present disclosure (in which case what is
9 present herein shall prevail). The referenced items are provided solely for their disclosure prior
10 to the filing date of the present application. Nothing herein is to be construed as an admission
11 that the disclosure is not entitled to antedate such material by virtue of prior disclosure.

12 [0333] Reference to a singular item, includes the possibility that there are plural of the same
13 items present. More specifically, as used herein and in the appended claims, the singular forms
14 “a,” “an,” “said” and “the” include plural referents unless the context clearly dictates
15 otherwise. It is further noted that the claims may be drafted to exclude any optional element.
16 As such, this statement is intended to serve as antecedent basis for use of such exclusive
17 terminology as “solely,” “only” and the like in connection with the recitation of claim
18 elements, or use of a “negative” limitation. Unless defined otherwise, all technical and
19 scientific terms used herein have the same meaning as commonly understood by one of
20 ordinary skill in the art to which this disclosure belongs.

21 [0334] This disclosure is not intended to be limited to the scope of the particular forms set
22 forth, but is intended to cover alternatives, modifications, and equivalents of the variations or
23 variations described herein. Further, the scope of the disclosure fully encompasses other
24 variations that may become obvious to those skilled in the art in view of this disclosure.

25

CLAIMS

We claim:

1. A tissue localization device, comprising:
 - a handle comprising a slidable delivery control;
 - a delivery needle extending out from the handle and comprising a needle lumen;
 - a pusher element partially within the needle lumen;
 - a localization element detachably held by the pusher element when in the needle lumen, wherein at least part of the localization element is configured to exit the delivery needle in response to a translation of the slidable delivery control in a first longitudinal direction; and
 - a liner partially encasing the pusher element, wherein the liner is positioned in between a portion of the pusher element and the needle lumen, wherein a portion of the localization element is encased by the pusher element and the liner.
2. The device of claim 1, wherein the liner comprises a metallic material.
3. The device of any of the preceding claims 1-2, further comprising a tracking wire coupled to the localization element, wherein at least a segment of the tracking wire is configured to be coiled or tied into a loop.
4. The device of claim 3, wherein at least part of the tracking wire is covered by a polymer jacketing.
5. The device of any of the preceding claims 1-4, wherein the slidable delivery control comprises a first interface surface and a second interface surface, wherein the handle comprises a proximal end and a distal end, and wherein the first interface surface is upwardly concave when viewed from the proximal end to the distal end and the second interface surface is upwardly concave when viewed from the distal end to the proximal end.
6. The device of any of the preceding claims 1-5, wherein the handle comprises a handle dorsal side, a handle ventral side opposite the handle dorsal side, and wherein the localization element is configured to curve in a direction of the handle dorsal side when deployed.

- 1 7. The device of claim 6, wherein the handle has an elongate slot along the handle dorsal
2 side, wherein the slidable delivery control is coupled to the pusher element via a
3 fastener extending through the elongate slot.
- 4 8. The device of any of the preceding claims 1-7, wherein the pusher element comprises a
5 delivery port at a distal end of the pusher element and wherein at least part of the
6 localization element is detachably held within the delivery port when the localization
7 element is within the needle lumen.
- 8 9. The device of any of the preceding claims 1-8, wherein the pusher element has a pusher
9 dorsal side, a pusher ventral side, and a pusher distal end, wherein the pusher distal end
10 is sloped and forms an obtuse angle with the pusher ventral side.
- 11 10. The device of any of the preceding claims 1-9, wherein the localization element
12 comprises an echogenic surface treatment.
- 13 11. The device of any of the preceding claims 1-10, further comprising a spring coupled to
14 a proximal end of the liner, wherein the spring is configured to be at least partially
15 compressed when the pusher element is translated toward a distal end of the delivery
16 needle relative to the liner in response to a translation of the slidable delivery control in
17 the first longitudinal direction.
- 18 12. A tissue localization device, comprising:
19 a handle comprising a delivery control;
20 a delivery needle extending out from the handle, wherein the delivery needle comprises
21 a needle lumen;
22 a pusher element configured to slidably translate within the needle lumen and coupled
23 to the delivery control, wherein the pusher element comprises a delivery port; and
24 a localization element, wherein the localization element comprises an interlocking
25 framework and wherein the interlocking framework is configured to interlock with
26 the delivery port of the pusher element when at least part of the pusher element
27 resides within the needle lumen and the interlocking framework is configured to
28 release from the delivery port when the delivery port exits the needle lumen.
- 29 13. The device of claim 12, wherein the interlocking framework of the localization element
30 comprises an eyelet frame and a shoulder portion, and wherein the eyelet frame is

1 detachably positioned within the delivery port when the localization element is within
2 the needle lumen.

3 14. The device of any of the preceding claims 12-13, further comprising a tracking wire
4 coupled to the localization element, wherein at least a segment of the tracking wire is
5 configured to be coiled or tied into a loop.

6 15. The device of any of the preceding claims 12-14, wherein the handle comprises a
7 handle dorsal side, a handle ventral side opposite the handle dorsal side, and wherein
8 the localization element is configured to curve in a direction of the handle dorsal side
9 when deployed.

10 16. A method for localizing tissue using a tissue localization device, the method
11 comprising:
12 advancing a needle tip of a delivery needle of the tissue localization device into a tissue
13 to an offset location near a target tissue site of the tissue;
14 positioning an ultrasound transducer proximal to the target tissue site on a tissue
15 surface of the tissue;
16 deploying a localization element comprising an echogenic surface treatment out of the
17 delivery needle into the tissue; and
18 moving the ultrasound transducer on the tissue surface while deploying the localization
19 element.

20 17. The method of claim 16, wherein deploying the localization element out of the delivery
21 needle into the tissue comprises pushing a slidable delivery control in a first
22 longitudinal direction along a handle of the tissue localization device.

23 18. The method of any of the preceding claims 16-17, further comprising compressing a
24 spring coupled to a proximal end of a liner partially encasing a pusher element coupled
25 to the slidable delivery control prior to deploying the localization element out of the
26 delivery needle.

27 19. The method of any of the preceding claims 16-18, further comprising retracting the
28 localization element into the delivery needle after at least part of the localization
29 element is deployed out of the delivery needle.

- 1 20. The method of any of the preceding claims 16-19, further comprising deploying the
2 localization element out of the delivery needle into a curved configuration, wherein the
3 curved configuration radially surrounds at least a portion of the target tissue site.
- 4 21. A tissue localization device, comprising:
5 a handle comprising a slidable delivery control;
6 a delivery needle extending out from the handle and comprising a needle lumen;
7 a pusher element partially within the needle lumen,
8 wherein the delivery needle comprises a beveled distal end,
9 wherein the beveled distal end comprises a needle tip, sharpened edges, and a
10 rounded edge; and
11 a localization element detachably held by the pusher element when in the needle
12 lumen, wherein at least part of the localization element is configured to exit the
13 beveled distal end of the delivery needle in response to a translation of the slidable
14 delivery control in a first longitudinal direction.
- 15 22. The device of claim 21, further comprising a liner positioned in between a portion of
16 the pusher element and the needle lumen.
- 17 23. The device of claim 22, wherein the liner comprises a metallic material.
- 18 24. The device of any of the preceding claims 21-23, further comprising a tracking wire
19 coupled to the localization element, wherein at least a segment of the tracking wire is
20 configured to be coiled or tied into a loop.
- 21 25. The device of claim 24, wherein at least part of the tracking wire is covered by a
22 polymer jacketing.
- 23 26. The device of claim 24, wherein at least part of the tracking wire is configured to align
24 secant with respect to a curve formed by the localization element when the localization
25 element and the at least part of the tracking wire are deployed.
- 26 27. The device of claim 24, wherein the tracking wire is coupled to the localization
27 element at a point in between a midpoint and a terminus of the localization element.
- 28 28. The device of any of the preceding claims 21-27, further comprising a spring coupled
29 to a proximal end of the liner, wherein the spring is configured to be at least partially
30 compressed when the pusher element is translated toward a distal end of the delivery

1 needle relative to the liner in response to a translation of the slidable delivery control in
2 the first longitudinal direction.

3 29. The device of any of the preceding claims 21-28, wherein the slidable delivery control
4 comprises a first interface surface and a second interface surface, wherein the handle
5 comprises a proximal end and a distal end, and wherein the first interface surface is
6 upwardly concave when viewed from the proximal end to the distal end and the second
7 interface surface is upwardly concave when viewed from the distal end to the proximal
8 end.

9 30. The device of any of the preceding claims 21-29, wherein the handle comprises a
10 handle dorsal side, a handle ventral side opposite the handle dorsal side, and wherein
11 the localization element is configured to curve in a direction of the handle dorsal side
12 when deployed.

13 31. The device of claim 30, wherein the handle has an elongate slot along the handle dorsal
14 side, wherein the slidable delivery control is coupled to the pusher element via a
15 fastener extending through the elongate slot.

16 32. The device of any of the preceding claims 21-31, wherein the pusher element
17 comprises a delivery port and at least a part of the localization element is detachably
18 held within the delivery port, wherein the localization element is configured to
19 automatically detach from the pusher element when at least part of the delivery port is
20 translated out of the delivery needle.

21 33. The device of claim 32, wherein the delivery port has a distal port side, a proximal port
22 side, and a port base, wherein the distal port side forms an acute angle with the port
23 base when viewed from a lateral side of the tissue localization device.

24 34. The device of any of the preceding claims 21-33, wherein the pusher element has a
25 pusher dorsal side, a pusher ventral side, and a pusher distal end, wherein the pusher
26 distal end is sloped and forms an obtuse angle with the pusher ventral side.

27 35. The device of claim 34, wherein the pusher distal end forms an acute angle with the
28 pusher dorsal side when viewed from a lateral side of the tissue localization device.

29 36. The device of claim 34, wherein the localization element comprises an eyelet frame, a
30 shoulder portion, and a narrow portion in between the eyelet frame and the shoulder

1 portion, and wherein the pusher distal end is configured to contact the shoulder portion
2 when the pusher element is translated in the first longitudinal direction.

3 37. The device of any of the preceding claims 21-36, wherein the localization element
4 comprises an echogenic surface treatment.

5 38. The device of claim 37, wherein the echogenic surface treatment comprises at least one
6 of a surface roughness and a pattern cut into a surface of the localization element.

7 39. The device of any of the preceding claims 21-38, wherein the delivery needle
8 comprises a needle dorsal side and a needle ventral side opposite the needle dorsal side,
9 wherein at least part of the rounded edge is along the needle dorsal side.

10 40. The device of claim 39, wherein the delivery needle comprises a needle dimple
11 proximal to the rounded edge along the needle dorsal side.

12 41. The device of any of the preceding claims 21-40, wherein the localization element has
13 a first configuration when within the needle lumen and the localization element has a
14 second configuration when deployed out of the delivery needle.

15 42. The device of claim 41, wherein the second configuration of the localization element is
16 a circular shape.

17 43. The device of any of the preceding claims 21-42, wherein the localization element
18 comprises a locator distal end and wherein the locator distal end comprises at least two
19 element tips.

20 44. The device of any of the preceding claims 21-43, wherein the localization element has
21 a curvature plane, wherein at least part of the localization element is curved in
22 alignment with the curvature plane, and another part of the localization element is
23 curved out of the curvature plane.

24 45. The device of any of the preceding claims 21-44, wherein the handle comprises a
25 handle lumen and at least part of the pusher element is configured to slidably translate
26 within the handle lumen.

27 46. A tissue localization device, comprising:

28 a handle comprising a slidable delivery control;

29 a delivery needle extending out from the handle and comprising a needle lumen;

30 a pusher element partially within the needle lumen;

1 a localization element detachably held by the pusher element when in the needle
2 lumen, wherein at least part of the localization element is configured to exit the
3 delivery needle in response to a translation of the slidable delivery control in a first
4 longitudinal direction; and
5 a flexible tracking wire coupled to the localization element, wherein the flexible
6 tracking wire is covered by a polymer jacketing and wherein at least a segment of
7 the flexible tracking wire is configured to be coiled or tied into a loop.

8 47. The device of claim 46, further comprising a liner positioned in between a portion of
9 the pusher element and the needle lumen.

10 48. The device of claim 47, wherein the liner comprises a metallic material.

11 49. The device of any of the preceding claims 47-48, further comprising a spring coupled
12 to a proximal end of the liner, wherein the spring is configured to be at least partially
13 compressed when the pusher element is translated toward a distal end of the delivery
14 needle relative to the liner in response to a translation of the slidable delivery control in
15 the first longitudinal direction.

16 50. The device of any of the preceding claims 46-49, wherein at least part of the tracking
17 wire is configured to align secant with respect to a curve formed by the localization
18 element when the localization element and the at least part of the tracking wire are
19 deployed.

20 51. The device of any of the preceding claims 46-50, wherein the tracking wire is coupled
21 to the localization element at a point in between a midpoint and a terminus of the
22 localization element.

23 52. The device of any of the preceding claims 46-51, wherein the slidable delivery control
24 comprises a first interface surface and a second interface surface, wherein the handle
25 comprises a proximal end and a distal end, and wherein the first interface surface is
26 upwardly concave when viewed from the proximal end to the distal end and the second
27 interface surface is upwardly concave when viewed from the distal end to the proximal
28 end.

29 53. The device of any of the preceding claims 46-52, wherein the handle comprises a
30 handle dorsal side, a handle ventral side opposite the handle dorsal side, and wherein

1 the localization element is configured to curve in a direction of the handle dorsal side
2 when deployed.

3 54. The device of claim 53, wherein the handle has an elongate slot along the handle dorsal
4 side, wherein the slidable delivery control is coupled to the pusher element via a
5 fastener extending through the elongate slot.

6 55. The device of any of the preceding claims 46-54, wherein the pusher element
7 comprises a delivery port and at least a part of the localization element is detachably
8 held within the delivery port, wherein the localization element is configured to
9 automatically detach from the pusher element when at least part of the delivery port is
10 translated out of the delivery needle.

11 56. The device of claim 55, wherein the delivery port has a distal port side, a proximal port
12 side, and a port base, wherein the distal port side forms an acute angle with the port
13 base when viewed from a lateral side of the tissue localization device.

14 57. The device of any of the preceding claims 46-56, wherein the pusher element has a
15 pusher dorsal side, a pusher ventral side, and a pusher distal end, wherein the pusher
16 distal end is sloped and forms an obtuse angle with the pusher ventral side.

17 58. The device of claim 57, wherein the pusher distal end forms an acute angle with the
18 pusher dorsal side when viewed from a lateral side of the tissue localization device.

19 59. The device of claim 57, wherein the localization element comprises an eyelet frame, a
20 shoulder portion, and a narrow portion in between the eyelet frame and the shoulder
21 portion, and wherein the pusher distal end is configured to contact the shoulder portion
22 when the pusher element is translated in the first longitudinal direction.

23 60. The device of any of the preceding claims 46-59, wherein the localization element
24 comprises an echogenic surface treatment.

25 61. The device of claim 60, wherein the echogenic surface treatment comprises at least one
26 of a surface roughness and a pattern cut into a surface of the localization element.

27 62. The device of any of the preceding claims 46-61, wherein the delivery needle
28 comprises a beveled distal end, a needle dorsal side, and a needle ventral side opposite
29 the needle dorsal side, wherein at least part of the beveled distal end is defined by a
30 rounded edge along the needle dorsal side.

- 1 63. The device of claim 62, wherein the delivery needle comprises a needle dimple
2 proximal to the rounded edge along the needle dorsal side.
- 3 64. The device of any of the preceding claims 46-63, wherein the localization element has
4 a first configuration when within the needle lumen and the localization element has a
5 second configuration when deployed out of the delivery needle.
- 6 65. The device of claim 64, wherein the second configuration of the localization element is
7 a circular shape.
- 8 66. The device of any of the preceding claims 46-65, wherein the localization element
9 comprises a locator distal end and wherein the locator distal end comprises at least two
10 element tips.
- 11 67. The device of any of the preceding claims 46-66, wherein the localization element has
12 a curvature plane, wherein at least part of the localization element is curved in
13 alignment with the curvature plane, and another part of the localization element is
14 curved out of the curvature plane.
- 15 68. The device of any of the preceding claims 46-67, wherein the handle comprises a
16 handle lumen and at least part of the pusher element is configured to slidably translate
17 within the handle lumen.
- 18 69. A tissue localization device, comprising:
19 a delivery needle comprising a needle lumen;
20 a pusher element configured to slidably translate within the needle lumen; and
21 a localization element detachably held by the pusher element, wherein the localization
22 element is configured to slidably translate within the needle lumen in response to
23 the translation of the pusher element, and
24 wherein at least part of the localization element is covered by a blue-oxide finish.
- 25 70. The device of claim 69, further comprising a liner positioned in between a portion of
26 the pusher element and the needle lumen.
- 27 71. The device of claim 70, wherein the liner comprises a metallic material.
- 28 72. The device of any of the preceding claims 69-71, further comprising a tracking wire
29 coupled to the localization element, wherein at least a segment of the tracking wire is
30 configured to be coiled or tied into a loop.

- 1 73. The device of claim 72, wherein at least part of the tracking wire is covered by a
2 polymer jacketing.
- 3 74. The device of claim 72, wherein at least part of the tracking wire is configured to align
4 secant with respect to a curve formed by the localization element when the localization
5 element and the at least part of the tracking wire are deployed.
- 6 75. The device of claim 72, wherein the tracking wire is coupled to the localization
7 element at a point in between a midpoint and a terminus of the localization element.
- 8 76. The device of any of the preceding claims 69-75, further comprising a spring coupled
9 to a proximal end of the liner, wherein the spring is configured to be at least partially
10 compressed when the pusher element is translated toward a distal end of the delivery
11 needle relative to the liner in response to a translation of the slidable delivery control in
12 the first longitudinal direction.
- 13 77. The device of any of the preceding claims 69-76, further comprising a handle coupled
14 to the delivery needle, wherein the handle has a handle lumen, and wherein at least part
15 of the pusher element is configured to be positioned within the handle lumen.
- 16 78. The device of claim 77, further comprising a slidable delivery control coupled to the
17 pusher element, wherein the slidable delivery control comprises a first interface surface
18 and a second interface surface, wherein the handle comprises a proximal end and a
19 distal end, and wherein the first interface surface is upwardly concave when viewed
20 from the proximal end to the distal end and the second interface surface is upwardly
21 concave when viewed from the distal end to the proximal end.
- 22 79. The device of any of the preceding claims 77, wherein the handle comprises a handle
23 dorsal side, a handle ventral side opposite the handle dorsal side, and wherein the
24 localization element is configured to curve in a direction of the handle dorsal side when
25 deployed.
- 26 80. The device of claim 79, wherein the handle has an elongate slot along the handle dorsal
27 side, wherein the slidable delivery control is coupled to the pusher element via a
28 fastener extending through the elongate slot.
- 29 81. The device of any of the preceding claims 69-80, wherein the pusher element
30 comprises a delivery port and at least a part of the localization element is detachably
31 held within the delivery port, wherein the localization element is configured to

1 automatically detach from the pusher element when at least part of the delivery port is
2 translated out of the delivery needle.

3 82. The device of claim 81, wherein the delivery port has a distal port side, a proximal port
4 side, and a port base, wherein the distal port side forms an acute angle with the port
5 base when viewed from a lateral side of the tissue localization device.

6 83. The device of any of the preceding claims 69-82, wherein the pusher element has a
7 pusher dorsal side, a pusher ventral side, and a pusher distal end, wherein the pusher
8 distal end is sloped and forms an obtuse angle with the pusher ventral side.

9 84. The device of claim 83, wherein the pusher distal end forms an acute angle with the
10 pusher dorsal side when viewed from a lateral side of the tissue localization device.

11 85. The device of claim 84, wherein the localization element comprises an eyelet frame, a
12 shoulder portion, and a narrow portion in between the eyelet frame and the shoulder
13 portion, and wherein the pusher distal end is configured to contact the shoulder portion
14 when the pusher element is translated in the first longitudinal direction.

15 86. The device of any of the preceding claims 69-85, wherein the localization element
16 comprises an echogenic surface treatment.

17 87. The device of claim 86, wherein the echogenic surface treatment comprises at least one
18 of a surface roughness and a pattern cut into a surface of the localization element.

19 88. The device of any of the preceding claims 69-87, wherein the delivery needle is
20 defined by a beveled distal end.

21 89. The device of claim 88, wherein the delivery needle comprises a needle dimple
22 proximal to the beveled distal end.

23 90. The device of any of the preceding claims 69-89, wherein the localization element has
24 a first configuration when within the needle lumen and the localization element has a
25 second configuration when deployed out of the delivery needle.

26 91. The device of claim 90, wherein the second configuration of the localization element is
27 a circular shape.

28 92. The device of any of the preceding claims 69-91, wherein the localization element
29 comprises a locator distal end and wherein the locator distal end comprises at least two
30 element tips.

1 93. The device of any of the preceding claims 69-92, wherein the localization element has
2 a curvature plane, wherein at least part of the localization element is curved in
3 alignment with the curvature plane, and another part of the localization element is
4 curved out of the curvature plane.

5 94. A tissue localization system, comprising:

6 a tissue localization device configured to be held by only one hand of a user, the tissue
7 localization device comprising:

8 a handle comprising a slidable delivery control,

9 a delivery needle extending from the handle and including a pusher element
10 coupled to the slidable delivery control, and

11 a localization element detachably held by the pusher element,

12 wherein the pusher element is configured to deploy at least part of the

13 localization element from the delivery needle into a tissue in

14 response to a translation of the slidable delivery control; and

15 an ultrasound transducer configured to be held by only one hand of a user and moved

16 on a surface of the tissue while the localization element is deployed into the tissue.

17 95. The device of claim 94, further comprising a liner positioned in between a portion of
18 the pusher element and the needle lumen.

19 96. The device of claim 95, wherein the liner comprises a metallic material.

20 97. The device of any of the preceding claims 94-96, further comprising a tracking wire
21 coupled to the localization element, wherein at least a segment of the tracking wire is
22 configured to be coiled or tied into a loop.

23 98. The device of claim 97, wherein at least part of the tracking wire is covered by a
24 polymer jacketing.

25 99. The device of any of the preceding claims 94-98, wherein the handle has a handle
26 lumen, and wherein at least part of the pusher element is configured to be positioned
27 within the handle lumen.

28 100. A method of localizing tissue using a tissue localization device, comprising:
29 positioning a needle tip of a delivery needle of the tissue localization device adjacent to
30 a target tissue site, wherein the delivery needle extends from a handle of the tissue
31 localization device;

1 translating a slidable delivery control of the tissue localization device in a first
2 longitudinal direction;
3 translating a localization element of the tissue localization device in the first
4 longitudinal direction through a needle lumen of the delivery needle in response to
5 the translation of the slidable delivery control; and
6 deploying the localization element out of the delivery needle, wherein at least part of
7 the localization element curves when deployed.

8 101. The method of claim 100, wherein the needle tip is positioned at an offset location
9 adjacent to a target tissue site.

10 102. The method of claim 101, wherein the offset location is separated from the target
11 tissue site by less than a difference between a diameter of the localization element and
12 a diameter of the target tissue site.

13 103. The method of any of the preceding claims 100-102, wherein translating the slidable
14 delivery control comprises holding the handle using one hand of a user and pushing the
15 slidable delivery control in the first longitudinal direction.

16 104. The method of any of the preceding claims 100-103, further comprising retracting the
17 localization element into the delivery needle after at least part of the localization
18 element is deployed out of the delivery needle.

19 105. The method of claim 104, wherein retracting the localization element comprises
20 translating a slidable delivery control in a second longitudinal direction opposite the
21 first longitudinal direction.

22 106. The method of any of the preceding claims 100-105, further comprising viewing a
23 position of the localization element in tissue using an ultrasound transducer.

24 107. The method of claim 106, further comprising moving the ultrasound transducer on a
25 tissue surface proximal to the target tissue site while deploying the localization
26 element.

27 108. The method of any of the preceding claims 100-107, further comprising:
28 retracting the needle tip of the delivery needle away from the target tissue site;
29 exposing a tracking wire coupled to the localization element when retracting the needle
30 tip of the delivery needle, wherein at least a segment of the tracking wire extends
31 out of the tissue of a patient; and

1 coiling the segment of the tracking wire extending out of the tissue of the patient into a
2 loop.

3 109. The method of claim 108, further comprising adhering the tracking wire coiled into
4 the loop to a dermis of the patient.

5 110. The method of any of the preceding claims 100-109, further comprising translating
6 the localization element out of the delivery needle via a pusher element coupled to the
7 slidable delivery control.

8 111. The method of claim 110, wherein deploying the localization element out of the
9 delivery needle comprises translating a delivery port of the pusher element out of the
10 needle lumen, wherein the delivery port detachably holds at least part of the
11 localization element.

12 112. The method of claim 110, further comprising at least partially compressing a spring
13 coupled to a proximal end of a liner partially encasing the pusher element prior to
14 deploying the localization element out of the delivery needle.

15 113. A method of localizing tissue using a tissue localization device, comprising:
16 positioning a needle tip of a delivery needle of the tissue localization device adjacent to
17 a target tissue site, wherein the delivery needle extends from a handle of the tissue
18 localization device;
19 translating a localization element of the tissue localization device in the first
20 longitudinal direction through a needle lumen of the delivery needle; and
21 deploying the localization element out of the delivery needle into a curved
22 configuration having a curvature plane in the tissue of the patient, wherein the
23 curvature plane does not intersect any portion of a suspect tissue mass in the tissue
24 of the patient.

25 114. The method of claim 113, wherein translating the localization element comprises
26 translating a slidable delivery control of the tissue localization device in a first
27 longitudinal direction, wherein the slidable delivery control is coupled to a pusher
28 element detachably holding the localization element.

29 115. The method of claim 114, wherein translating the slidable delivery control comprises
30 holding the handle using one hand of a user and pushing the slidable delivery control in
31 the first longitudinal direction.

1 116. The method of claim 114, wherein deploying the localization element out of the
2 delivery needle comprises translating a delivery port of the pusher element out of the
3 needle lumen, wherein the delivery port detachably holds at least part of the
4 localization element.

5 117. The method of claim 114, further comprising at least partially compressing a spring
6 coupled to a proximal end of a liner partially encasing the pusher element prior to
7 deploying the localization element out of the delivery needle.

8 118. The method of any of the preceding claims 113-117, wherein the needle tip is
9 positioned at an offset location adjacent to a target tissue site.

10 119. The method of claim 118, wherein the offset location is separated from the target
11 tissue site by less than a difference between a diameter of the localization element and
12 a diameter of the target tissue site.

13 120. The method of any of the preceding claims 113-119, further comprising retracting the
14 localization element into the delivery needle after at least part of the localization
15 element is deployed out of the delivery needle.

16 121. The method of claim 120, wherein retracting the localization element comprises
17 translating a slidable delivery control in a second longitudinal direction opposite the
18 first longitudinal direction.

19 122. The method of any of the preceding claims 113-121, further comprising viewing a
20 position of the localization element in tissue using an ultrasound transducer.

21 123. The method of claim 122, further comprising moving the ultrasound transducer on a
22 tissue surface proximal to the target tissue site while deploying the localization
23 element.

24 124. The method of any of the preceding claims 113-123, further comprising:
25 retracting the needle tip of the delivery needle away from the target tissue site;
26 exposing a tracking wire coupled to the localization element when retracting the needle
27 tip of the delivery needle, wherein at least a segment of the tracking wire extends
28 out of the tissue of a patient; and
29 coiling the segment of the tracking wire extending out of the tissue of the patient into a
30 loop.

1 125. The method of claim 124, further comprising adhering the tracking wire coiled into
2 the loop to a dermis of the patient.

3 126. A method of locating a suspect tissue mass within a tissue of a patient, comprising:
4 pulling, periodically, on a segment of a tracking wire extending outside a body of the
5 patient, wherein a distal end of the tracking wire is coupled to a localization
6 element deployed within the tissue of the patient;

7 palpating a dermis covering the tissue of the patient while pulling on the segment of the
8 tracking wire; and
9 locating the suspect tissue mass based on a tension exhibited by the tracking wire being
10 pulled and a movement felt by the palpating.

11 127. The method of claim 126, further comprising viewing a position of the localization
12 element in the tissue using an ultrasound transducer.

13 128. The method of any of the preceding claims 126-127, wherein the localization
14 element comprises an echogenic surface treatment.

15 129. The method of claim 128, wherein the echogenic surface treatment comprises at
16 least one of a surface roughness and a pattern cut into a surface of the localization
17 element.

18 130. A tracking wire to locate a target tissue site, comprising:

19 a wire having a wire distal segment and a wire proximal segment opposite the wire
20 distal segment, wherein at least part of the wire distal segment is secured to part of
21 another segment of the wire in between the wire distal segment and the wire
22 proximal segment at an attachment site along the wire,

23 wherein the segment of the wire in between the wire distal segment and the
24 attachment site is formed as a loop; and

25 a polymer jacketing covering at least part of the wire.

26 131. The tracking wire of claim 130, wherein the attachment site is covered by the
27 polymer jacketing.

28 132. The tracking wire of any of the preceding claims 130-131, wherein the wire
29 comprises stainless steel.

30 133. The tracking wire of any of the preceding claims 130-132, wherein at least a portion
31 of the wire is configured to be deployed into the tissue of a patient.

