



(51) International Patent Classification:

A61M 5/158 (2006.01)

(21) International Application Number:

PCT/US2018/012302

(22) International Filing Date:

04 January 2018 (04.01.2018)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/443,469 06 January 2017 (06.01.2017) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: LYMPH NODE ACCESS NEEDLE

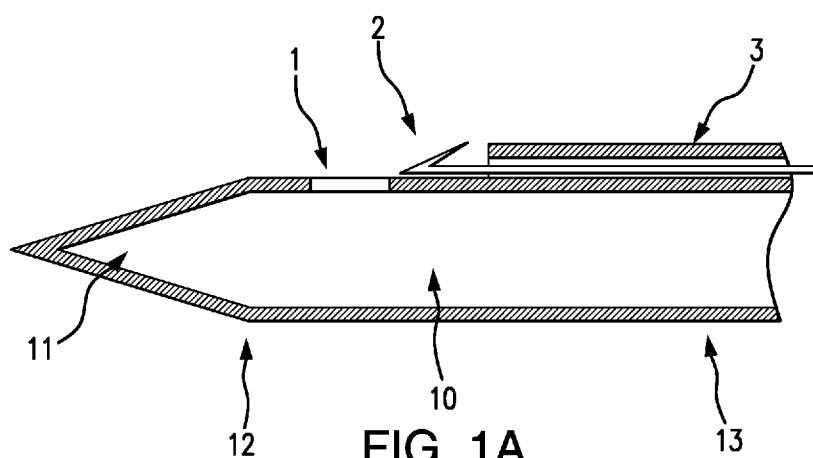


FIG. 1A

(57) Abstract: The presently disclosed subject matter relates to needles that can be secured in tissue of interest and methods of using the same. In particular, the present disclosure provides needles that can be secured in a lymph node and methods of their use. In further embodiments, the disclosure provides methods of performing intranodal lymphangiogram using the disclosed needles.



LYMPH NODE ACCESS NEEDLE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to United States Provisional Application Serial
5 No. 62/443469, filed on January 6, 2017, which is incorporated by reference herein in its entirety.

BACKGROUND

The lymphatic system plays a key role in fat and protein transport and the
10 removal of interstitial fluid from soft tissues. Imaging of the lymphatic system can be crucial to understanding its role in disease processes and to planning lymphatic interventions. This can be especially important with the development of newer minimally invasive lymphatic interventional techniques (Nadolski, 2013; Itkin, 2010). However, despite growing recognition of the role of the lymphatic system in many
15 disease processes, certain techniques for imaging of the lymphatic system have lagged behind the well-developed methods for imaging of the cardiovascular system (Vogt, 2013; Sharma, 2008).

Until recently, pedal lymphangiography has been the main method to image the lymphatic system. Ultrasound-guided intranodal injection of oil-based contrast agent has
20 been introduced as an alternative to traditional pedal lymphangiography. This technique can be faster and less invasive and, as a result has largely replaced pedal lymphangiogram as the method of choice for imaging of the central lymphatic system during percutaneous lymphatic interventional procedures. As a result, lymphatic imaging and intervention has become more common. The Intranodal lymphangiogram
25 technique has also found use in connection with a Magnetic Resonance ("MR") imaging technique, MR lymphangiogram.

Intranodal lymphangiogram employs an ultrasound guidance to place a small gauge needle in the center of the lymph node. A contrast material is then slowly injected into the lymph node. The lymphatic system is then imaged. A technical problem with
30 intranodal lymphangiogram can be easy dislodgement of the needle from the lymph node. Such dislodgement can cause the contrast material to be leaked into the surrounding tissue and will result in poor imaging. For at least that reason, there remains a need in the art to secure the needle in the lymph node.

SUMMARY

The presently disclosed subject matter relates to needles for delivering a liquid into a lymph node, including needles further comprise a securing device. The disclosed subject matter further relates to methods for securing a needle in a lymph node and
5 methods for performing intranodal lymphangiogram.

In certain embodiments, the disclosed subject matter relates to needles for delivering a liquid to a lymph node where the needle has a proximal end, a distal end and a side wall. In certain embodiments, the proximal end of the needle can be attached to a vessel housing a liquid to be delivered to the lymph node through the needle. In certain
10 embodiments, the vessel housing a liquid is a syringe. The tip of the needle is at the distal end. In certain embodiments, the tip of the needle is inserted into the lymph node. In certain embodiments, the tip of the needle is inserted through the lymph node, and the side wall of the needle is exposed to the interior of the lymph node. In certain embodiments, the needle has a liquid delivery opening on the side wall of the needle. In
15 certain embodiments, the needle further includes a securing device.

In certain embodiments, the tip of the needle is closed. In a closed tip, liquid cannot escape from the tip of the needle. In other embodiments, the tip of the needle is open. In an open tip, liquid can escape from the tip of the needle.

