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(54) Title: DRAINAGE DEVICE AND METHOD

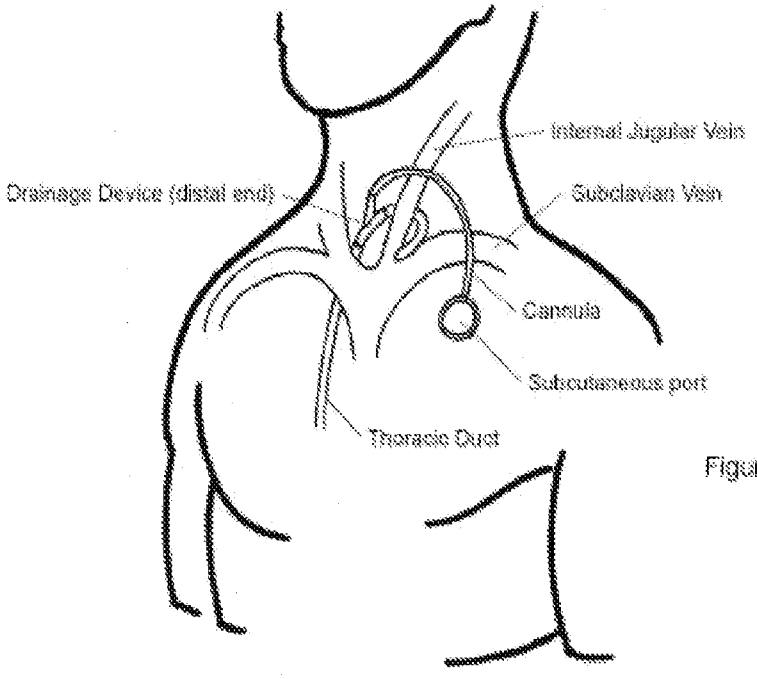

Figure 2A

(57) Abstract: A device and method for draining excess lymph fluid is disclosed. The device can be fixed to the blood vessel adjacent to the thoracic duct. The device can have a port for withdrawing lymph fluid exiting the thoracic duct. The device can have a cannula and/or subcutaneous port to draw the lymph fluid away from the thoracic duct and reduce hemostatic pressure in the lymphatic system.

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TITLE OF THE INVENTION

DRAINAGE DEVICE AND METHOD

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CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/204,893, filed 12 January 2009, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present device and method relate generally to accessing, draining and monitoring the lymphatic system. This device can be used to treat volume overload in heart failure, pulmonary edema, after surgical procedures and in other disease states in which interstitial volume removal or lymphatic sampling are of use.

2. Description of the Related Art

[0003] Congestive heart failure affects 5.5 million Americans and is a leading cause of death in the U.S. Each year over one million patients are hospitalized for heart failure and 90% of these are diagnosed with volume overload. Volume overload in patients with heart failure is an acute manifestation of a chronic decrease in cardiac performance such that the heart is unable to pump and circulate the volume of blood returning from the venous system. As a result, blood accumulates in the pulmonary and peripheral tissues. A common and potentially life threatening consequence of decompensated heart failure is pulmonary edema, which presents as shortness of breath and poor oxygenation, both indicative of fluid accumulation in lung tissues and small airways. If left untreated, patients are at risk for hypoxic arrest and death. Peripheral swelling and venous distension are also common, although not as life threatening.

[0004] In most cases, patients with this presentation are known to be suffering from a chronic heart condition and are taking prescribed diuretic medications to control their volume status. The sudden onset of volume overload is due to either a miscalculation

in salt and fluid intake or poor medication compliance on the part of the patient, or a result of a worsening heart condition, renal impairment, or resistance to diuretic medications.

[0005] Once diagnosed, the initial therapy for volume overload in decompensated heart failure is intravenous diuresis. Despite the use of intravenous diuretics in 90% of overload patients, the average hospital admission time is 4.3 days and over half of those discharged will return within 6 months with the same diagnosis. It is suggested that the high readmission rate is due to inadequate volume reduction during their previous admission. Furthermore, approximately 30% of chronic heart failure patients on diuretics will develop resistance or renal failure as a result of their medication and require more invasive and higher risk therapies to control their volume status. These interventions include mechanical ventilation with positive pressure, central venous ultrafiltration or hemodialysis.

[0006] The physiology of pulmonary edema suggests fluid accumulation in the small airways is the direct result of increased hydrostatic pressure in the surrounding capillaries, which leak first into the interstitial space between the capillary bed and the airway. This extracellular space is composed of protein matricies and small lymphatic channels designed specifically to accommodate homeostatic changes in pressure by draining any excess interstitial fluid which is not immediately resorbed by the venous capillary bed. These lymphatic channels combine as they travel towards the neck, eventually forming one large channel called the thoracic duct. The thoracic duct rejoins the systemic venous system at the lymphovenous junction, near the confluence of the left internal jugular and subclavian veins. In the case of clinically significant pulmonary edema, the hydrostatic forces generated by a failing heart quickly overwhelm the lymphatic system and blood plasma overflows into the smaller airways. In this case, the lymphatic system is limited by volume capacity and higher than expected flow pressures generated by the venous system into which the thoracic duct is draining.

[0007] The human lymphatic system has been accessed previously for the purposes of sampling and draining lymphatic fluid to treat blood cancers, transplant rejection, pancreatitis and rheumatoid arthritis. These maneuvers have involved open surgery and acute cannulation of the thoracic duct in small numbers of patients with extracorporeal processing of lymphatic fluid. The majority of the fluid was returned to the patient after processing.

[0008] While the function and overloading of the lymphatic system in pulmonary edema is well documented, current therapies for volume overload focus on systemic pharmaceutical diuresis or direct drainage of the vascular compartment to filter and remove blood plasma. Therefore, there exists a need for a therapy to monitor and manage pulmonary and systemic volume overload by manipulation and drainage of the existing lymphatic system. Drainage of lymphatic fluid specifically from the thoracic duct can quickly reverse the interstitial fluid imbalance in the pulmonary tissues and offload a significant amount of peripheral volume. Furthermore, lymphatic fluid is pre-filtered and does not include red blood cells or platelets which need to be separated and returned to the patient in conventional hemodialysis and ultrafiltration.

[0009] Outside of heart failure, development of this device will provide a much needed tool to accelerate research and treatment in a range of related disease states such as cancer, HIV, organ transplant, and autoimmune disorders.

[0010] Interstitial fluid accumulation can become a critical issue in any post-operative patient and is especially concerning after heart surgery, when it is important to limit cardiac stress. In these critical care and post-surgical volume management situations, and at other times, thoracic duct drainage in at-risk patients can augment volume management and prevent overload.

[0011] Fluid in the thoracic duct contains a high percentage of circulating CD-4 lymphocytes, the target cell for HIV. In animal models, drainage and characterization of T-cells by thoracic duct drainage can answer some of the fundamental immunological questions about recirculating lymphocyte pools to help develop new vaccine and antiviral therapies.

[0012] An early method of immune suppression in organ transplantation was thoracic duct drainage. The open cannulation procedure and subsequent wound care was challenging and unsuccessful in many patients. Once immune suppressive medications became more effective, this approach was abandoned altogether.

SUMMARY OF THE INVENTION

[0013] The device described herein can enable repeated fluid communication between an internal body vessel and an extracorporeal fluid reservoir, such as a syringe. The device can have a cannula. The cannula can enable fluid communication between the vessel and an external accessing device. The device can be in fluid communication with the vessel with or without occluding the vessel. If fluid is not being withdrawn

from the cannula, the fluid in the body vessel can bypass the cannula. The device can remain in a fixed position in the vessel. The device can be secured internally, externally, or a combination thereof, to the body vessel. The cannula can be secured along the internal lumen of the body vessel by stabilizing members. The stabilizing members can support the vessel. The stabilizing members can be a single balloon, for example positioned at the junction of the thoracic duct and the innominate vein, or two balloons, for example positioned on opposite sides of the thoracic duct port as the thoracic duct merges into the innominate vein. The stabilizing members can include anchoring hooks and/or loops. The device, such as on the outer perimeter of the balloon, can have an ingrowth matrix to promote endothelial growth into the device to fix the device to the surrounding tissue, such as the vessel wall.

[0014] The device can be anchored in and/or to the vessel without occluding the vessel, for example even in very small vessels. The device can be able to puncture the vessel wall. The cannula can create the path for fluid flow external to the vessel and/or a means to access the vessel. The device can include an access port. The device can include a pressure sensor. The device can include valves to control fluid flow. The device can include a reservoir to hold fluid that has traveled through the cannula.