- 1 134. The tracking wire of any of the preceding claims 130-133, wherein a segment of the
2 wire in between the wire distal segment and the wire proximal segment is configured to
3 be tied into a knot around a portion of a localization element.
- 4 135. A method of preparing a tissue localization assembly, comprising:
5 threading a wire distal segment of a wire through an aperture of a localization element;
6 securing at least part of the wire distal segment to part of another segment of the wire
7 in between the wire distal segment and the wire proximal segment at an attachment
8 site along the wire,
9 wherein the segment of the wire in between the wire distal segment and the
10 attachment site forms a loop; and
11 covering at least part of the wire with a polymer jacketing.
- 12 136. The method of claim 135, further comprising covering the attachment site with the
13 polymer jacketing.
- 14 137. The method of any of the preceding claims 135-136, further comprising inserting a
15 segment of the wire into a lumen of a pusher element of a tissue localization device.
- 16 138. The method of claim 137, further comprising positioning at least a part of the
17 localization element coupled to the wire into a delivery port of the pusher element.
- 18 139. The method of claim 138, further comprising slidably translating the pusher element
19 into a lumen of a delivery needle of the tissue localization device.
- 20 140. A tissue localization device, comprising:
21 a handle comprising a rotatable delivery control;
22 a delivery needle extending out from the handle; and
23 a localization element in a first configuration when within the delivery needle, wherein
24 the localization element is configured to be deployed into a second configuration
25 out of the delivery needle when the delivery control is rotated in a first rotational
26 direction, and wherein a part of the localization element is detachably held by a
27 distal end of a pusher element configured to longitudinally translate within the
28 delivery needle.
- 29 141. The device of claim 140, wherein the localization element is configured to be
30 retracted into the delivery needle when the rotatable delivery control is rotated in a
31 second rotational direction.

- 1 142. The device of any of the preceding claims 140-141, further comprising a sound-
2 generating element configured to produce sound when at least part of the localization
3 element exits the delivery needle.
- 4 143. The device of claim 142 wherein the sound-generating element comprises a spring.
- 5 144. The device of any of the preceding claims 140-143, further comprising a tactile
6 feedback-generating element, wherein the tactile feedback-generating element is
7 configured to produce tactile feedback at least part of the time when the localization
8 element exits the delivery needle.
- 9 145. The device of any of the preceding claims 140-144, wherein the rotatable delivery
10 control comprises a knob.
- 11 146. The device of any of the preceding claims 140-145, wherein the handle comprises an
12 orientation arch comprising a curvature and the localization element is configured to
13 curve in a direction matching the curvature of the orientation arch when deployed.
- 14 147. The device of any of the preceding claims 140-146, further comprising a tracking
15 wire coupled to the localization element.
- 16 148. The device of any of the preceding claims 140-147, further comprising a drive pipe
17 within a handle lumen of the handle, wherein the drive pipe is configured to rotate
18 within the handle lumen in response to a rotation of the rotatable delivery control.
- 19 149. The device of any of the preceding claims 140-148, further comprising a car element
20 coupled to the pusher element, wherein the car element is configured to translate
21 longitudinally within a pipe lumen of the drive pipe in response to the rotation of the
22 drive pipe.
- 23 150. A method of localizing tissue using a tissue localization device, comprising:
24 positioning a delivery needle of the tissue localization device adjacent to a target tissue
25 site;
26 rotating a rotatable delivery control of the tissue localization device in a first rotational
27 direction;
28 translating a localization element of the tissue localization device in a first longitudinal
29 direction through a needle lumen of the delivery needle in response to the rotation
30 of the rotatable delivery control; and

1 deploying the localization element out of the delivery needle adjacent to or at the target
2 tissue site, wherein at least part of the localization element curves when deployed.

3 151. The method of claim 150, further comprising holding a handle of the tissue
4 localization device using one hand of a user and rotating the rotatable delivery control
5 in the first rotational direction using at least one finger of the same hand of the user.

6 152. The method of any of the preceding claims 150-151, further comprising retracting the
7 localization element into the delivery needle after at least part of the localization
8 element is deployed out of the delivery needle.

9 153. The method 152, further comprising holding a handle of the tissue localization device
10 using one hand of a user and rotating the rotatable delivery control in a second
11 rotational direction using at least one finger of the same hand of the user to retract the
12 localization element into the delivery needle.

13 154. The method of any of the preceding claims 150-153, wherein translating the
14 localization element in the first longitudinal direction further comprises translating a
15 pusher element within a drive pipe of the tissue localization device in response to the
16 rotation of the rotatable delivery control.

17 155. The method of claim 154, wherein the pusher element comprises a tactile feedback-
18 generating element and the method further comprises creating tactile feedback by the
19 tactile feedback-generating element when the localization element is partially deployed
20 out of a distal tip of the delivery needle.

21 156. The method of claim 154, wherein the pusher element comprises a sound-generating
22 element and the method further comprises generating a sound using the sound-
23 generating element when the localization element is partially deployed out of a distal
24 tip of the delivery needle.

25 157. The method of claim 154, wherein translating the pusher element within the drive
26 pipe further comprises translating a car element coupled to the pusher element, wherein
27 the car element is longitudinally translated within the drive pipe in response to a
28 rotation of the drive pipe.

29 158. The method of claim 154, wherein the drive pipe is rotated in response to a rotation
30 of the rotatable delivery control.

1 159. The method of any of the preceding claims 150-158, further comprising retracting a
2 distal tip of the delivery needle away from the target tissue site.

3 160. The method of claim 159, further comprising exposing a tracking wire coupled to the
4 localization element when retracting the distal tip of the delivery needle.

5 161. A tissue localization device, comprising:

6 a delivery needle comprising a needle lumen;

7 a localization element slidably translatable within the needle lumen, wherein the

8 localization element is detachable from the delivery needle; and

9 a liner in the needle lumen, wherein the liner is slidably translatable relative to the

10 needle lumen and is radially between the needle lumen and at least part of the

11 localization element.

12 162. The device of claim 161, further comprising:

13 a handle comprising a slidable delivery control, wherein the delivery needle extends
14 from the handle;

15 a pusher element partially within the needle lumen, wherein the localization element is
16 detachably held by the pusher element and wherein the localization element is
17 detachable from the pusher element in response to a translation of the slidable
18 delivery control in a first longitudinal direction.

19 163. The device of claim 162, wherein the localization element is releasable from the liner
20 when a distal end of the pusher element is translated longitudinally beyond the liner.

21 164. The device of any of the preceding claims 162-163, wherein the slidable delivery
22 control comprises a first interface surface and a second interface surface, wherein the
23 handle comprises a proximal end and a distal end, and wherein the first interface
24 surface is upwardly concave when viewed from the proximal end to the distal end and
25 the second interface surface is upwardly concave when viewed from the distal end to
26 the proximal end.

27 165. The device of any of the preceding claims 162-164, wherein the handle comprises a
28 handle dorsal side, a handle ventral side opposite the handle dorsal side, and wherein
29 the localization element is configured to curve in a direction of the handle dorsal side
30 when deployed.

- 1 166. The device of claim 165, wherein the handle has an elongate slot along the handle
2 dorsal side, wherein the slidable delivery control is coupled to the pusher element via a
3 fastener extending through the elongate slot.
- 4 167. The device of any of the preceding claims 162-166, wherein the pusher element
5 comprises a delivery port at a distal end of the pusher element and wherein at least part
6 of the localization element is detachably held within the delivery port when the
7 localization element is within the needle lumen.
- 8 168. The device of any of the preceding claims 162-167, wherein the pusher element has a
9 pusher dorsal side, a pusher ventral side, and a pusher distal end, wherein the pusher
10 distal end is sloped and forms an obtuse angle with the pusher ventral side.
- 11 169. The device of any of the preceding claims 162-168, further comprising a spring
12 coupled to a proximal end of the liner, wherein the spring is configured to be at least
13 partially compressed when the pusher element is translated toward a distal end of the
14 delivery needle relative to the liner in response to a translation of the slidable delivery
15 control in the first longitudinal direction.
- 16 170. The device of any of the preceding claims 161-169, wherein the localization element
17 comprises an echogenic surface treatment.
- 18 171. The device of any of the preceding claims 161-170, further comprising a tracking
19 wire coupled to the localization element, wherein at least a segment of the tracking
20 wire is configured to be coiled or tied into a loop.
- 21 172. A tissue localization device, comprising:
22 a delivery needle comprising a needle lumen;
23 a pusher element slidably translatable within the needle lumen, wherein the pusher
24 element comprises a delivery port; and
25 a localization element comprising an interlocking framework, wherein the interlocking
26 framework is interlockable with the delivery port when at least part of the pusher
27 element resides within the needle lumen, and wherein the interlocking framework
28 is releasable from the delivery port when the delivery port exits the needle lumen.
- 29 173. The device of claim 172, further comprising a handle comprising a delivery control,
30 wherein the delivery needle extends out from the handle and wherein the delivery
31 control is coupled to the pusher element.

174. The device of any of the preceding claims 172-173, wherein the interlocking framework of the localization element comprises an eyelet frame and a shoulder portion, and wherein the eyelet frame is detachably positioned within the delivery port when the localization element is within the needle lumen.
175. The device of any of the preceding claims 172-174, further comprising a tracking wire coupled to the localization element, wherein at least a segment of the tracking wire is configured to be coiled or tied into a loop.
176. A method for using a tissue localization device, comprising:
- translating a localization element of the tissue localization device in a first longitudinal direction through a needle lumen of a delivery needle of the tissue localization device;
 - deploying a localization element of the tissue localization device out of the delivery needle into tissue;
 - retracting the localization element into the needle lumen after at least part of the localization element is deployed out of the delivery needle;
 - repositioning the tip of the delivery needle; and
 - redeploying the localization element out of the delivery needle into the tissue.
177. The method of claim 176, further comprising deploying the localization element out of the delivery needle into a curved configuration having a first curvature plane and redeploying the localization element out of the delivery needle into the curved configuration having a second curvature plane.
178. The method of any of the preceding claims 176-177, further comprising:
- positioning an ultrasound transducer on the tissue; and
 - moving the ultrasound transducer on the tissue while translating the localization element.
179. The method of any of the preceding claims 176-178, further comprising:
- advancing a needle tip of the delivery needle into the tissue to an offset from a target tissue site of the tissue; and
 - deploying the localization element out of the delivery needle by pushing a slidable delivery control of the tissue localization device in the first longitudinal direction along a handle of the tissue localization device.

1 180. The method of claim 179, further comprising compressing a spring coupled to a
2 proximal end of a liner partially encasing a pusher element coupled to the slidable
3 delivery control prior to deploying the localization element out of the delivery needle.
4

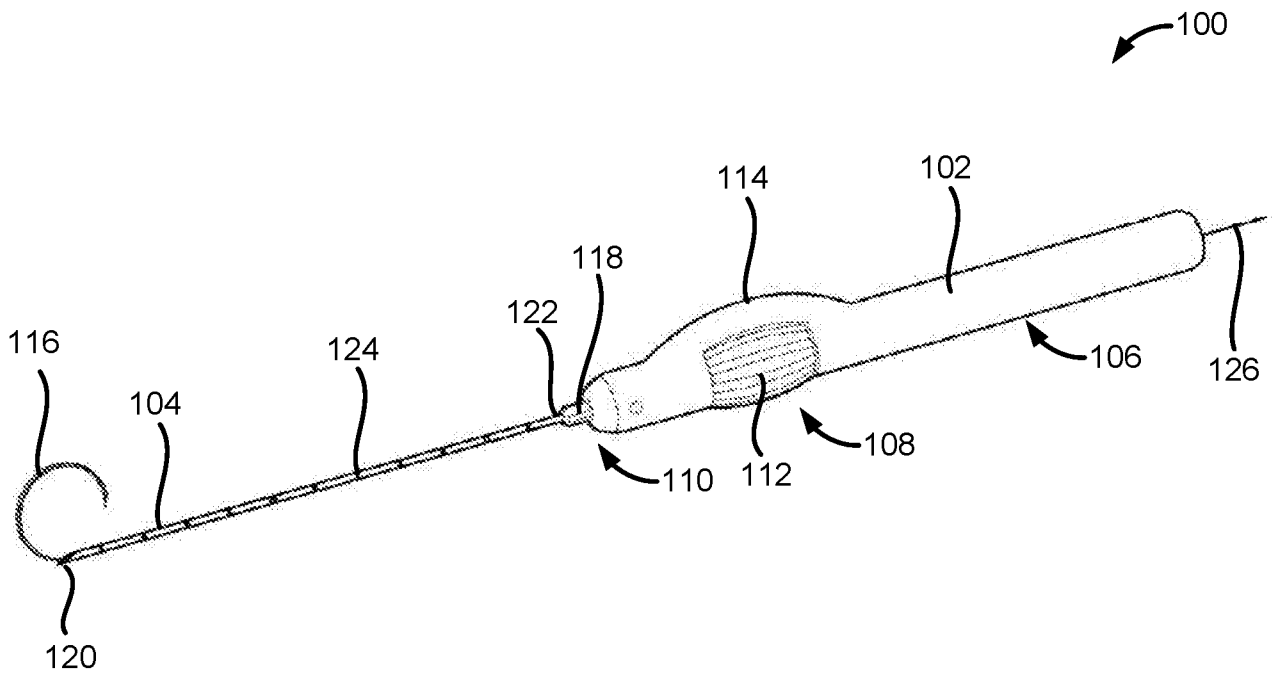


FIG. 1A

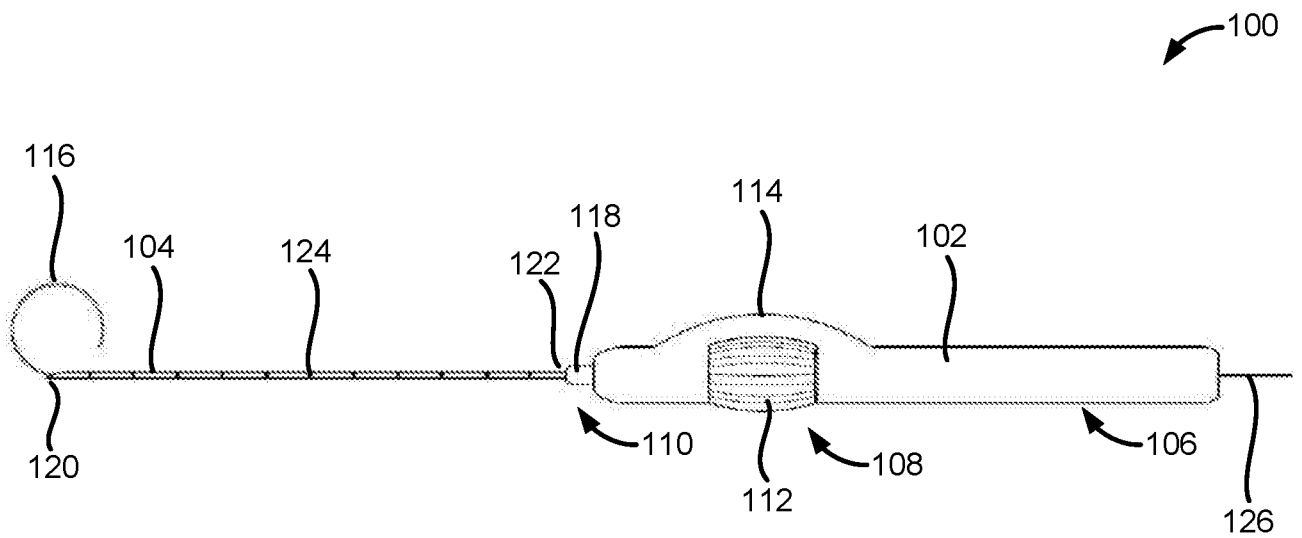


FIG. 1B

100

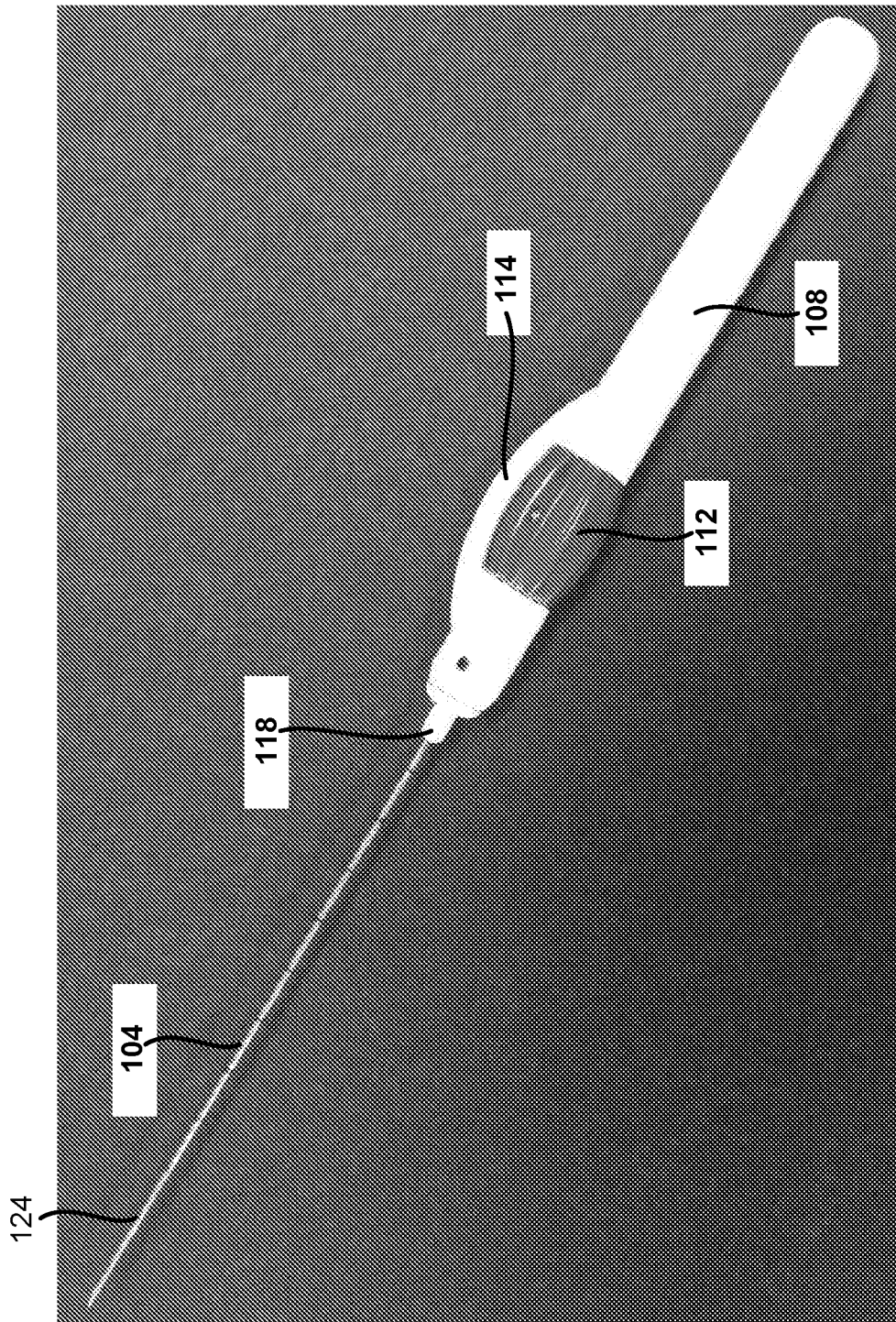
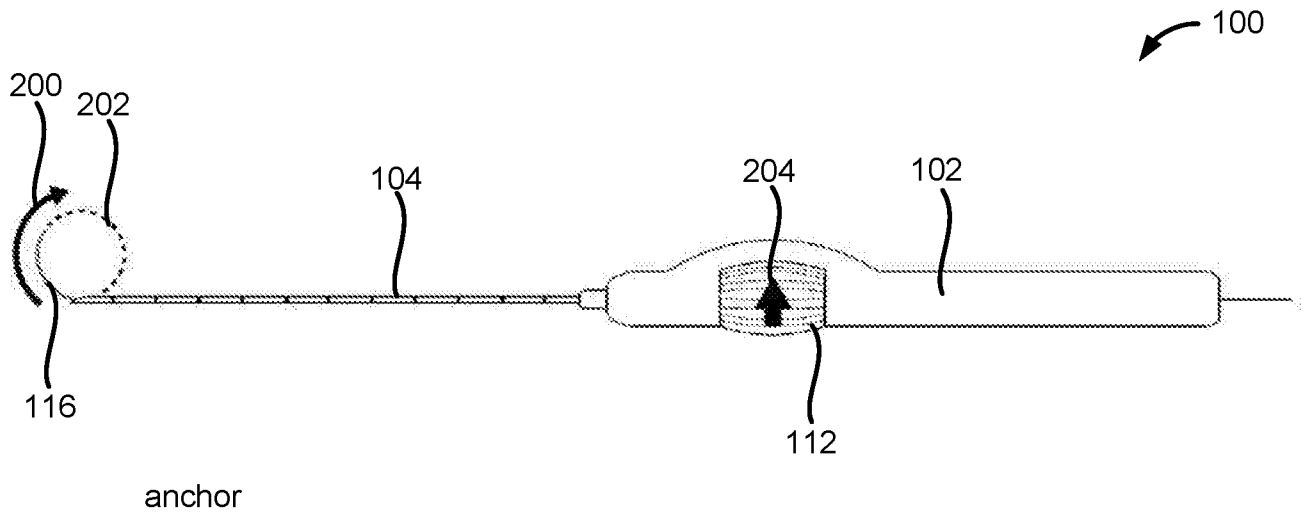
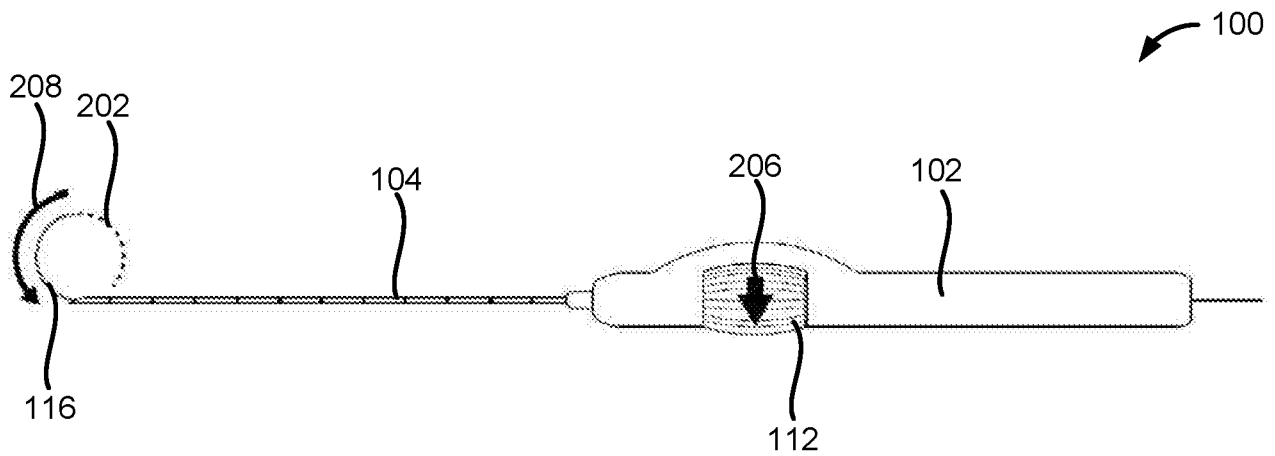


FIG. 1C

**FIG. 2A****FIG. 2B**

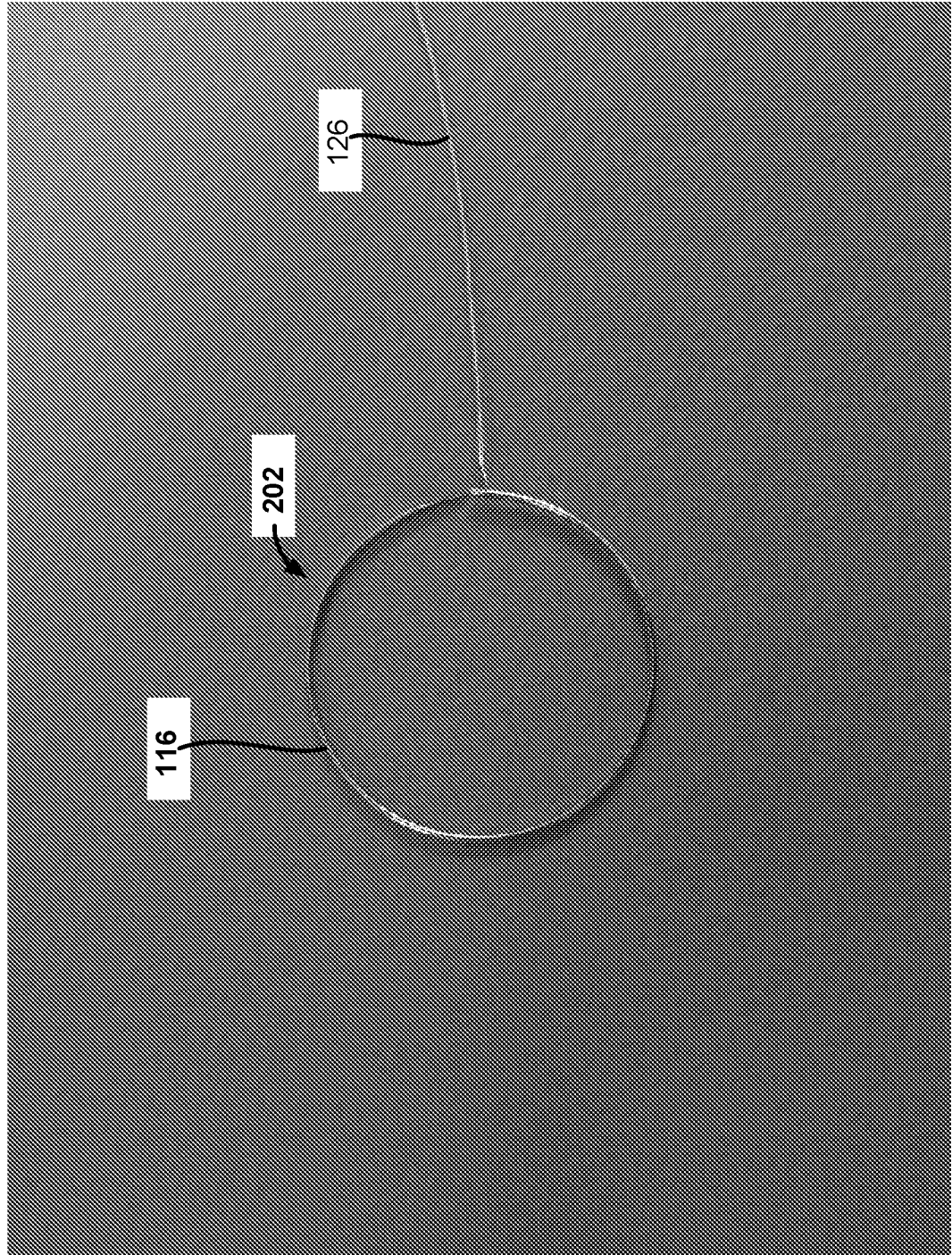
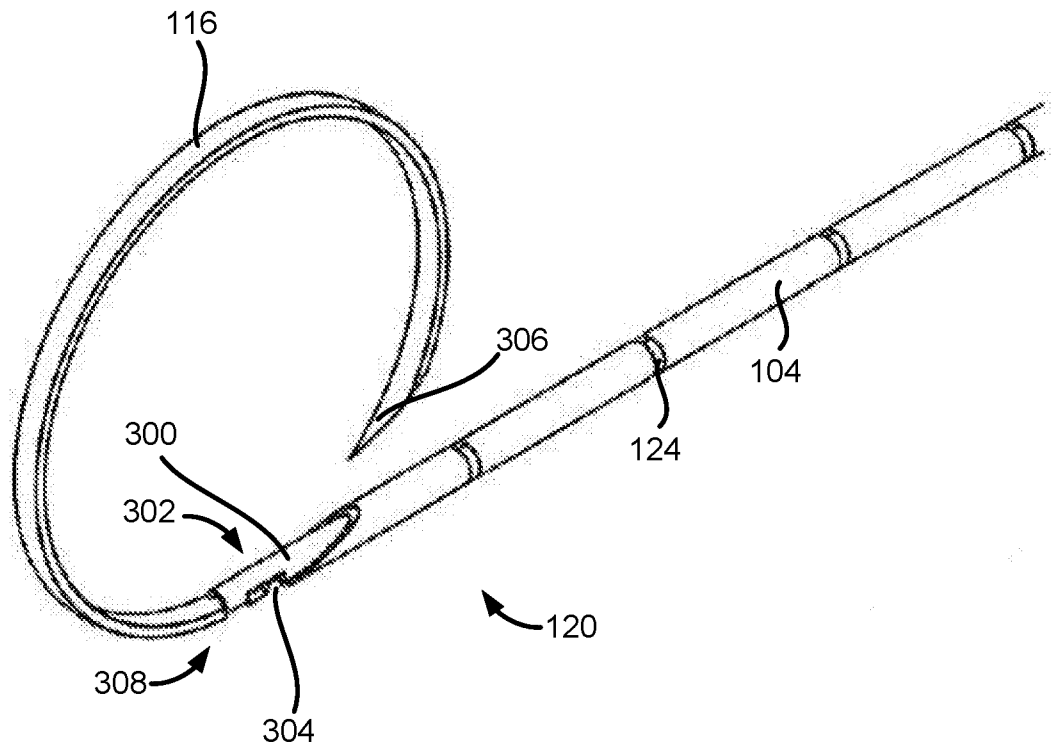
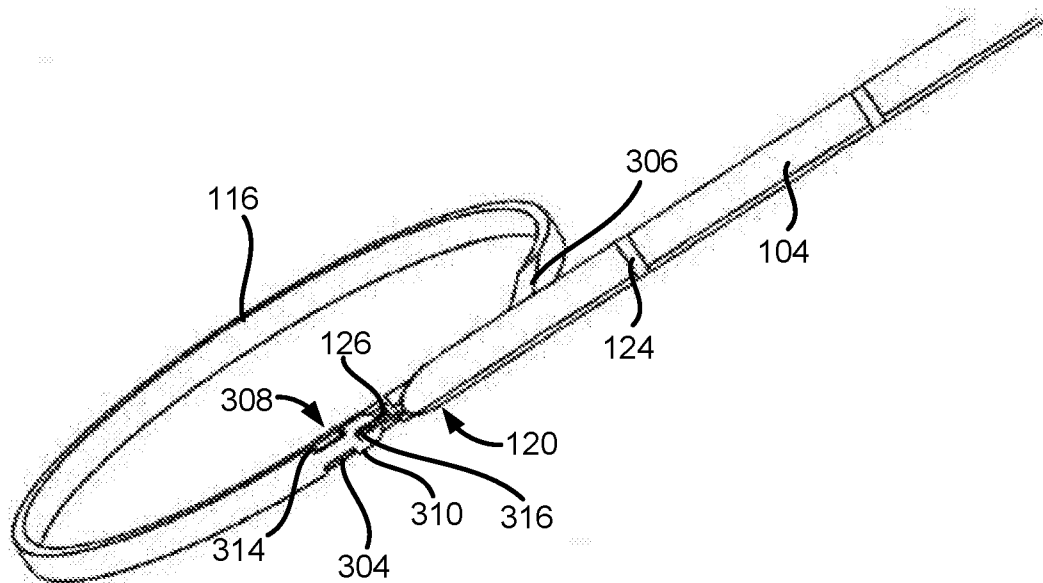