In certain embodiments, there is a channel outside of and adjacent to the side wall
20 of the needle. The securing device can be housed within the channel outside of and adjacent to the side wall of the needle. In certain embodiments, the securing device can be a deployable securing hook. The deployable securing hook can be arrow shaped, curved, or any other shape capable of securing the needle in the lymph node. In other embodiments, the securing device can be glue. In such embodiments, the glue can be
25 likewise housed in a channel outside of and adjacent to the side wall of the needle. The glue would be deployable through the channel into tissue surrounding, but not in the lymph node.

Certain embodiments can include a securing device that is located within the side wall of the needle. In certain embodiments, the securing device can be a deployable
30 securing hook. The deployable securing hook can be arrow shaped, curved, or any other shape capable of securing the needle in the lymph node.

Certain embodiments can include a securing device that includes a spiral element. The spiral element can be advanced through a separate channel that is located inside the

needle. In certain embodiments, the spiral element is deployed proximal to the lymph node. In certain embodiments, the spiral element is deployed distal to the lymph node.

In certain embodiments, the securing device is an inflatable member. The inflatable member can be inflated through a separate channel located inside the needle.

5 In certain embodiments, the inflatable member is deployed proximal to the lymph node. In certain embodiments, the inflatable member is deployed distal to the lymph node. In certain embodiment, the inflatable member is a balloon.

In certain embodiments, the presently disclosed subject matter further relates to methods for securing a needle in a lymph node. In certain embodiments, such methods
10 include placing a needle comprising a securing device in a lymph node and deploying the securing device. In certain embodiments, the securing device is a deployable securing hook. In certain embodiments, the securing device is glue. In certain embodiments, the method can further include administering a liquid through the needle into the lymph node. In certain embodiments, the liquid is a contrast agent. In certain embodiments, the
15 liquid is a therapeutic agent. In certain embodiments, the liquid can be any liquid that needs to be delivered to the lymph node. In certain embodiments, the method can further include retracting the securing device and removing the needle from the lymph node.

In certain embodiments, the presently disclosed subject matter further relates to methods for performing intranodal lymphangiogram. In certain embodiments, the
20 methods include placing a needle which includes a securing device in a lymph node and deploying the securing device. In certain embodiments, the method can also include administering a liquid through the needle into the lymph node. In certain embodiments, the method can further include retracting the securing device and removing the needle from the lymph node. In certain embodiments, the liquid administered through the
25 needle into the lymph node is a contrast agent.

BRIEF DESCRIPTION OF THE FIGURES

Figures 1A-1H shows exemplary embodiments of needles according to the presently disclosed subject matter.

30

DETAILED DESCRIPTION

The lymphatic system plays a crucial role in the transport of excess fluid and metabolites from the tissues back to the circulatory system. Lymphatic abnormalities are

associated with several disease processes, including cirrhosis and congestive heart failure, among others (Dumont, 1962; Dumont, 1960). Lymphatic malformations and injuries can result in leakage of lymph into tissue, including chylothorax, chylous ascites, and chylous pericardium, conditions that can be associated with substantial mortality and morbidity (Mallick, 2003). One of the main challenges in finding a treatment for these conditions has been a lack of simple minimally invasive high-spatial- and high-temporal-resolution imaging techniques for visualization of the lymphatic system.

Previously, in patients with central lymphatic circulatory disorders, conventional lymphography was the main modality for diagnosis and for guiding therapy. Cope et al. (Cope, 1999) first reported on the use of pedal lymphangiography to guide transabdominal percutaneous thoracic duct embolization procedures for treatment of chylothorax. Until recently, pedal lymphangiographically guided percutaneous embolization procedures were the main method used to treat both traumatic and nontraumatic chylous leaks (Marcon, 2011). Ultra sound -guided intranodal injection of oil-based contrast agent has been introduced as an alternative to traditional pedal lymphangiography (Nadolski, 2012; Rajebi, 2011). This technique is faster and less invasive and is now becoming the method of choice for imaging of the central lymphatic system during percutaneous lymphatic interventional procedures.

During intranodal lymphangiography, a fine-needle is placed into a lymph node while guided by ultrasound. Needle placement is followed by slow injection of a liquid, such as a contrast agent, to opacify the lymphatic system. The main technical problem with this procedure is easy dislodgement of the needle from the lymph node, which results in contrast agent leaking into the surrounding tissue.

The presently disclosed subject matter relates to methods and devices for delivering a liquid to a lymph node. In particular, in certain embodiments, the present disclosure relates to needles comprising a securing device for delivering a liquid to a lymph node and methods for securing needles in a lymph node using such devices. In certain embodiments, it further relates to methods of performing intranodal lymphangiogram using the disclosed needles.

Unless otherwise defined, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art.

Needles

In certain embodiments, the present disclosure relates to needles used to deliver a liquid to a lymph node that further contains a securing device. Accordingly, the present disclosure relates to needles that prevent dislodgement from the lymph node.

