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(54) **APPARATUS FOR CONTAINING AND DELIVERING THERAPEUTIC AGENTS**

GERÄT ZUR AUFNAHME UND ABGABE VON THERAPEUTISCHEN MITTELN

APPAREIL POUR CONTENIR ET ADMINISTRER DES AGENTS THÉRAPEUTIQUES

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Description

BACKGROUND

[0001] The present embodiments relate generally to medical devices, and more particularly to apparatus for delivering therapeutic agents to a target site.

[0002] There are several instances in which it may become desirable to introduce therapeutic agents into the human or animal body. For example, therapeutic drugs or bioactive materials may be introduced to achieve a biological effect. The biological effect may include an array of targeted results, such as inducing hemostasis, sealing perforations, reducing restenosis likelihood, or treating cancerous tumors or other diseases.

[0003] Many of such therapeutic agents are injected using an intravenous (IV) technique and via oral medicine. While such techniques permit the general introduction of medicine, in many instances it may be desirable to provide localized or targeted delivery of therapeutic agents, which may allow for the guided and precise delivery of agents to selected target sites. For example, localized delivery of therapeutic agents to a tumor may reduce the exposure of the therapeutic agents to normal, healthy tissues, which may reduce potentially harmful side effects.

[0004] Localized delivery of therapeutic agents has been performed using catheters and similar introducer devices. By way of example, a catheter may be advanced towards a target site within the patient, and then the therapeutic agent may be injected through a lumen of the catheter to the target site. Typically, a syringe or similar device may be used to inject the therapeutic agent into the lumen of the catheter. However, such a delivery technique may result in a relatively weak stream of the injected therapeutic agent.

[0005] Moreover, it may be difficult or impossible to deliver therapeutic agents in a targeted manner in certain forms, such as a powder form, to a desired site. For example, if a therapeutic powder is held within a syringe or other container, it may not be easily delivered through a catheter to a target site in a localized manner that may also reduce potentially harmful side effects.

[0006] Reference is directed to WO2008/008845, which discloses various multi-reservoir pump devices for different medical applications, including drug delivery, biosensing, and dialysis. The document discloses a pump and reservoir device, which includes a remote pump that is in fluid communication with a reservoir and mixing component through a flexible conduit. The reservoir and mixing component includes a substrate with drug-containing reservoirs arrayed therein. Each reservoir has two openings on opposed sides of the substrate. Reservoir caps are provided over these openings and can be actively disintegrated to allow pumped carrier fluid to flow into and through the reservoirs and then into a mixing space. The fluidized drug then can flow out of the device through a discharge tube.

[0007] It may be noted that, although an end of the discharge tube is connected to the reservoir and mixing component, there is no suggestion that an end of the discharge tube be positioned within the reservoir and mixing component

The document notes generally that, in some of the disclosed constructions, the pump may produce sufficient turbulence to mix drug molecules from the reservoir and the carrier fluid sufficient to form a solution or ordered mixture. It further notes that sufficient turbulence can also be created by incorporating baffles within a flow channel (though it should be noted that it is unclear whether the specific pump and reservoir device discussed above includes such a flow channel) and/or by adding a static or dynamic mixer/agitator.

[0008] Reference is further directed to WO2005/100980, which discloses disposable sample testing devices. In one disclosed construction, the device is in the form of a single disposable unit that includes a measuring component or volume chamber, reagents located in a mixing chamber or area, and an analysis portion (test chamber).

[0009] The document teaches that the sample and reagent are mixed in the mixing chamber. It is disclosed that a mixing pin may be provided in the mixing chamber to assist mixing. The document asserts the two areas around the pin induce a reversed mixing pattern, disrupting the laminar flow completely, resulting in more effective mixing.

[0010] Reference is still further directed to US2007/240989, which discloses microfluidic pumps and mixers driven by induced-charge electro-osmosis.

[0011] It may be noted that, in one disclosed construction, a tear-drop asymmetric shaped conductor is used to produce a directed induced-charge electro-osmotic flow under the influence of an AC electric field.