FIG. 2C

**FIG. 3A****FIG. 3B**

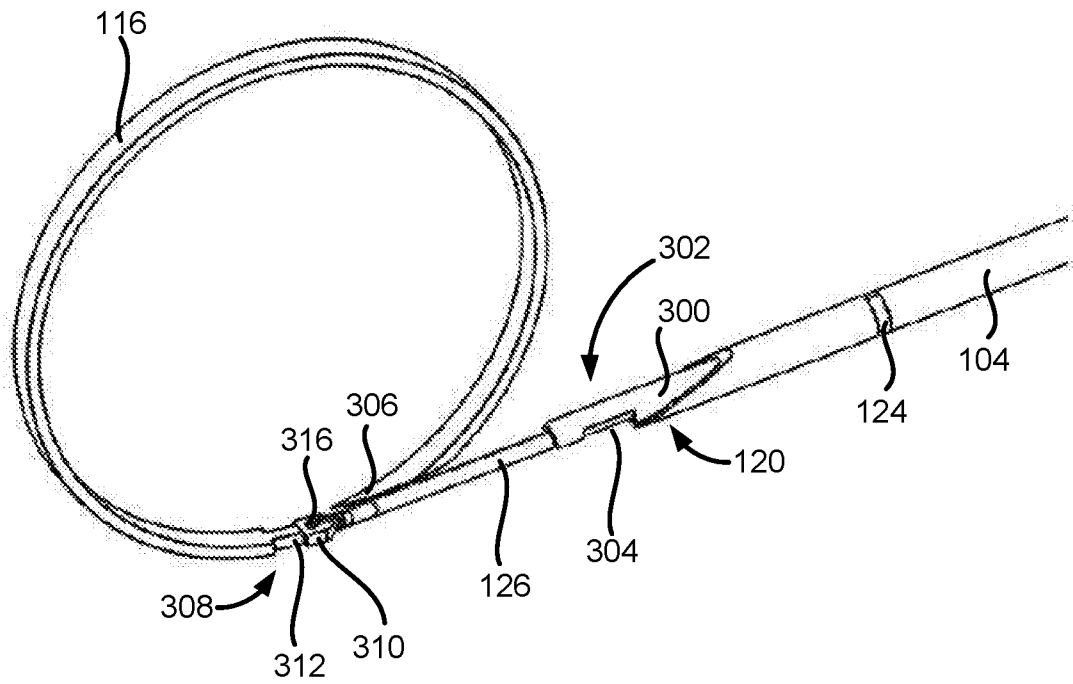


FIG. 3C

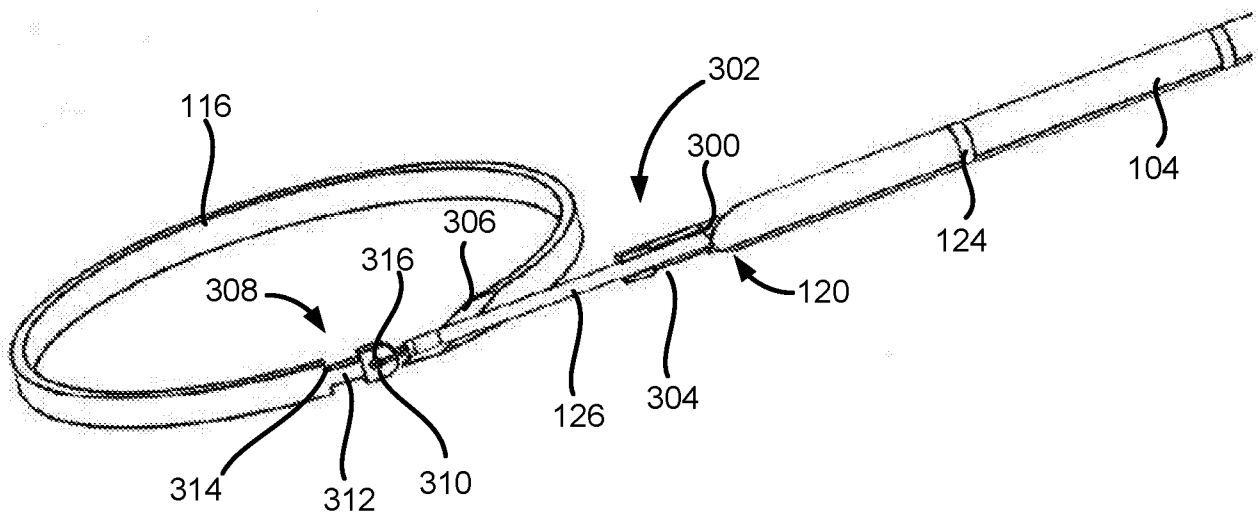


FIG. 3D

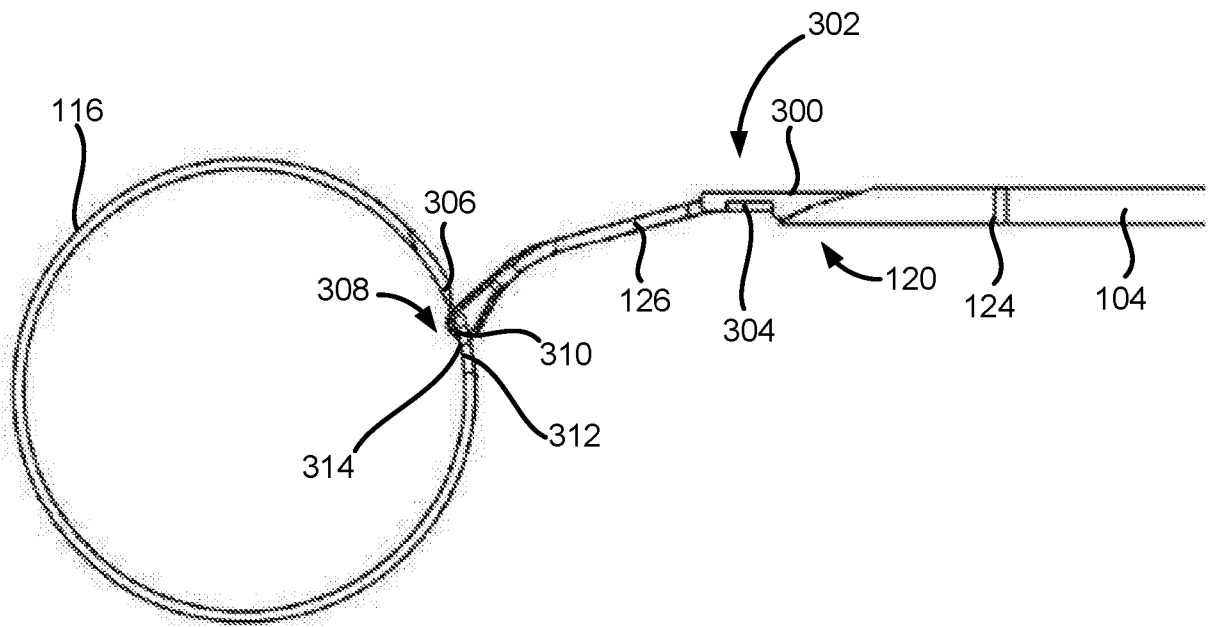


FIG. 3E

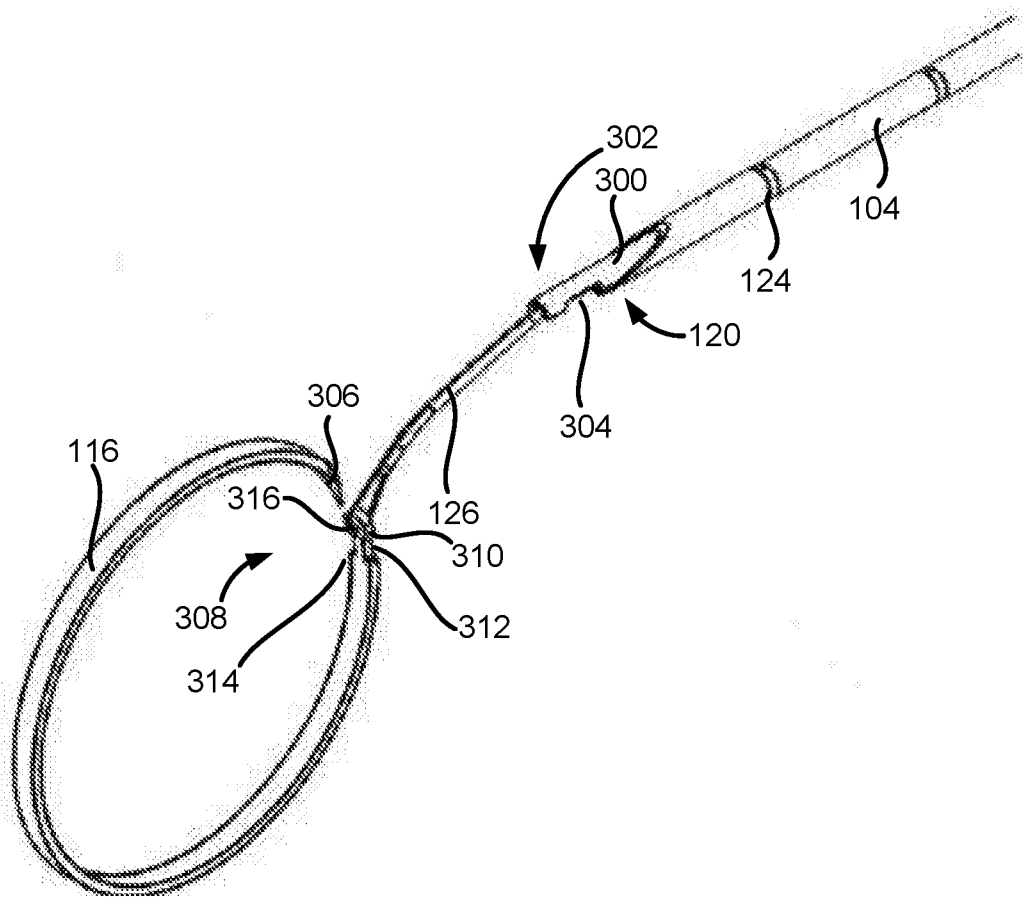


FIG. 3F

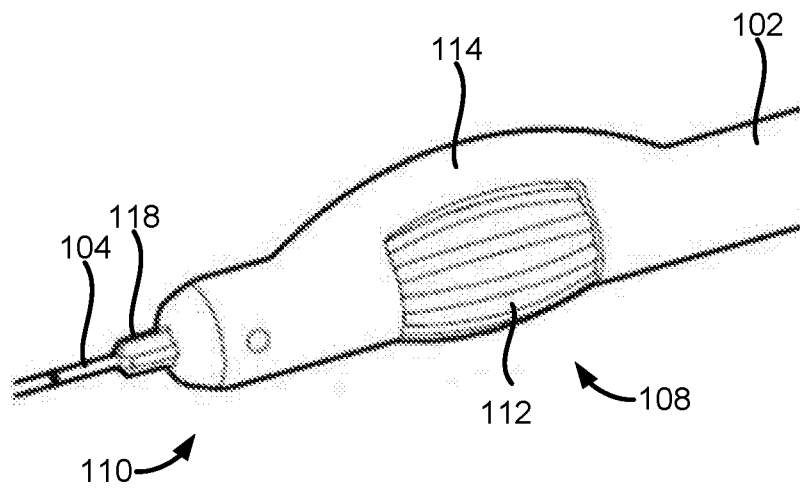


FIG. 4A

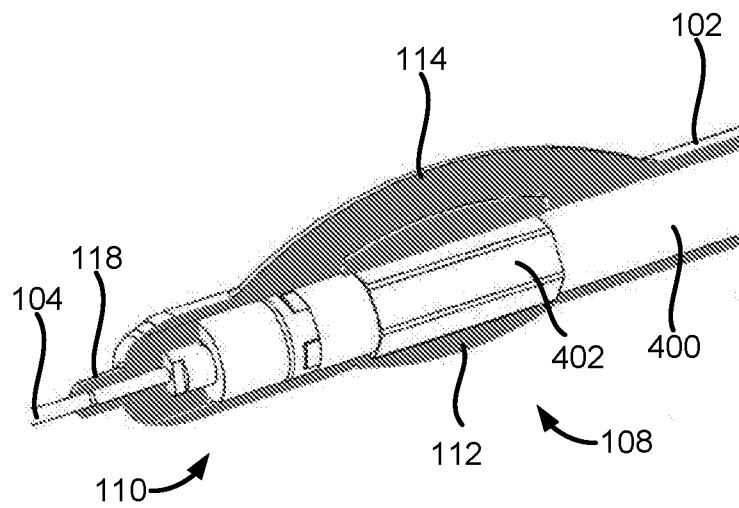


FIG. 4B

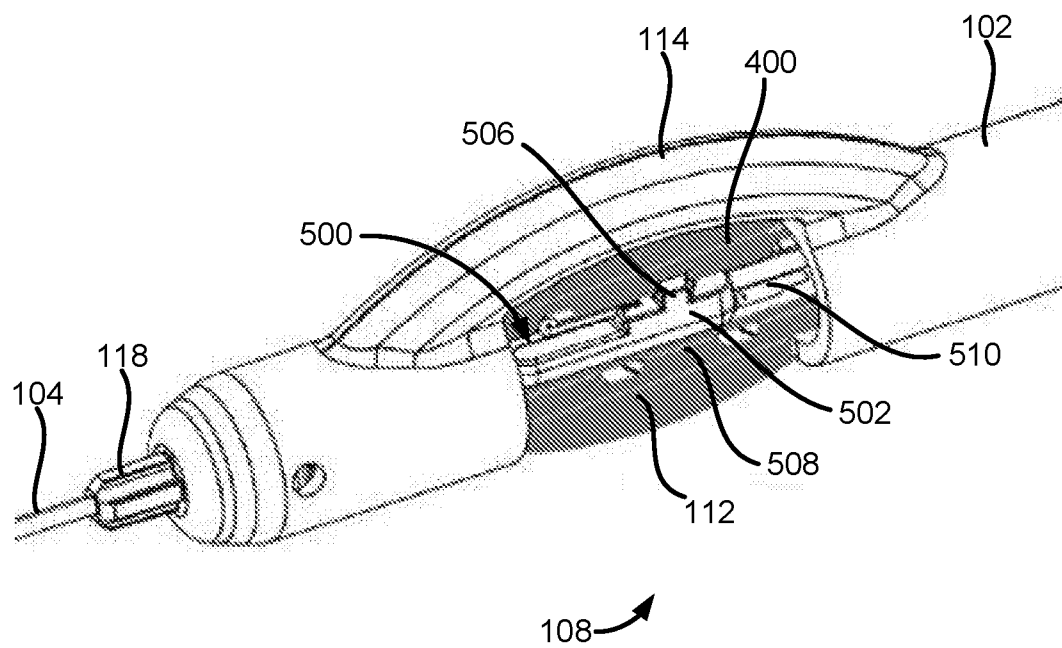


FIG. 5A

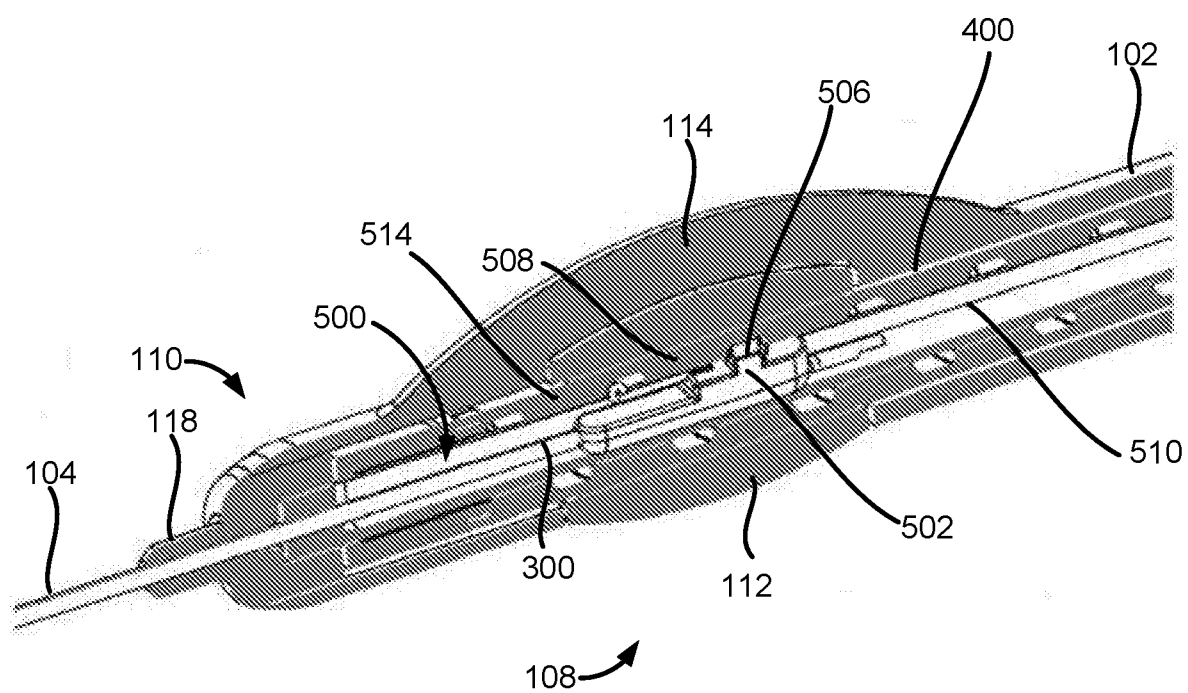


FIG. 5B

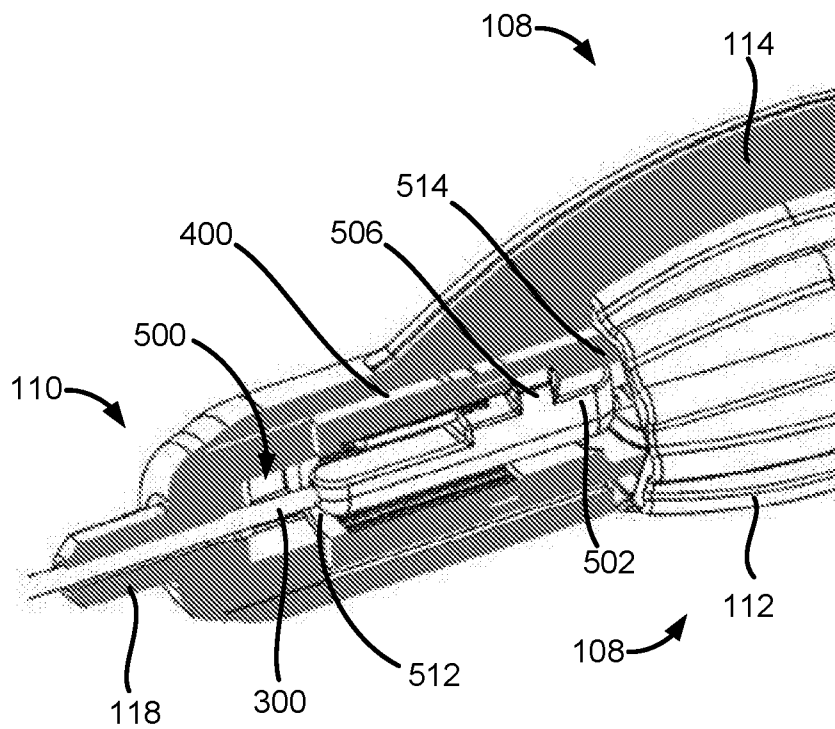


FIG. 5C

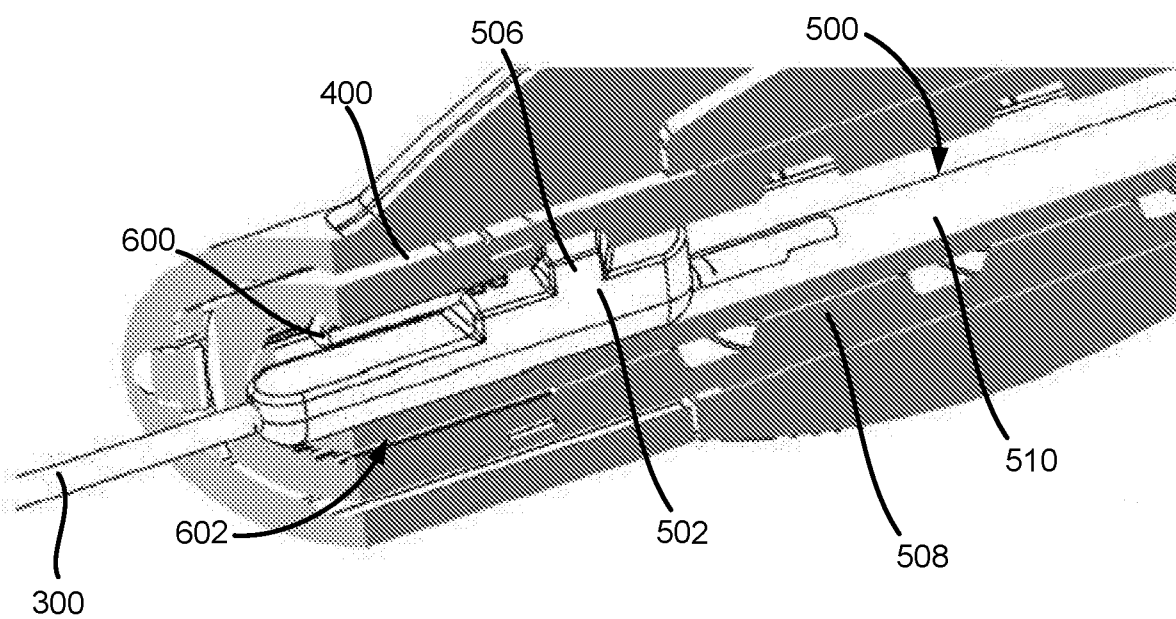


FIG. 6A

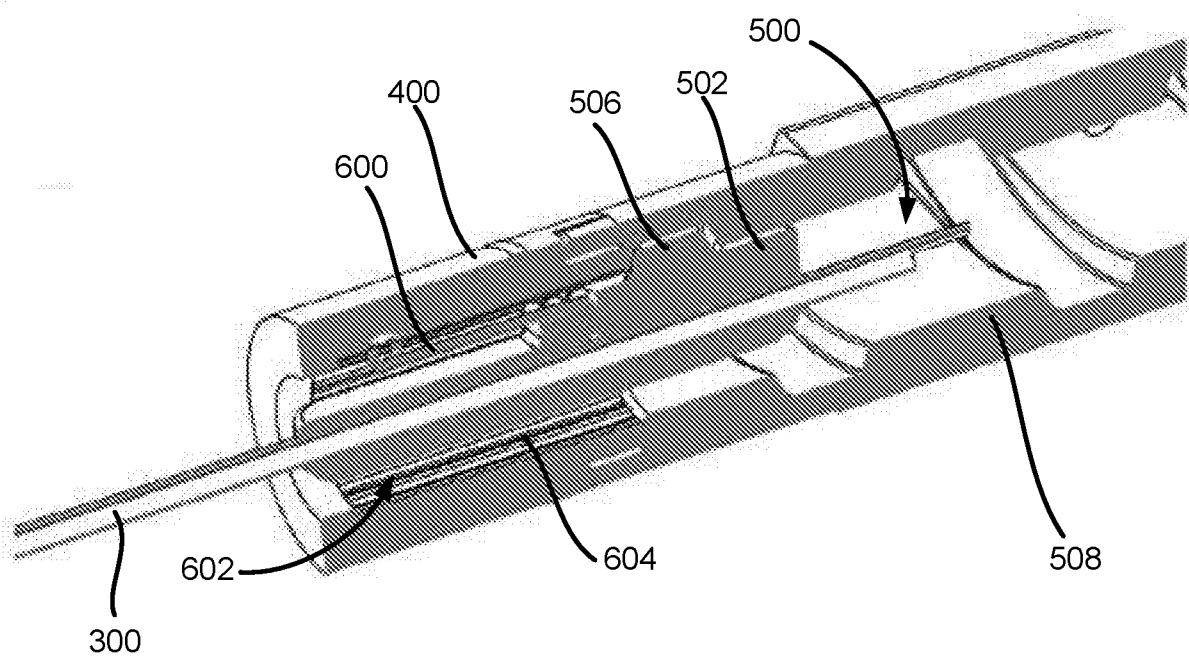


FIG. 6B

