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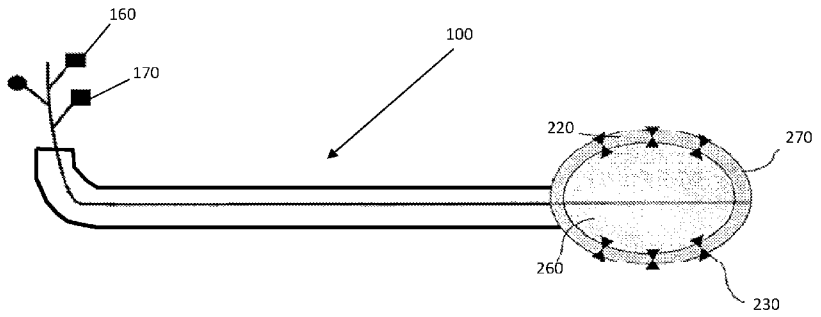


FIGURE 2

(57) Abstract: Disclosed is a system and method for the placement of elongate medical members within a patients body using coaptive ultrasound. In a particularly preferred embodiment, a flexible tube includes a first balloon at a distal end of the tube, and a second balloon at the distal end of the tube and positioned within the first balloon. The first and second balloons are inflatable to form one or more echogenic windows between them, which echogenic window may be detected from within a patient's body by an ultrasound probe that is external to the patient's body. Detection of such echogenic window is used to identify an acceptable location on the patient's body at which to insert a guidewire configured to receive an elongate medical member without damage to surrounding patient tissues or organs.

# METHOD AND APPARATUS FOR COAPTIVE ULTRASOUND GASTROSTOMY

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is based upon and claims priority from co-pending U.S. Provisional Patent Application Serial No. 62/318,449 entitled "Method and Apparatus for Coaptive Ultrasound Gastrostomy," filed with the United States Patent and Trademark Office on April 5, 2016, by the inventor herein, the specification of which is incorporated herein by reference in its entirety.

## FIELD OF THE INVENTION

The present invention relates generally to placement of medical devices within a body in the medical field, and more particularly to methods and devices for ultrasound-guided placement of medical devices, such as catheters, conduits, carriers, electrodes, and the like, including a percutaneous gastrostomy tube, into a patient's body. Certain aspects of the invention particularly relate to methods and devices for ultrasound guided gastrostomy tube placement.

## BACKGROUND OF THE PRIOR ART

A wide variety of medical procedures require placement of medical devices at various locations within a patient's body. For instance, certain procedures may require the placement of electrodes within a patient's spine, or attachment of electrodes to heart tissue, or the like. In other procedures, medical staff may wish to place temperature probes or heating wires at various locations within patient's body. Further, for cancer treatment, medical staff may wish to place radioactive seeds or deliver therapeutic medications deep within a patient's body, including directly into internal organs. In still other procedures, medical staff may wish to

place catheters or other fluid or material-carrying conduits within the patient's body for delivery of medications or other materials, for carrying forceps, biopsy instruments or the like into the patient's body, for providing suctioning to various parts of a patient's body, and many other procedures involving the placement of medical devices within the patient's body. Procedures for placing such medical devices vary widely from application to application, but all carry the common aspect of presenting challenge to the medical staff in manipulating such medical devices within the patient's body to route them to their intended location and position them for their intended use at that location.

More particularly, often times medical procedures require manipulation of a catheter or other conduit through portions of the patient's body that are not easily accessible, and thus make maneuvering of the conduit to its intended location quite challenging. For instance, it may be medically necessary to place conduits within internal body cavities to provide for the drainage of unwanted fluid, to provide for the infusion of medications into internal organs or elsewhere in the body, to provide for direct nutritional supplementation to patients unable to orally consume adequate nutrition, and the like. The procedures for guiding such conduits to their intended locations in a patient's body can be difficult to perform and can risk serious injury to the patient if not performed properly.

One such procedure that presents significant challenges is the placement of gastrostomy tubes for patients requiring direct nutritional supplementation into the stomach. Enteral feeding has been recommended when a patient has a functioning gut but is unable to eat for seven to fourteen days. When enteral feeding is anticipated to be required for longer than 30 days, a gastrostomy tube is preferred over a nasoenteric tube. The placement of gastronomy tubes has become a frequently required procedure, with more than 215,000 being placed annually in the United States. The vast majority of such procedures are performed by consultants, such as gastroenterologists and interventional radiologists, as opposed to an

emergency room doctor, an intensivist, or patient's primary physician. This is because those specialized consultant physicians have access to and have been trained on the expensive equipment that one must use to safely enter (i.e., cannulate) the stomach (i.e., gastrostomy). This expensive equipment includes endoscopes, fluoroscopes, and computed tomography (CT) scanners, all of which require specialized training and skill to operate properly.

The most common method for initial gastrostomy tube insertion is Percutaneous Endoscopic Gastrostomy ("PEG"), involving placing of a tube into the patient's stomach. When performing a typical PEG process, a patient is placed in the supine position. A nasal or oral gastric tube is then introduced into the patient's stomach. Gastric fluid is removed using suction, such as through fenestrations at the distal end of the nasal or oral gastric tube. The stomach is then insufflated by way of the gastric tube or an endoscope. In one method, the endoscope has a light at the distal end. When illuminated, the practitioner is supposed to identify a suitable puncture site that is free from interposed organs and large vessels by noting where the light from the endoscope shines through the abdominal skin of the patient. An incision is then made at the identified target site, and a sheathed needle is then entered into the insufflated stomach. A guide wire is then introduced through the abdominal sheath and into the stomach. A snare or forceps located at the distal end of the endoscope is manipulated to capture the end of the guide wire. The endoscope is then extracted, pulling the guide wire along and ultimately causing the guide wire to exit through the mouth or nose. Applicant is aware of two preferred methods to complete the gastrostomy after the guide wire has been routed from the outside of the patient's abdomen, into their stomach, up their esophagus and out through their mouth or nose: the Ponsky-Gauderer (pull-(on) string) method (the "PG method"), and the Sacks-Vine (push-over –wire) method (the "SV method").

If the PG method is selected, the gastrostomy tube is tied to the end of the guide wire that has exited through the patient's nose or mouth. The abdominal end of the guide wire is then pulled until the gastrostomy tube extends out from the hole in the abdomen, with the proximal end of the gastrostomy tube (having an enlarged end, or bumper, therein to prevent it from passing through the stomach wall and out of the patient's abdomen) remaining within and providing access to the interior of the patient's stomach. If the SV method is selected, the gastrostomy tube is placed over the guide wire and is pushed toward the stomach from the patient's mouth until it extends out from the abdominal hole. Again, the gastrostomy tube has a bumper to prevent the tube from passing entirely through the abdominal hole and causing the proximal end to remain in the stomach.