[0015] The device may be used to remove lymphatic fluid in patients experiencing pulmonary edema. When the patient is not experiencing pulmonary edema for example, the lymphatic fluid may flow through the vessel past the cannula. When the patient is experiencing higher than normal flow of lymphatic fluid for example, the fluid may activate an entrance mechanism to the cannula and/or signal that the device needs to be accessed. When the device is accessed, fluid may be withdrawn from the lumen through the cannula. When the patient is experiencing pulmonary edema or at the onset of pulmonary edema, the device may be accessed.

[0016] The device can allow fluid communication between a lymphatic vessel and an external reservoir. For example, the device can open the wall of (i.e., access) the thoracic duct. The device can drain fluid from the lymphatic vessel. For example, the cannula can drain fluid from the thoracic duct. The device can drain lymphatic fluid from the lymphatic system, for example, when the patient becomes fluid-overloaded or suffers from congestive heart failure. The device can help prevent and/or treat congestive heart failure and pulmonary edema, for example, by drainage of the lymphatic system.

[0017] The device may access blood vessels. The device may access central venous or arterial vessels. The device may withdraw fluid from the vessels. The device may withdraw blood from blood vessels. The device may store the fluid in a reservoir. The device may access the portal vein. The device may access the proximal portal vein, before the triad. The device may measure the pressure in blood vessels. The device may measure portal hypertension.

[0018] The device can be placed in a stationary fashion in a blood vessel adjacent to the thoracic duct. The device can have a port positioned adjacent to the opening of the thoracic duct into the innominate, internal jugularm or sublclavian vein or the junction thereof. The device can be used to passively or actively (e.g., by applying negative pressure) withdraw lymphatic fluid as is exits the thoracic duct into the adjacent vein. The device's port which is adjacent to the thoracic duct can be in fluid communication with a drainage cannula and/or subcutaneous port that can be used to withdraw the lymph fluid.

[0019] The device can be deployed adjacent to the opening of the thoracic duct into the innominate vein. The device can be deployed in a minimally invasive fashion, such as through a subclavian or other intravascular delivery. The thoracic duct opening can be identified using a visualization method. For example, the thoracic duct opening can be identified using an intra-venous ultrasound (IVUS) probe. The IVUS probe can be in a liquid-inflatable (e.g., saline) balloon. The thoracic duct opening can be identified using a sensor to identify changes in the intravascular fluid composition. For example, lymph fluid is typically more alkaline than blood, so a pH sensor can be deployed into the innominate vein to locate the peak pH when in the vicinity of the thoracic duct to locate the opening of the thoracic duct into the innominate vein. A combination of methods, such as those disclosed herein, can be used to identify the thoracic duct opening to coordinate placement of the device.

[0020] A user may singularly or repeatedly access the device, for example, to sample lymph fluid for monitoring of triglycerides, lymphocytes, or lymphatic protein content in chronic conditions such as hyperlipidemia, cancer, immune deficiencies or auto-immune disorders.

[0021] A user may singularly or repeatedly access the device, for example, to sample lymph fluid and/or for reduction of fluid volume in patients experiencing or at risk for volume overload, and/or pulmonary edema and/or chronic heart failure and/or acute exacerbation of chronic heart failure.

[0022] Periodic monitoring of lymphocyte antigen, for example after solid organ transplant, can provide an early warning of graft rejection and a more accurate indication of the level of immune suppression. For example, lymph fluid can be withdrawn through the device and analyzed after a high risk graft or transplant procedure. For example, the device can be implanted and lymph fluid can be removed through the device and analyzed for graft rejection after a heart, lung, kidney, skin, liver or small intestine transplant or graft. The device can provide a safe and minimally invasive method of lymphatic access, which could be provided with a transcutaneous catheter. Routine drainage of sensitized lymphocyte subpopulations could help prevent or rescue an acute episode of rejection.

[0023] As a clinical modality, catheter drainage of the thoracic duct through the device can remove the lymph fluid to deplete large numbers of CD-4 cells (for example, $CD\text{-}4^+$ T cells). Combining drainage with conventional pharmacological therapy to decrease the infection rate in remaining CD-4 cells can promote a shift towards a virus-free state and represents an intriguing alternative to current treatment for HIV or other infectious diseases with similar modalities.

SUMMARY OF THE DRAWINGS

[0024] Figure 1A illustrates the major venous anatomy of the chest and neck and the location of the thoracic duct.

[0025] Figure 1B illustrates the location of the thoracic duct outlet as it enters the central venous system.

[0026] Figure 2A illustrates a variation of the drainage device placed in the thoracic duct with a subcutaneous port under the skin of the left chest wall.

[0027] Figure 2B illustrates a variation of the drainage device in deployed in a thoracic duct.

[0028] Figure 2C illustrates a variation of a subcutaneous port and in-line sensor.

[0029] Figure 3A illustrates a variation of the drainage device in which the intraluminal member has the shape of a closed cylinder.

[0030] Figure 3A' illustrates a variation of the drainage device in which the intraluminal member has the shape of a hemi-cylinder.

[0031] Figure 3B illustrates a variation of the device deployed in a thoracic duct in which the intraluminal member has the shape of an incomplete cylinder.

[0032] Figure 3B' illustrates a variation of the device of Figure 3B.

[0033] Figures 4A through 4C illustrate a variation of a method for delivery of a two-piece intra-ductal device.

[0034] Figures 5A through 5C illustrate a variation of a method for delivery of a one-piece intra-ductal device.

[0035] Figure 6A illustrates a variation of the device deployed in the central venous system in opposition to the thoracic duct outlet.

[0036] Figure 6B is an end view of the device of Figure 6A.

[0037] Figure 6C is a close-up of the distal end of the device of Figure 6A.

[0038] Figure 7 illustrates a variation of the device deployed in the central venous system in opposition to the thoracic duct outlet.

[0039] Figures 8A through 8C illustrate a variation of a method for delivery of a variation of the device into the central venous system using intravascular ultrasound guidance.

DETAILED DESCRIPTION:

[0040] The device disclosed enables removal of fluid from a vessel within the body. For example, the device can be placed in a lymph or blood vessel to remove lymph fluid from the body. The removal of lymph fluid can reduce the hemostatic pressure in the lymphatic system, reducing symptoms of congestive heart failure.

[0041] The device can access the lumen of a body vessel. For example, a lymphatic vessel and/or blood vessel. Fluid can drain from the vessel into the device. For example, the device can be in fluid communication with the thoracic duct or central veins (e.g., sbclavian vein, internal jugular vein, superior vena cava, and innominate vein) shown in Figures 1A and Figure 1B. The device can reduce the pressure within the lumen by draining and removing excess fluid. The excess fluid can be stored in the device. The excess fluid can flow through a port and removed percutaneously. The device could treat pulmonary edema, for example, by reducing the pressure in the interstitial space, such as around the alveoli.

[0042] The device can have a cannula, intraluminal and extraluminal members, and one or more of the following: access port, sensor, pressure sensor, flow meter, reservoir.

[0043] Fluid overload, or hypervolemia, is a medical condition where there is too much fluid in the blood. The total body fluid can be too much for the heart to pump. Under normal physiological conditions, this would result in fluid building up in the

tissue. The thoracic duct outlet would typically allow lymph fluid to drain from the thoracic duct into the innominate vein, but when the blood pressure in the innominate vein becomes to high compared to the lymph fluid pressure in the thoracic duct, the lymph fluid cannot properly drain through the thoracic duct outlet and may prevent proper draining of the lymph system and exit the lymphatic system in a pathological manner.

[0044] Figure 2A illustrates a variation of the drainage device placed inside the thoracic duct. The draining device can be in fluid communication with a tube or cannula. The drainage device can be connected to and in fluid communication with a subcutaneous port, for example via the cannula. The drainage device can be placed anywhere along the cervical thoracic duct. The cannula can drain fluid from the draining device to an internal or external reservoir or port, such as the subcutaneous port. The subcutaneous port can be drained, for example, by occasional access by a percutaneous needle.

[0045] Figure 2B illustrates that the drainage device may include intraluminal and extraluminal members. The intraluminal and/or extraluminal members can be cylindrical and/or conical in shape.

[0046] The intraluminal member of the device can be inserted into the thoracic duct lumen. The intraluminal member can be hollow. The intraluminal member can be in fluid communication with the body lumen, for example the thoracic duct. The intraluminal member can be capable of carrying fluid from the body lumen. The intraluminal member can be in continuous or discontinuous (i.e., temporary, or sequentially repeating off and on by automatic or manual control) fluid communication with the body lumen. The cannula can access the vessel without significantly occluding the vessel. The intraluminal member can occupy some of the cross sectional area of the vessel the intraluminal member is accessing. The intraluminal member can occupy a small amount of the cross sectional area of the blood vessel. The extraluminal member of the device can be in fluid communication with both the intraluminal member and the cannula. The extraluminal member can cross the full thickness of the thoracic duct wall.