5 In certain embodiments, needles according to the disclosed subject matter can deploy a securing device to anchor the needle inside the lymph node for administration of a liquid to the lymph node.

As shown in Figure 1A, in certain embodiments, the needle (10) can have a closed tip (11) at the distal end (12) of the needle. In certain embodiments, the proximal end (13) of the needle can be attached to a vessel housing a liquid to be delivered to the lymph node through the needle. In certain embodiments, the tip of the needle is pointed.
10 This facilitates puncturing the skin and surrounding tissue to reach the lymph node. The closed tip does not allow liquid to escape out of the distal end (12) of the needle (10). This exemplary embodiment also includes an opening (1) in the side wall of the needle. The opening, for example, but not by way of limitation, can be 1-100 mm away from the tip of the needle. In other embodiments, the opening (1) in the side wall can be 1-50, 1-25, 1-10, 1-5, or 1-2 mm away from the tip of the needle. The opening (1) in the side wall of the needle does allow liquid to escape from the needle into the surrounding tissue.
15

In certain embodiments, the needle (10) can include a securing device. In the non-limiting exemplary embodiment depicted in Figure 1A, the securing device is composed of a separate channel (3) and a deployable securing hook (2). In certain
20 embodiments, the separate channel (3) runs parallel to the needle (10). In the depicted non-limiting exemplary embodiment, the channel (3) ends before the opening (1) in the side wall of the needle. The deployable securing hook (2) is housed within the channel (3). The deployable securing hook (2) can be of any shape that provides resistance when deployed and does not interfere with delivery of liquid through the needle (10) to the lymph node. An exemplary, non-limiting deployable securing hook (2) shape is an arrow shape, as depicted in Figure 1A. A further non-limiting example of a deployable
25 securing hook shape (2) is curved out away from the side wall of the needle (10), as depicted in Figure 1B. In certain embodiments, the deployable securing hook (2) is further retractable.
30

In certain embodiments, the needle (10) has an open tip (14), as depicted in Figure 1C. In that non-limiting exemplary embodiment, the deployable securing hook

(2) is housed within the needle (10) and no exterior channel is present. As described above, the deployable securing hook (2) can have any shape that deploys into the surrounding tissue and secures the needle in the lymph node (4), including an arrow shape, a curved shape, or any other appropriate shape. In certain embodiments, upon deployment, the deployable securing hook (2) obstructs the open tip (14) of the needle (10) such that liquid can no longer exit through the tip of the needle. The embodiment in Figure 1C also has an opening (1) in the side wall of the needle through which liquid is delivered to the lymph node (4).

In certain embodiments, the disclosed needle has a securing device which includes glue. In the non-limiting exemplary embodiment in Figure 1D, for example, the glue can be housed within a channel (5) adjacent to the needle (10). In embodiments that have an opening (1) on the side of the needle (10) and a closed tip (11) at the distal end (12) of the needle (10), the channel (5) can end before or after the opening (1), but should be sufficiently distant from the opening (1) that glue does not get in the opening (1) or in the lymph node (4). The glue in the side channel (5) should not come into contact with the liquid in the needle. Glue described herein can be any biocompatible adhesive compound.

In certain embodiments, the needle has an open tip (14) that is located at the distal end (12) of the needle (10), and the securing device is a spiraling element (6) that is located inside the needle (10), as depicted in Figure 1E. The spiraling element (6) is deployed in spinning motion to enter the lymph node (4) and secure it when the needle tip (15) is introduced inside the lymph node. The tip (15) of the needle is positioned inside the lymph node (4) and the liquid is then delivered to the lymph node (4) around the spiraling element (6). At the end of the injection the spiraling element (6) is retracted back into the side wall of the needle.

In certain embodiment, the disclosed needle has a securing device which includes a spiral element (6). In the non-limiting exemplary embodiment in Figure 1F, for example, the spiral element (6) is advanced through a separate channel (7) that is located inside the needle (10). The spiral element (6) is deployed proximal to the lymph node (4) and secure the needle (10) when the needle tip (15) is positioned inside the lymph node (4) and the liquid is then delivered to the lymph node (4) through the opening (1). The opening (1) can locate at the needle tip (15) or on the side of the needle .

In another non-limiting exemplary embodiment in Figure 1G, for example, the spiral element (6) is deployed distal to the lymph node (4) through the separate channel (7) that is located inside the needle (10), and the liquid is delivered to the lymph node (4) through the opening (1) that is located on the side of the needle (10).

5 In certain embodiments, the disclosed needle has a securing device which includes an inflatable member (8) as depicted in Figure 1H. The inflatable element (8) is inflated through a separate channel (9) located inside the needle (10) and deployed proximal or distal to the lymph node to secure the needle (10). In certain embodiment, the inflatable member is a balloon.