Alternatively, percutaneous gastrostomy placement can be performed using gastropexy methods. Gastropexy wires are inserted into the stomach via the angiocatheter and used to tether the stomach. Standard gastropexy techniques are then used to place the gastrostomy tube over a guide wire inserted only within the stomach.

Even with skilled consultant physicians handling these procedures, complications can occur including tube misplacement, inadvertent injury to surrounding tissues during placement, infections, tube clogging, and tube dislodgement during use. When such complications occur outside of the hospital, patients will often come to a hospital emergency room for help. However, as the gastrostomy procedures require specialized skill in handling, emergency medicine physicians are often unable to perform the necessary procedures, and must instead call upon such specialist consultants, which adds to the overall expense and delay in treating the patient's issue, or risk of further complication or injury if someone lacking sufficient specialized skill attempts to address the issue.

Accordingly, there is a need in the art for a device and method that will allow for placement of a medical device into a patient's body, such as the performance of percutaneous

gastrostomies, at the bedside and that will no longer require the expertise and equipment of specialist medical personnel, such as a gastroenterologist or other specialist. It would be advantageous to provide a method and device that would reduce the difficulties associated with installing medical devices inside of a patient's body, including medical instrument carriers, medication carriers, electrodes, probes, catheters and other conduits, and more particularly a gastrostomy tube, and that would thereby reduce the risks of injury associated with previously known methods and devices.

## DESCRIPTION OF THE INVENTION

Disclosed herein is a system and method for placement of a catheter, conduit, or other elongate member, and more particularly a gastrostomy tube, within a patient's body. Such system and method are suitable for use in therapeutic interventional and /or diagnostic procedures, and may be useful for placement of medical devices, including catheters or other conduits, in varied tissue planes and cavities in a patient's body, including by way of non-limiting example the thorax, abdomen, blood vessels, and pericardium, for diagnostic, therapeutic, and/or procedural purposes. For example, such system and method may be useful in the placement of a catheter within a patient's stomach during a procedure for placement of a gastrostomy tube. Further, such system and method may be useful in the positioning of a suction tube within a patient's body to remove unwanted fluid. As used herein, all of such carriers, catheters, conduits, delivery devices, internal probes and sensors, electrodes, and the like that are intended for insertion into a patient's body are referred to generally as "elongate medical members."

By allowing visual confirmation through the use of readily-available ultrasound equipment, internal catheter, conduit, or other elongate medical member placement can be achieved without the need for expensive, specialized equipment, such as endoscopes,

fluoroscopes, and CT scanners. Thus, the system and method disclosed herein will enable acute care physicians, such as emergency medicine physicians and critical care physicians (i.e., intensivists), or other healthcare providers trained in the art of ultrasound, to place such catheters, conduits, and other elongate medical members safely and reliably.

With regard to certain aspects of an embodiment of the invention, the system and method may be used for inserting gastrostomy tubes in a simple bedside procedure without requiring the use of specialized consultants or specialized equipment including endoscopes, fluoroscopes, and CT scanners. The system and method make use of more widely available medical devices that require less specialized training to use, such as ultrasounds, feeding tubes, guide wires, and dilators. By allowing a wider population of medical operators to perform such procedures, the system and method disclosed herein offer safer, more immediate and more cost-effective care. For example, unlike endoscopes, ultrasound ensures that an adequate window for percutaneous gastrostomy tube insertion is present by providing visual confirmation that no bowel, organs, or blood vessels obstruct the cannulation tract between the skin surface and the stomach wall. Further, with this procedure, emergency medicine physicians may easily re-insert dislodged gastrostomy tubes and immediately discharge patients back to their residence instead of admitting them for traditional gastrostomy placement to be performed by a specialist consultant, thus saving time and decreasing consultation costs, hospital admission costs, patients' stress, and the risk of nosocomial infection. Geriatricians and rehabilitation physicians may likewise use the system and method disclosed herein in nursing home and rehabilitation facilities. This practice could dramatically reduce overall costs by eliminating patient transportation costs and thus avoiding all hospital fees.

In accordance with certain aspects of an embodiment, methods and devices are disclosed herein for inserting a gastrostomy tube into a patient. In one exemplary

embodiment, a device is provided comprising a flexible tube having a distal end and proximal end, wherein the distal end comprises an inner balloon and an outer balloon, wherein the inner balloon communicates with a first port at the proximal end of the device via a first lumen, and the outer balloon communicates with a second port at the proximal end of the device via a second lumen, wherein the outer balloon is configured to form around the inner wall of a patient's stomach when inflated, and wherein the space between the outer and inner balloon is configured to create an echogenic window when filled with a fluid. In another example embodiment, the device further comprises a snare head within the inner balloon, wherein the snare head communicates with a snare release at the proximal end of the device via a cord that runs the length of the device. In alternative embodiments, a snare is not provided. Instead, one or more of the balloons are configured to receive and couple with a guidewire. In combination with the balloon functionality, guidewires are employed that have tips that are capable of coupling with the conduit. One example configuration is a deployable anchor. The deployable anchor may take the form of a "T" shape or a bulky knot that forms once inside the coupling balloon. Other deployable anchor types may also be used. In other embodiments, the device further comprises one or more rivets between the inner and outer balloon to prevent the echogenic window from collapsing. In yet other embodiments, the inner balloon of the device has one or more ridges that creates one or more cavities between the outer balloon and the inner balloon.

Single balloon configurations of the device are also provided.

In other embodiments a kit is provided for inserting an elongate medical member, such as a gastrostomy tube, into a patient in need comprising an ultrasound device, a double balloon conduit, a guidewire, an angiocatheter and an elongate medical member, such as a gastrostomy tube.

Methods of ultrasound guided guidewire insertion for, for example, gastrostomy tube placement are also provided comprising: inserting the distal end of a double balloon conduit into a patient's body (e.g., into a patient's stomach through their mouth); attaching the necessary pumps to the device; inflating the outer balloon and inner balloon with one or more gases or liquids to create an echogenic window; using an ultrasound probe in conjunction with the echogenic window to identify an acceptable location on the patient's body to insert the guidewire; inserting an angiocatheter into that location under ultrasound guidance; inserting a guidewire into the incision; capturing the distal end of the guidewire; deflating the balloon assembly; and retracting the device from the patient's body.

## BRIEF DESCRIPTION OF THE DRAWINGS

The numerous advantages of the present invention may be better understood by those skilled in the art by reference to the accompanying figures in which:

Figure 1 is a schematic view of an example double balloon conduit device of the present invention;

Figure 2 is a schematic view of the double balloon conduit with a deployed balloon assembly;

Figure 3 illustrates an example distal end of the device with a deployed balloon assembly, in which the inner balloon includes ridges to prevent the collapse of the echogenic window;

Figure 4 illustrates an example distal end of the device with a retracted balloon assembly;

Figure 5 is a flow chart that demonstrates one method of using the double balloon conduit device; and

Figure 6A-C illustrate the method steps described in Figure 5.