[0047] The drainage device can remain in a given position in the vessel by hooks and barbs. The drainage device can maintain the position without hooks and barbs. The extraluminal member may be secured to the cannula. The cannula can hold the drainage device in place. The exterior surface of the drainage device, such as along

the intraluminal member, can have an ingrowth matrix configured to promote tissue ingrowth to anchor the drainage device to the surrounding tissue, such as the endothelium or intima of the blood vessel.

[0048] The intraluminal and extraluminal members may be rigid. The intraluminal and extralunimal members may be flexible. The intraluminal and/or extraluminal members can have soft grafts and/or reinforcing self-expandable or balloon-expandable metal or polymer stents. Portions of the intraluminal or extraluminal members may be more rigid, for example the extraluminal member. Portions of the intraluminal or extraluminal members may be more flexible, for example the intraluminal member.

[0049] The device can enable indirect access to the vessel. The device can be accessed by a needle on a syringe, and the device can include an access port. The access port can be in fluid communication with the vessel. The access port can be connected to the cannula and the cannula can be in fluid communication with the vessel.

[0050] Figure 2C illustrates that the access port can be a subcutaneous access port. The access port may include a gel port. The gel port can be self-sealing, for example re-sealing after removal of the access device, such as a needle. The access port may be in fluid communication with the cannula.

[0051] The device may include one or more sensors. The sensors may include pressure sensors, pH sensors, ultrasound sensors, and/or volume sensors. The sensors may detect temperature and/or changes in temperature and/or impedance and/or changes in impedance and/or chemical composition of the fluid (such as acidity and alkalinity) and/or changes in chemical composition of the fluid. The sensors may detect pressure and/or changes in pressure in the vessel and/or in the cannula and/or in the device. The sensors may detect flow volume and/or changes in flow volume in the cannula and/or in the vessel and/or in the device. Figure 2C shows that a sensor may be connected to the cannula between the intraluminal member and the subcutaneous access port. The sensor may be in fluid communication with the vessel, for example the thoracic duct.

[0052] The sensor may have a means to signal the patient to high pressure. The sensor may signal when drainage of fluid is necessary. For example, the sensor may be in communication with an external device. The sensor may signal the external device. The external device may notify the patient.

[0053] The sensor may enable a physical deformation of some component of the device at a specified threshold. For example, the sensor may be a pressure sensor. The pressure sensor may be comprised of a valve and a chamber. The valve may allow fluid to pass into a reservoir only at a certain pressure. The reservoir may expand when it has fluid. The expansion may be detectable by the patient and/or by physical exam.

[0054] Figure 3A shows that the intraluminal member can be tubular or cylindrical. Figure 3A' illustrates that the intraluminal member can have a semi-cylindrical or partially tubular structure where the halves of the tube, as measured from the center of the base of the cannula, are identical. When implanted in a vessel, the intraluminal member can promote laminar flow through the vessel. The intraluminal member can have a smooth surface, for example on the surface facing the vessel into which the member is implanted. The intrauminal member can aid in flow of fluid through the vessel.

[0055] Figures 3B and 3B' illustrate that the intraluminal member can be or have a self-expanding (i.e., elastically deformable) or balloon-expanding (i.e., plastically deformable) metal, plastic, or biodegradable wireframe or stent.

[0056] The device may be delivered to a vessel lumen over guidewires in separate parts. Some or all members may be expandable. Some or all members may have two configurations.

[0057] A guidewire may be used to help place the device. The guidewire may be inserted trans-abdominally. The guidewire may be advanced into the lymphatic system. The guidewire may be advanced up the lymphatic system, with the flow of lymphatic fluid, towards the thoracic duct. The same or a second guidewire may puncture the thoracic duct. The guidewire may be advanced towards the skin. An incision may be made in the chest. The incision may be made until the guidewire is able to be advanced to the skin. The cannula and/or an access port may be loaded on the guidewire. The access port may be inserted into the body and connected to the cannula.

[0058] Figures 4A through 4D illustrate that the device can be implanted in the thoracic ductFigure 4A illustrates that the device may be placed over a guidewire. The guidewire could be placed from the proximal lymphatic system using standard interventional radiology techniques. For example, the guidewire could be placed trans-abdominally. The cysterna chyli could be cannulated and a guidewire could be

advanced in the lymphatic system. The guidewire could be advanced until it is at the thoracic duct. The cannula may be expanded once in the desired position. The cannula may be expanded in the thoracic duct. As another example, a vein, such as the internal jugular vein, could be cannulated with a hollow needle. The guidewire could be advanced into the junction of the thoracic duct to the venous system, then into the lymphatic system. This could be achieved with a curved-tip wire. Once in the correct position the device could be deployed. Once the device is in the correct position the device could be expanded. The device could be expanded using a balloon, for example.

[0059] Figure 4A shows that the intraluminal member may have a compressed configuration. The intraluminal member can be delivered over a guidewire from the distal end of the vessel. Figure 4B shows that the intraluminal member may have a second, expanded configuration. The intraluminal member may have an aperture in its expanded formation for inserting and connecting the extraluminal member. Figure 4C shows the extraluminal member can be delivered in a compressed configuration over a guidewire from the distal vessel. The guidewire can be passed trhough the exit hole in the intraluminal member. The extraluminal member can be passed through the exit hole in the intraluminal member over the guidewire. Figure 4D shows that the extraluminal member can be expanded and connected to the intraluminal member. The cannula may be connected to the stabilizing members after implantation.

[0060] Figures 5A through 5C illustrate that the cannula and the stabilizing members can be part of a unitary body. The cannula and the stabilizing members can all be part of a unitary body with no seams between components.

[0061] Figure 5A illustrates that the device can be delivered over a guidewire to the target vessel as a unitary body. In Figure 5A, the device can be delivered to the vessel from a proximal location outside the vessel. In Figures 5B and 5C, the device can be radially expanded once the device has been positioned inside the thoracic duct.

[0062] The device and/or the access points to the vessel can be detectable using a visualization technology, for example ultrasound. Fluid from the vessel can be withdrawn through the drainage device by another device, for example a needle.

[0063] The drainage device can be accessed by any number of other devices. The accessing devices may be capable of transporting fluid, and/or measuring pressure. For example, access can entail percutaneous cannulation of the device by a needle. Access can include access of the cannula and/or access of another member of the

device. For example, access can include percutaneous cannulation of a subcutaneous access port of the device.

[0064] The cannula connected to the drainage device may include one or more valves. The valves may be pressure activated. Fluid pressure in the vessel lumen may open the valve. Fluid flow above normal physiological flow can open the valve. Once open, fluid can flow up the cannula. This may signal the patient. The signal may be physical. For example, the fluid may cause the access port to deform in a way that is detectable to the patient. The device can have a valve in the cannula that controls access to a reservoir. The valve may selectively open when the pressure of the lymphatic fluid reaches above the normal physiological pressure of the specific patient. The valve can be a one-way valve, such that fluid may never flow back to the vessel. The valve can be a pressure valve as fluid goes from the vessel towards the tip of the cannula, but allows free flow from the tip of the cannula back towards the base of the cannula. The device may be removable. The device may be collapsible. The components may have joints. For example, the tubular stabilizing members can be magnetic, and deform if a magnetic tube is placed at the core, along the longitudinal axis. The device can be collapsed under vacuum pressure. The device can be collapsed and removed. Use of the device and/or draining the lymphatic system can be used as a step to reverse and/or treat pulmonary edema and/or volume overload and/or acute heart failure and/or chronic heart failure and/or acute exacerbation of chronic heart failure.

[0065] Access can include acute cannulation and/or a means to leave behind an implanted device. Access may include trans-venous access, which may include trans-jugular, subclavian and/or femoral. Access may include access through soft tissue, which may include trans-cutaneous, which could include abdominal access and/or access through thoracic structures and/or access by way of and/or through nuchal structure.

[0066] Access may be aided by imaging modalities. Imaging modalities may include ultrasound, flouroscopy, x-ray, magnetic resonance, computed tomography, direct vision, and/or magnified vision.

[0067] The lymphatic system may include the thoracic duct, and/or cisterna chyli and/or any vessel that carries the fluid and/or all vessels that carry the fluid.