10 Any or all components of the needles described herein can be made from, for example, single or multiple stainless steel alloys, nickel titanium alloys, cobalt-chrome alloys, nickel-cobalt alloys, molybdenum alloys, tungsten-rhenium alloys, polymers such as polyethylene terephthalate (PET), polyester, polyester amide, polypropylene, aromatic polyesters, such as liquid crystal polymers, ultra high molecular weight
15 polyethylene fiber and/or yarn, polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ketone (PEK), polyether ether ketone (PEEK), polyether ketone ketone (PEKK), nylon, polyether-block co-polyamide polymers, aliphatic polyether polyurethanes, polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as polyglycolic acid
20 (PGA), poly-L-glycolic acid (PLGA), polylactic acid (PLA), poly-L-lactic acid (PLLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic, radioactive, radiopaque materials or combinations thereof. Non-limiting examples of radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys,
25 tantalum, and gold. Alternatively or additionally, one or more components of the disclosed devices can be made from a biomaterial or coated with a biomaterial. Non-limiting examples of a biomaterial include tissue, collagen, allograft, autograft, heterograft, xenograft, bone cement, morselized bone, osteogenic powder and beads of bone. Alternatively or additionally, one or more components of the disclosed devices
30 can be coated with a polymer, chemical or biomaterial to make it more biocompatible or hydrophilic, or to prevent deposition of lipids or protein onto the walls and/or surfaces of the device. In certain embodiments, the needles of the disclosed subject matter can be disposable.

In certain embodiments, the needles of the disclosed subject matter are 15 gauge, 16 gauge, 17 gauge, 18 gauge, 19 gauge, 20 gauge, 21 gauge, 22 gauge, 23 gauge, 24 gauge, 25 gauge, 26 gauge, 27 gauge, 28 gauge, 29 gauge, 30 gauge, 31 gauge, 32 gauge, 33 gauge, or 34 gauge. In a preferred embodiment, the needle is 25 gauge. In another preferred embodiment, the needle is 26 gauge.

Methods of Use

In certain embodiments, the presently disclosed subject matter further relates to methods for securing one or more of the needles disclosed above in a tissue. For example, but not by way of limitation, the present disclosure provides methods for securing the disclosed needles within a lymph node.

In certain embodiments, the needle is placed in a lymph node. In those embodiments, the opening of the needle is placed so that liquid can be delivered from the needle through the opening of the needle into the lymph node and not the surrounding tissue. As discussed above, in certain embodiments, the liquid is delivered through an opening in the side wall of the needle. In such embodiments, the tip of the needle can extend beyond the lymph node, but the portion of the needle containing the opening must be in the lymph node.

In certain embodiments, the securing device is deployed after the needle is placed in the lymph node. The securing device can be any device suitable for anchoring the needle in place, including, by way of non-limiting example, those discussed in detail above. In certain embodiments, the liquid is administered through the needle into the lymph node after the securing device is deployed. In further embodiments, the securing device is retractable. In further embodiments, the method can also include removing the needle.

In certain embodiments, the liquid delivered to the lymph node is a contrast agent. Contrast agents are typically used to enhance image contrast, i.e., to “highlight” an organ of interest from surrounding tissue during medical imaging. Suitable contrast agents are well known to a person of skill in the art. Non-limiting examples of contrast agents include oil based iodinated contrast agent (lipiodol), water soluble iodinated contrast agents, gadolinium based contrast agent, iron based contrast agent and gold nanoparticles contrast agents. In certain embodiments, the contrast agent is an ethiodized oil.

In certain embodiments, the liquid delivered to the lymph node is a therapeutic agent. Therapeutic agents can include any compound capable of treating a patient, including chemical, biological, genetic and cellular compounds. In certain embodiments, the therapeutic agent treats a condition of the lymphatic system.

5 The presently disclosed subject matter further relates to methods for performing a medical procedure. For example, but not by way of limitation, the present disclosure provides methods for performing intranodal lymphangiogram.

10 In certain embodiments, the method includes placing the needle with a securing device in a tissue. The tissue can be soft tissue such as liver parenchyma or muscles or fat or connecting tissue or kidney tissue. In certain embodiments, the method can include placing the needle with a securing device in a lymph node. In certain embodiments, the method can further comprise deploying the securing device into the surrounding tissue, as discussed above. In certain embodiments, the method can comprise administering a liquid through the needle into the target tissue. In certain
15 embodiments, the method can comprise administering a liquid through the needle into the lymph nodes. In certain embodiments, the method can further comprise the step of retracting the securing device, as discussed above. In certain embodiments, the methods can also include the step of removing the needle from the tissue. By way of non-limiting example, in certain embodiments, the methods can also include the step of removing the
20 needle from the lymph node. In certain methods for performing intranodal lymphangiogram, the liquid delivered can be a contrast agent, as discussed above. In certain embodiments, the methods for performing intranodal lymphangiogram can be combined with other medical procedures. For example, other medical procedures include, but are not limited to catheterization of a part of the lymphatic system, catheterization of the thoracic duct, lymphatic embolization, thoracic duct embolization,
25 selective lymphatic embolization, direct percutaneous embolization, injection of the therapeutic agent into the lymphatic system any other type of lymphatic embolization.