## BEST MODE(S) FOR CARRYING OUT THE INVENTION

The invention summarized above may be better understood by referring to the following description, claims, and accompanying drawings. This description of an embodiment, set out below to enable one to practice an implementation of the invention, is not intended to limit the preferred embodiment, but to serve as a particular example thereof. Those skilled in the art should appreciate that they may readily use the conception and specific embodiments disclosed as a basis for modifying or designing other methods and systems for carrying out the same purposes of the present invention. Those skilled in the art should also realize that such equivalent assemblies do not depart from the spirit and scope of the invention in its broadest form.

Figure 1 is a schematic view of the double balloon conduit 100. Conduit 100 includes a flexible tube 110 having a distal end 120 and a proximal end 130. The flexible tube 110 is preferably sized to extend from the patient's mouth to the distal end of the patient's stomach. In the figure the patient's stomach is marked as 197 and the esophagus is marked as 199. These elements are not part of the invention but rather are included for illustrative purposes.

Proximal end 130 includes a sump port 150, inner balloon port 160, and outer balloon port 170. Sump port 150 communicates with one or more sump fenestrations 355 (Figures 3 and 4) located at the distal end 120 of the double balloon conduit 100. One or more central lumens extend the length of the double balloon conduit 100 to allow for passage of fluid, gases, or other material between the distal end 120 and outside of the patient. The sump port 150 may be configured to communicate with a manual or mechanical pumping system to assist with the removal of debris. Inner balloon port 160 communicates with an inner balloon 260 located at the distal end 120 of the double balloon conduit 100. One or more lumens extend the length of the double balloon conduit 100 to allow for the inner balloon 260 to be

inflated or deflated. The inner balloon port 160 may be connected to an external fluid handler (e.g., a pump) to inject or remove fluid or gas from the inner balloon 260. Outer balloon port 170 communicates with an outer balloon 270 at the distal end 120 of the double balloon conduit 100 via one or more lumens that run the length of the double balloon conduit 100. Outer balloon port 170 may also be connected to a pump to inject or remove fluids or gasses from the outer balloon 270. In certain embodiments, the inner balloon pump and outer balloon pump are programmed to run in tandem with each other so that the balloons 260 and 270 will expand and contract in tandem with each other. The pumps may also be programed to pump to a predetermined pressure to ensure proper expansion of the balloons 260 and 270.

Figure 1 also illustrates optional snare release 140. The snare release communicates with a snare head located at the distal end of the double balloon conduit in embodiments that are configured to snare. Such snare configurations and snare releases 140 are of well-known construction to those skilled in the art, and thus are not further detailed here.

Figure 2 is an expanded schematic view of the double balloon conduit 100 while a balloon assembly is deployed. In the illustrated embodiment, inner balloon 260 is nested within outer balloon 270 and inflated. The outer balloon 270 is configured to expand to the inner surface of the patient's stomach when insufflated via the outer balloon port 170. The shape of the inner balloon 260 and outer balloon 270 may vary provided that the outer balloon 270 is sized to contact the inner surface of a patient's stomach at the location in which the gastrostomy tube is to be placed. The shape of the balloons 260 and 270 also allow for one or more cavities 220 between the inner balloon 260 and outer balloon 270 when inflated.

In preferred embodiments, the outer balloon 270 is filled with a fluid, such as water, saline, or other ultrasound-compatible fluid, and the inner balloon 260 is filled with a fluid that may be the same fluid as in the outer balloon or a different fluid, such as air or other non-

toxic gas. When the cavity 220 between inner balloon 260 and outer balloon 270 is filled with ultrasound-compatible fluid, it provides an echogenic window for safely placing the gastrostomy tube. The echogenic window and ultrasound placement improves visualization of subcutaneous tissues and the inner balloon 260 and outer balloon 270 beneath the subcutaneous tissues, and prevents accidental piercing of the bowel, vessels, spleen, liver, or other organs that could jeopardize the health of the patient. By creating one or more echogenic windows 220 between inner balloon 260 and outer balloon 270 and placing the PEG tube by ultrasound, an operator may easily ensure that insertion of an angiocatheter into a patient's stomach is carried out at the intended location and with minimal risk of inadvertently piercing other organs or patient tissues.

Different mechanisms are provided herein to prevent the inner balloon 260 from eliminating the echogenic window by coming into contact with the outer balloon 270. In certain embodiments, one or more spacers, such as rivets 230, are provided between the two balloons 260 and 270. The rivets 230 maintain the preferred distance between the inner and outer balloons 260 and 270. The rivets 230 may be located around the entire surface of the inner balloon 260 or just the area where the echogenic window is desired.

Alternatively, one or both of balloons 260 and 270 may themselves incorporate spacers that are configured to maintain cavities 220 between the two balloons 260 and 270. Figure 3 is an exploded view of the distal end of the double balloon conduit 100 having a deployed balloon head. Inner balloon 260 incorporates spacers in the form of one or more ridges 310 that maintain the desired spacing between inner balloon 260 and outer balloon 270. The size, number and location of the ridges 310 may vary depending on the application, such as location within the patient and purpose for placement. In other non-illustrated embodiments, the material properties of the inner and outer balloons 260 and 270 are chosen to maintain the spacing between the two balloons 260 and 270 when deployed. For example,

stiffer materials can be employed to prevent the migration of the inner balloon 260 as it is filled with air. Another example configuration includes an expandable frame within the inner balloon 260 that will prevent the inner balloon 260 from contacting the outer balloon 270. Differential pressurization of the balloons 260 and 270 can also be used to obtain the desired configuration and response.

Figure 3 illustrates other features of the distal end 120 of the double balloon conduit 100. In certain embodiments, snare 245 of traditional configuration extends through the inner balloon 260 and includes a snare head 347 to capture elements passing through the balloons 260 and 270. Sump fenestrations 355 are also illustrated, extending through a sidewall of flexible tube 110. The fenestrations 355 may vary in size, shape and orientation, depending on the patient needs. In certain embodiments, two or more fenestrations 355 are provided to reduce the likelihood of clogging.

Inner balloon tubing 360 and outer balloon tubing 370 allow for balloons to communicate with their respective ports 160 and 170 at the proximal end of the double balloon conduit 100. In the illustrated embodiment, a single tube for each of balloon 260 and 270 is provided. However, in alternative embodiments, two or more tubes may be used to supply each balloon 260 and 270. Multiple tubes may be preferred when there are multiple cavities between the inner balloon 260 and outer balloon 270. Separate tubes may be used to provide different pressures within the cavities 220 or when the cavities 220 are completely independent of the others.