[0068] Removal of the fluid may include draining the fluid to a reservoir inside and/or outside the body. A reservoir inside the body may include another area of the

body, whether or not it is a cavity (i.e. the arms). A reservoir outside the body may include a container and/or an unenclosed area, draining the fluid to a naturally occurring and/or man-made container. Draining may be by way of continuous drainage and/or intermittent drainage, for example draining can be activated when the pressure in the thoracic duct exceeds a predetermined amount. Such drainage can be by way of implanting a valve at the distal end of the thoracic duct; and/or by way of accessing a port; and/or by way of applying a mechanical force to the duct and/or to a lymphatic vessel and/or to the lymphatic system; and/or by way of canulating the duct and/or a lymphatic vessel. The port can be permanently implanted.

[0069] The device may be accessed, for example by a needle. Fluid may be withdrawn from the interior lumen, through the device. The overall fluid volume of the patient may be reduced.

[0070] The device may reside in the central venous system. The device may occlude or cover the outlet of the thoracic duct in the central venous system. The device may seal permanently or temporarily against the outlet of the thoracic duct. The device can fluidly isolate the thoracic duct outlet port from the venous system. For example the distal balloon and proximal balloon can be positioned on opposite sides of the thoracic duct outlet port, and the lymph collection port (e.g., an aperture or valve on in fluid communication with the lymph drainage cannula) can be placed adjacent to the thoracic duct outlet port. The device may be activated to seal against the thoracic duct outlet only when drainage is required. Figure 6A illustrates a variation of the device which seals against the thoracic duct using inflatable balloons. The device may allow for venous blood to pass through it when the balloons are inflated. Figure 6B illustrates the pass-through lumen of the inflated balloons.

[0071] The device in the central venous system may be comprised of a self-expanding metallic structure. The structure may be assembled from one piece or multiple parts. The device may be delivered to the central venous system over a guidewire. Figure 7 illustrates a self-expanding central venous device deployed in opposition to the thoracic duct outlet. The device can have self-expanding nitinol struts and braces.

[0072] Figure 8 illustrates delivering a central venous device with an inflatable balloons over a guidewire. The location where the device will be deployed may be determined using an intravascular imaging modality, such as intravascular ultrasound. In Figure 8A, an intravascular ultrasound probe can used to locate the thoracic duct outlet from the internal jugular vein. Once the location of the outlet has been

determined, the intravascular ultrasound probe is removed and the balloon catheter is deployed as depicted in Figure 8B. In Figure 8C, the balloon catheter can be expanded in place to cover the outlet of the thoracic duct. Lymphatic fluid can be withdrawn from the cannula.

[0073] The device may be implanted. The implantation may be using a minimally invasive technique, for example those techniques commonly used by interventional radiologists and/or interventional cardiologists. The device may enter the body at a point in the vessel more distal to the desired position. For example, the device may enter trans-abdominally into the cysterna chyli. The device may be manipulated through the vessel. Visualization aids may aid in advancing the device and/or a guidewire. For example, fluoroscopy may be used. Mechanical aids can be used to advance the device and/or a guidewire. Once in the desired position, the vessel may be punctured. Using such a technique, the complications associated with open surgery can be avoided.

[0074] Any or all elements of the Device and/or other devices or apparatuses described herein can be made from, for example, a single or multiple stainless steel alloys, nickel titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g., ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHROME® from Carpenter Metals Corp., Wyomissing, PA), nickel-cobalt alloys (e.g., MP35N® from Magellan Industrial Trading Company, Inc., Westport, CT), molybdenum alloys (e.g., molybdenum TZM alloy, for example as disclosed in International Pub. No. WO 03/082363 A2, published 9 October 2003, which is herein incorporated by reference in its entirety), tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO 03/082363, polymers such as polyethylene teraphathalate (PET), polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), poly ester amide (PEA), polypropylene, aromatic polyesters, such as liquid crystal polymers (e.g., Vectran, from Kuraray Co., Ltd., Tokyo, Japan), ultra high molecular weight polyethylene (i.e., extended chain, high-modulus or high-performance polyethylene) fiber and/or yarn (e.g., SPECTRA® Fiber and SPECTRA® Guard, from Honeywell International, Inc., Morris Township, NJ, or DYNEEMA® from Royal DSM N.V., Heerlen, the Netherlands), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ketone (PEK), polyether ether ketone (PEEK), poly ether ketone ketone (PEKK) (also poly aryl ether ketone ketone), nylon, polyether-block co-polyamide polymers (e.g., PEBAX® from

ATOFINA, Paris, France), aliphatic polyether polyurethanes (e.g., TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as polyglycolic acid (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, a biomaterial (e.g., cadaver tissue, collagen, allograft, autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads of bone) any of the other materials listed herein or combinations thereof. Examples of radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum and gold.

[0075] Any or all elements of the Device and/or other devices or apparatuses described herein, can be, have, and/or be completely or partially coated with agents and/or a matrix a matrix for cell ingrowth or used with a fabric, for example a covering (not shown) that acts as a matrix for cell ingrowth. The matrix and/or fabric can be, for example, polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), poly ester amide (PEA), polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone, any other material disclosed herein, or combinations thereof.

[0076] The device and/or elements of the device and/or other devices or apparatuses described herein and/or the fabric can be filled, coated, layered and/or otherwise made with and/or from cements, fillers, glues, and/or an agent delivery matrix known to one having ordinary skill in the art and/or a therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can be osteogenic and osteoinductive growth factors.

[0077] Examples of such cements and/or fillers includes bone chips, demineralized bone matrix (DBM), calcium sulfate, coralline hydroxyapatite, biocoral, tricalcium phosphate, calcium phosphate, polymethyl methacrylate (PMMA), biodegradable ceramics, bioactive glasses, hyaluronic acid, lactoferrin, bone morphogenic proteins (BMPs) such as recombinant human bone morphogenetic proteins (rhBMPs), other materials described herein, or combinations thereof.

[0078] The agents within these matrices can include any agent disclosed herein or combinations thereof, including radioactive materials; radiopaque materials;

cytogenic agents; cytotoxic agents; cytostatic agents; thrombogenic agents, for example polyurethane, cellulose acetate polymer mixed with bismuth trioxide, and ethylene vinyl alcohol; lubricious, hydrophilic materials; phosphor cholene; anti-inflammatory agents, for example non-steroidal anti-inflammatories (NSAIDs) such as cyclooxygenase-1 (COX-1) inhibitors (e.g., acetylsalicylic acid, for example ASPIRIN® from Bayer AG, Leverkusen, Germany; ibuprofen, for example ADVIL® from Wyeth, Collegeville, PA; indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from Merck & Co., Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp., Peapack, NJ; COX-1 inhibitors); immunosuppressive agents, for example Sirolimus (RAPAMUNE®, from Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP) inhibitors (e.g., tetracycline and tetracycline derivatives) that act early within the pathways of an inflammatory response. Examples of other agents are provided in Walton et al, Inhibition of Prostoglandin E_2 Synthesis in Abdominal Aortic Aneurysms, *Circulation*, July 6, 1999, 48-54; Tambiah et al, Provocation of Experimental Aortic Inflammation Mediators and Chlamydia Pneumoniae, *Brit. J. Surgery* 88 (7), 935-940; Franklin et al, Uptake of Tetracycline by Aortic Aneurysm Wall and Its Effect on Inflammation and Proteolysis, *Brit. J. Surgery* 86 (6), 771-775; Xu et al, Sp1 Increases Expression of Cyclooxygenase-2 in Hypoxic Vascular Endothelium, *J. Biological Chemistry* 275 (32) 24583-24589; and Pyo et al, Targeted Gene Disruption of Matrix Metalloproteinase-9 (Gelatinase B) Suppresses Development of Experimental Abdominal Aortic Aneurysms, *J. Clinical Investigation* 105 (11), 1641-1649 which are all incorporated by reference in their entireties.

Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one). Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

CLAIMS

We claim:

1. A device for accessing a body lumen comprising:

a tubular furcated structure having a main branch, a first leg and a second leg, wherein the main branch is at a first longitudinal end of the graft, and wherein the first and second legs are at a second longitudinal end of the structure, and wherein the second leg comprises a cannula.

2. The device of Claim 1, wherein the cannula comprises a sharp tip.

3. The device of Claim 1, wherein the cannula comprises a barb.

4. The device of Claim 1, wherein the cannula comprises a stint.

5. The device of Claim 1, wherein the cannula comprises a curved wire.

6. The device of Claim 1, wherein the cannula has a base longitudinally proximal to the main branch and a tip longitudinally distal to the main branch, and wherein the base is wider than the tip.

7. The device of Claim 1, wherein the cannula has a tip longitudinally distal to the main branch and wherein the tip comprises a structural reinforcement.