[0012] It is proposed that the general teaching of the document may be applied to drug delivery devices which convey fluid from a reservoir to an outlet port. In one example, it is suggested that mixing of drug concentrations may take place in the device.

SUMMARY

[0013] The present embodiments provide apparatus suitable for containing a therapeutic agent and delivering it to a target side as stated in the independent claim 1 and its dependent claims. The apparatus generally comprises at least one container for holding a therapeutic agent, and a pressure source for facilitating delivery of the therapeutic agent.

[0014] In one embodiment, the pressure source may be placed in selective fluid communication with a proximal end of the container. Fluid from the pressure source may flow through at least a portion of the container to urge the therapeutic agent through a distal end of the container and towards the target site. The pressure source may comprise a compressed gas dispenser.

[0015] At least one tube member, such as a catheter, may be used to facilitate delivery of the therapeutic agent from the container to the target site. The catheter may be placed in fluid communication with the distal region of the container. In use, fluid from the pressure source urges the therapeutic agent through the container, through the catheter, and then distally towards the target site.

[0016] The container has a proximal end and a distal end that may be closed by pregnable sealing members. The container is designed to control the flow of therapeutic agent through the tube member in order to provide a consistent, uniform amount with each use. In one embodiment, the container comprises a tube member held preferably at about the radial center of the container near the distal end. A plug holds the tube member in place and has an outer diameter that is approximately equal to the interior of the container, so that it prevents any therapeutic agent that does not pass through the tube member from exiting the distal end of the container.

[0017] In one embodiment, a flow obstruction member is placed preferably at about the radial center of the container and proximally adjacent to the tube member. A support member, comprised of a wire or other suitable material, is coupled to the flow obstruction member and is held in place by a support structure. The support structure and support member, in combination, maintain the flow obstruction member in place. When fluid from the pressure source enters the container, it forces therapeutic agent to travel around the flow obstruction member so that a certain amount of therapeutic agent is directed through the tube member to be delivered to the target site.

[0018] In another embodiment, the container does not contain a tube member, but instead comprises flow obstruction members placed along the interior of the container that are designed to promote the delivery of a consistent, uniform amount of therapeutic agent with each use.

[0019] In any of the embodiments, switches may be placed at the proximal and distal ends of the container in order to control when fluid from the pressure source may enter the container and push the therapeutic agent into the catheter. If pregnable seals are used, the switches may also be used to perforate the seals surrounding the container. Additionally, a valve may be placed in fluid communication between the pressure source and the container so that the fluid from the pressure source bypasses the container entirely and then enters the catheter in order to clear the catheter of any excess therapeutic agent.

[0020] Other features and advantages of the invention will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional features and advantages be within the scope of the invention, and be encompassed by the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The invention can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

FIG. 1 is a side sectional view of an apparatus for containing and delivering therapeutic agent to a target site in a patient.

FIG. 2 is a schematic view of a first embodiment of a container.

FIG. 3 is a side sectional view illustrating the first embodiment of FIG. 2 with a therapeutic agent present inside the container.

FIG. 4 is an end view of a flow obstruction member, and a support structure and support member of the embodiment of FIG. 2.

FIG. 5 is a side view of the tube member and the plug of the embodiment of FIG. 2.

FIG. 6 is a side sectional view of the embodiment of FIG. 2 with switches depicted in a closed state.

FIG. 7 is a side sectional view of the embodiment of FIG. 2 with switches depicted in an open state.

FIG. 8 is a schematic view of a therapeutic agent being forced past a flow obstruction member and into a tube member.

FIG. 9 is a schematic view of therapeutic agent being forced past an alternative flow obstruction member and into the tube member.

FIG. 10 is a flow chart view depicting components of an exemplary system for containing and delivering a therapeutic agent to a target site in a patient.

FIG. 11 is a schematic view of an apparatus for containing and delivering a therapeutic agent to a target site in a patient in accordance with one embodiment.