Figure 4 is an exploded view of the distal end 120 of the double balloon conduit 100 with the inner balloon 260 and outer balloon 270 retracted. The balloon assembly 410 (including, in combination, inner balloon 260 and outer balloon 270) is configured to retract within the distal end 120 of the double balloon conduit 100 to make it low profile and help facilitate passage of the double balloon conduit 100 into and out of the stomach. In certain

embodiments, the balloon assembly 410 is connected to a cord that runs the length of the double balloon conduit 100 to the proximal end 130. This cord is used to fully retract the balloon assembly 410 after inflation. In other embodiments, the snare release 140 can be configured to perform this task.

Additional features of the double balloon conduit 100 may be used to help secure the guidewire to the distal end 120 of the double balloon conduit 100 and also ensure the guidewire is pulled through the patient as the double balloon conduit 100 is removed. For example, guidewires having anchoring features may be used. In this case, the distal tip of the guidewire can expand or otherwise change shape to help create an anchor inside one or both of the balloons 260 and 270. One example anchor is a "T" shape and another is a bulky knot. In such configuration, the anchor may be inserted into inner balloon 260 before inner balloon 260 is deflated. Thus, as inner balloon 260 is deflated, it surrounds the anchor within inner balloon 260, such that pulling double balloon conduit 100 out of the patient's mouth or nose will likewise cause inner balloon 260 to pull the anchor, along with the attached guidewire.

Other anchoring devices would be recognized in the field and do not deviate from the spirit of the invention. Alternatively, or in conjunction with the anchor, the guidewire may have a magnetic tip that is configured to communicate with, or attract, a magnetic tip that can be added to the distal end 120 of the double balloon conduit 100. This magnetic attraction can also help facilitate passage through the patient.

Single balloon configurations are also provided. In certain single balloon examples, the balloon is configured to expand until at least a portion of the balloon's outer face is resting against at least a portion of the inner wall of the patient's stomach. The balloon is configured to expand when it is filled with fluid or another echogenic material. When the balloon is sufficiently full it creates an echogenic window for ultrasound guided guidewire placement. In other single balloon configurations, the balloon has one or more pouches on its surface that

are configured to fill with fluid or another echogenic material. When the balloon is sufficiently inflated with a gas, the one or more pouches are pressed against the wall of the stomach. When filled, the pouches create an echogenic window for ultrasound guided guidewire placement. In another single balloon configuration, the balloon's pouches are made from echogenic materials and do not require infusion with echogenic materials.

Figure 5 is a flow chart that depicts the steps for inserting a guidewire into a patient for placement of an elongate medical member, such as a gastrostomy tube, using a device according to at least certain aspects of and embodiment of the present invention. In step 501, the distal end 120 of the double balloon conduit 100 is passed into the patient's mouth and down into the patient's stomach. Next, in step 502, the pumps are attached to the sump port 150 and inner and outer balloon ports 160 and 170. Outer balloon 270 and inner balloon 260 are deployed in step 503. The order of the balloon deployment will generally depend on the configuration of the double balloon conduit 100. In certain embodiments, the inner and outer balloons 260 and 270 will deploy simultaneously, while in other embodiments, the inner balloon 260 will be filled first with a fluid and then the one or more cavities 220 between the inner and outer balloons 260 and 270 will be filled with a fluid to form an echogenic window.

In step 504, an ultrasound probe will be used to select an appropriate location for inserting the angiocatheter needle. More particularly, an ultrasound probe will be used to detect the location of the echogenic window between inner balloon 260 and outer balloon 270. Step 505 includes inserting the angiocatheter into the stomach once a location is identified that is clear of obstructions. Inserting the needle is monitored by ultrasound.

Step 506 includes inserting the guidewire into the stomach through at least one of the balloons 260 and 270. In embodiments that include a snare, the guidewire passes through the snare head in order to be captured. In embodiments that use a snare, step 507 includes retracting the snare 245 into the distal end 120 of the double balloon conduit 100, thereby

securing the guidewire. When using a device that utilizes a guidewire anchor, the guidewire anchor is deployed or secured inside one or more of the balloons 260 and 270. The balloon assembly 410 is then emptied / deflated and retracted into the distal end 120 as well. In step 508 the entire assembly is removed from the patient's mouth. The guidewire can then be used to insert a gastrostomy tube using known techniques.

The steps described above and in Figure 5 are partially illustrated in Figures 6a-6c. Figure 6a shows a deployed outer balloon 270 and inner balloon 260. Cavities 220 are filled with water or saline to create an echogenic window. Ultrasound probe 610 is used to identify an appropriate site of entry for the angiocatheter needle, 620, and guidewire, 630. Figure 6b shows the distal end 120 of the double balloon conduit 100 after the guidewire 630 has been captured by the snare and the balloon assembly 410 has been retracted. Figure 6c shows the guidewire 630 remaining after the device has been removed from the patient's mouth.

In the foregoing specification, the invention has been described with reference to specific embodiments thereof. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the invention. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. Throughout this specification and the claims, unless the context requires otherwise, the word “comprise” and its variations, such as “comprises” and “comprising,” will be understood to imply the inclusion of a stated item, element or step or group of items, elements or steps but not the exclusion of any other item, element or step or group of items, elements or steps. Furthermore, the indefinite article “a” or “an” is meant to indicate one or more of the item, element or step modified by the article.

Having now fully set forth the preferred embodiments and certain modifications of the concepts underlying the present invention, various other embodiments as well as certain variations and modifications of the embodiments herein shown and described will obviously

occur to those skilled in the art upon becoming familiar with said underlying concepts. It should be understood, therefore, that the invention may be practiced otherwise than as specifically set forth herein.

## INDUSTRIAL APPLICABILITY

The present invention is applicable to devices and methods for placing medical devices into patients, particularly through ultrasound-guided placement. The devices can be made in industry and practiced in the medical device field.

## CLAIMS

What is claimed is:

1. A device for placement of an elongate medical member, comprising:

a flexible tube having a distal end and a proximal end opposite said distal end;

a first balloon affixed to said distal end of said flexible tube;

a second balloon affixed to said distal end of said flexible tube and positioned within an interior of said first balloon;

wherein each of said first balloon and said second balloon are inflatable and are configured to form at least one echogenic window between an interior of said first balloon and an exterior of said second balloon.

2. The device of claim 1, further comprising a plurality of spacers between said first balloon and said second balloon.

3. The device of claim 2, wherein said spacers comprise rivets positioned between an interior face of said first balloon and an exterior face of said second balloon.

4. The device of claim 2, wherein said spacers comprise a plurality of ridges on an exterior face of said second balloon.