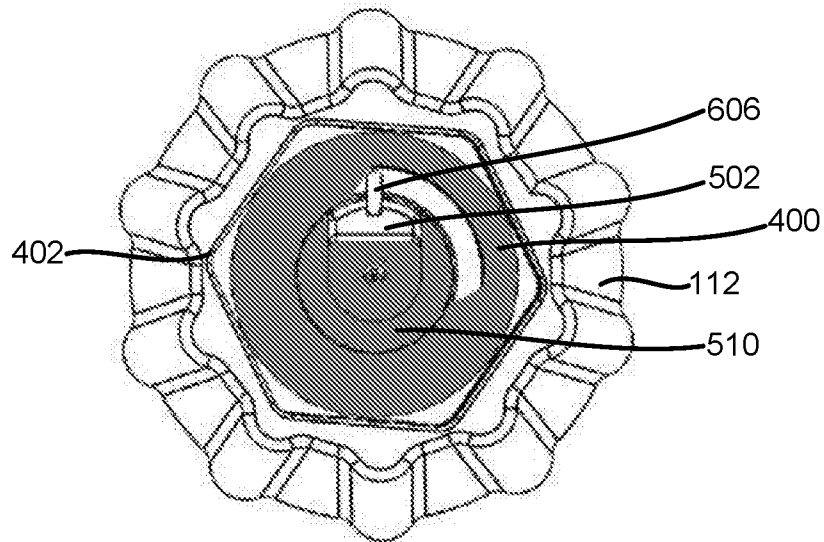


FIG. 6C

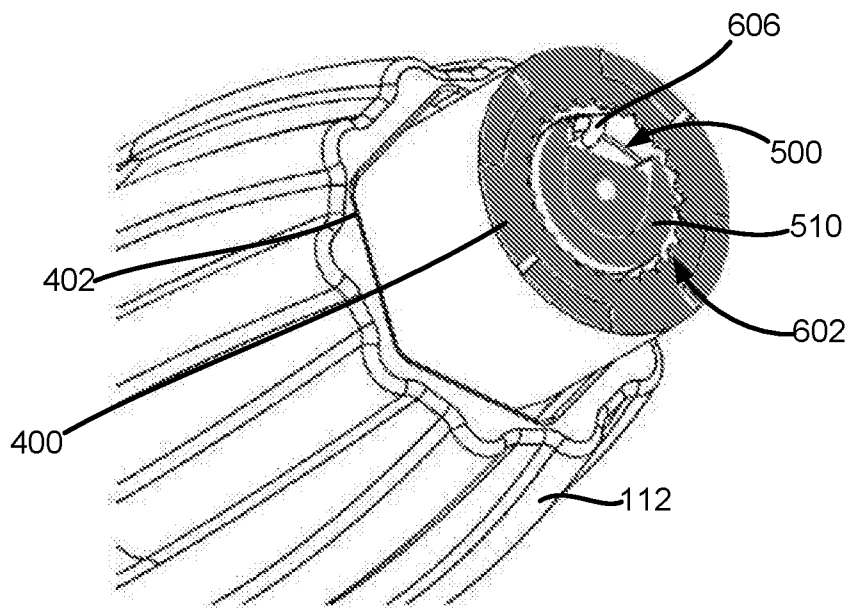


FIG. 6D

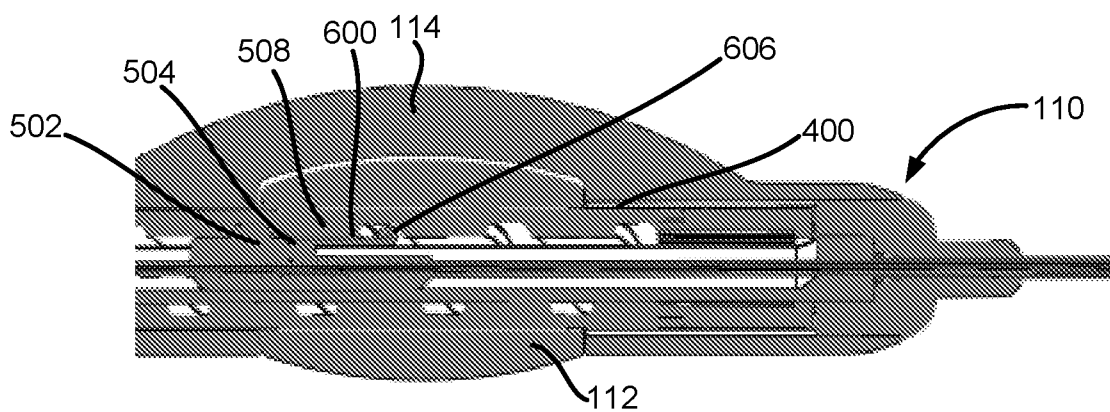


FIG. 6E

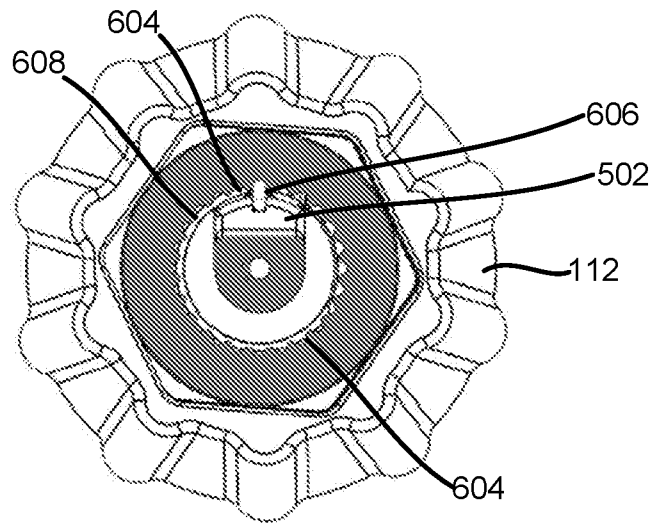


FIG. 6F

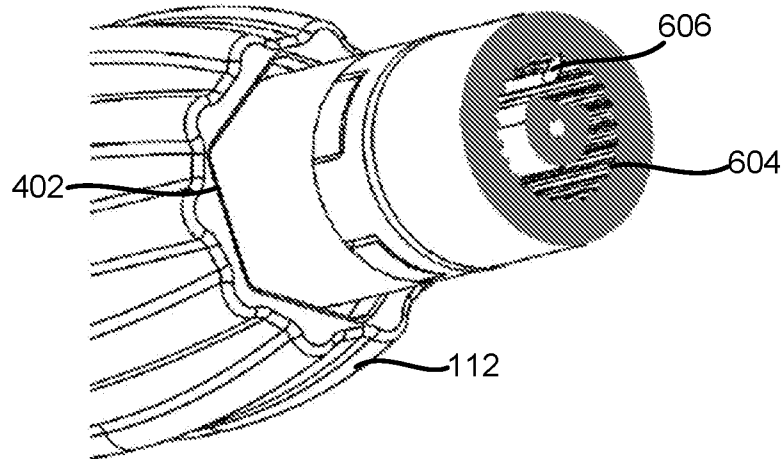


FIG. 6G

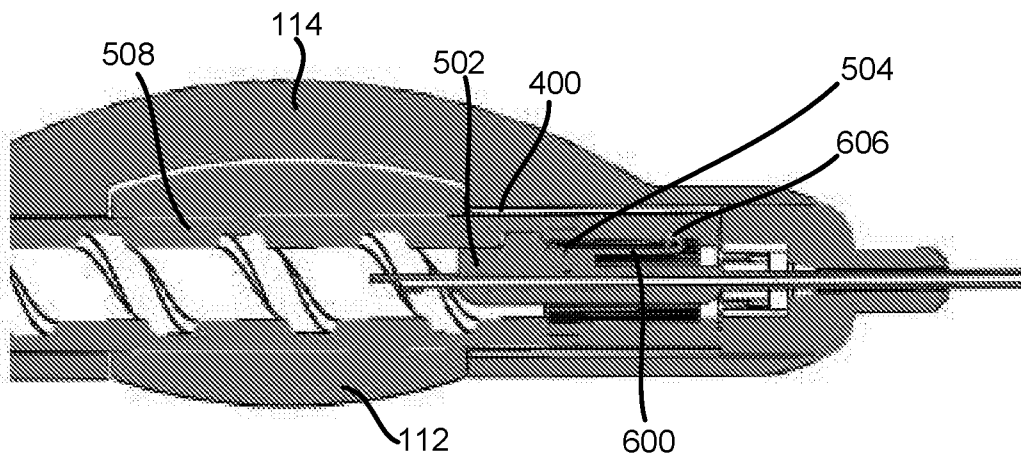
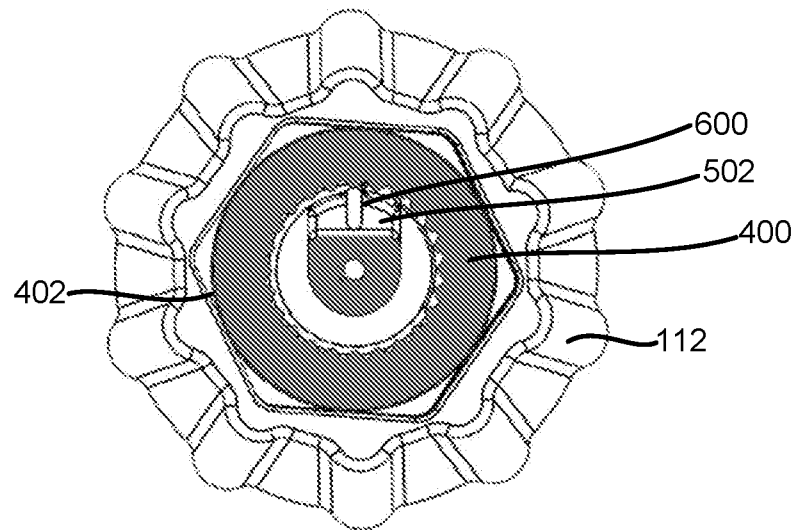
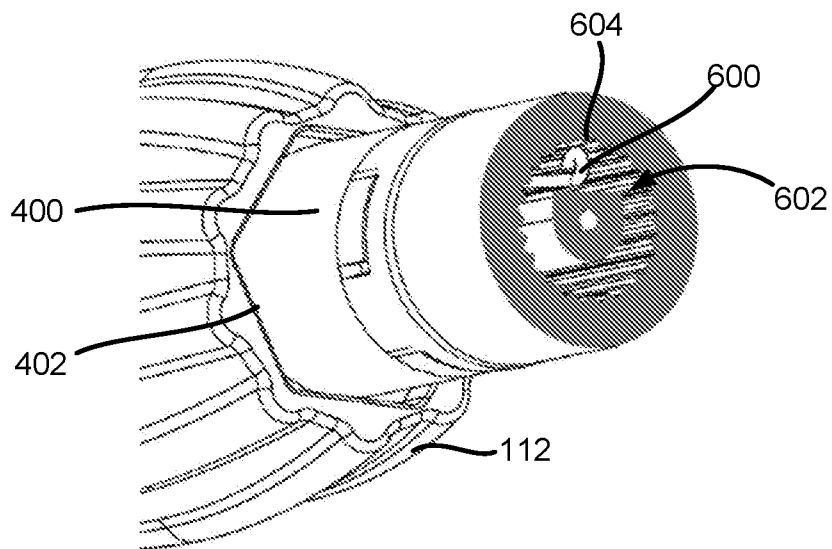
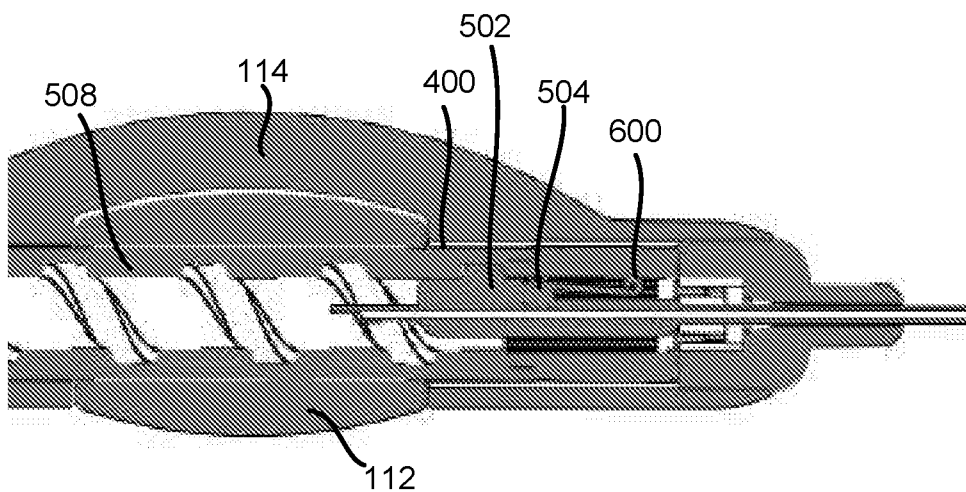


FIG. 6H

**FIG. 6I****FIG. 6J****FIG. 6K**

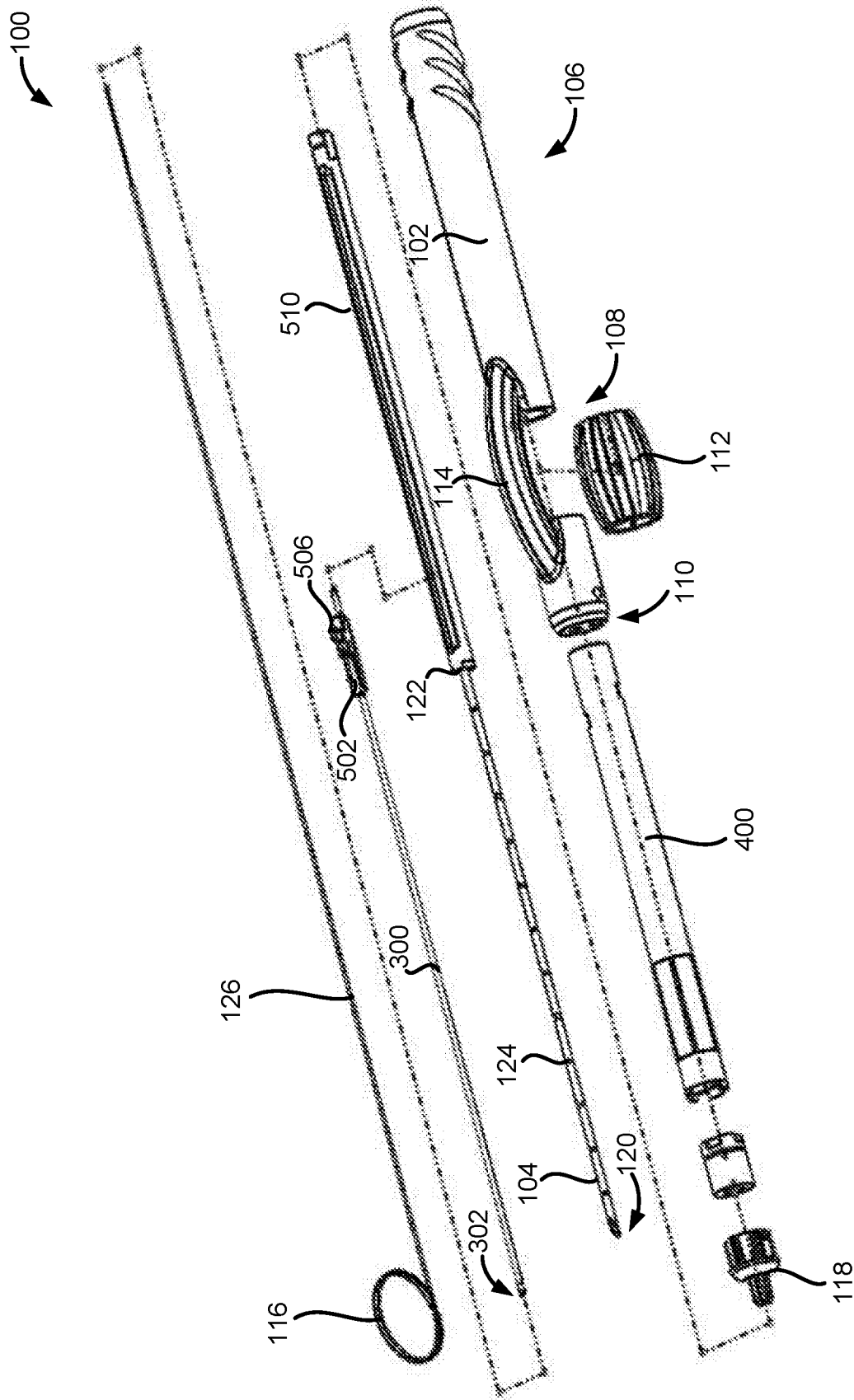
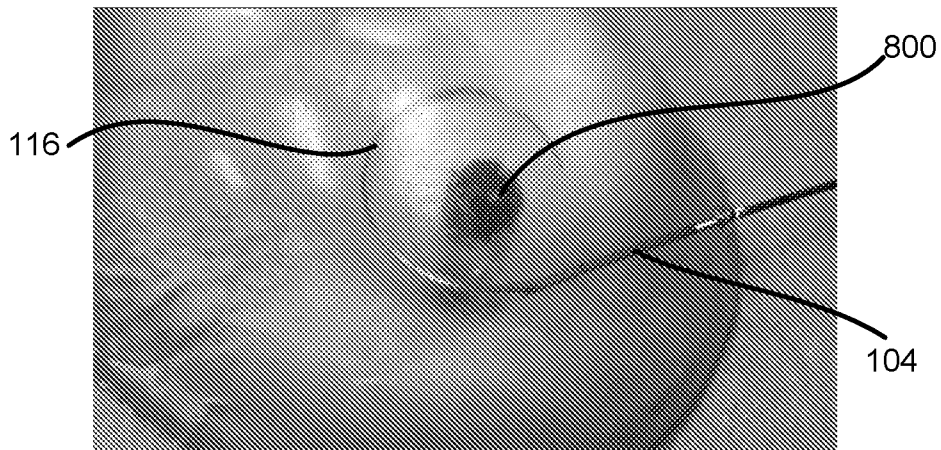
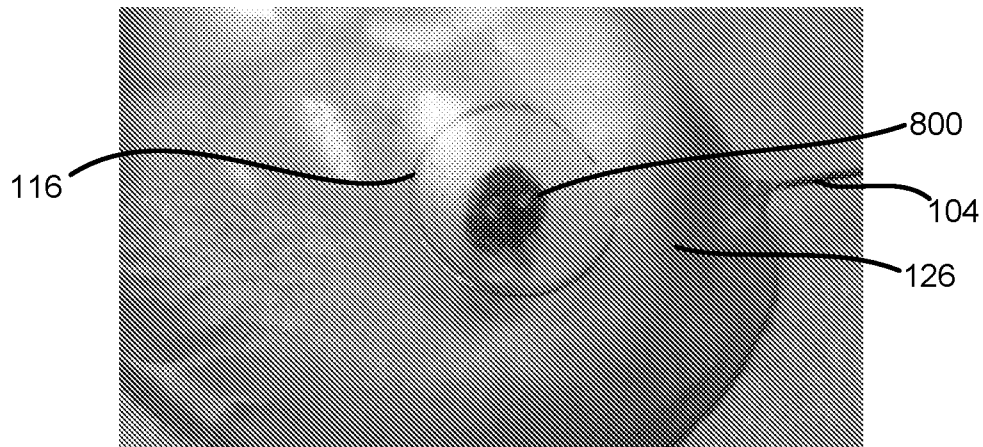
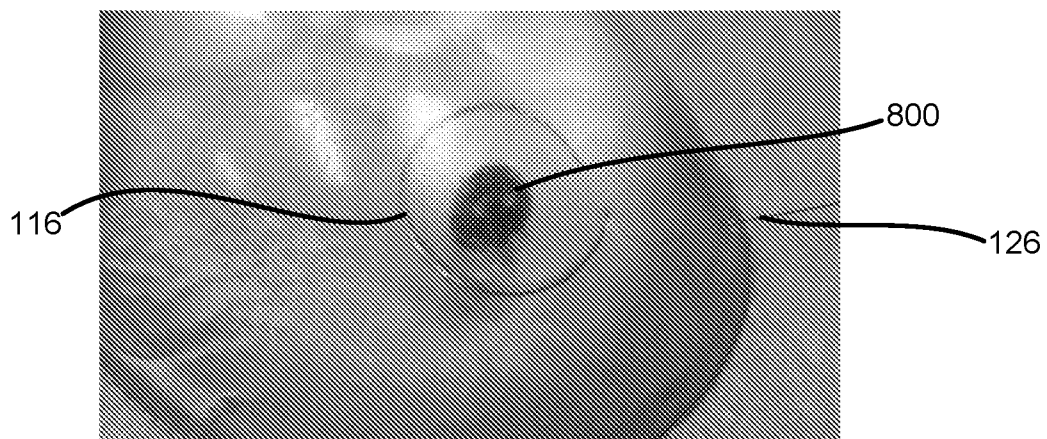