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30 The following references are herein incorporated in their entirety.
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* * * *

- Although the presently disclosed subject matter and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the presently disclosed subject matter as defined by the appended claims. Moreover, the
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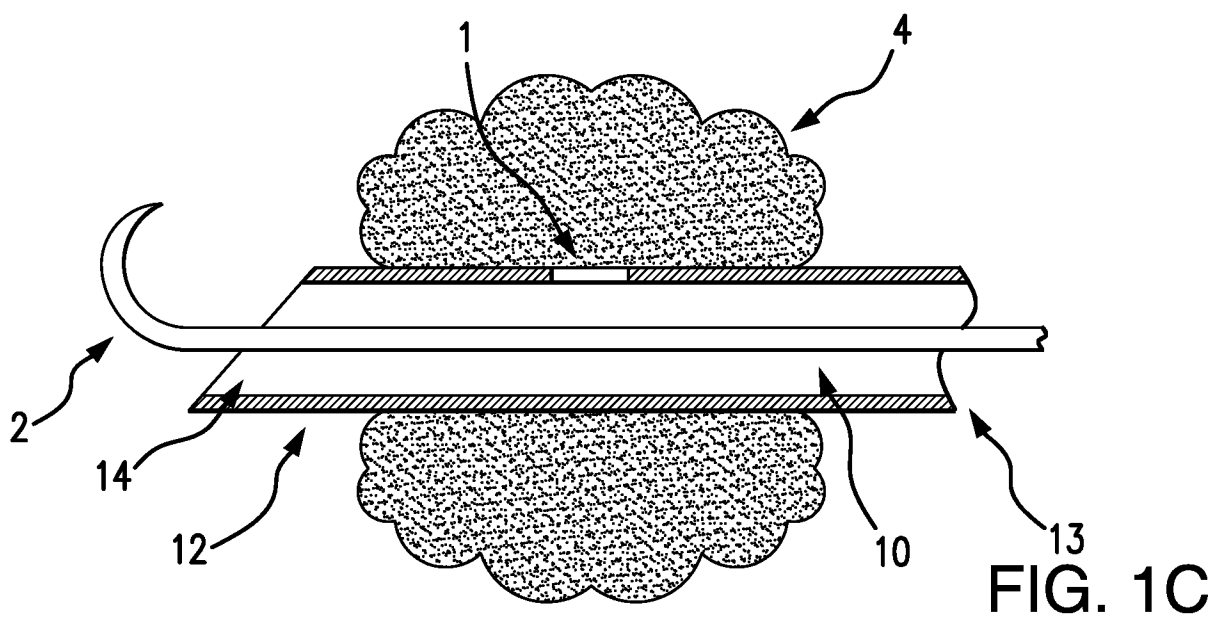
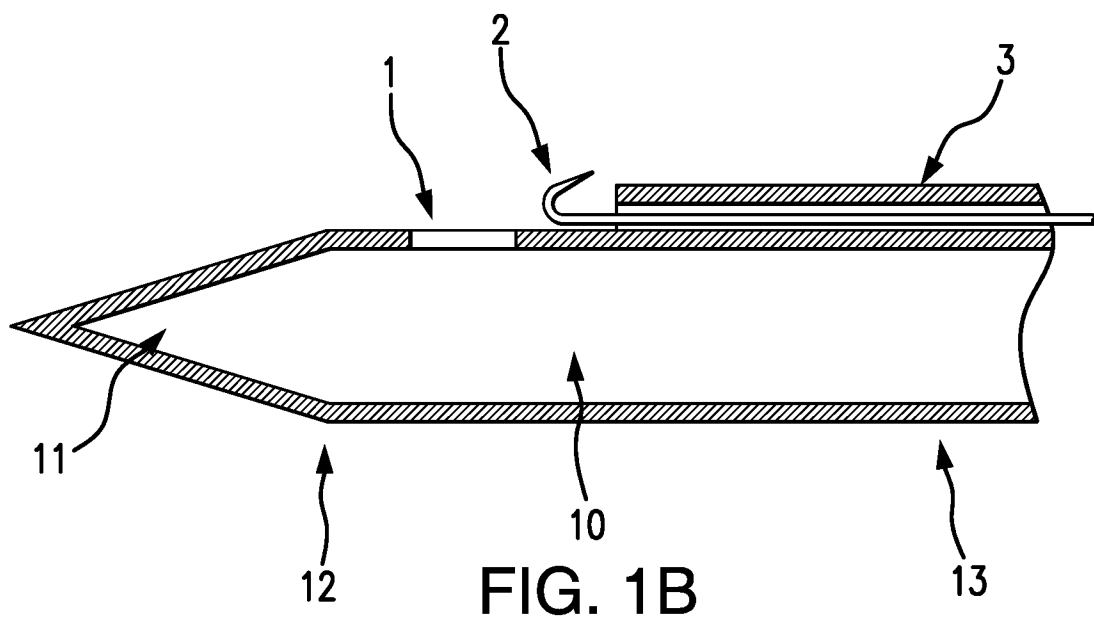
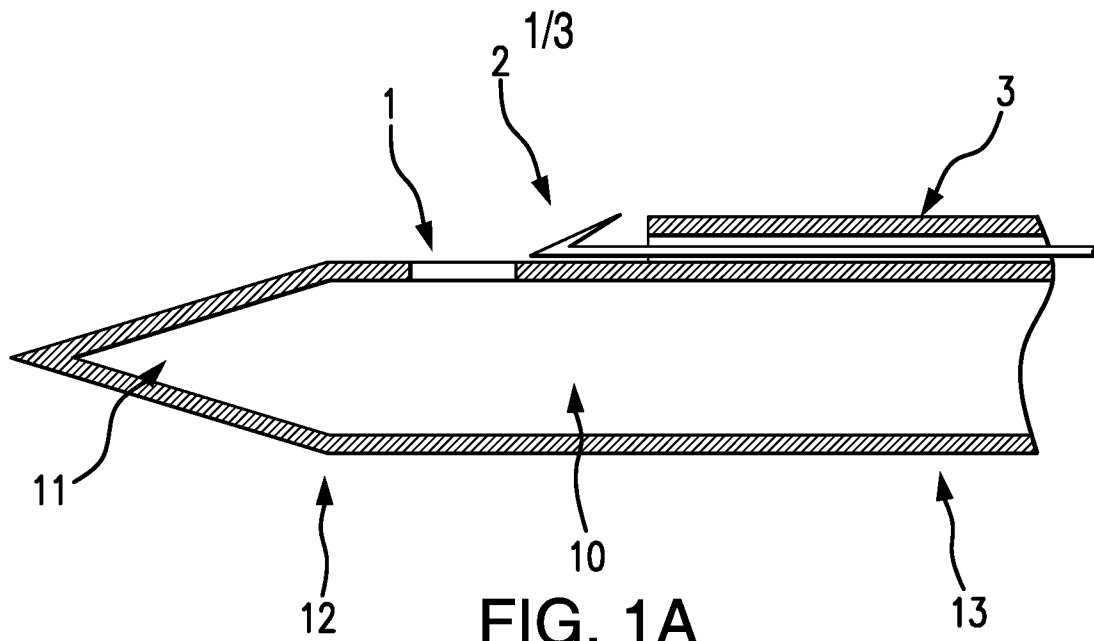
scope of the presently disclosed subject matter is not intended to be limited to the particular embodiments described in the specification. Accordingly, the appended claims are intended to include within their scope such modifications.