5. The device of claim 1, further comprising a first lumen extending along said flexible tube from said proximal end to an interior of said first balloon, and a second lumen extending along said flexible tube from said proximal end to an interior of said second balloon.

6. The device of claim 5, further comprising an open channel extending through said flexible tube.

7. The device of claim 6, further comprising at least one opening extending through said flexible tube into said open channel, said at least one opening positioned adjacent the distal end of said flexible tube and proximal to said first balloon and said second balloon.

8. The device of claim 1, further comprising a snare extending through said elongate member and having a closeable snare head positioned within said second balloon.

9. A device for placement of an elongate medical member within a patient's body, comprising:

a flexible tube having a distal end and a proximal end opposite said distal end; and

a balloon affixed to said distal end of said flexible tube, said balloon having a pouch on an exterior wall of said balloon, said pouch having an echogenic material therein;

wherein said balloon is inflatable so as to position said pouch in contact with an interior of a patient's stomach upon inflation.

10. The device of claim 9, further comprising a lumen extending along said flexible tube from said proximal end to an interior of said balloon.

11. The device of claim 9, further comprising an open channel extending through said flexible tube.

12. The device of claim 11, further comprising at least one opening extending through said flexible tube into said open channel, said at least one opening positioned adjacent the distal end of said flexible tube and proximal to said balloon.

13. The device of claim 9, further comprising a snare extending through said elongate member and having a closeable snare head positioned within said second balloon.

14. A method for placing an elongate medical member within a patient's body, comprising the steps of:

providing a flexible tube having a distal end and a proximal end opposite said distal end, a first balloon affixed to said distal end of said flexible tube, and a second balloon affixed to said distal end of said flexible tube and positioned within an interior of said first balloon;

inserting said distal end of said flexible tube into a patient's body;

inflating said first balloon and said second balloon with one or more fluids to form an echogenic window; and

detecting a location of said echogenic window within a patient and to identify an acceptable location on the patient's body to insert a guidewire configured to receive said elongate medical member.

15. The method of claim 14, wherein said detecting step further comprises using an ultrasound probe to detect said location of said echogenic window.

16. The method of claim 14, further comprising the steps of:

inserting an angiocatheter at said acceptable location so that said angiocatheter extends into said second balloon;

inserting a guidewire through said angiocatheter so that a distal end of said guidewire is positioned within said second balloon;

capturing said distal end of said guidewire from a proximal end of said flexible tube;

deflating said first balloon and said second balloon; and

retracting said flexible tube from said patient.

17. The method of claim 14, wherein a plurality of spacers are provided between said first balloon and said second balloon.

18. The method of claim 17, wherein said spacers comprise rivets positioned between an interior face of said first balloon and an exterior face of said second balloon.

19. The method of claim 17, wherein said spacers comprise a plurality of ridges on an exterior face of said second balloon.

20. The method of claim 14, wherein said flexible tube further comprises a first lumen extending along said flexible tube from said proximal end to an interior of said first balloon, and a second lumen extending along said flexible tube from said proximal end to an interior of said second balloon.

21. The method of claim 20, wherein said flexible tube further comprises an open channel extending through said flexible tube.

22. The method of claim 21, wherein said flexible tube further comprises at least one opening extending through said flexible tube into said open channel, said at least one opening positioned adjacent the distal end of said flexible tube and proximal to said first balloon and said second balloon.

23. The method of claim 21, wherein a snare extends through said elongate member, said snare having a closeable snare head positioned within said second balloon.

24. A kit for placing an elongate medical member within a patient's body, comprising:

a flexible tube having a distal end and a proximal end opposite said distal end, a first balloon affixed to said distal end of said flexible tube, and a second balloon affixed to said distal end of said flexible tube and positioned within an interior of said first balloon, wherein each of said first balloon and said second balloon are inflatable and are configured to form at least one echogenic window between an interior of said first balloon and an exterior of said second balloon;

a guidewire;

an angiocatheter; and

an elongate medical member.

25. The kit of claim 24, further comprising an ultrasound probe.

26. The kit of claim 24, wherein a plurality of spacers are provided between said first balloon and said second balloon.

27. The kit of claim 26, wherein said spacers comprise rivets positioned between an interior face of said first balloon and an exterior face of said second balloon.

28. The kit of claim 26, wherein said spacers comprise a plurality of ridges on an exterior face of said second balloon.

29. The kit of claim 24, wherein said flexible tube further comprises a first lumen extending along said flexible tube from said proximal end to an interior of said first balloon, and a second lumen extending along said flexible tube from said proximal end to an interior of said second balloon.

30. The kit of claim 29, wherein said flexible tube further comprises an open channel extending through said flexible tube.

31. The kit of claim 30, wherein said flexible tube further comprises at least one opening extending through said flexible tube into said open channel, said at least one opening positioned adjacent the distal end of said flexible tube and proximal to said first balloon and said second balloon.

32. The kit of claim 30, wherein a snare extends through said elongate member, said snare having a closeable snare head positioned within said second balloon.