FIG. 7

**FIG. 8A****FIG. 8B****FIG. 8C**

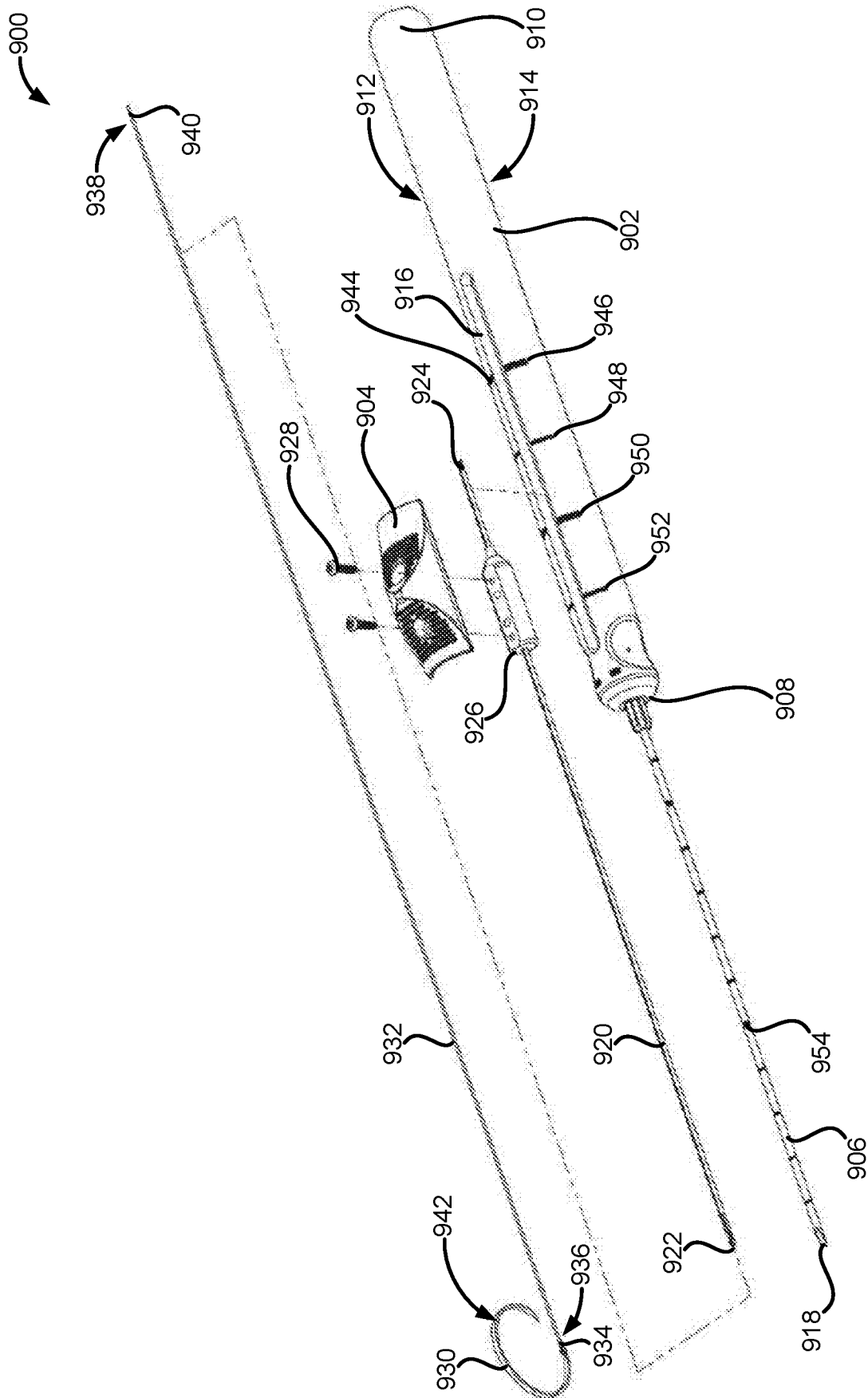


FIG. 9

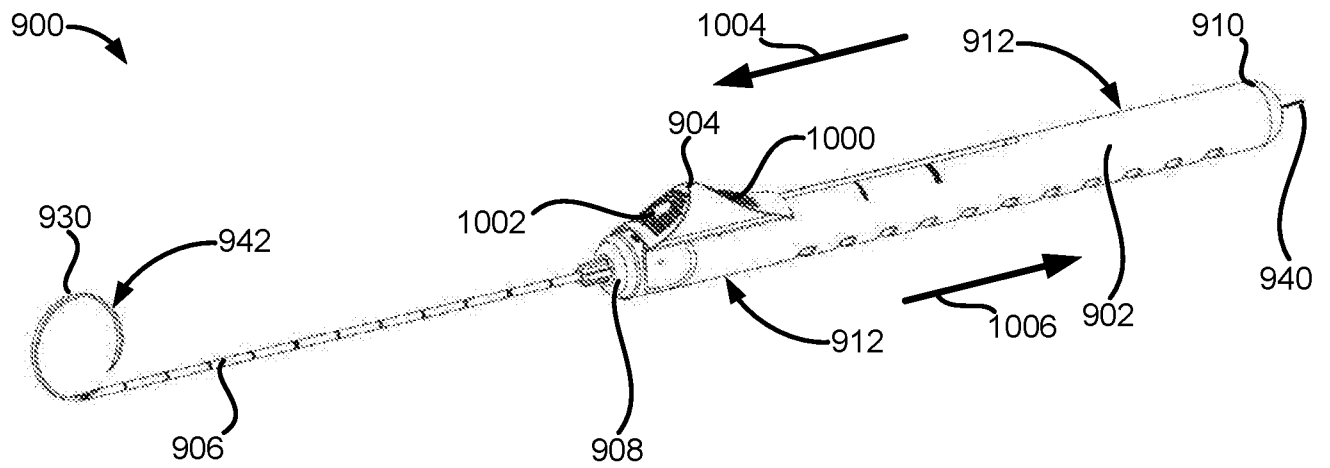


FIG. 10A

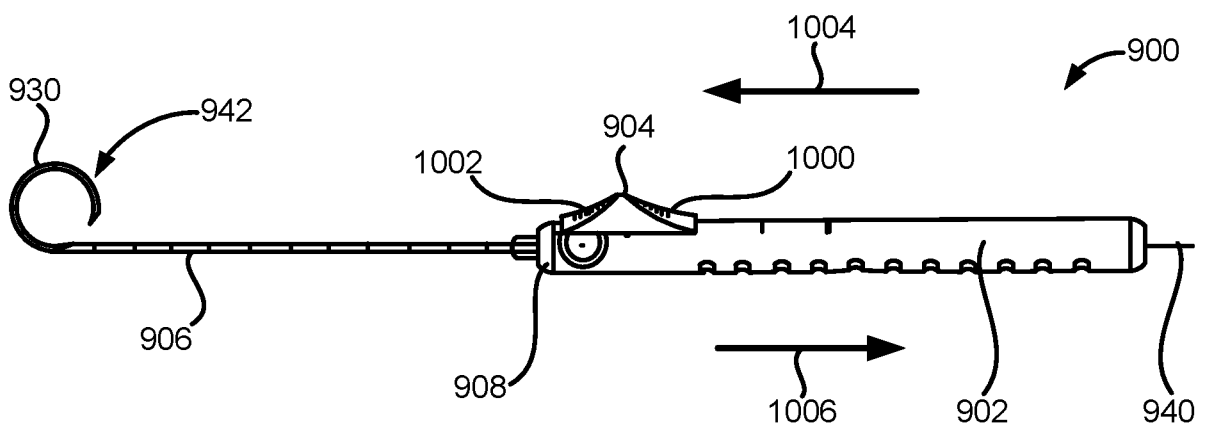


FIG. 10B

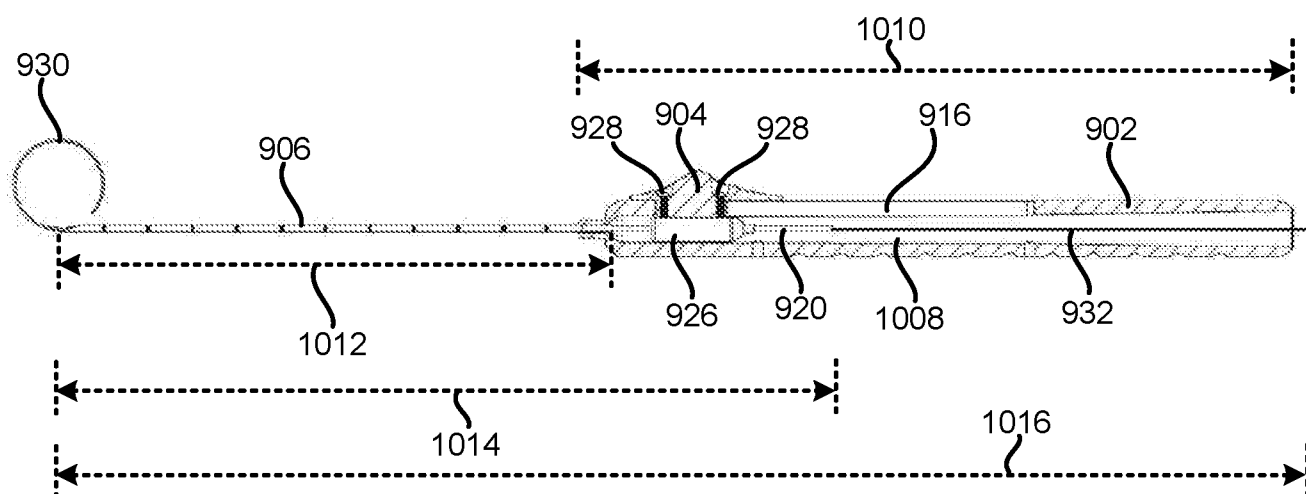


FIG. 10C

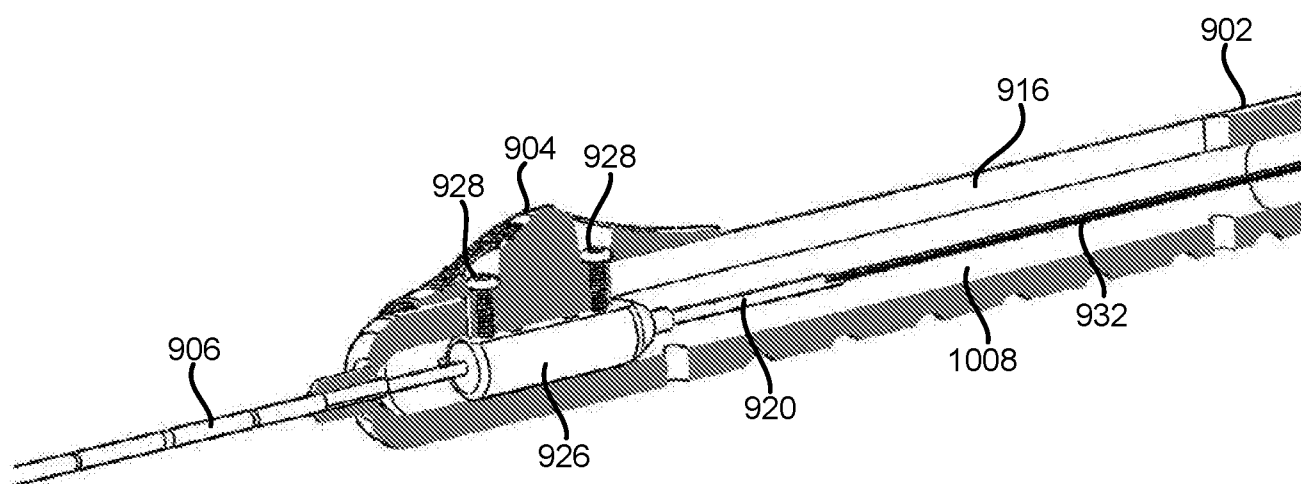


FIG. 10D

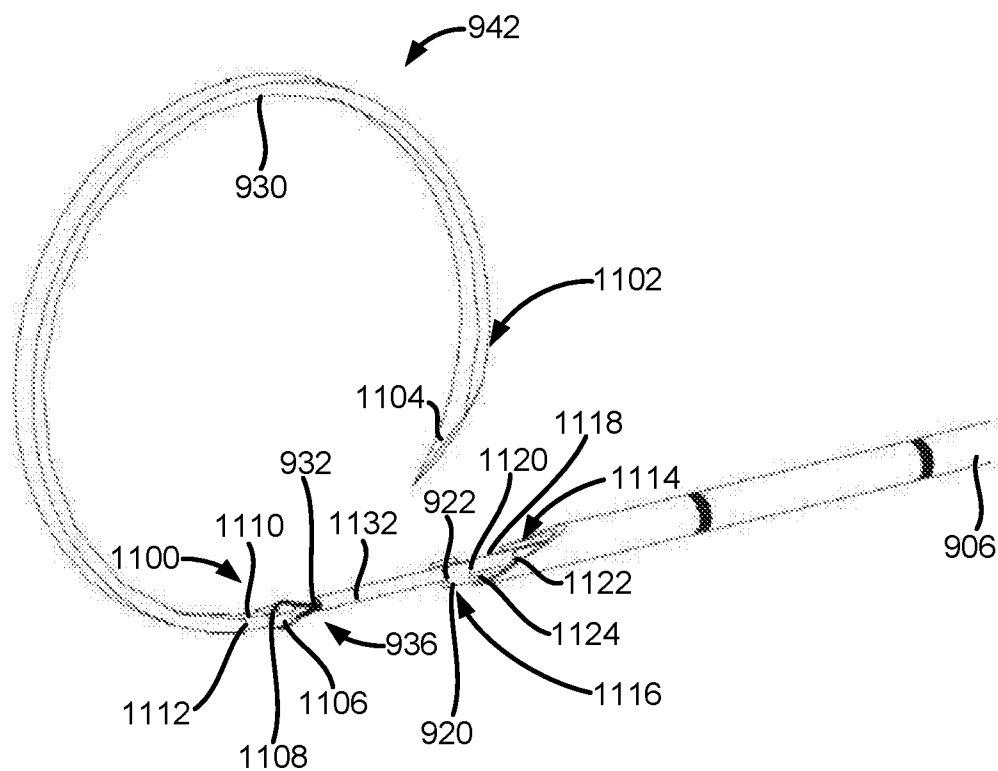


FIG. 11A

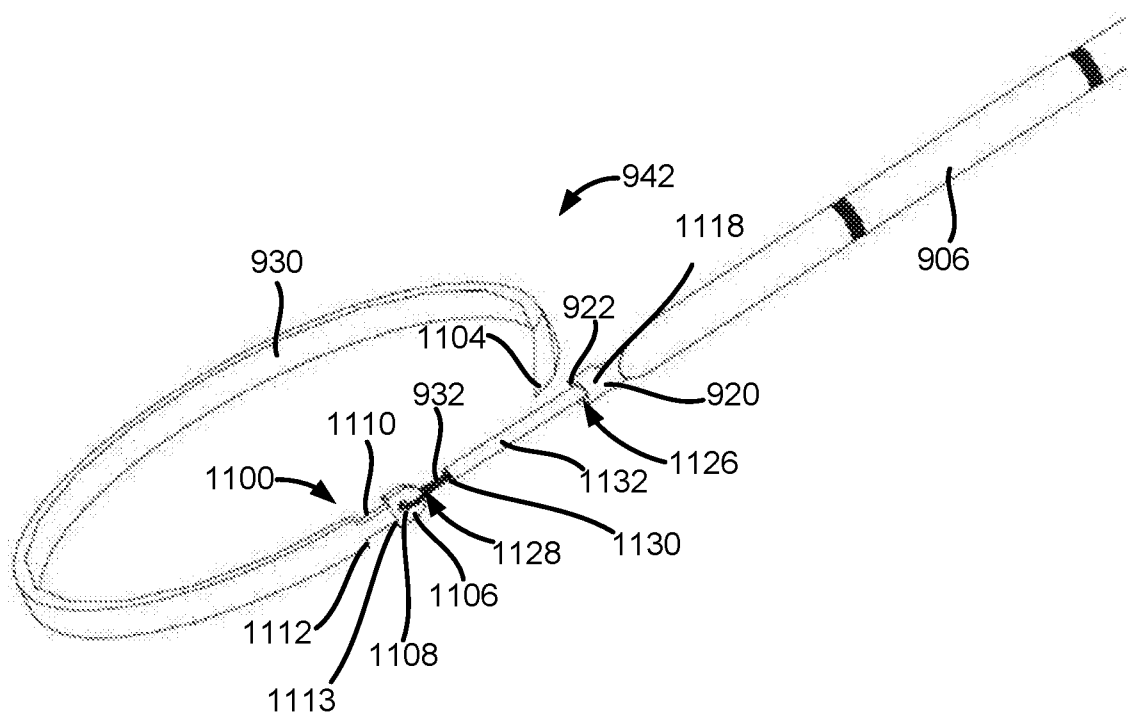
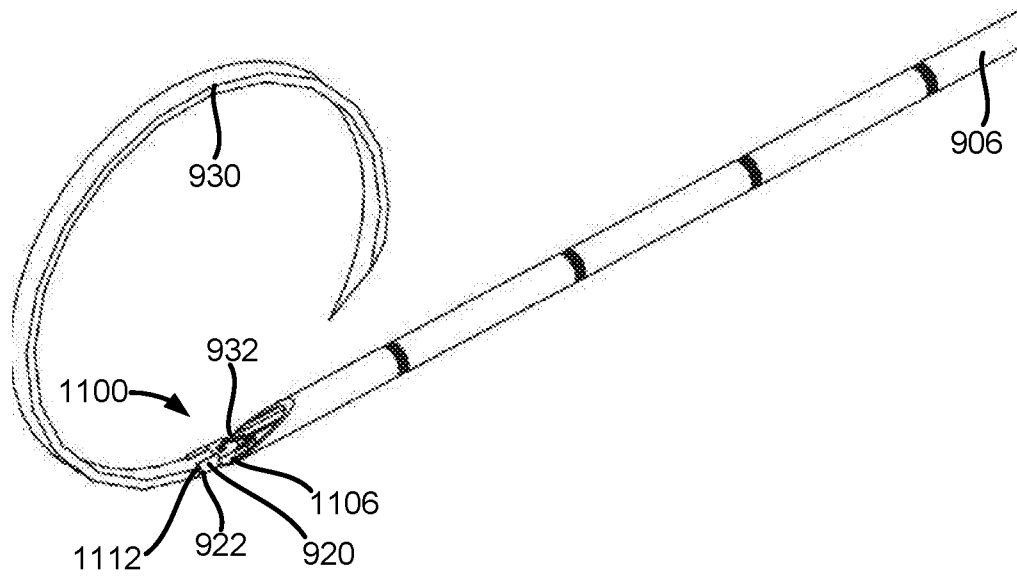
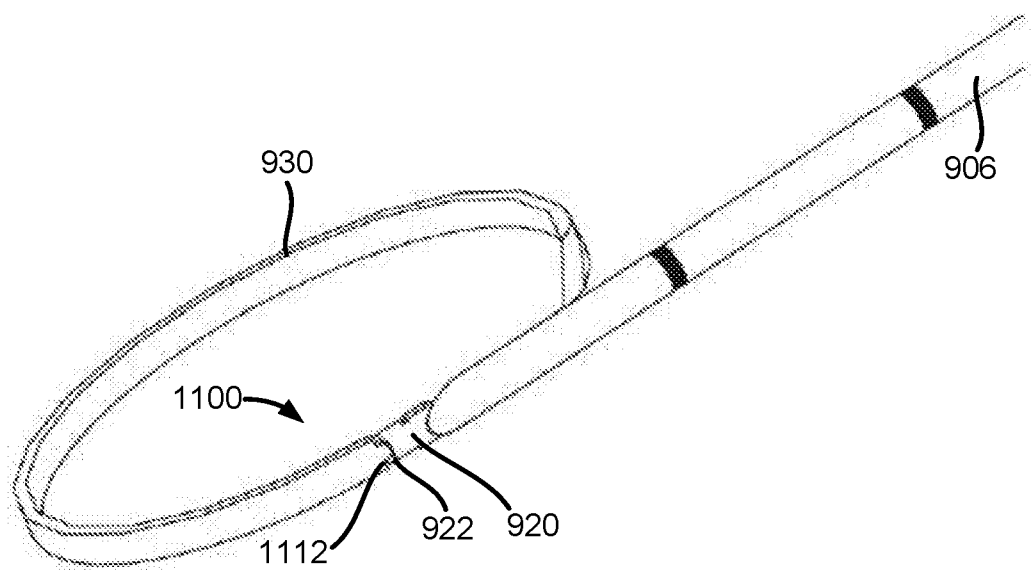


FIG. 11B

**FIG. 11C****FIG. 11D**

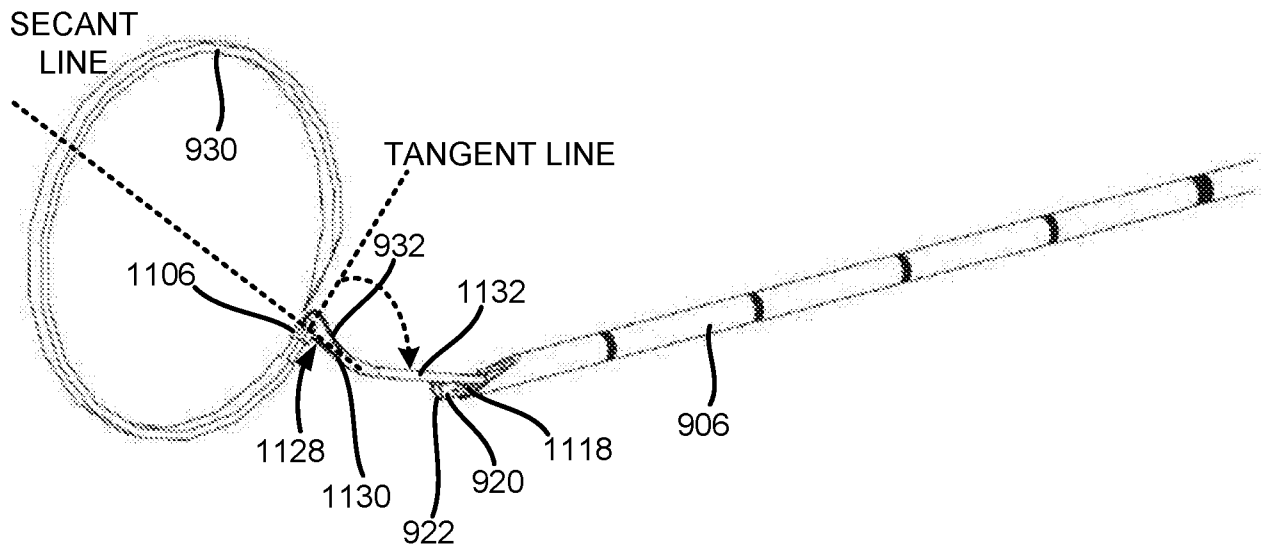


FIG. 11E

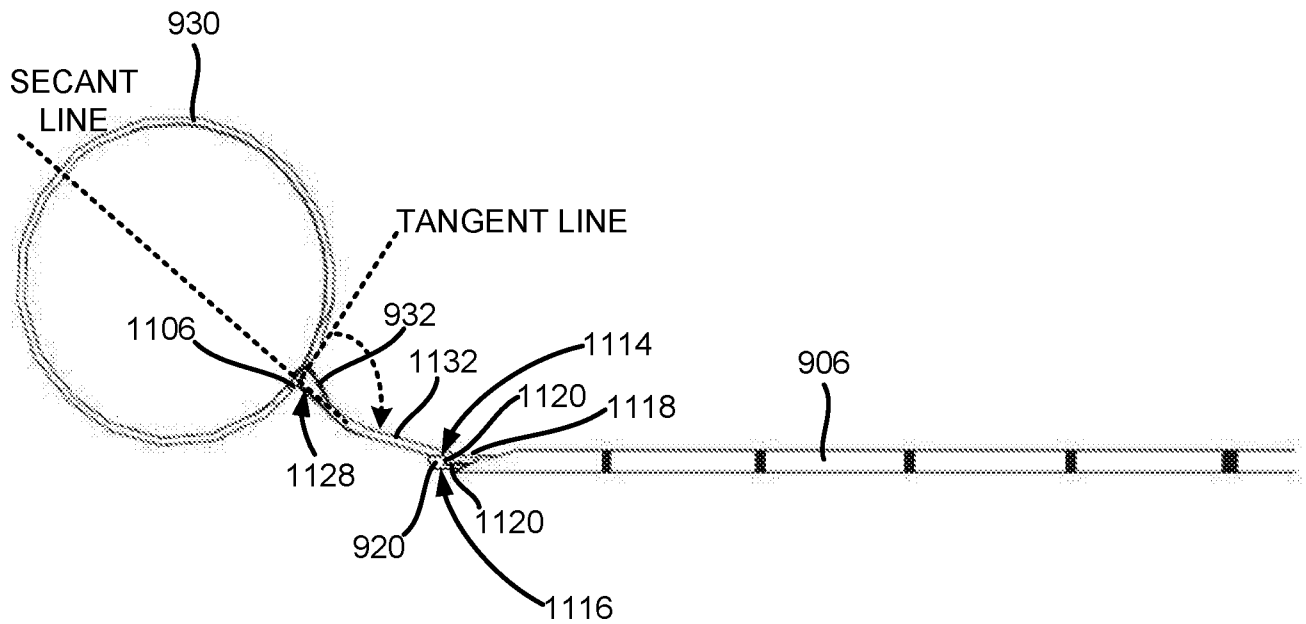


FIG. 11F

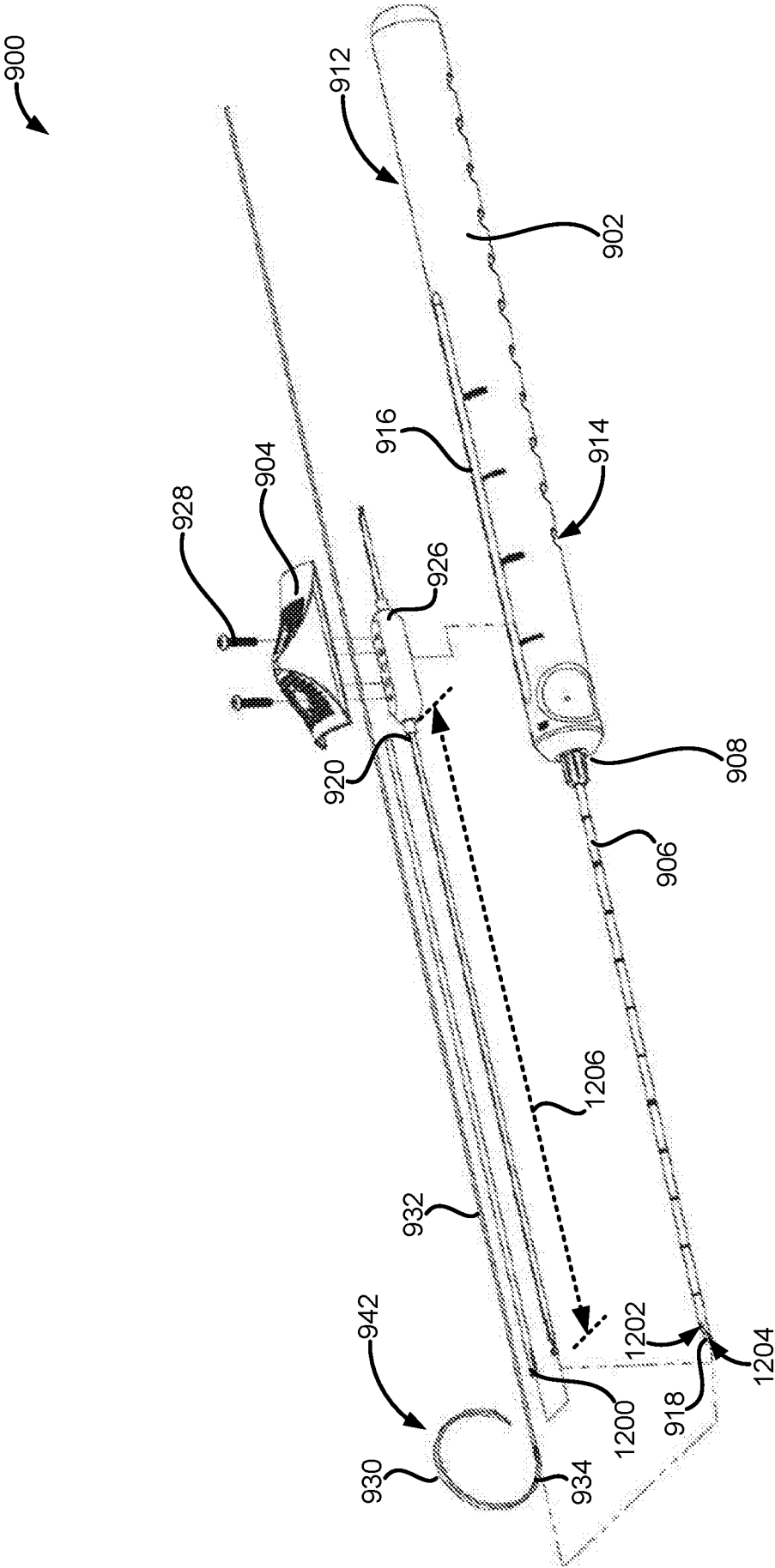
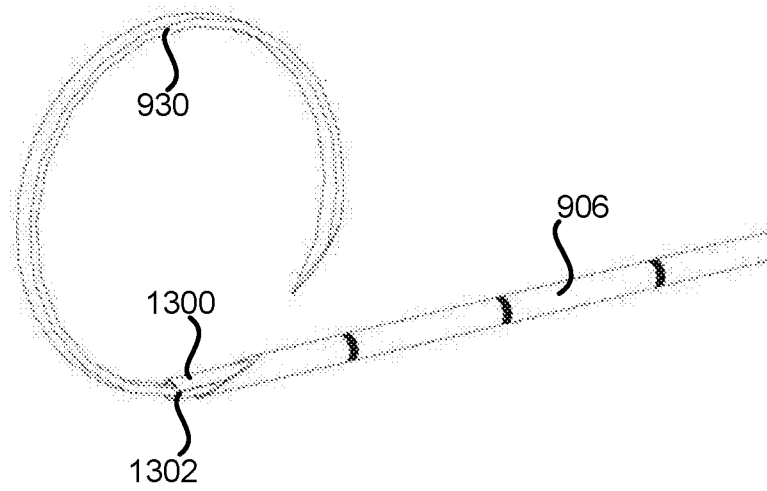
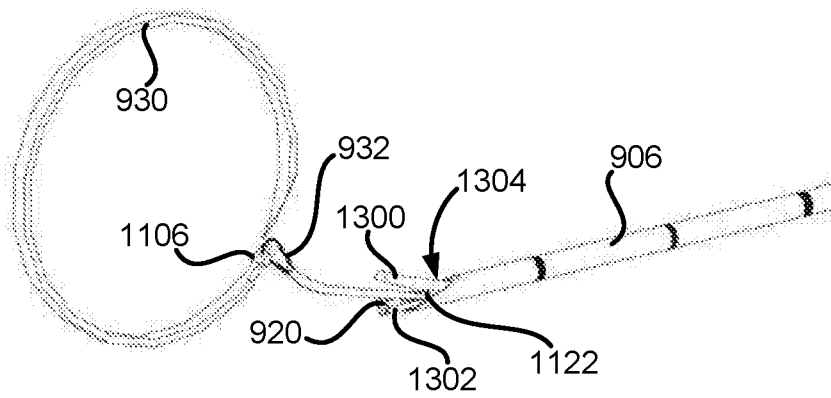
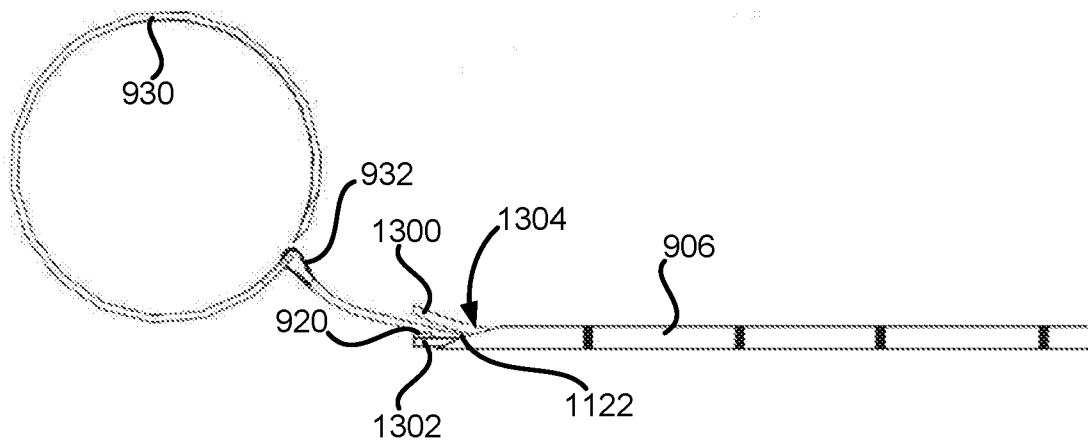