8. The device of Claim 1, wherein the second leg can be resilient.

9. The device of Claim 8, wherein the second leg is configured to resiliently extend outward from the main branch.

10. The device of Claim 1, wherein the main branch forms a main flow channel, and wherein the second leg forms a second leg flow channel, and wherein the second flow channel is narrower than the main flow channel.

11. The device of Claim 1, wherein the second leg flow channel is narrow enough to create a turbulent flow.

12. The device of Claim 1, wherein the device comprises an anti-clotting material.

13. The device of Claim 12, wherein the anti-clotting material comprises a coating on the structure.

14. The device of Claim 12, wherein the structure is impregnated with the anti-clotting material.

15. The device of Claim 1, wherein the structure comprises an anti-infection material.

16. The device of Claim 1, wherein the anti-infection material comprises a coating on the structure.

17. The device of Claim 12, wherein the structure is impregnated with the anti-infection material.

18. The device of Claim 1, wherein the structure has a texture configured to reduce clotting.

19. The device of Claim 1, wherein the device comprises Heparin.

20. The device of Claim 1, wherein the device comprises an anti-fibrin chemical.

21. The device of Claim 1, wherein the device comprises Plavix.

22. The device of Claim 1, wherein the main branch has a main branch diameter, and wherein the first leg has a first leg diameter, and wherein the main branch diameter is substantially unequal to the first leg diameter.

23. The device of Claim 1, wherein the cannula has a cannula longitudinal axis and wherein the main branch has a main branch longitudinal axis, and wherein the main branch longitudinal axis and the cannula longitudinal axis form a main branch angle, and wherein the main branch angle is about 90 degrees.

23b. The device of claim 23 where the main branch angle is less than 90 degrees.

23c. The device of claim 23 where the main branch angle is greater than 90 degrees.

24. The device of Claim 23, wherein the first leg has a first leg longitudinal axis, and wherein the first leg longitudinal axis and the cannula longitudinal axis form a first leg angle, and wherein the first leg angle is about 90 degrees.

25. The device of Claim 1, wherein the cannula has a cannula longitudinal axis and wherein the first leg has a first leg longitudinal axis, and wherein the first leg longitudinal axis and the cannula longitudinal axis form a first leg angle, and wherein the first leg angle is about 90 degrees.

26. The device of Claim 1, wherein the main branch comprises a stent.

27. The device of Claim 1, wherein the main branch comprises a first stent, and wherein the first leg comprises a second stent.

28. The device of Claim 1, wherein the main branch has a main branch terminal end, and wherein the main branch terminal end has a tapered configuration.

29. The device of Claim 28, wherein the first leg has a first leg terminal end, and wherein the first leg terminal end has a tapered configuration.

30. The device of Claim 1, wherein the first leg has a first leg terminal end, and wherein the first leg terminal end has a tapered configuration.

31. The device of Claim 1, wherein main branch has a side hole, and wherein the cannula is configured to pass through the side hole.

32. The device of Claim 31, wherein the cannula is fixed to the side hole and held in place by the pressure on it from the sidewalls of the main branch

33. The device of Claim 31, wherein the bottom of the cannula is fixedly attached to the main branch.

34. The device of Claim 1, wherein the cannula is manipulatably attached to the main branch.

35. The device of Claim 1, wherein the cannula is manipulatably attached to the first leg.

36. The device of claim 1, wherein the cannula is attached to the main branch by an expandable member.

37. The device of claim 1, wherein the cannula comprises an expandable member.

38. A device for accessing a body lumen comprising:
a tubular cannula, and stabilizing members,
wherein the stabilizing members is at a first longitudinal end of the cannula.

39. A method for decreasing fluid volume in a patient comprising:
accessing a subcutaneous port that is in fluid communication with a lymphatic vessel; and
withdrawing fluid from the lymphatic vessel.

40. A method for withdrawing lymphatic fluid from a body comprising:
accessing a lymphatic vessel with a channel; and
fixedly attaching the channel to the vessel;
wherein the channel is in fluid communication with a port.

41. The method of Claim 40, wherein fixedly attaching comprises expanding a part of the channel within the vessel.

42. The method of Claim 40, wherein fixedly attaching comprises inserting an element into the vessel wall.

43. The method of claim 42, wherein the attaching comprises inserting hooks/barbs into the vessel wall.

44. The method of claim 43, wherein the attaching comprises stitching through the vessel wall.

45. The method of claim 41, wherein fixedly attaching comprises attaching an element external to the vessel to an element interior to the vessel wall.

46. A method for treating edema comprising:

draining fluid from a lymphatic vessel when the pressure in the lymphatic vessel is greater than the normal physiological fluid flow pressure; and

stopping a draining of fluid from a lymphatic vessel when the pressure in the lymphatic vessel returns to normal physiological fluid flow and/or when the patient is no longer volume overloaded

47. A method for evaluating fluid status in heart failure by non-invasive assessment of lymphatic pressure.

48. A method for draining fluid from a body comprising:

positioning a device having an aperture in a blood vessel, with the aperture positioned adjacent to a thoracic duct opening; and

removing fluid through the aperture.

49. The method of Claim 48, further comprising, anchoring the aperture to the blood vessel.

50. The method of Claim 49, wherein anchoring comprises hooking to the blood vessel.

51. The method of Claim 49, wherein anchoring comprises placing an ingrowth matrix adjacent to the blood vessel wall.

52. The method of Claim 49, wherein anchoring comprises inflating a first balloon.

53. The method of Claim 52, wherein the first balloon is positioned at the thoracic duct opening.

54. The method of Claim 52, wherein anchoring comprises inflating a second balloon.

55. The method of Claim 54, wherein the first balloon is distal to the thoracic duct opening and wherein the second balloon is proximal to the thoracic duct opening.

56. The method of Claim 48, wherein positioning comprises locating the thoracic duct.

57. The method of Claim 56, wherein locating the thoracic duct comprises:

translating a pH sensor through the blood vessel;

detecting a pH level with the pH sensor; and

tracking the pH level detected and wherein when the pH sensor, wherein when the pH level reaches a maximum and then decreases, the device emits a signal indicating the pH sensor just passed the thoracic duct.

58. The method of Claim 57, wherein locating the thoracic duct comprises translating an intravascular ultrasound transducer through the blood vessel, and wherein the ultrasound transducer is in a balloon inflated with a liquid.

59. A method of treating human immunodeficiency virus comprising:

positioning a drainage port adjacent to the thoracic duct; and

applying a negative pressure to remove lymph fluid from the thoracic duct.

60. A method for decreasing fluid volume in a patient comprising:

accessing a subcutaneous port that is in fluid communication with a blood vessel adjacent to the lymphatic vessel outlet; and

withdrawing fluid from the subcutaneous port.

61. A method for accessing the thoracic duct comprising:

fluidly isolating the thoracic duct outlet from the venous system.

62. The method of Claim 61, wherein fluidly isolating comprises inflating a first balloon in the venous system distal to the thoracic duct outlet.

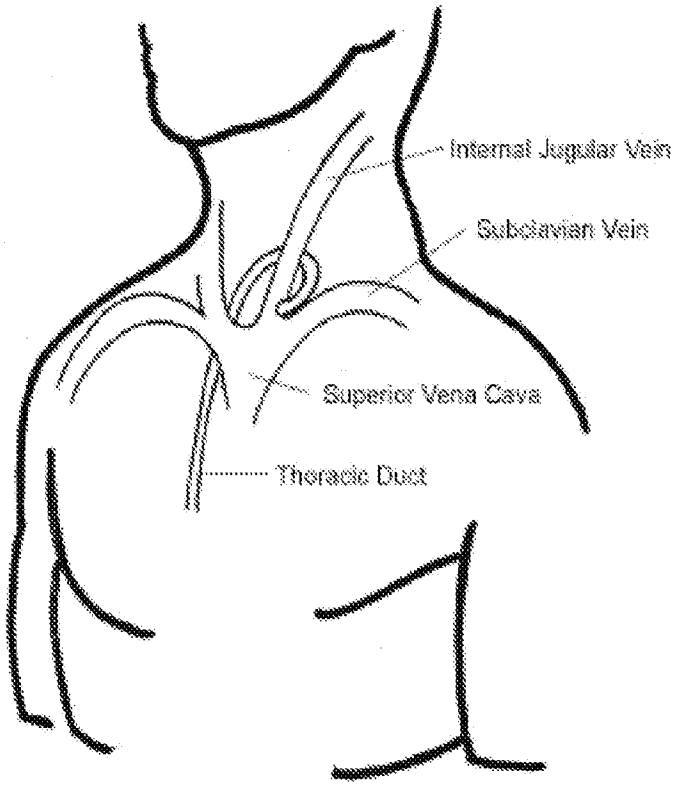
63. The method of Claim 62, wherein fluidly isolating comprises inflating a second balloon in the venous system distal to the thoracic duct outlet.