FIG. 12 is a schematic view of an apparatus for clearing a therapeutic agent out of a catheter.

FIG. 13 is a perspective view of a distal end of an exemplary end-viewing endoscope and a needle that may be used in conjunction with the apparatus of FIG. 1.

FIG. 14 is a side sectional view of an alternative embodiment of a container.

FIG. 15 is a side sectional view of one embodiment of a catheter in a delivery state.

FIG. 16 is a side sectional view of one embodiment of a catheter in a deployed state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0022] In the present application, the term "proximal" refers to a direction that is generally towards a physician during a medical procedure, while the term "distal" refers

to a direction that is generally towards a target site within a patient's anatomy during a medical procedure.

[0023] Referring now to FIG. 1, a first embodiment of an apparatus suitable for containing and delivering a therapeutic agent to a target site within a patient is shown. The apparatus comprises a pressure source 70 and a container 18 and a catheter 46. For example, as shown in FIG. 1, the pressure source 70 comprises a pressurized fluid cartridge 72, and a housing 71 that at least partially encapsulates or covers the pressurized fluid cartridge 72.

[0024] The pressure source 70 may comprise one or more components capable of producing or furnishing a fluid having a desired pressure. In one embodiment, the pressure source 70 may comprise a pressurized fluid cartridge 72 comprised of a selected gas or liquid - or a combination of gas and liquid - such as carbon dioxide, nitrogen, or any other suitable gas or liquid that may be compatible with the human body. The pressurized fluid cartridge 72 may contain the gas or liquid at a relatively high, first predetermined pressure, for example, around 12 MPa (1,800 psi) inside of the cartridge. The fluid may flow from the pressurized fluid cartridge 72 through a pressure regulator, such as regulator valve 73 having a pressure outlet, which may reduce the pressure to a lower, second predetermined pressure or to achieve a set flow rate. Solely by way of example, the second predetermined pressure may be in the range of about 0.21 MPa (30 psi) to about 0.55MPa (80 psi), although any suitable pressure may be provided for the purposes described below. Therapeutic agent is disposed within the container 18. The pressure source 70 propels fluid from the pressurized fluid cartridge 72 distally through the container 18 and through the catheter 46. In other embodiments, the pressure source 70 may comprise a compressible ball or a syringe. An inner diameter d1 of the catheter 46 may vary, but a preferred inner diameter ranges from about 2.16mm (.085 inches) to about 2.54mm (.100 inches).

[0025] Referring now to FIGS. 1-5, further features of the container 18 are described in greater detail. In this embodiment, the apparatus comprises a container 18 that has an outer surface area 21 that is generally cylindrical, and has a preferred outer diameter ranging from about 23mm (.90 inches) to about 28mm (1.10 inches). The container 18 further comprises an interior surface 19 and a thickness 23, wherein a preferred thickness is about 2.5mm (.10 inches) to about 7.6mm (.30 inches). The container 18 is configured to hold a therapeutic agent 33. The container 18 further comprises a support structure 24 that is preferably near a proximal end 32 of the container 18, but that could be disposed at almost any position in the container 18. The support structure 24 is connected to a flow obstruction member 26 via a support member 28. The flow obstruction member 26 is preferably positioned at about the radial center of the container 18. The support structure 24 preferably projects inwardly towards the radial center of the container 18. In this em-

bodiment, the flow obstruction member 26 is generally spherical and the support structure 24 is generally cylindrical, preferably the support structure 24 is a ring or short-cylinder sized to fit inside the interior surface 19 of container 18. A diameter of the flow obstruction member 26 may vary, but a preferred range is about 6.4mm (.25 inches) to about 8.9mm (.35 inches). The support member 28 may comprise a wire, rod, or other suitable materials for holding the flow obstruction member 26 in place. The support structure 24, flow obstruction member 26, and support member 28 also may be composed of one solid piece.