FIG. 12

**FIG. 13A****FIG. 13B****FIG. 13C**

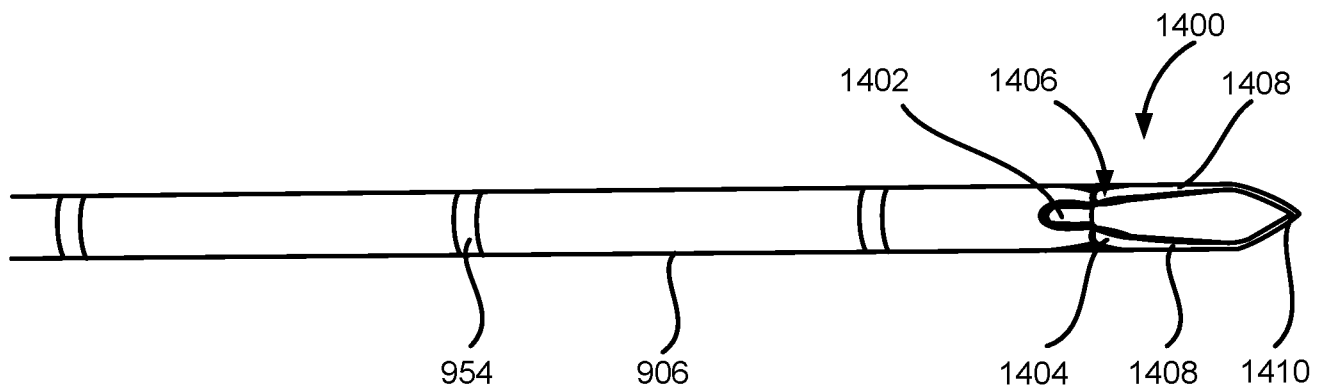


FIG. 14A

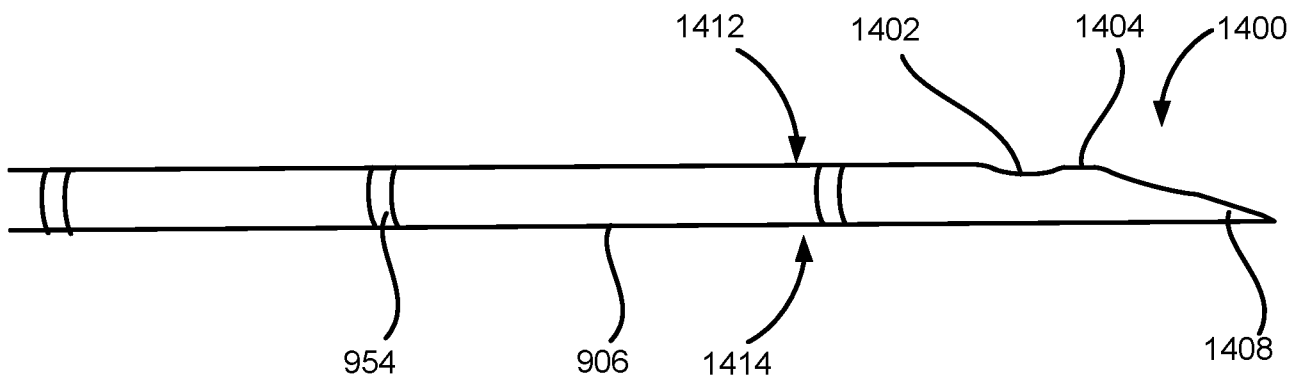


FIG. 14B

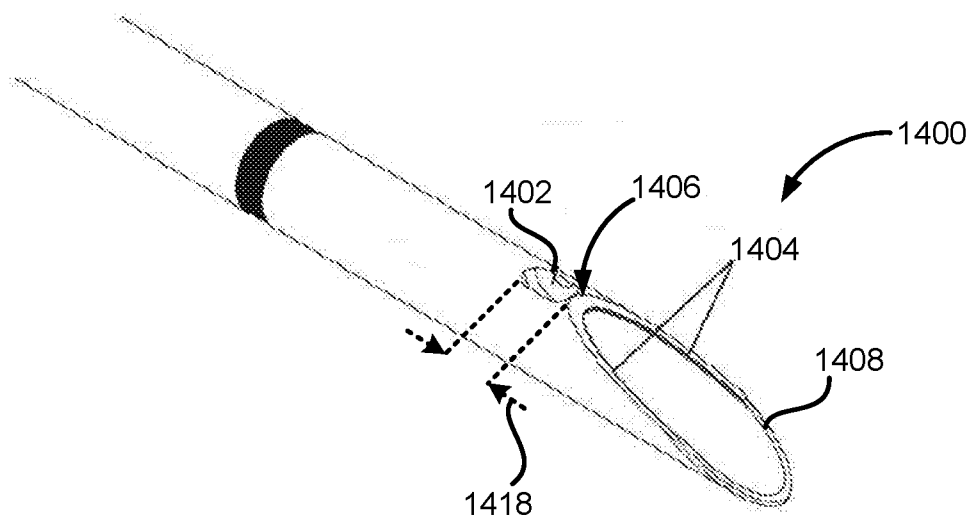


FIG. 14C

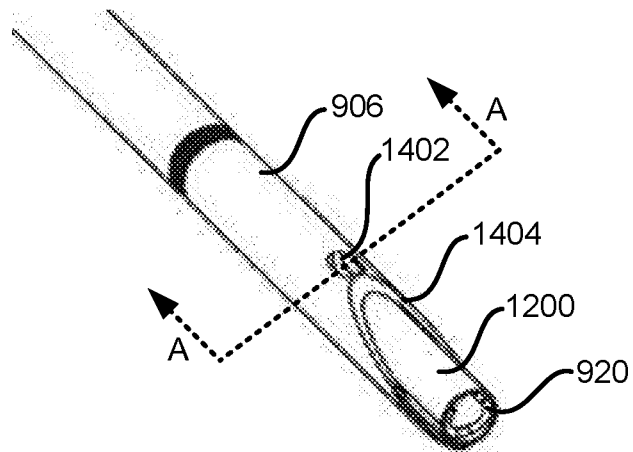


FIG. 14D

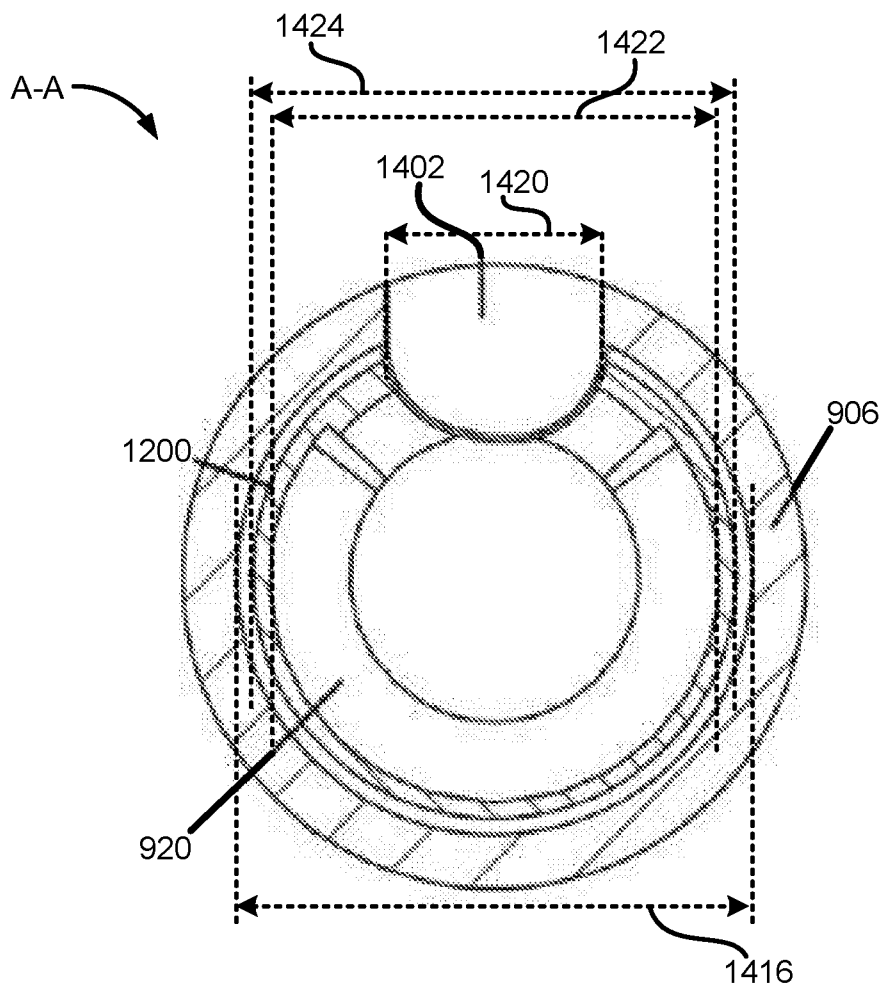


FIG. 14E

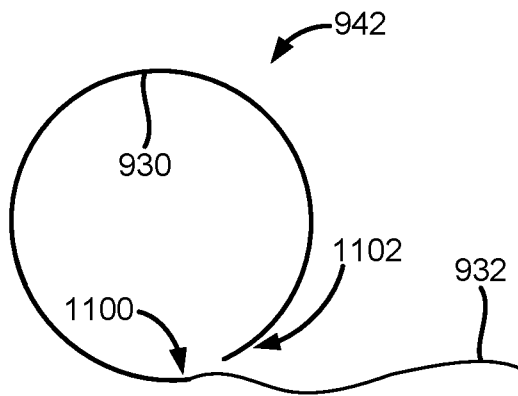


FIG. 15A

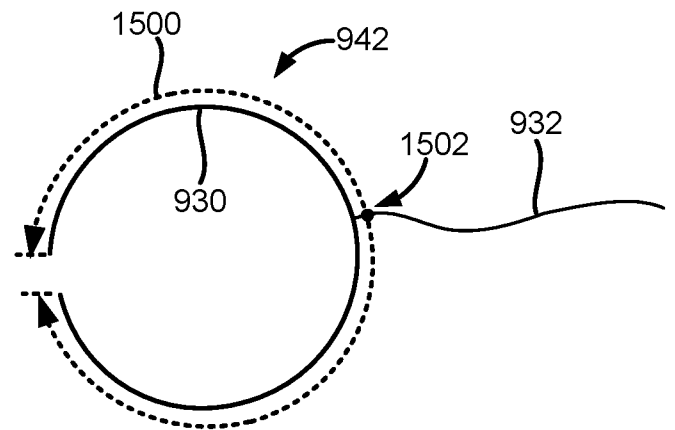


FIG. 15B

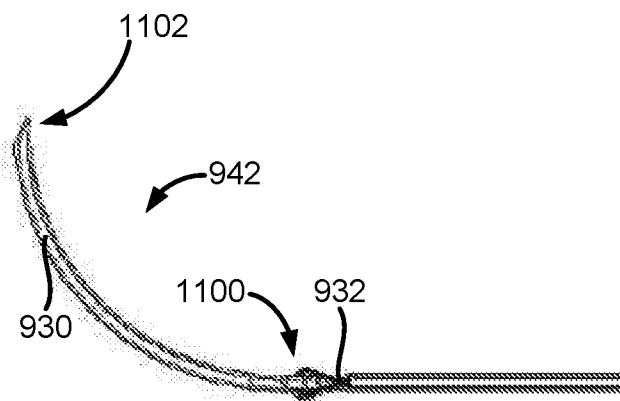


FIG. 15C

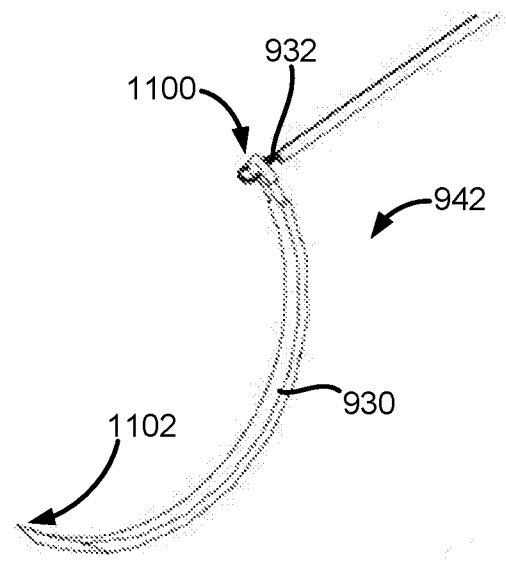


FIG. 15D

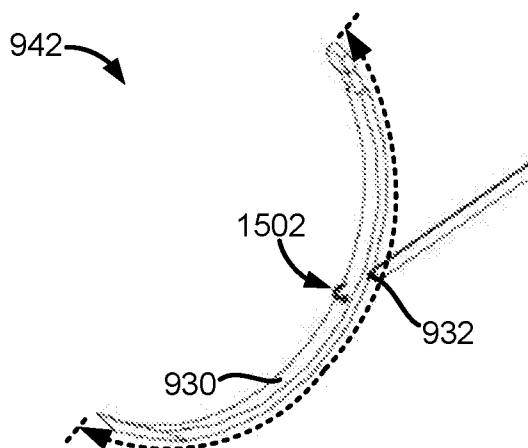


FIG. 15E

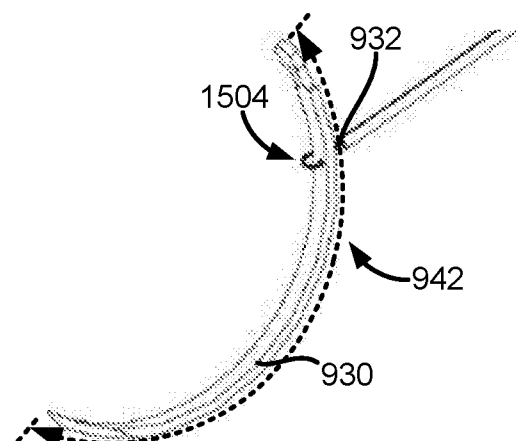
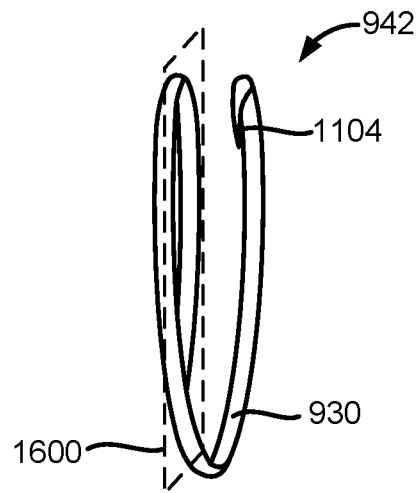
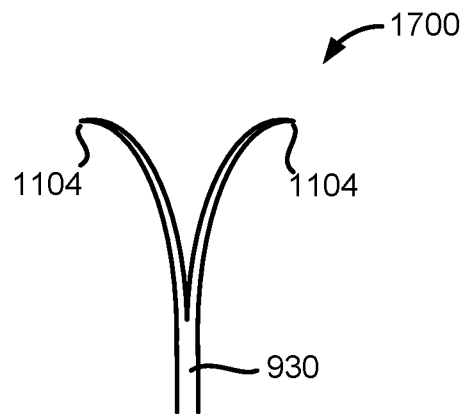
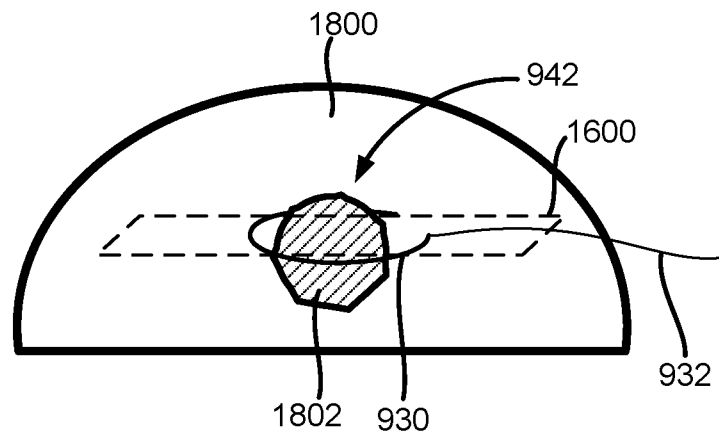
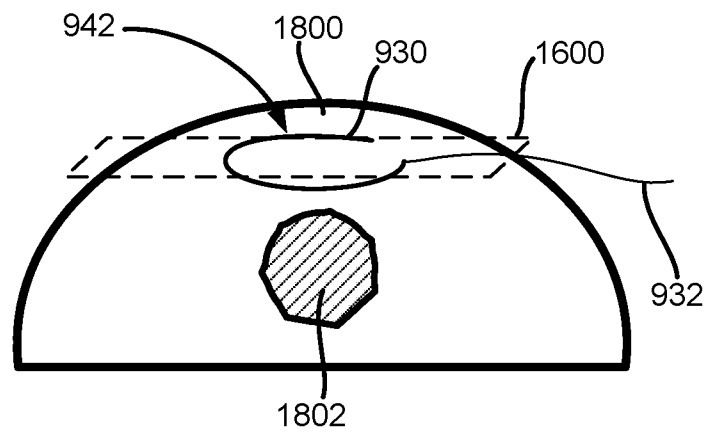
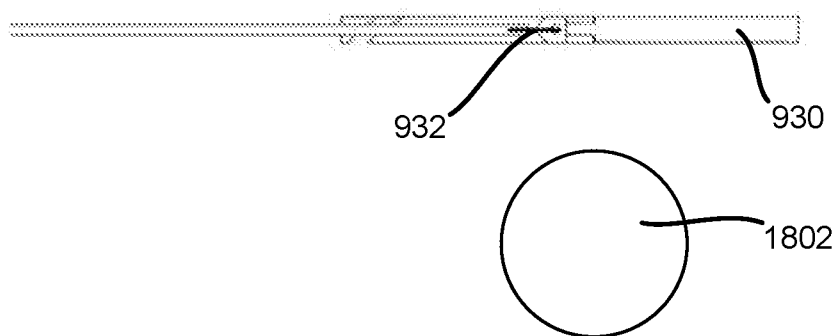
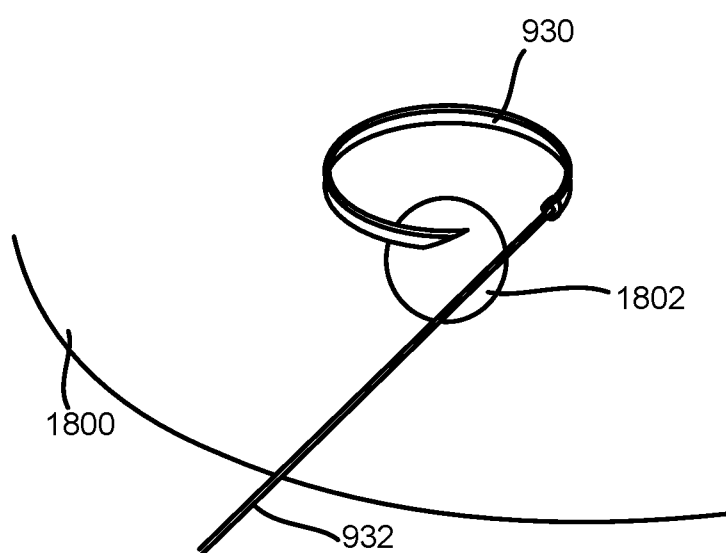
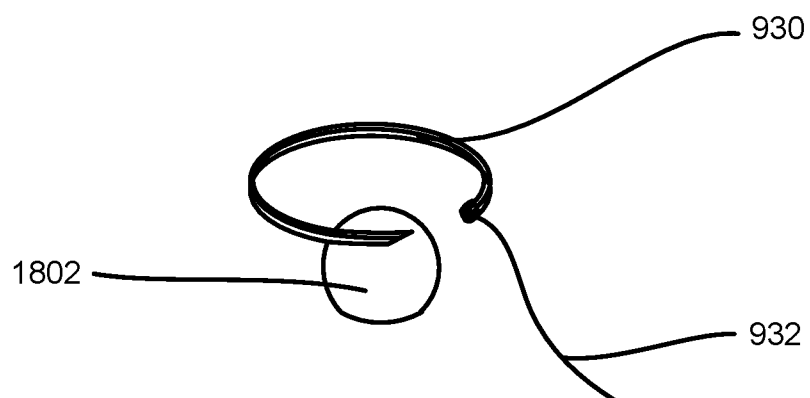
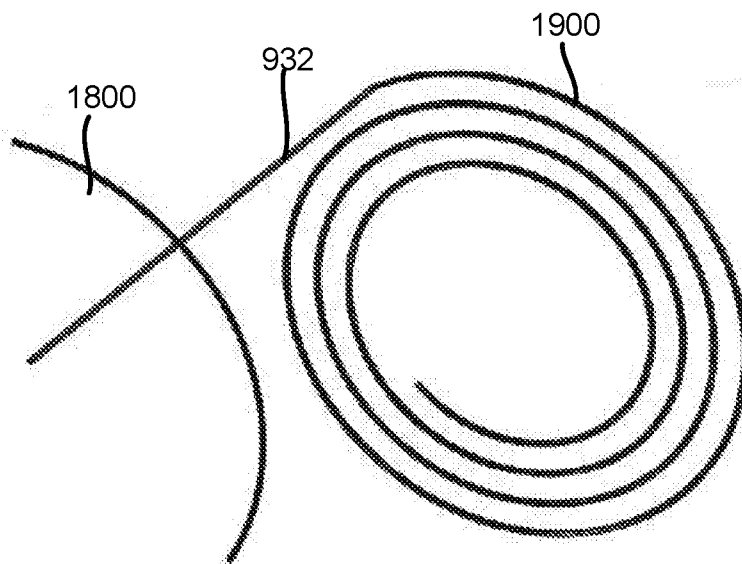
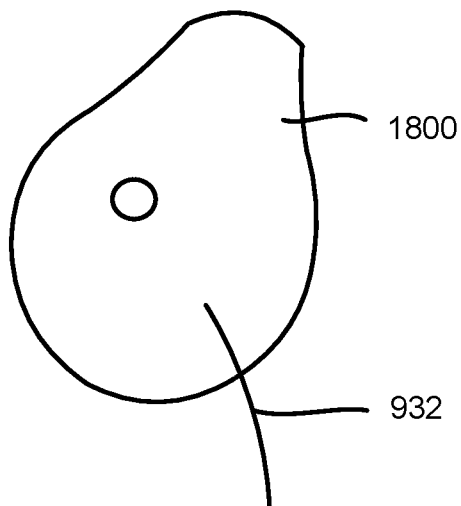
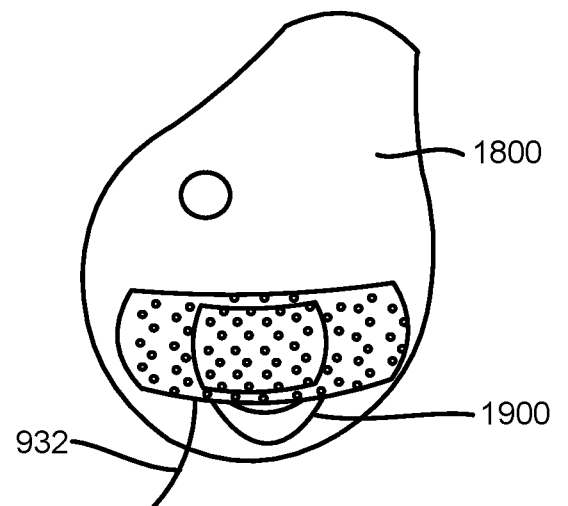


FIG. 15F

**FIG. 16****FIG. 17**

**FIG. 18A****FIG. 18B**

**FIG. 18C****FIG. 18D****FIG. 18E**

**FIG. 19A****FIG. 19B****FIG. 19C**

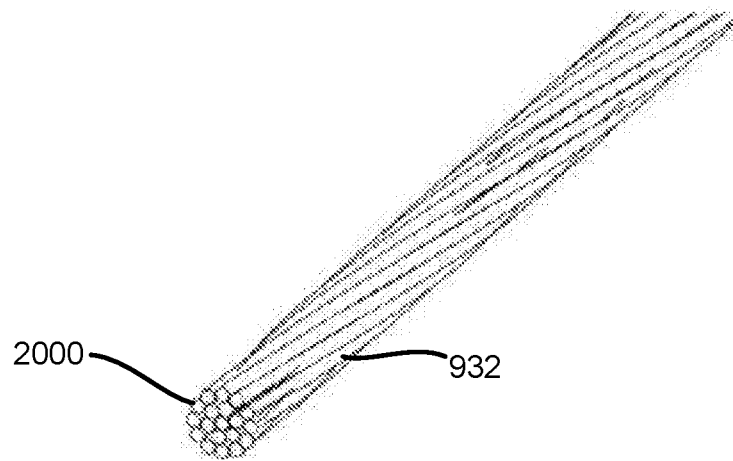


FIG. 20A

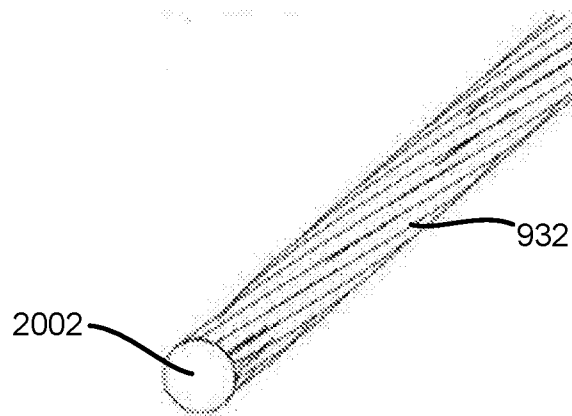


FIG. 20B

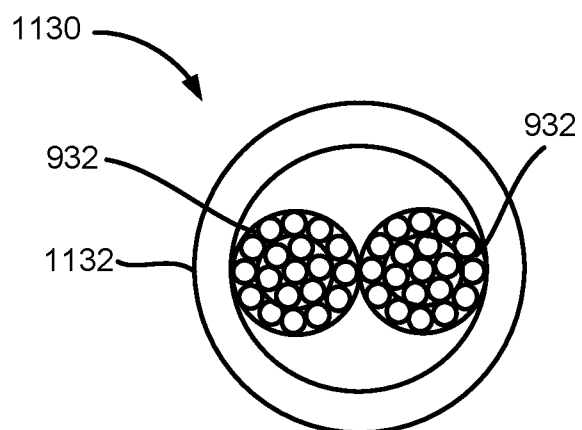


FIG. 20C

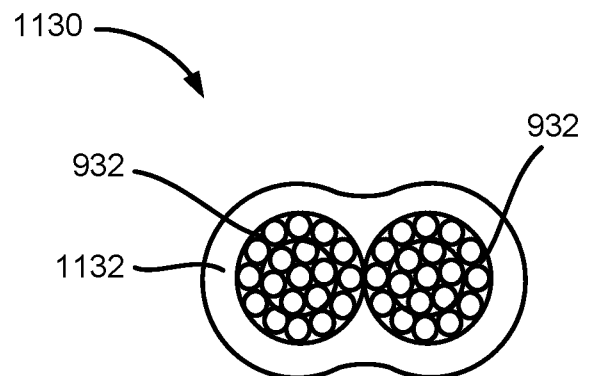
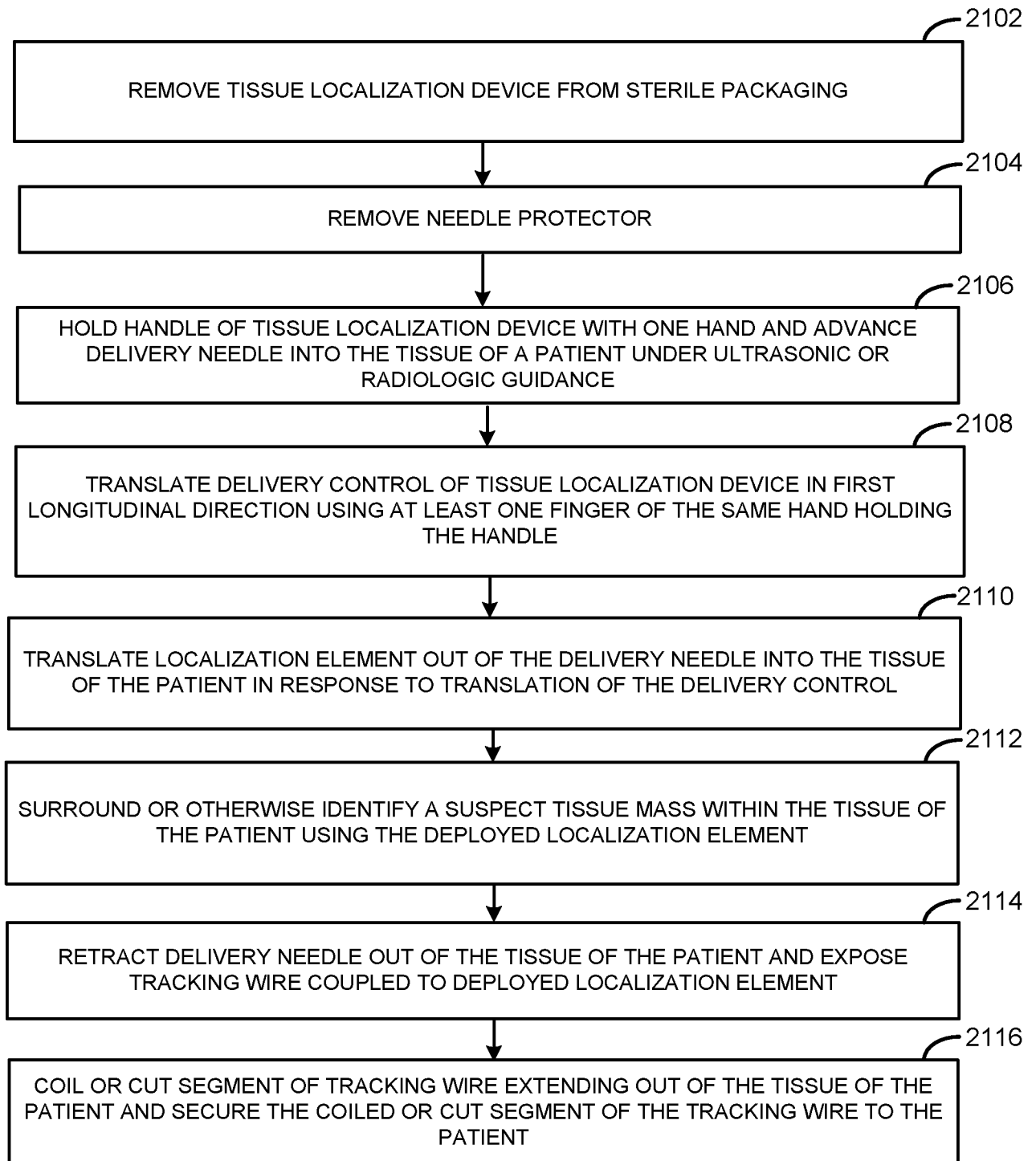
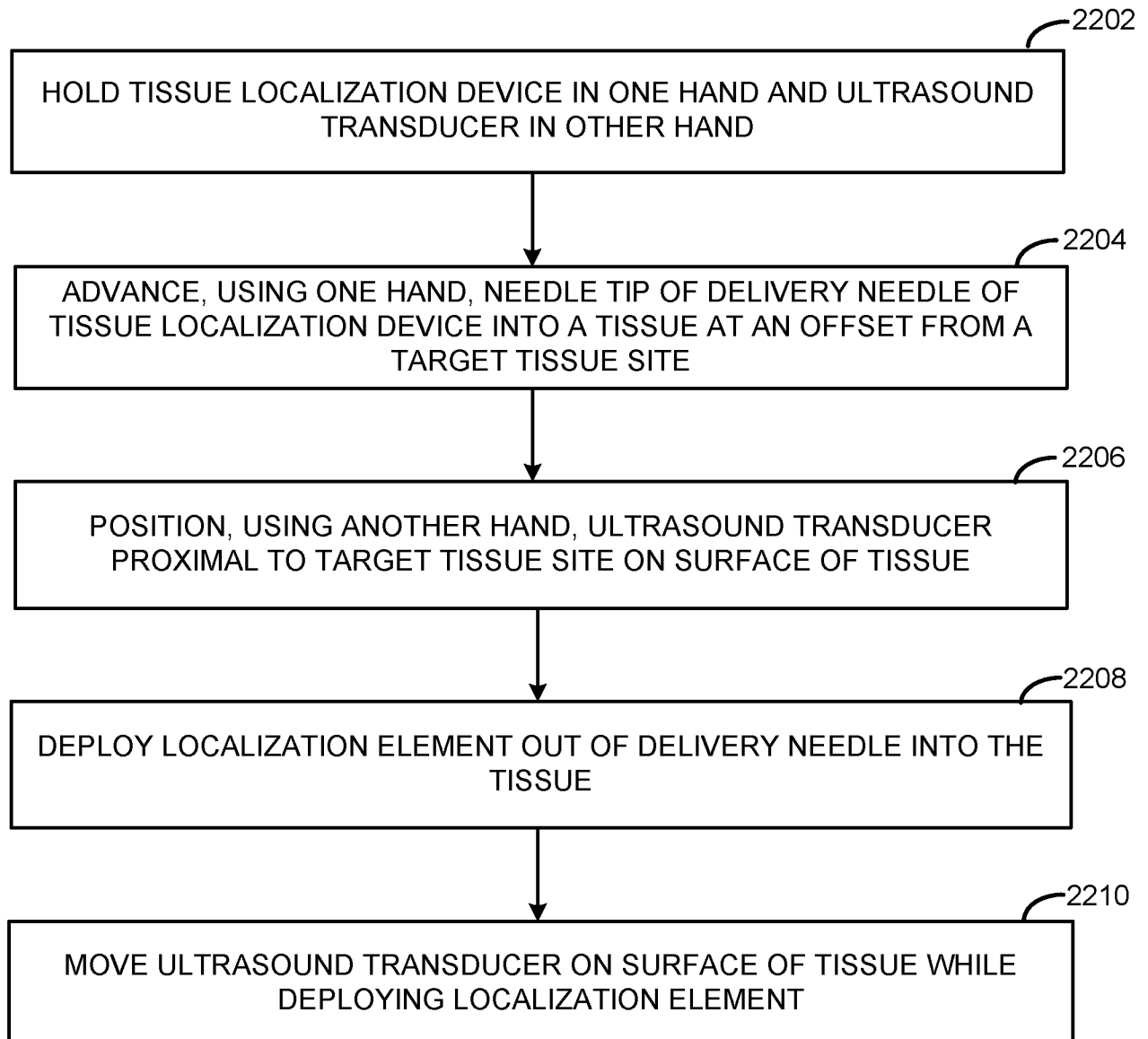