We Claim:

1. A needle for delivering a liquid to a lymph node comprising:
 - a. a proximal end;
 - 5 b. a distal end;
 - c. a side wall;
 - d. a liquid delivery opening on the side wall of the needle; and
 - e. a securing device
 - f. a tip
- 10 wherein the proximal end is attached to a vessel housing a liquid to be delivered to the lymph node and the tip of the needle is at the distal end.
2. The needle of claim 1, wherein the tip of the needle is closed.
- 15 3. The needle of claim 1, wherein the tip of the needle is open.
4. The needle of claim 2 further comprises a channel outside of and adjacent to the side wall of the needle.
- 20 5. The needle of claim 4, wherein the securing device is housed within the channel.
6. The needle of claim 5, wherein the securing device is a deployable securing hook.
7. The needle of claim 6, wherein the deployable securing hook is arrow shaped.
- 25 8. The needle of claim 6, wherein the deployable securing hook is curved away from the needle.
9. The needle of claim 3, wherein the securing device comprises a deployable
30 securing hook that is housed within the side wall of the needle.
10. The needle of claim 9, wherein the deployable securing hook is arrow shaped.

11. The needle of claim 9, wherein the deployable securing hook is curved away from the needle.
12. The needle of claim 5, wherein the securing device is glue.
13. The needle of claim 3, wherein the securing device comprises a spiraling element that is housed within the side wall of the needle.
14. The needle of claim 1, further comprises a separate channel located inside the needle.
15. The needle of claim 14, wherein the security device is deployed through the separate channel.
16. The needle of claim 15, wherein the security device is a spiraling element.
17. The needle of claim 15, wherein the security device is an inflatable member.
18. The needle of claim 17, wherein the inflatable member is a balloon.
19. A method for securing a needle in a lymph node for a procedure comprising:
- a. placing a needle comprising a securing device in a lymph node; and
 - b. deploying the securing device.
20. The method of claim 19, further comprising administering a liquid through said needle into the lymph node.
21. The method of claim 20, wherein the liquid is a contrast agent.
22. The method of claim 20, wherein the liquid is a therapeutic agent.
23. The method of claim 20, further comprising retracting the securing device and removing the needle from the lymph node

24. The method of claim 19, wherein the securing device is a deployable securing hook.
- 5 25. The method of claim 19, wherein the securing device is glue.
26. The method of claim 19, wherein the needle further comprises a liquid delivery opening on the side of the needle.
- 10 27. A method for performing intranodal lymphangiogram comprising:
- a. placing a needle comprising a securing device in a lymph node;
 - b. deploying the securing device;
 - c. administering a liquid through said needle into the lymph node;
 - d. retracting the securing device; and
 - 15 e. removing the needle from the lymph node.
28. The method of claim 27 wherein the liquid is a contrast agent.