64. The method of Claim 61, wherein fluidly isolating comprises positioning a drainage port in the venous system adjacent to the thoracic duct outlet, wherein the drainage port is positioned between the first balloon and the second balloon.

65. The method of Claim 61, wherein fluidly isolating comprises positioning a drainage port in the venous system adjacent to the thoracic duct outlet.

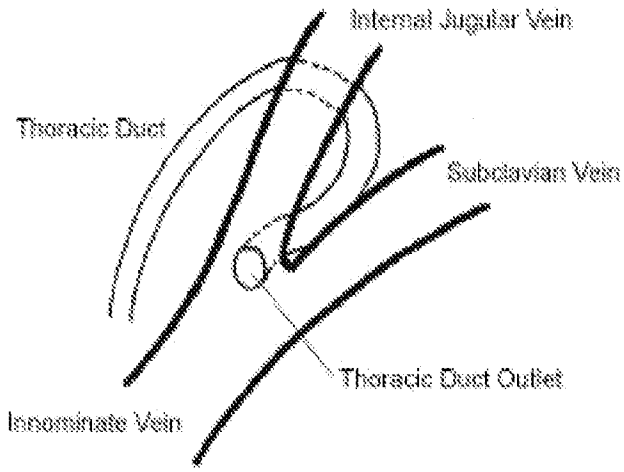
66. The method of Claim 65, further comprising anchoring the drainage port against a wall of the venous system.

Figure 1A



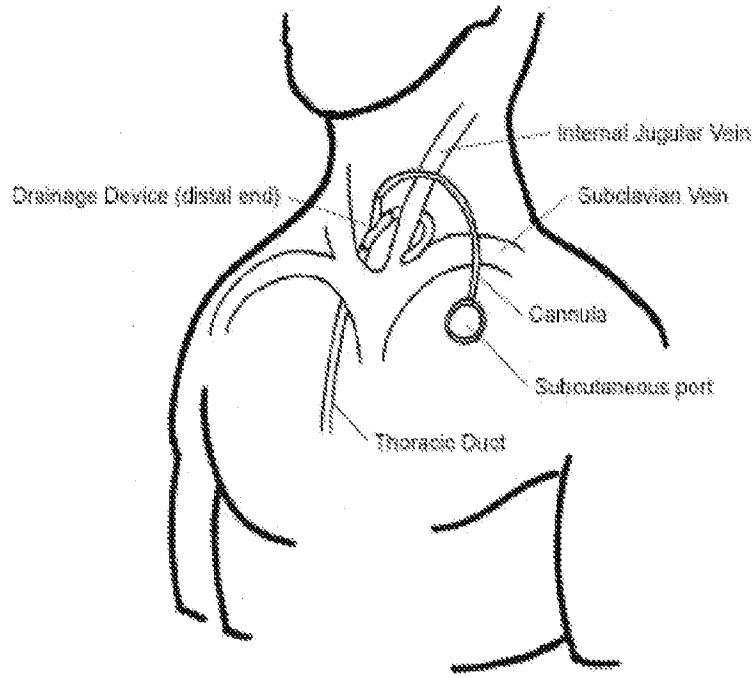
NOT INVENTION

Figure 1B



NOT INVENTION

Figure 2A



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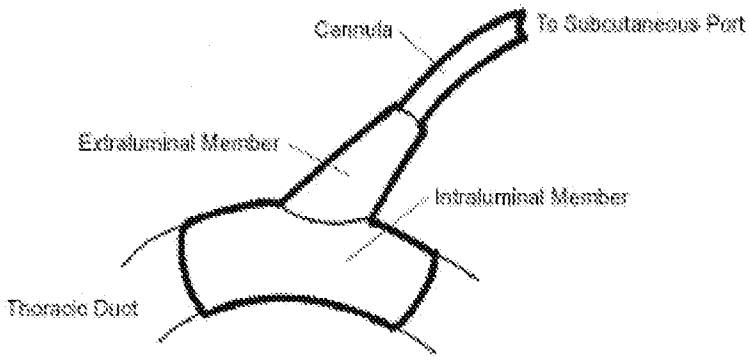


Figure 2C

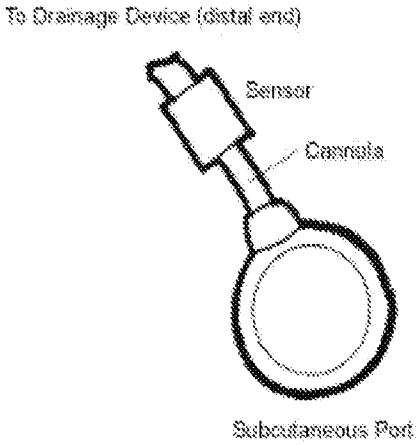


Figure 3A

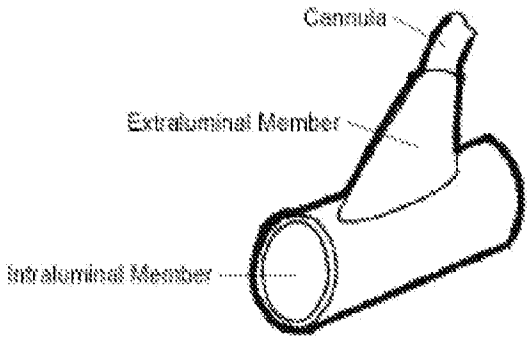


Figure 3A'

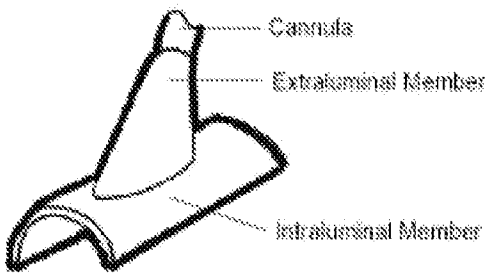


Figure 3B

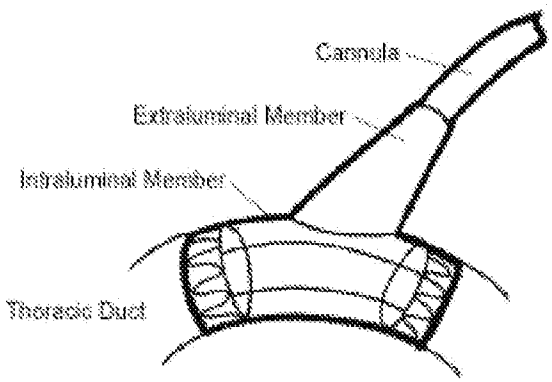


Figure 3B'