FIG. 20D

2100 →

**FIG. 21**

2200 **FIG. 22**

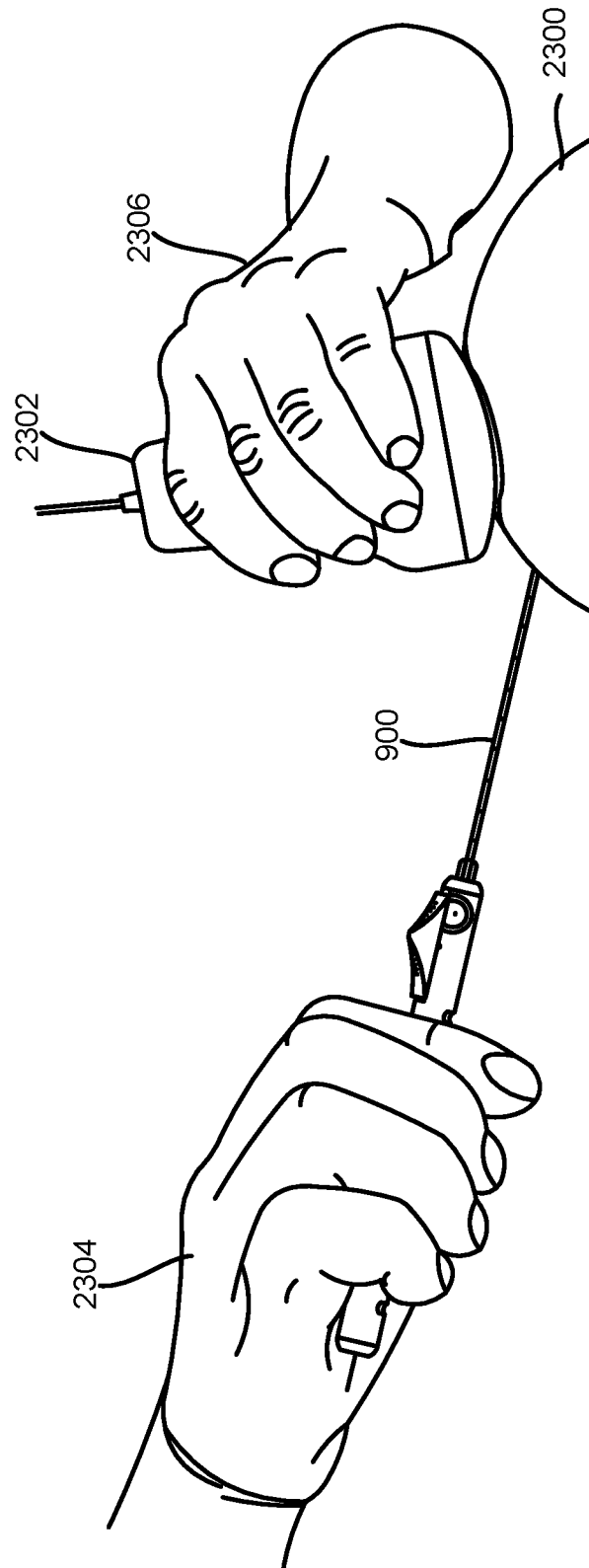


FIG. 23A

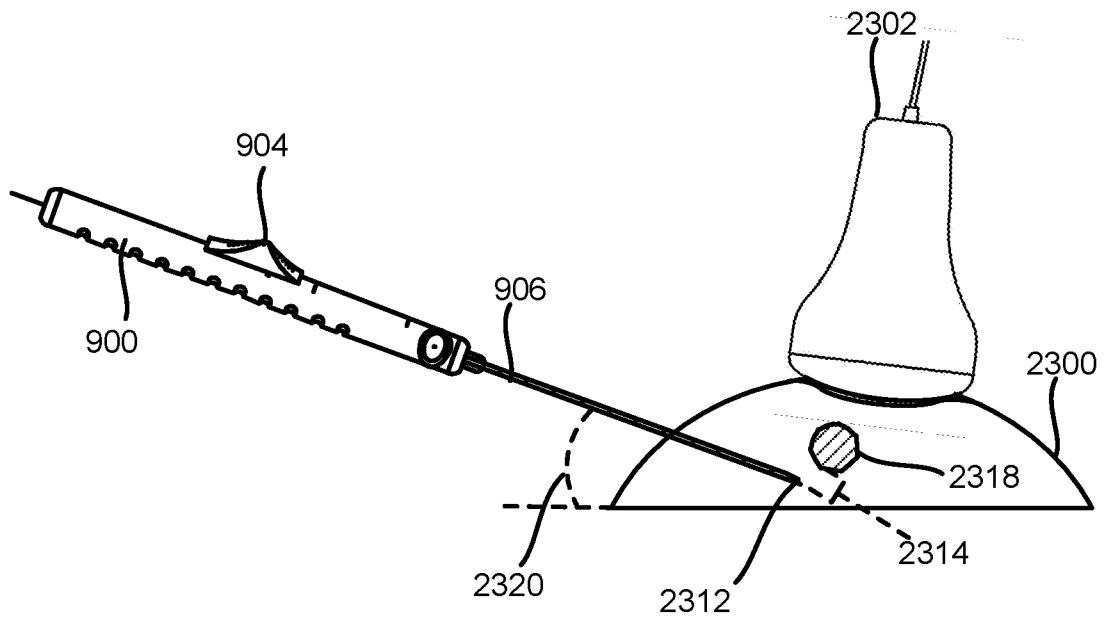


FIG. 23B

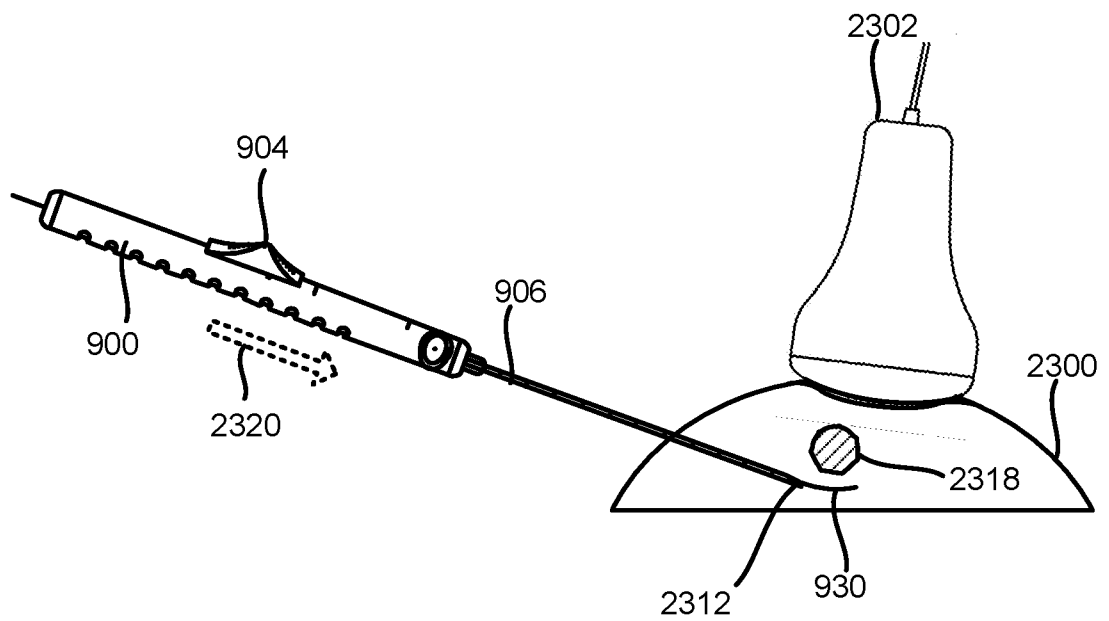


FIG. 23C

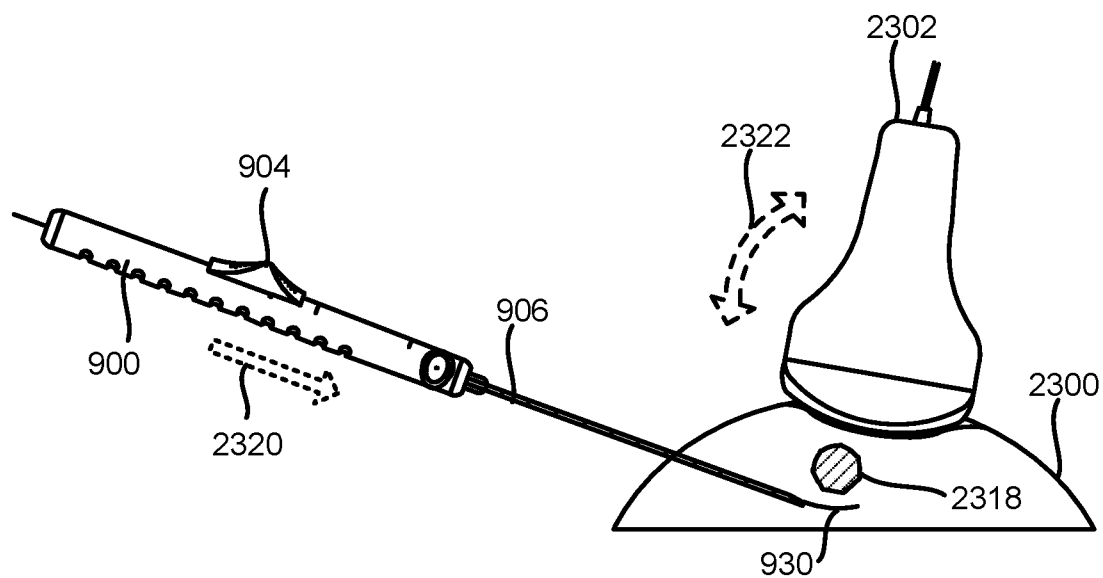


FIG. 23D

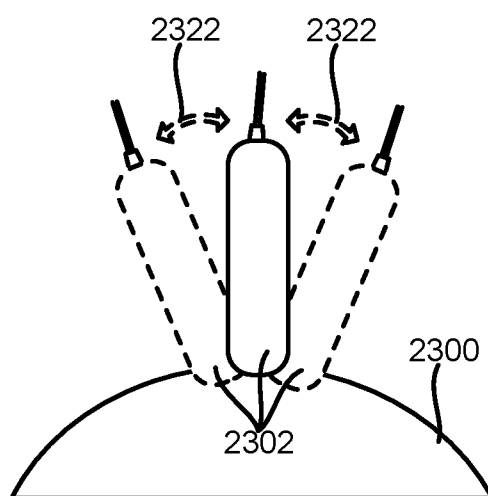


FIG. 23E

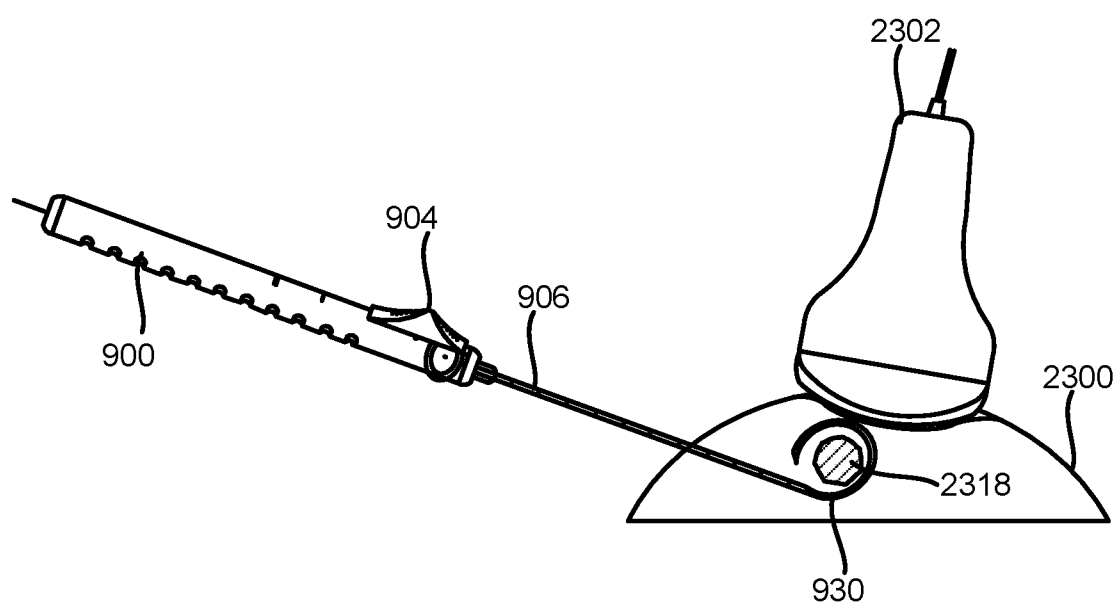


FIG. 23F

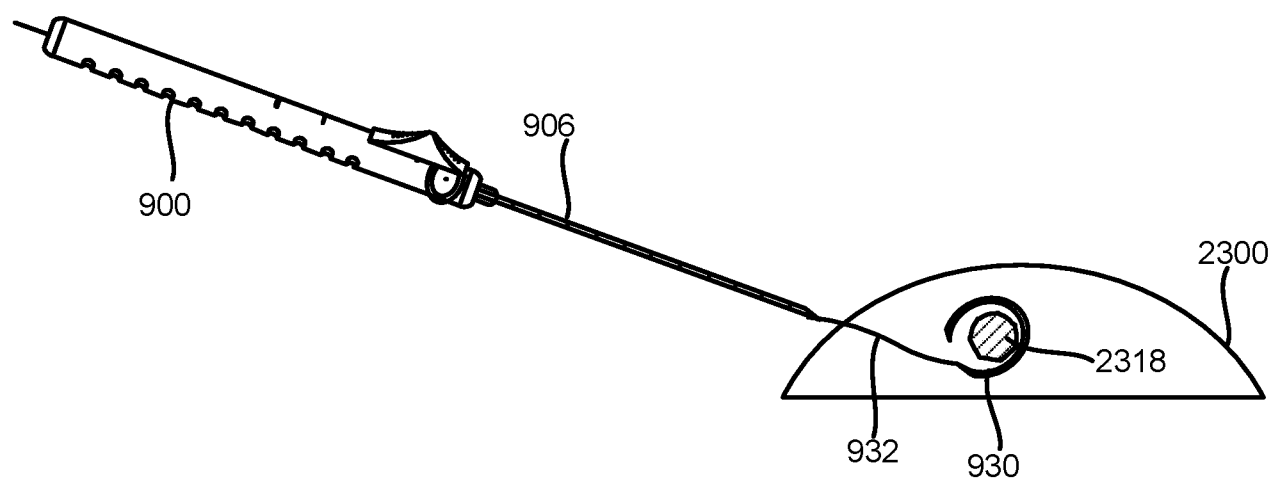
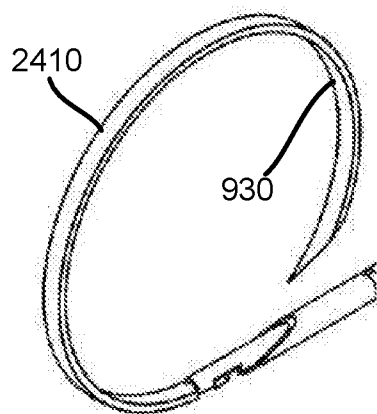
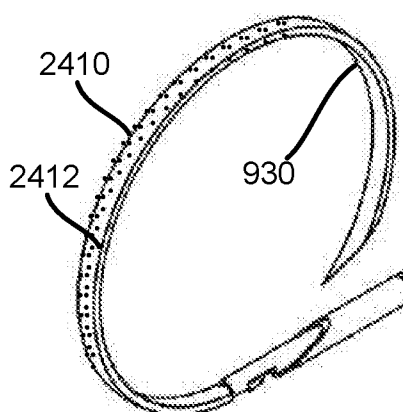
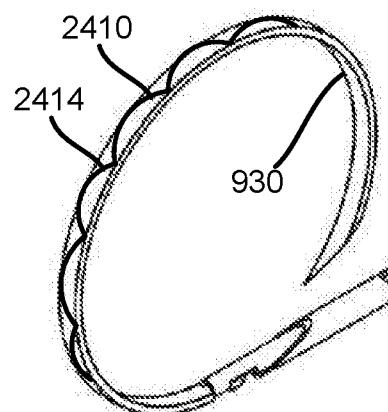
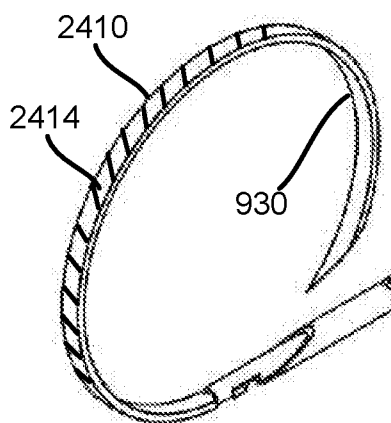
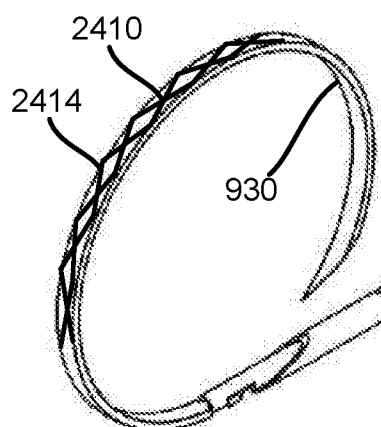
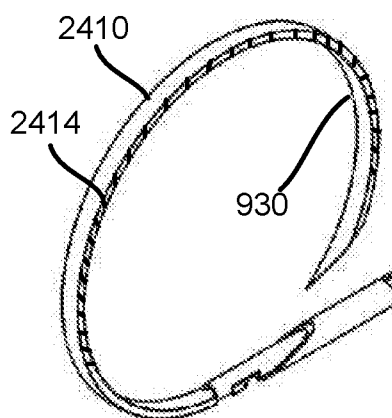
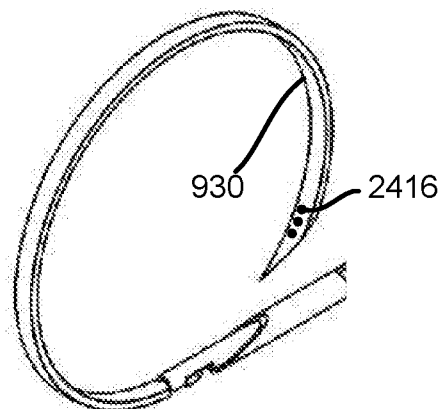
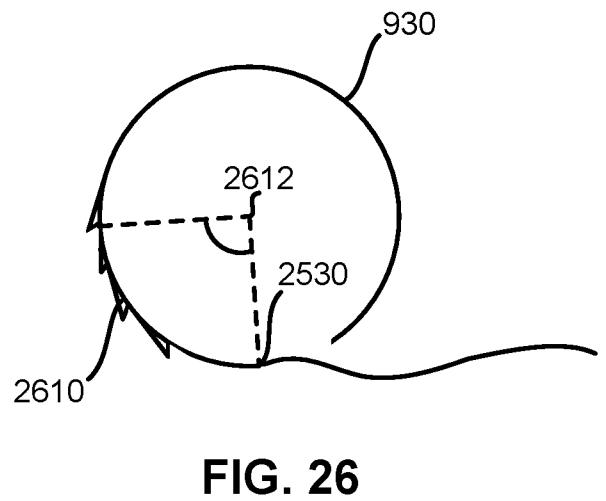
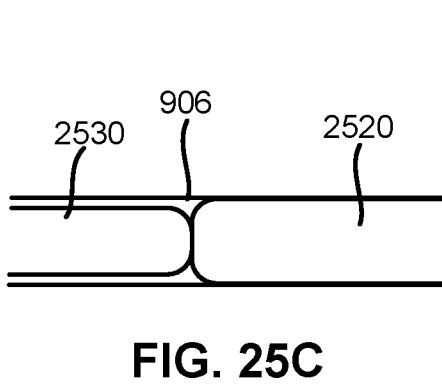
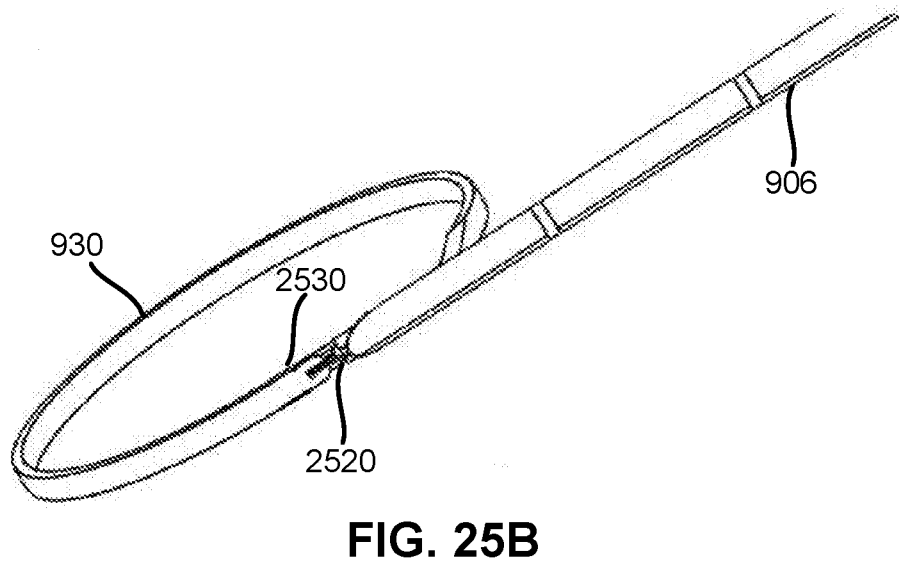
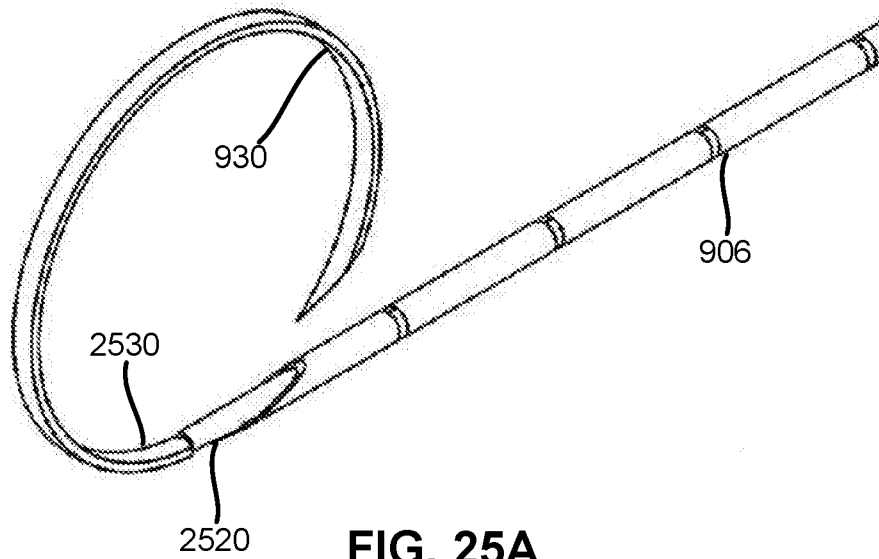