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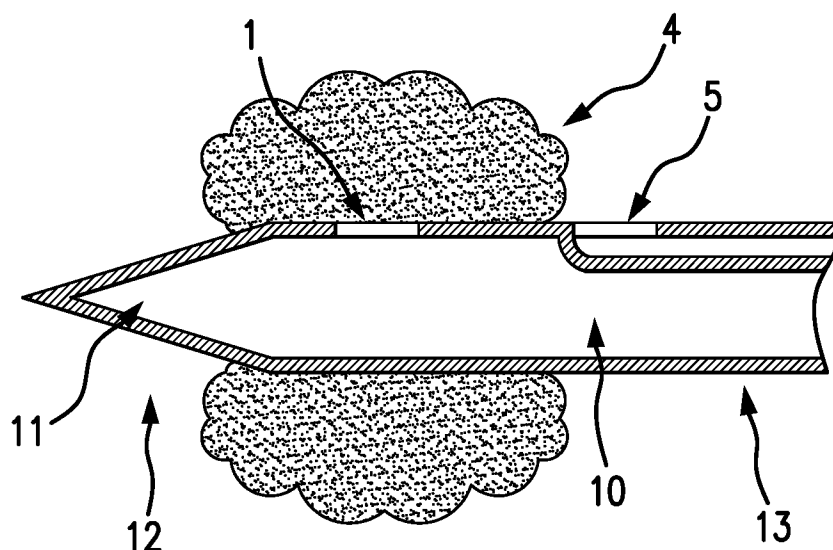