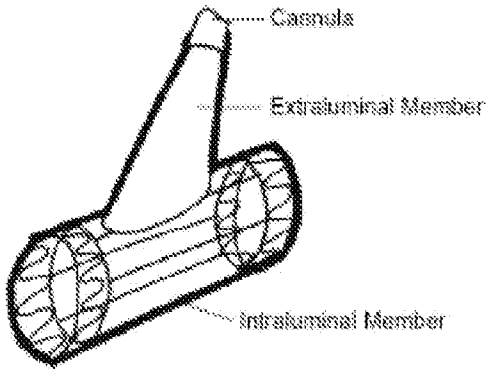


Figure 4A

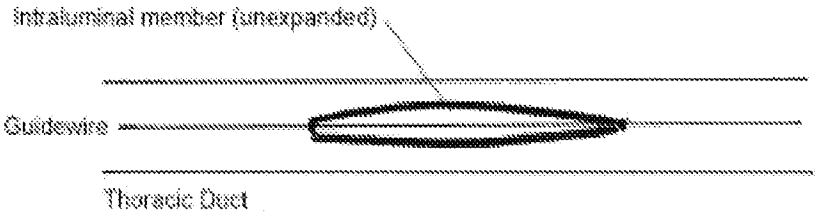


Figure 4B

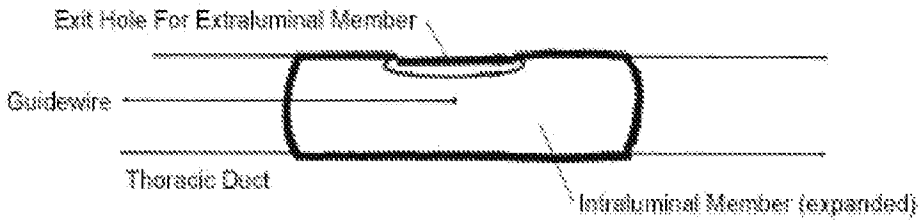


Figure 4C

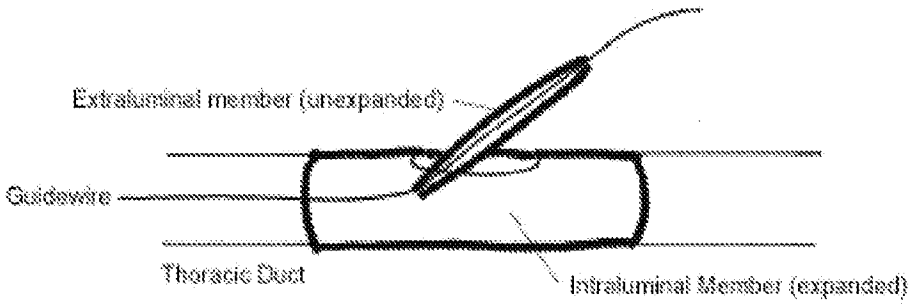


Figure 4D

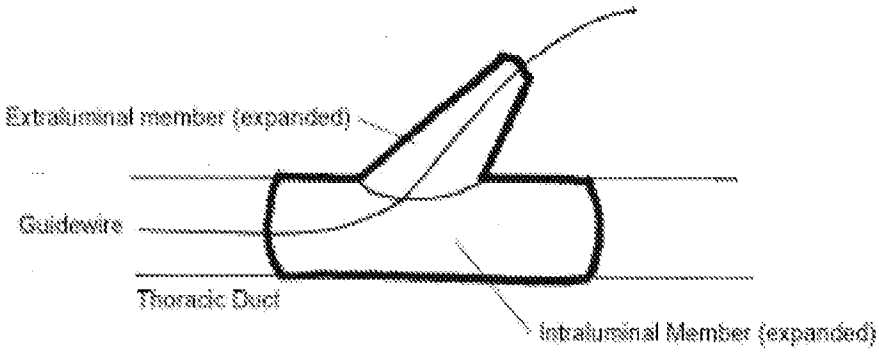


Figure 5A

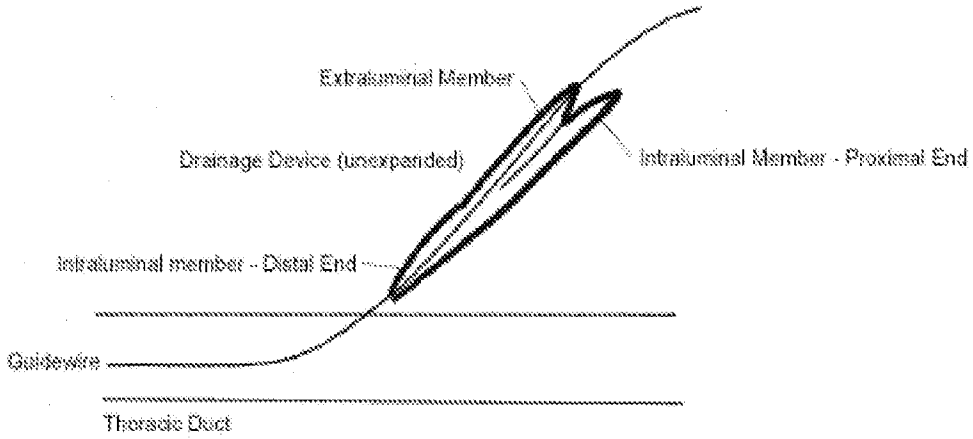


Figure 5B

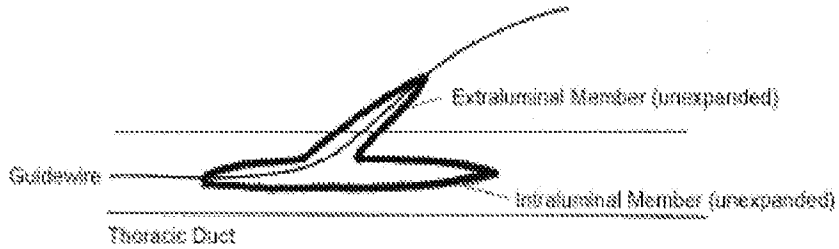
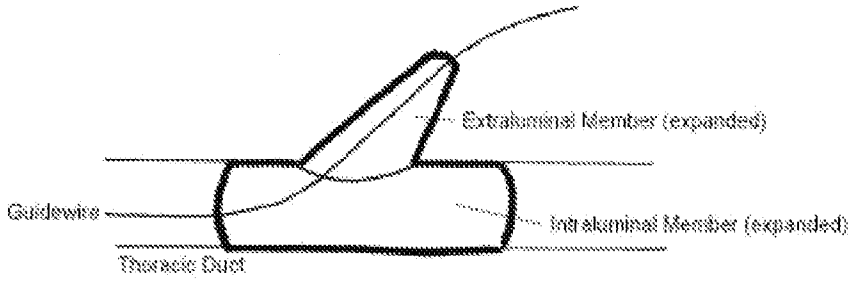