33. The kit of claim 24, wherein said guidewire further comprises a deployable anchor at a distal end of said guidewire.

34. The kit of claim 33, wherein said anchor further comprises a T shaped branch at said distal end of said guidewire.

35. The kit of claim 33, wherein said anchor further comprises a knot at said distal end of said guidewire.

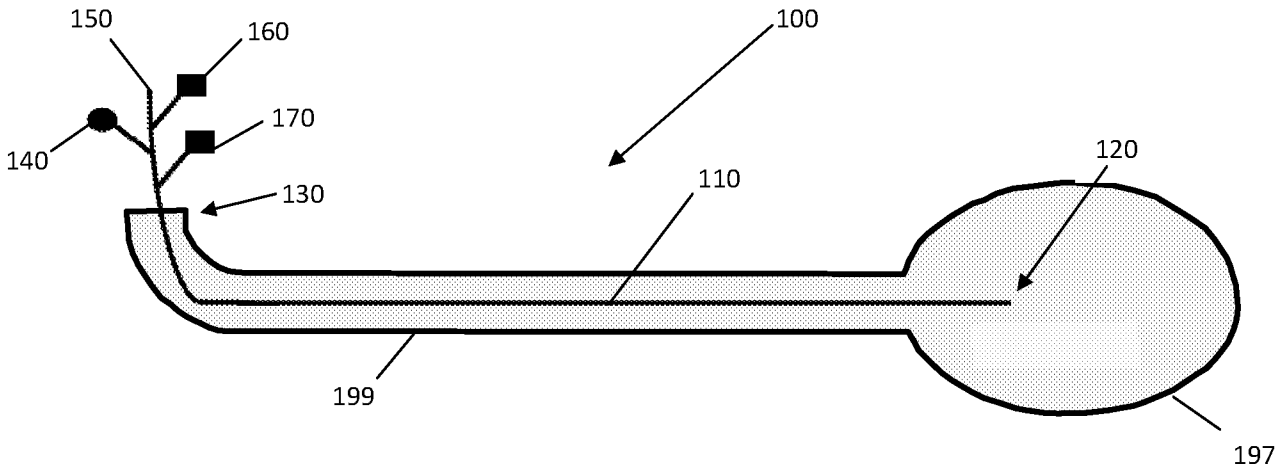


FIGURE 1

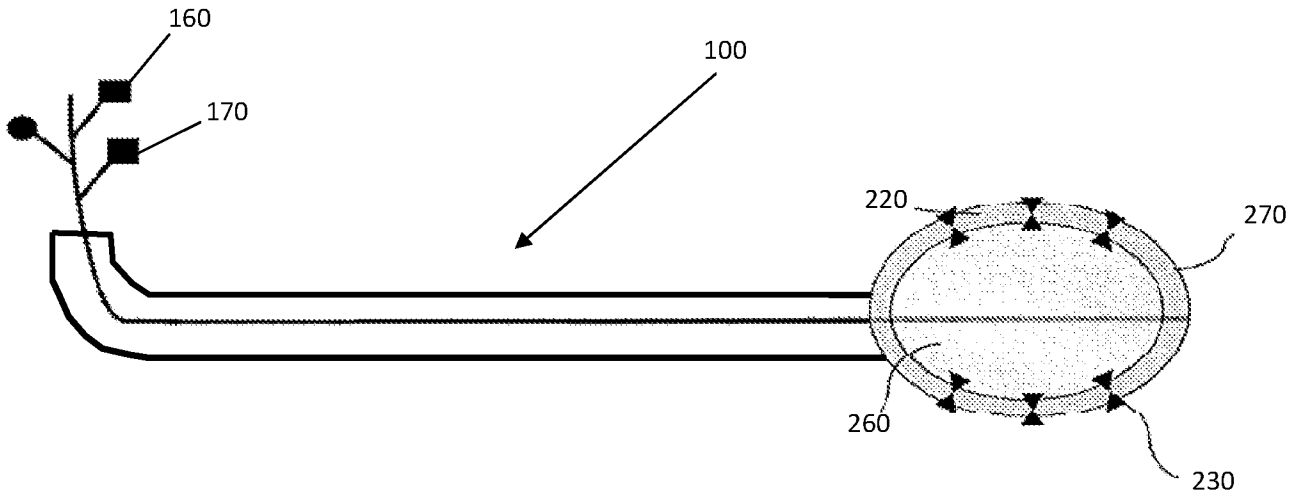


FIGURE 2

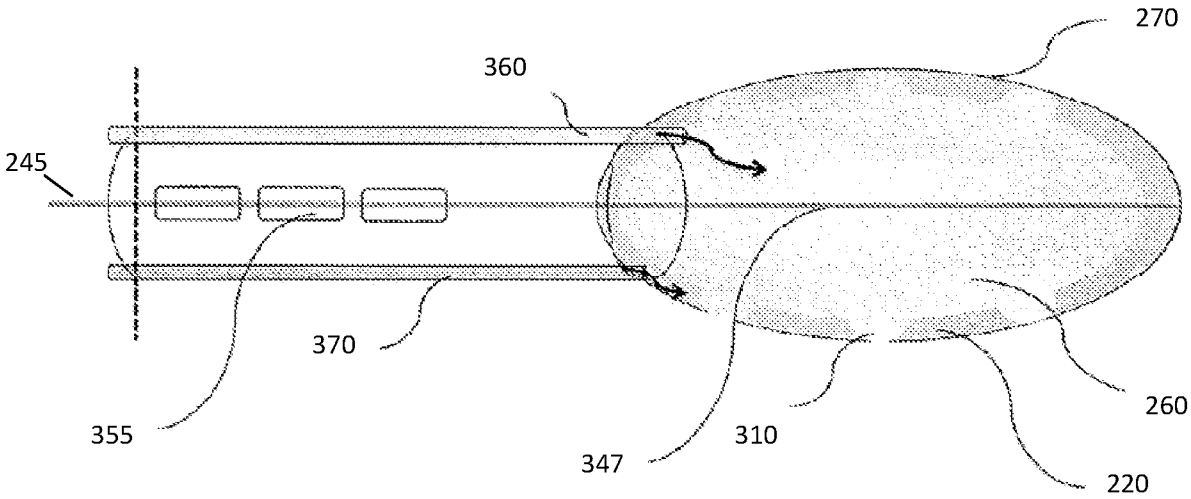