FIG. 23G

**FIG. 24A****FIG. 24B****FIG. 24C****FIG. 24D****FIG. 24E****FIG. 24F****FIG. 24G**



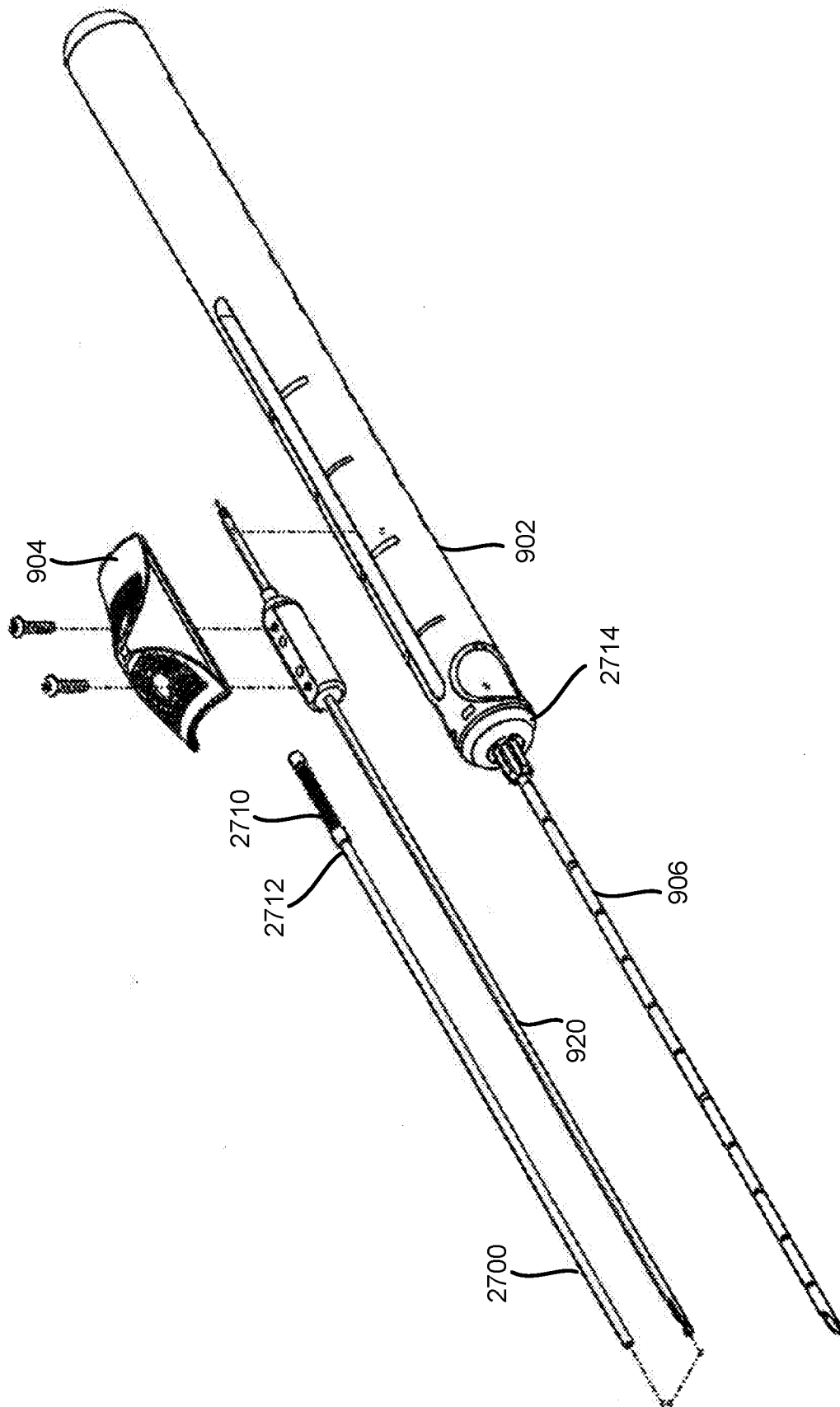
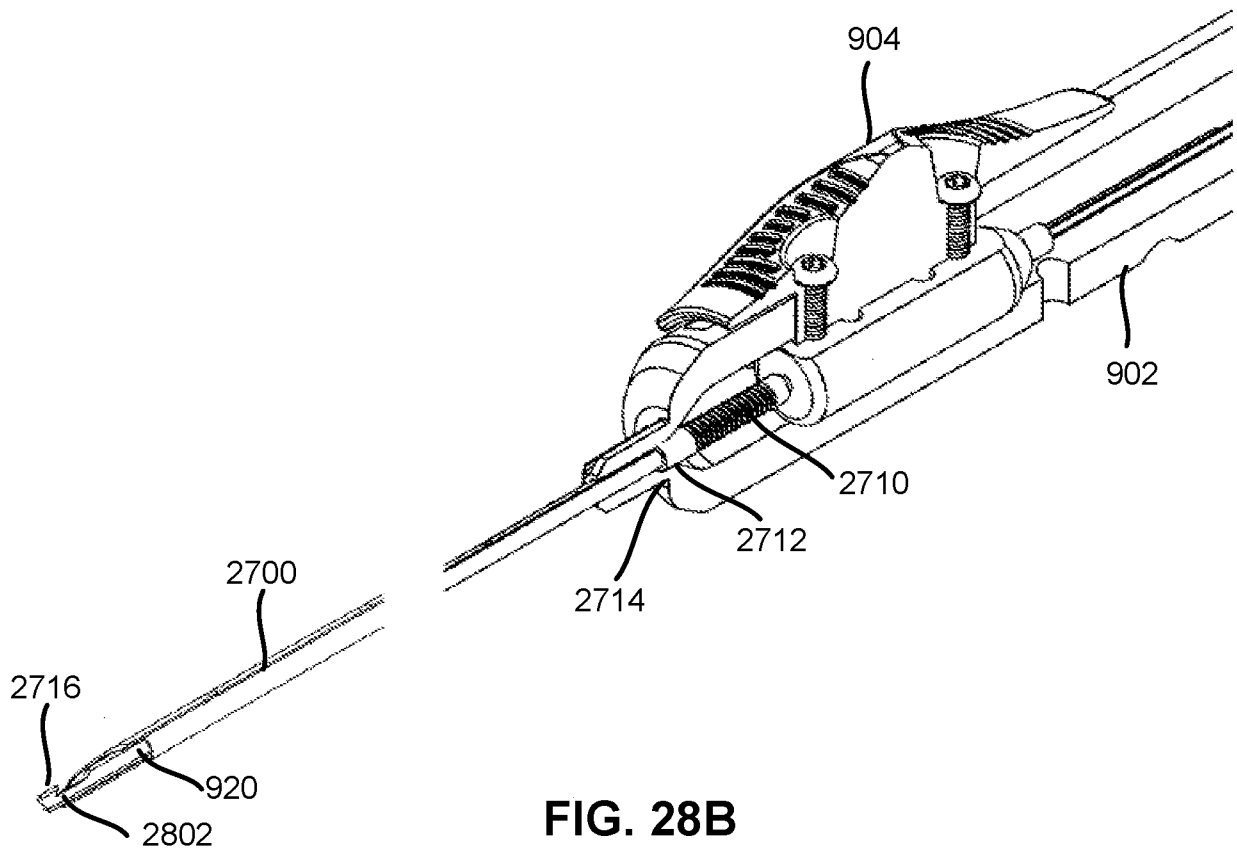
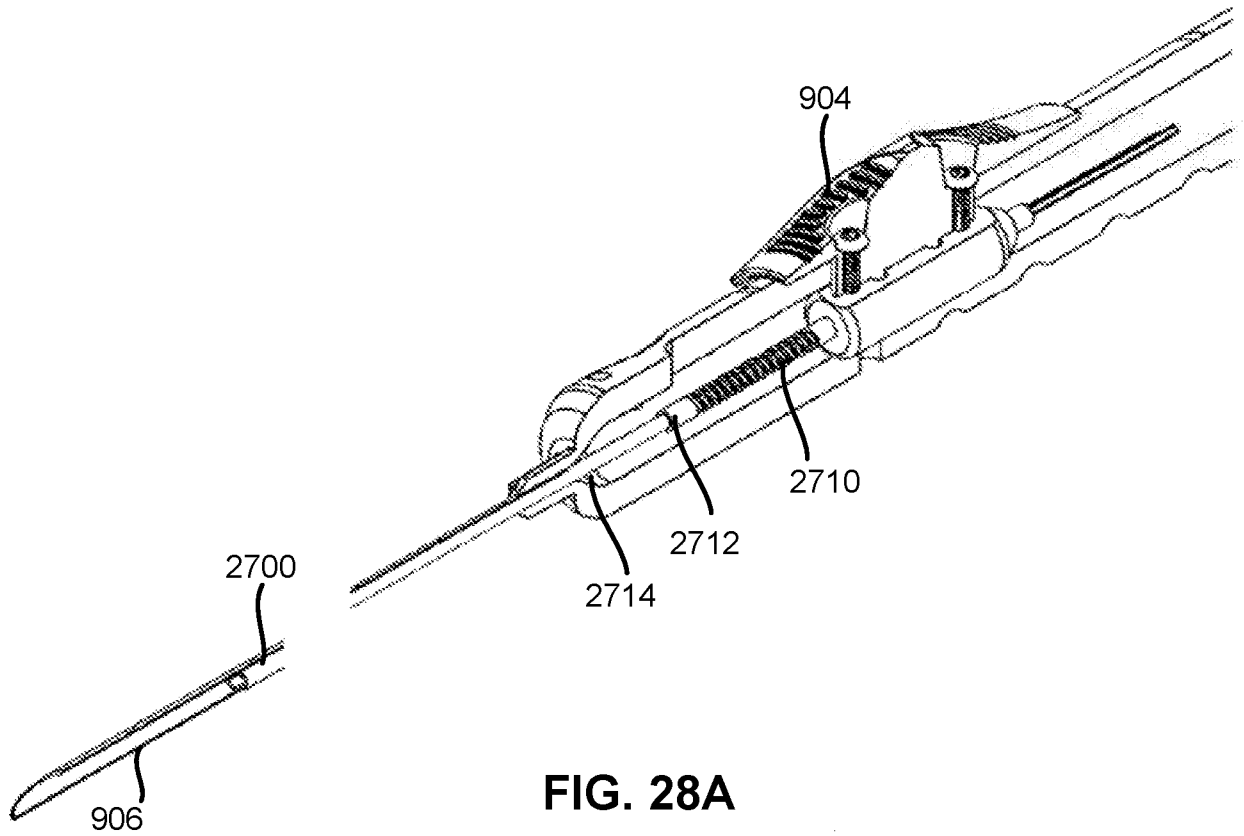
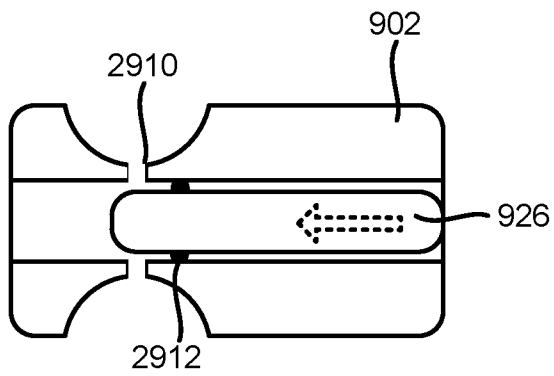
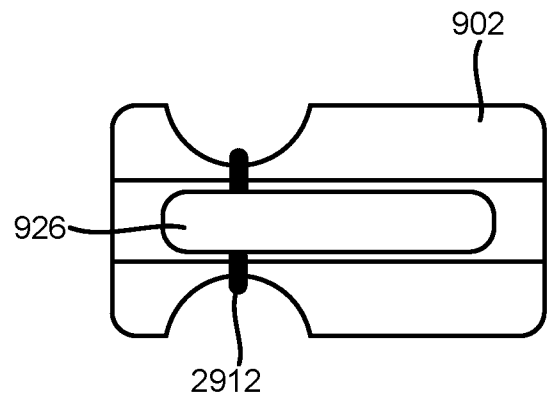
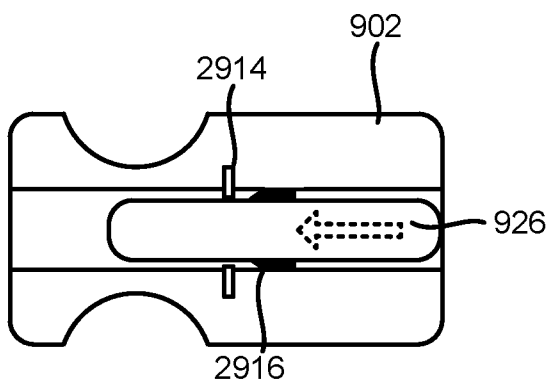
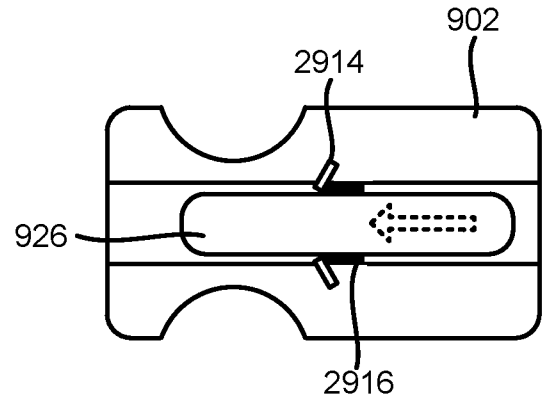
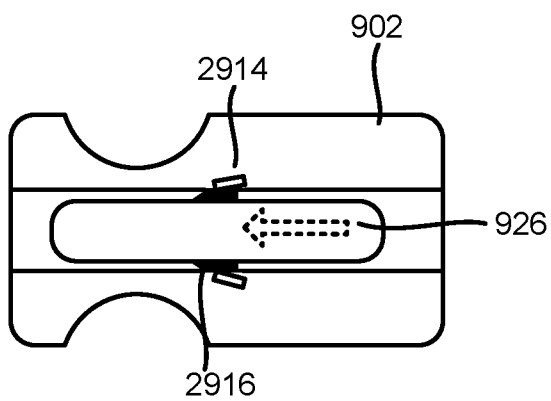
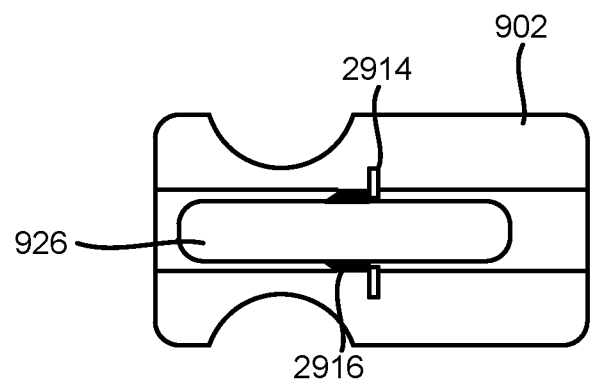


FIG. 27



**FIG. 29A****FIG. 29B****FIG. 29C****FIG. 29D****FIG. 29E****FIG. 29F**

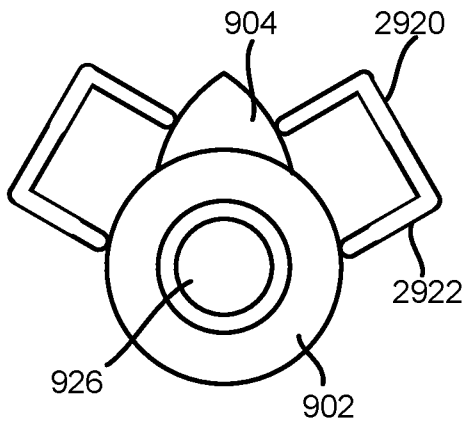


FIG. 29G

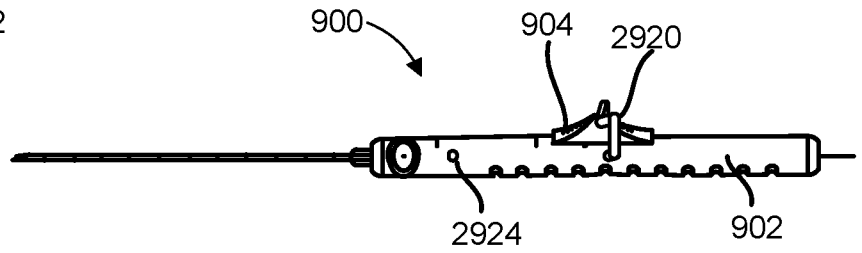


FIG. 29H

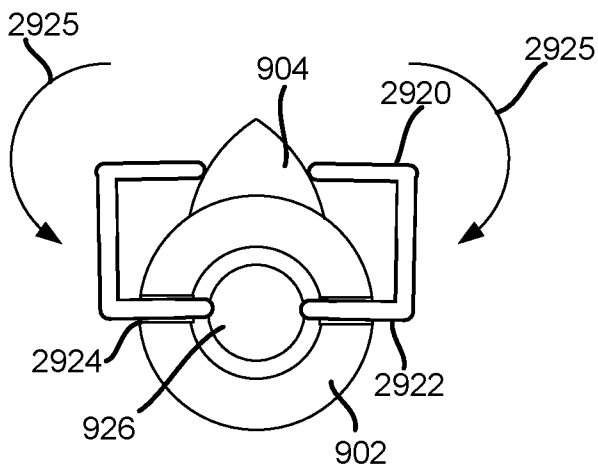


FIG. 29I

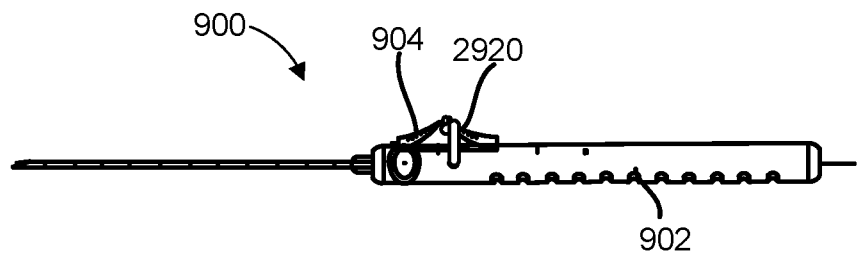


FIG. 29J

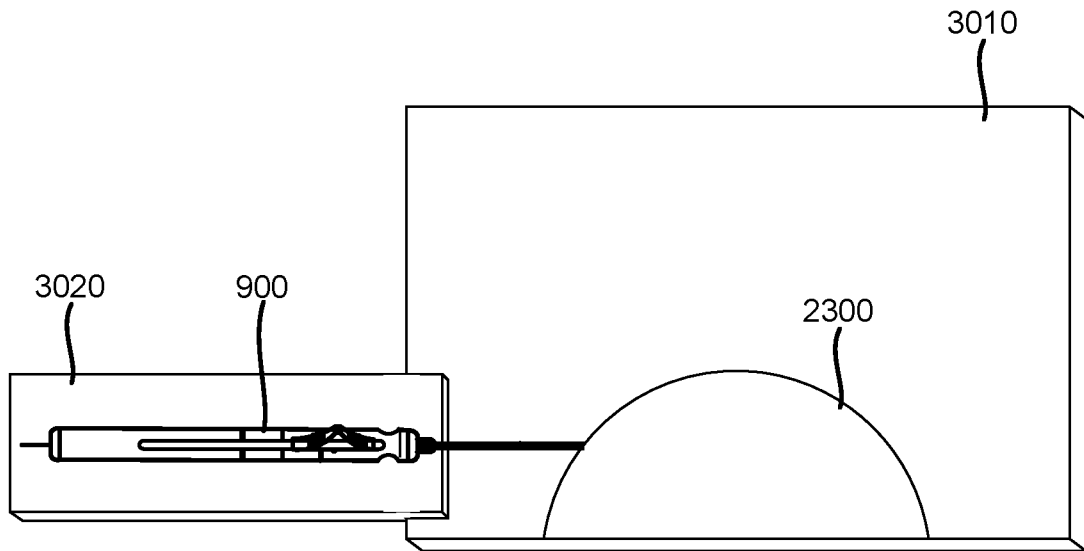


FIG. 30A

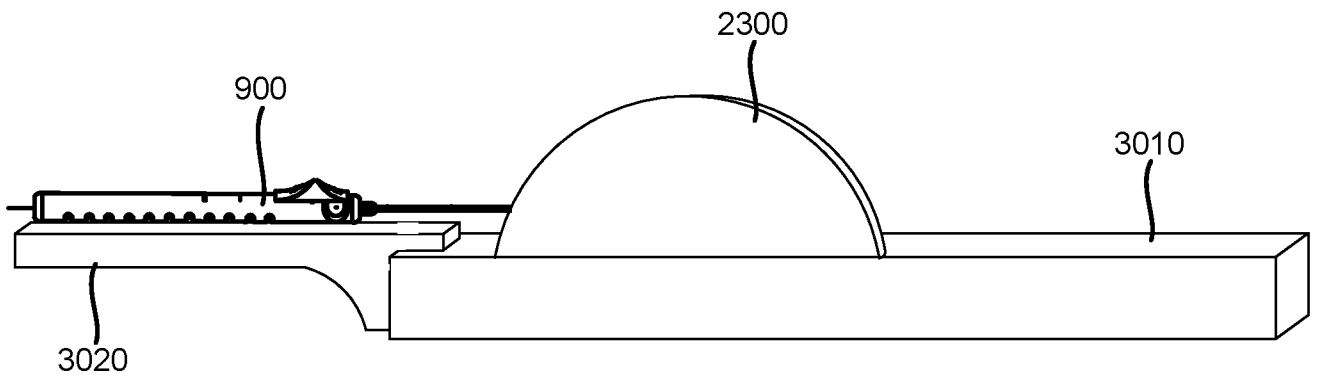


FIG. 30B

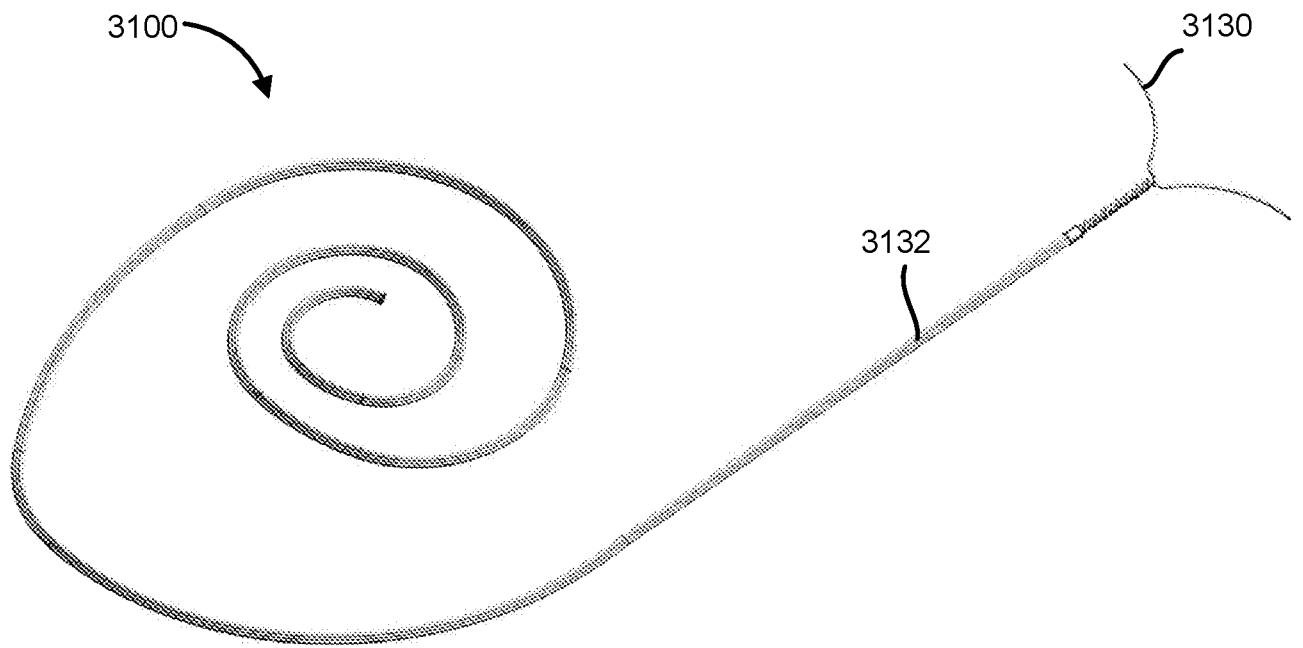


FIG. 31A

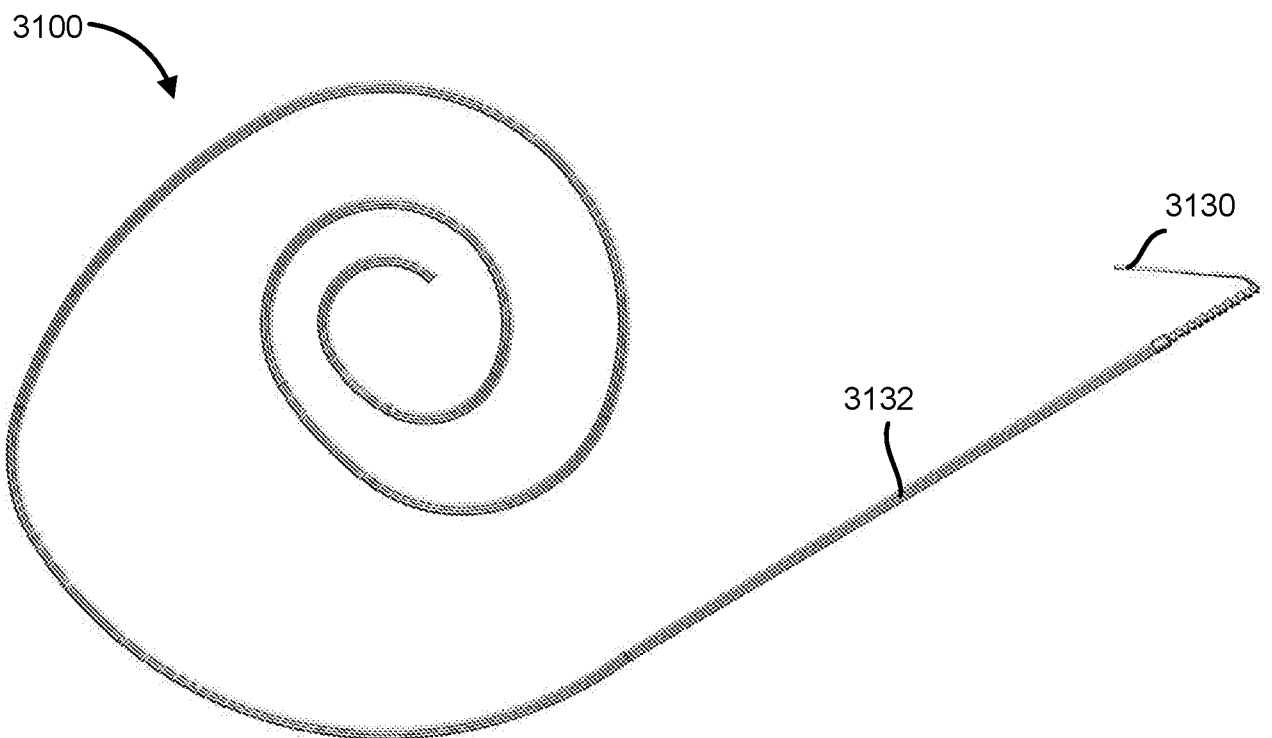


FIG. 31B

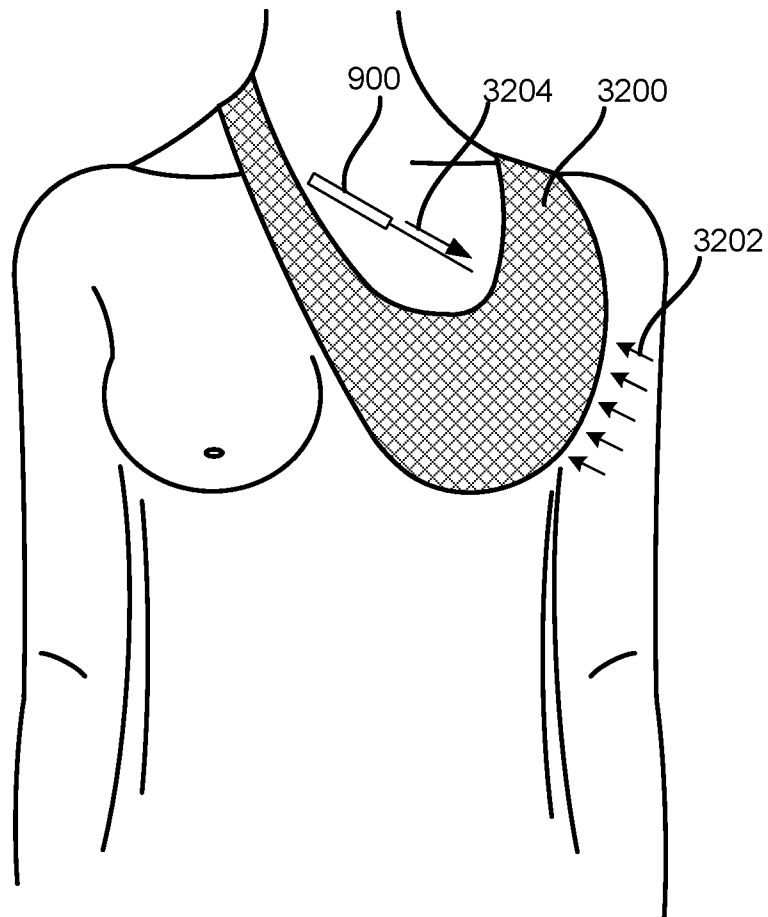
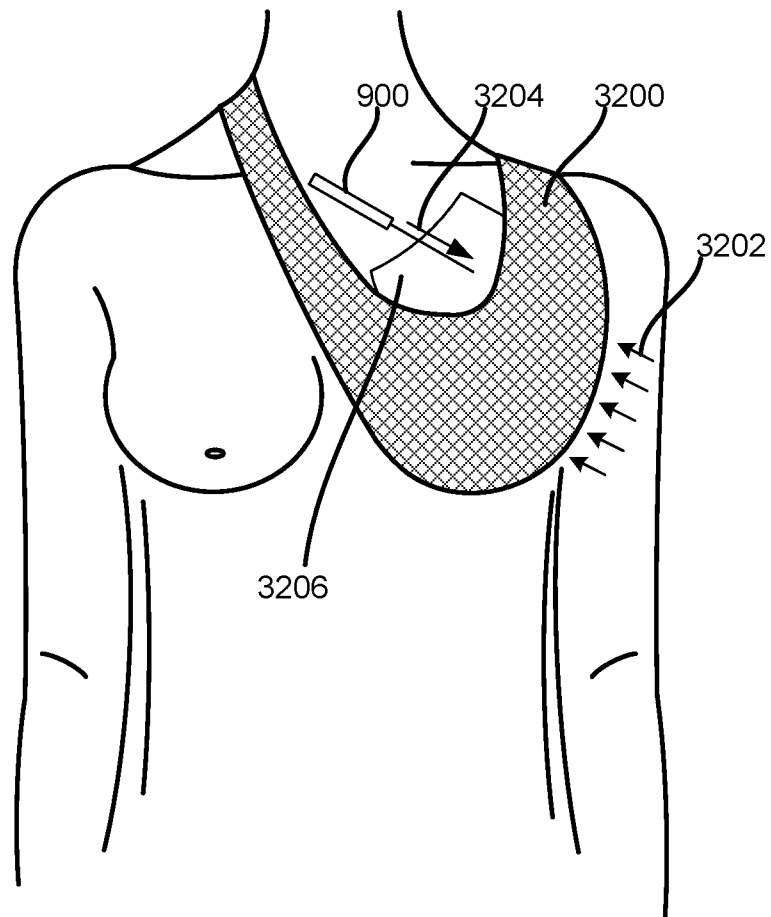


FIG. 32A

**FIG. 32B**

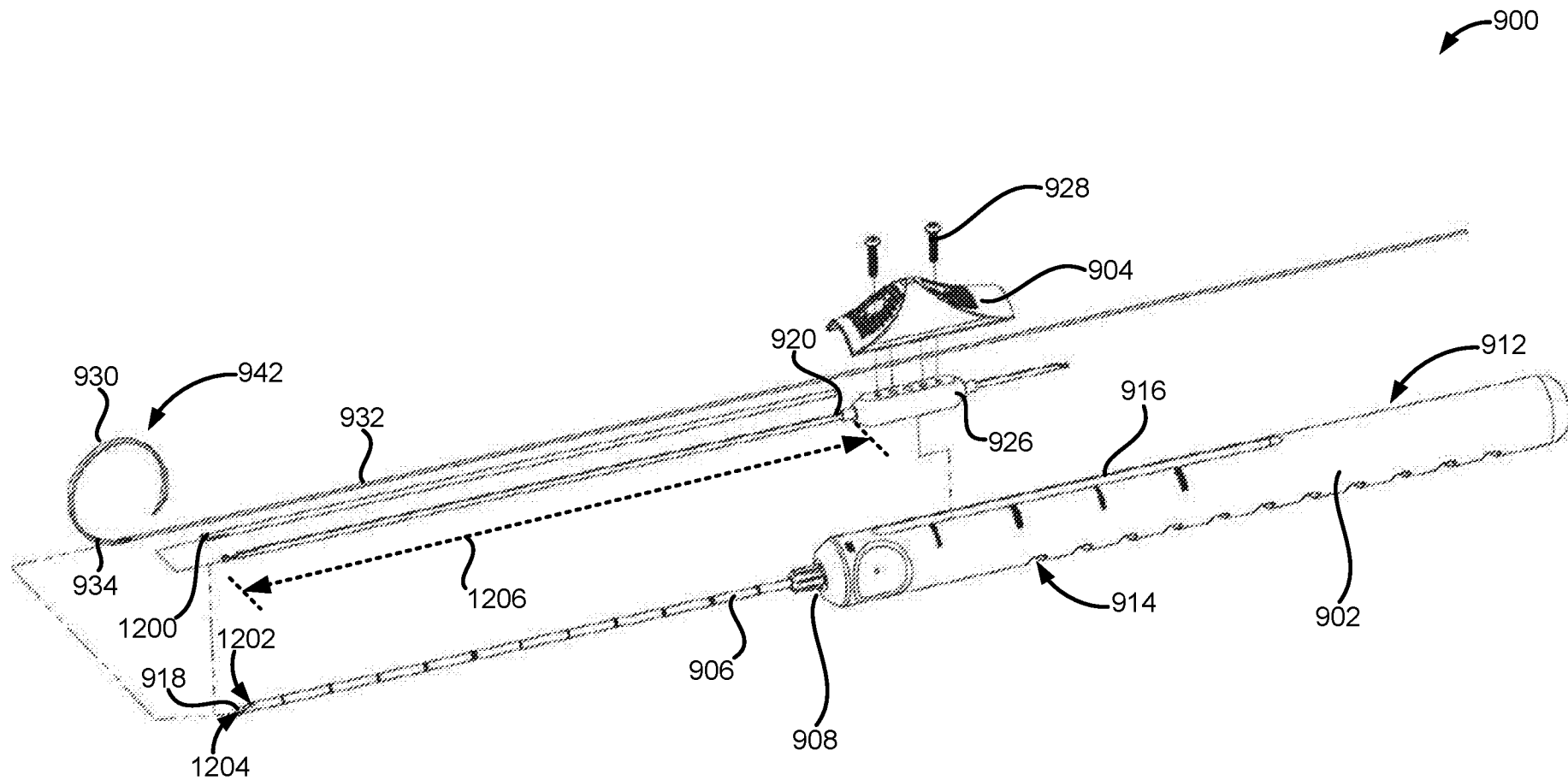


FIG. 12