Figure 5C



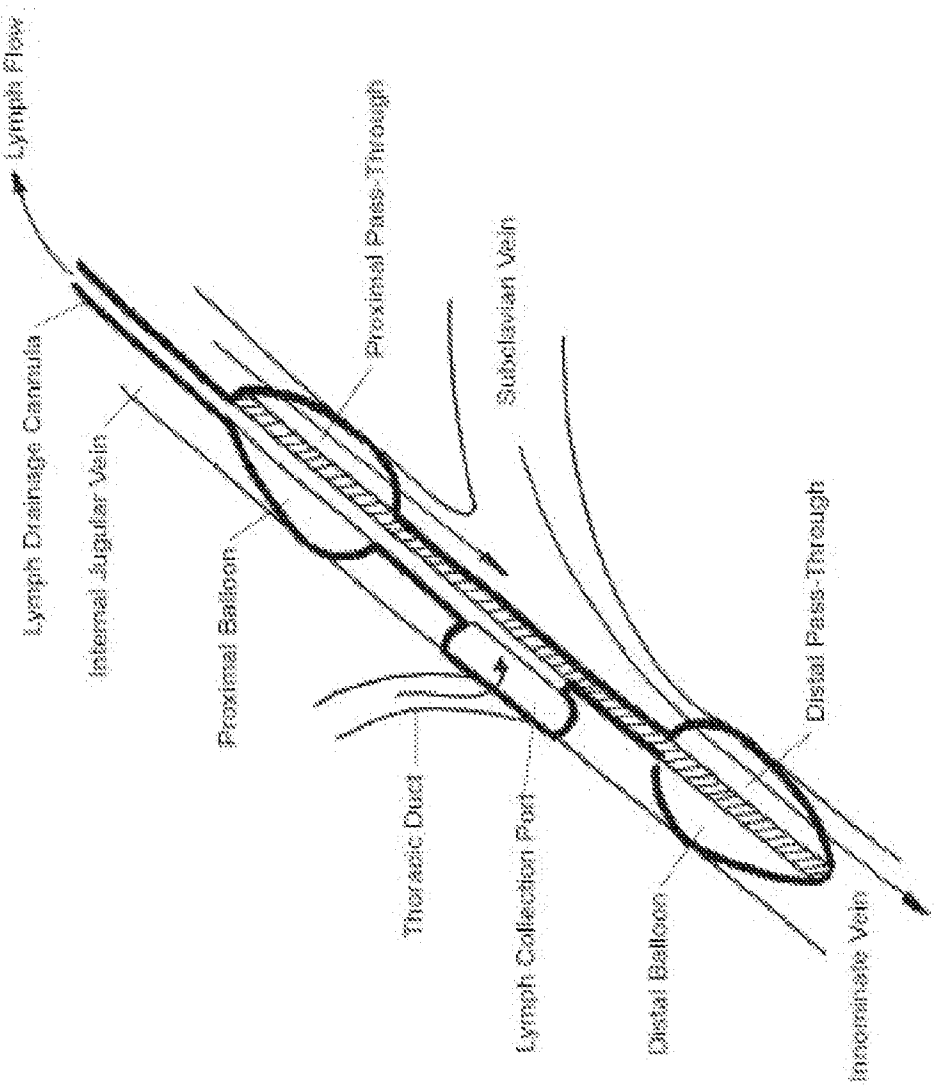


Figure 6A

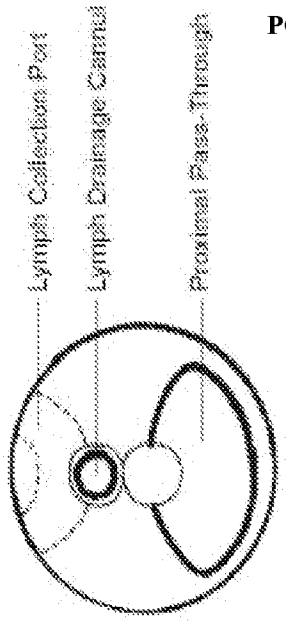


Figure 6B

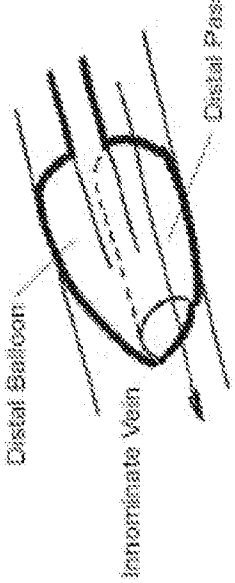
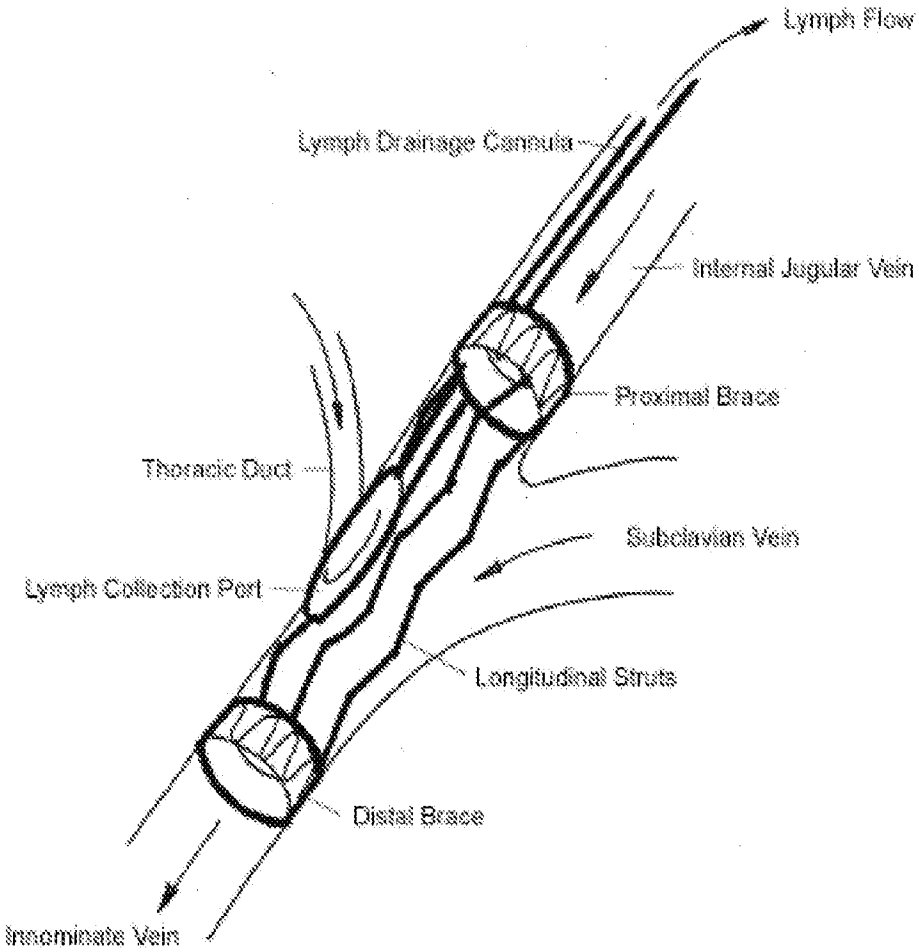
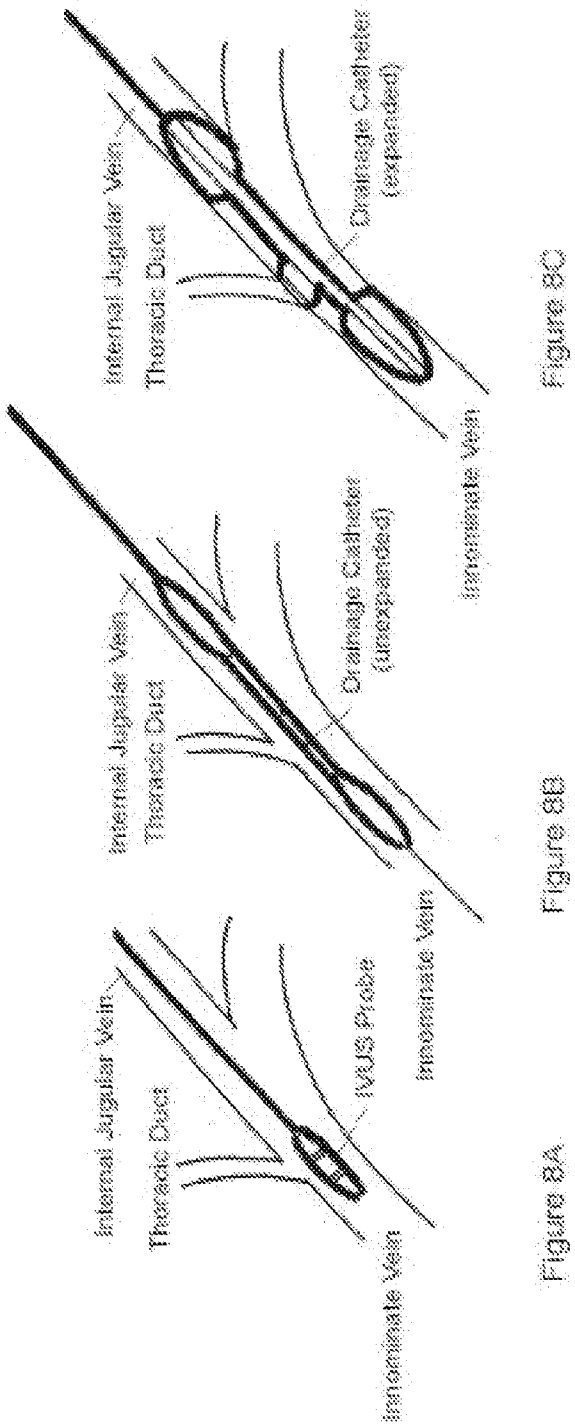


Figure 6C

Figure 7


Lymph Flow
Lymph Drainage Cannula
Internal Jugular Vein
Proximal Brace
Thoracic Duct
Subclavian Vein
Lymph Collection Port
Longitudinal Struts
Distal Brace
Innominate Vein


Internal Jugular Vein
Thoracic Duct
IVUS Probe
Innominate Vein
Figure 8A
Internal Jugular Vein
Thoracic Duct
Drainage Catheter (unexpanded)
Innominate Vein
Figure 8B
Internal Jugular Vein
Thoracic Duct
Drainage Catheter (expanded)
Innominate Vein
Figure 8C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/000073

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 39/02 (2010.01)
USPC - 604/175
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)
IPC(8) - A61M 39/02; A61F 2/06 (2010.01)
USPC - 604/288.01,93.01,174,175

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO EAST System (US, USPG-PUB, EPO, DERWENT), PatBase

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 6,042,569 A (FINCH JR et al) 28 March 2000 (28.03.2000) entire document	1-3, 8-14, 20-25, 28, 31-35, 38 --- 4-7, 15-19, 26, 27, 29, 30, 36, 37
Y	US 6,152,945 A (BACHINSKI et al) 28 November 2000 (28.11.2000) entire document	4, 5, 26, 27
Y	US 2004/0210296 A1 (SCHMITT et al) 21 October 2004 (21.10.2004) entire document	6, 29, 30
Y	US 2005/0251180 A1 (BURTON et al) 10 November 2005 (10.11.2005) entire document	7
Y	US 2005/0228474 A1 (LAGUNA) 13 October 2005 (13.10.2005) entire document	15-17, 19
Y	US 4,822,341 A (COLONE) 18 April 1989 (18.04.1989) entire document	18
Y	JP 2-206468 A (TSUCHIMOTO) 16 August 1990 (16.08.1990) entire document	36, 37

☐ Further documents are listed in the continuation of Box C. ☐

* 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
16 May 2010	21 MAY 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/000073

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:

Group I, claims 1-38 are drawn to a device for accessing a body lumen.

Group II, claims 39-46 and 48-60 are drawn to a method for decreasing and draining fluid volume in a patient.

Group III, clam 47 is drawn to a method for evaluating fluid status in heart failure.

Group IV, clams 61-66 are drawn to a method for isolating a thoracic duct.

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.:
1-38

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.