FIGURE 3

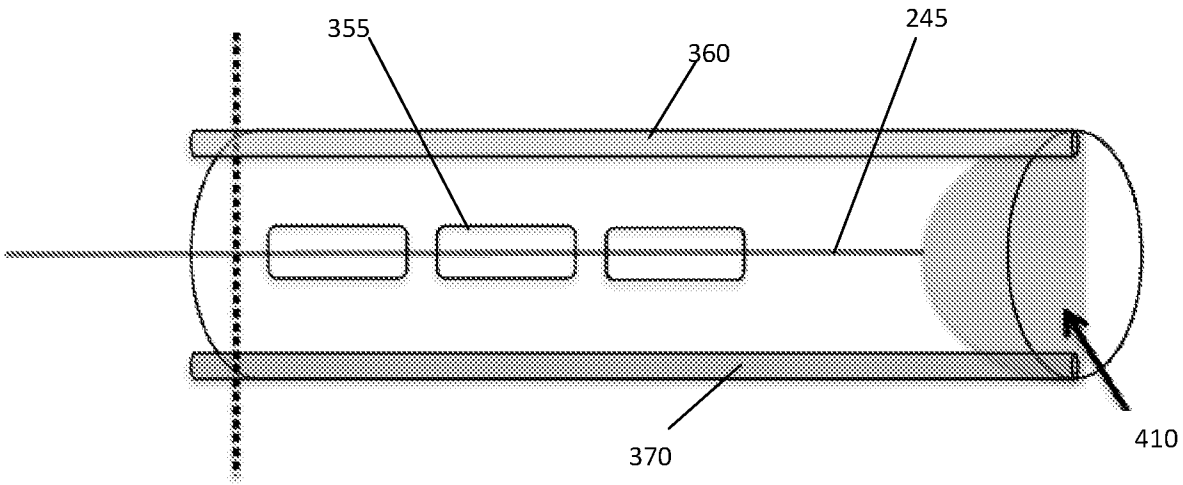


FIGURE 4

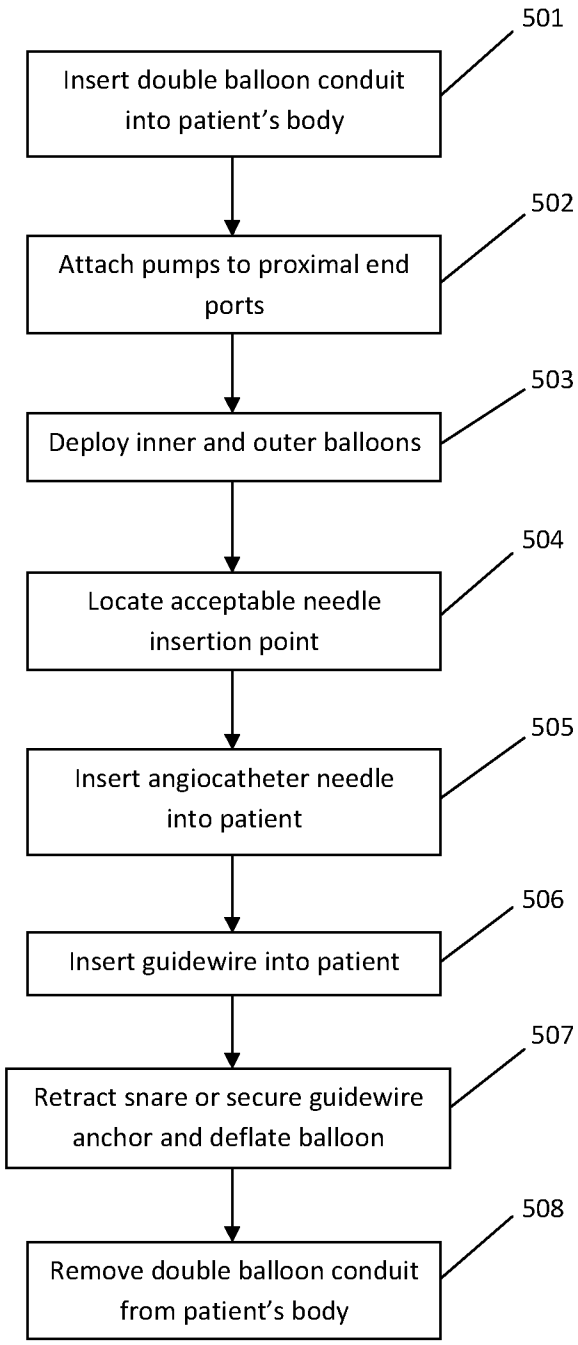
501
Insert double balloon conduit into patient's body
502
Attach pumps to proximal end ports
503
Deploy inner and outer balloons
504
Locate acceptable needle insertion point
505
Insert angiocatheter needle into patient
506
Insert guidewire into patient
507
Retract snare or secure guidewire anchor and deflate balloon
508
Remove double balloon conduit from patient's body