FIG. 1D

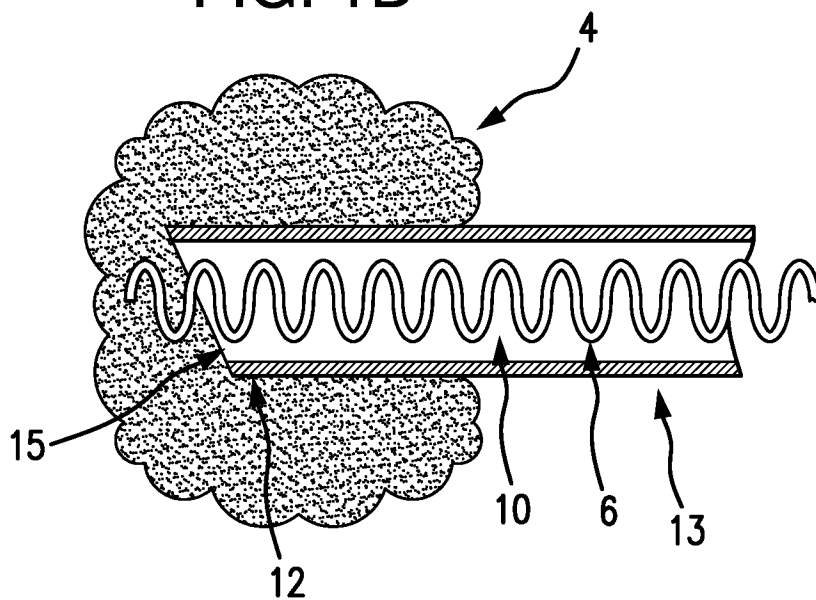


FIG. 1E

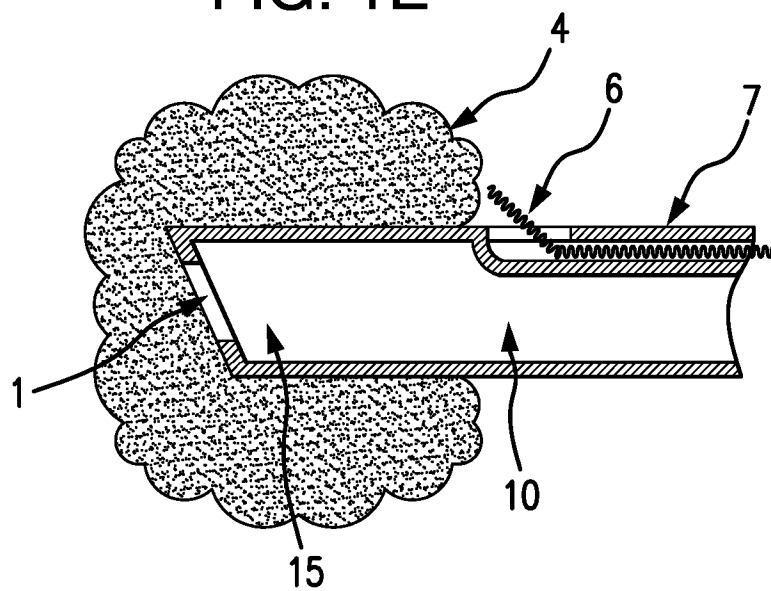


FIG. 1F

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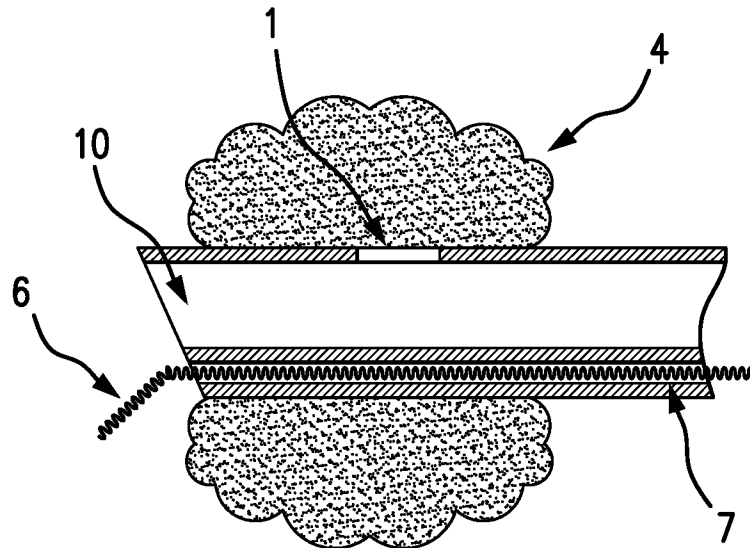


FIG. 1G

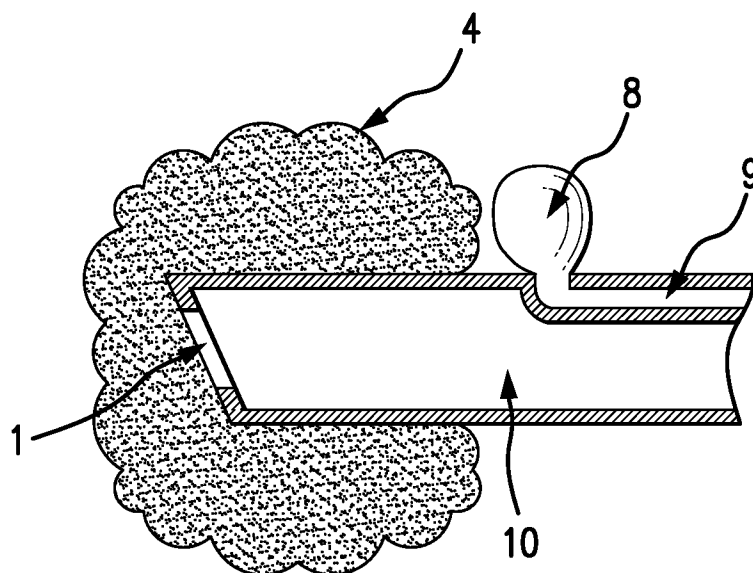


FIG. 1H

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 18/12302

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 5/158 (2018.01)

CPC - A61M 5/158, 2005/1586, 5/3291

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2016/0074626 A1 (ETHICON INC) 17 March 2016 (17.03.2016) see especially para [0044], [0046]-[0049], [0051]-[0054], [0057], [0065], fig 1, 4A-I, 5A-D, 9A, 12A, 12B, 12D	1-11, 13-16, 19-24, 26-28 ----- 12, 17-18
X --- Y	US 2002/0007130 A1 (BURBANK et) 17 January 2002 (17.01.2002) see especially para [0044], [0046], [0047], fig 1, 3A-C	19, 25 ----- 12
Y	US 5,167,239 A (COHEN et al) 1 December 1992 (01.12.1992) see especially col 5, ln 13-26, fig 1, 2	17-18
A	US 2008/0065029 A1 (RACZ) 13 March 2008 (13.03.2008) see whole document	1-28
A	US 2004/0106891 A1 (LANGAN et al) 3 June 2004 (03.06.2004) see whole document	1-28
A	US 2002/0115943 A1 (BURBANK et al) 22 August 2002 (22.08.2002) see whole document	1-28
A	US 2002/0019595 A1 (OSBORNE et al) 14 February 2002 (14.02.2002) see whole document	1-28
A	US 5,234,426 A (RANK et al) 10 August 1993 (10.08.1993) see whole document	1-28
A	US 5,011,473 A (GATTURNA) 30 April 1991 (30.04.1991) see whole document	1-28



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Date of the actual completion of the international search

16 February 2018

Date of mailing of the international search report

27 MAR 2018

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