**FIGURE 5**

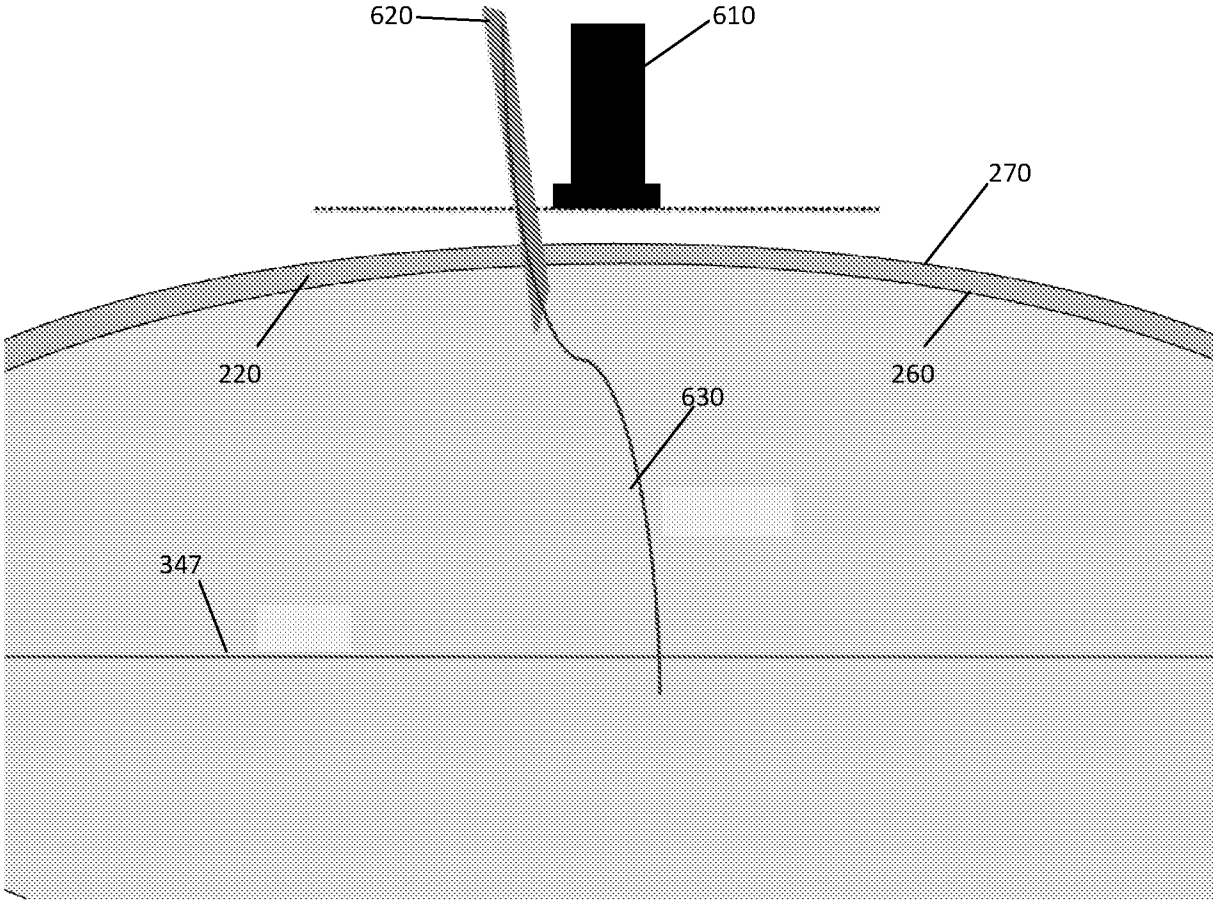


FIGURE 6A

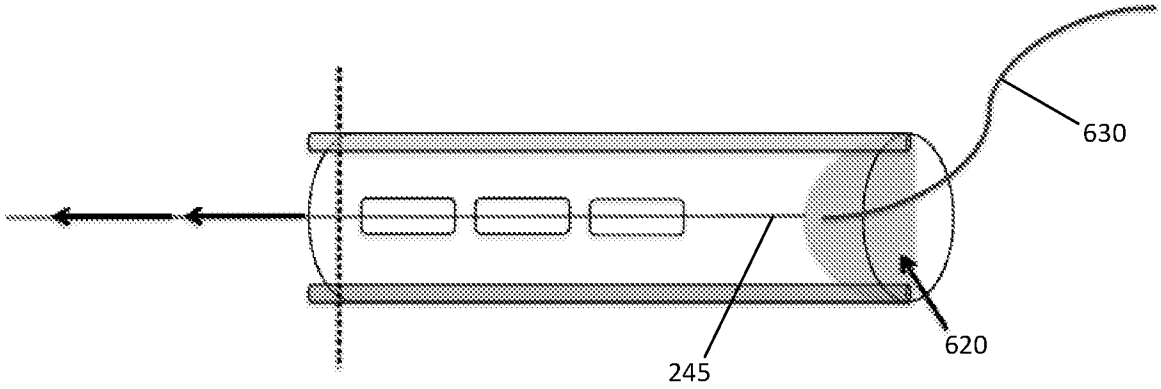


FIGURE 6B

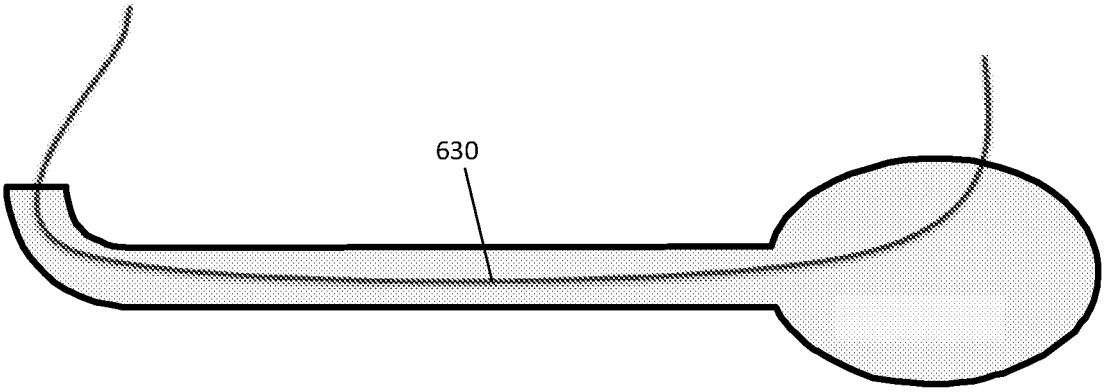


FIGURE 6C

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/26141

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/10 (2017.01)
CPC - A61M 25/10, A61M 2025/1013, A61M 2025/1015, A61M 25/1011

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 | US 2014/0039358 A1 (MUFFIN INCORPORATED) 06 February 2014 (06.02.2014) fig 1, 2, para [0029], [0032]-[0033], [0047] | 1, 5-7 |
| Y | | 2, 4, 8, 24-25, 29-35 |
| A | | 3, 27 |
| Y | US 2014/0200504 A1 (ROCHA-SINGH) 17 July 2014 (17.07.2014) fig 10A, 10B, 11, para [0061] -[0062] | 2, 4, 24, 26, 28 |
| A | | 3, 27 |
| Y | US 2016/0081652 A1 (TROPELLO) 24 March 2016 (24.03.2016) fig 2, 10, abstract, para [0033], [0035], [0039], [0048] | 8, 24-26, 28-35 |
| Y | US 2008/0045863 A1 (BAKOS) 21 February 2008 (21.02.2008) fig 6, 7 | 33-34 |
| Y | US 2009/0198153 A1 (SHRIVER) 06 August 2008 (06.08.2006) fig 4, para [0029, [0058], [0118] | 33, 35 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 28 July 2017 | 25 AUG 2017 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/26141

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-8, 24-35 directed to a device/kit for placement of an elongate medical member having an inner and outer balloon.

Group II: Claims 9-13 directed to a device for placement of an elongate medical member within a patient's body having a single balloon

Group III: Claims 14-23 directed to a method for placing an elongate medical member within a patient's body.

----Continued on Supplemental Page----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-8, 24-35

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/26141

Continuation of Box III: Observations where unity of invention is lacking

Special Technical Elements

Group I contains the special technical features of a first balloon affixed to said distal end of said flexible tube; a second balloon affixed to said distal end of said flexible tube and positioned within an interior of said first balloon; wherein each of said first balloon and said second balloon are inflatable and are
configured to form at least one echogenic window between an interior of said first balloon and an exterior of said second balloon, not required by Groups II-III.

Group II contains the special technical features of a balloon affixed to said distal end of said flexible tube, said balloon having a pouch on an exterior wall of said balloon, said pouch having an echogenic material therein, not required by Groups I or III.

Group III contains the special technical features of a method comprising: inserting said distal end of said flexible tube into a patient's body;
inflating said first balloon and said second balloon with one or more fluids to form an echogenic window; and
detecting a location of said echogenic window within a patient and to identify an acceptable location on the patient's body to insert a guidewire configured to receive said elongate medical member, not required by Groups I-II.

Common Technical Elements

Groups I and II share the common technical features of a flexible tube having a distal end and a proximal end opposite said distal end; and a balloon affixed to said distal end of said flexible tube. However, these shared technical features fail to make a contribution over the prior art of US 5,867,988 to Briscoe, et al. (hereinafter 'Briscoe'), which teaches a flexible tube (12, fig 1) having a distal end (14) and a proximal end (16) opposite said distal end (fig 1, col 3, ln 33-39);
and a balloon (18) affixed to said distal end of said flexible tube (fig 1, col 3, ln 33-39).

Groups I and III share are related as an apparatus (group I) and a method of use (group III). Gropus I and III share the common technical features of claim 1. The apparatus is known in the art as shown in US 2014/0039358 A1 to Zhou, et al. (hereinafter 'Zhou').

Regarding claim 1, Zhou discloses a device for placement of an elongate medical member, comprising:
a flexible tube (102) having a distal end and a proximal end opposite said distal end (fig 1, 2, para [0029]);
a first balloon (142) affixed to said distal end of said flexible tube (fig 2, para [0029]);
a second balloon (154) affixed to said distal end of said flexible tube and positioned within an interior of said first balloon (fig 2, para [0029]);
wherein each of said first balloon and said second balloon are inflatable (para [0032]) and are configured to form at least one echogenic window between an interior of said first balloon and an exterior of said second balloon (intended use, see para [0033] which describes used of echogenic media for inner balloon - capable of inflation of second balloon).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.