[0026] The container 18 further comprises a tube member 22 that has a distal end 37 that is located near a distal end 30 of the container 18. A diameter of the tube member 22 may vary, but a preferred range in outer diameter is about 5.8mm (.23 inches) to about 6.9mm (.27 inches) and a preferred inner diameter d2 ranges from about 4.8mm (.19 inches) to about 5.6mm (.22 inches). The tube member 22 extends to a position proximate to the flow obstruction member 26. While a distance r1 from the tube member 22 to the flow obstruction member 26 may vary, a preferred range of distance r1 is about .25 mm to about .35 mm. The distal end 37 of the tube member 22 may extend distally up to or beyond the distal end of the container 18. The tube member 22 preferably does not directly abut or touch the flow obstruction member 26, and is held preferably at about the radial center of the container 18 by a plug 20. In this embodiment, the plug 20 is disc-shaped. An outer diameter of the plug 20 is equal to or slightly less than a diameter of an interior surface 19 of the container 18 so as to form a seal between the plug 20 and the interior surface 19 to prevent any therapeutic agent from reaching the distal end 30 of the container 18 without passing through the tube member 22. The container 18 may also be sealed by sealing members 25, with one at the distal end 30 as depicted in FIG. 2 and another sealing member 25 located at the proximal end 32 (not shown). In alternative embodiments where the distal end 37 of the tube member 22 extends distally past the distal end 30 of the container 18, the sealing member 25 would encapsulate the distal end 37 of the tube member 22.

[0027] The container 18 may comprise any suitable size and shape for holding a therapeutic agent 33. In alternative embodiments wherein the container is not cylindrical in shape, the support structure 24 and the plug 20 will be made out of shapes necessary to prevent therapeutic agent from reaching the distal end 30 through routes other than through the tube member 22.

[0028] The flow obstruction member 26 may comprise any suitable shape for controlling the rate of flow of the therapeutic agent into the tube member 22. When fluid from the pressure source 70 enters the container 18 through an inlet port 35, the fluid travels around the flow obstruction member 26 and tends to travel along the surface of the flow obstruction member 26. As the fluid continues past the tube member 22, the fluid creates a pres-

sure differential wherein the resulting lower pressure within the tube member 22 draws therapeutic agent 33 into the tube member 22. Without the flow obstruction member 26, the therapeutic agent 33 would flow in a haphazard, turbulent manner toward the distal end of the container 18, and a non-uniform amount of therapeutic agent 33 would pass through the tube member 22. As depicted in FIGS. 8 and 9, the flow obstruction members produce a more laminar flow of therapeutic agent 33, and therefore, a uniform amount of therapeutic agent 33 passes through the tube member 22. Arrows labeled 1 indicate the flow of the fluid around the flow obstruction member 26, and arrows labeled 2 represent the therapeutic agent 33 being drawn into the tube member 22. The more laminar flow caused by the flow obstruction member 26 may result in a generally uniform dispersion of the therapeutic agent 33 and the fluid within the tube member 22. A preferred ratio of fluid to therapeutic agent 33 may range from about 1:5 to about 1:1, but is most preferably about 1:1. The more laminar flow caused by the flow obstruction member 26 may also result in a consistent volumetric flow rate, which is a range of about +/- 10% of a predetermined flow rate. The uniformity and consistency of the mixture and its flow may vary depending on the fluid and agent used (e.g., based on particle size, density, viscosity, etc.) as will readily be appreciated by those skilled in the art.

[0029] Depicted in FIGS. 8 and 9 are a sphere-shaped flow obstruction member 26 and a tear drop-shaped flow obstruction member 26', respectively. Referring to FIG. 9, the tip of the "tear" extends longitudinally toward the tube member 22. In another embodiment, the flow obstruction member 26 may comprise a dimpled sphere shape, similar to a golf ball. The tear drop-shaped flow obstruction member 26' of FIG. 9 may result in a more laminar flow than the sphere-shaped flow obstruction member 26 of FIG. 8 and is preferred.

[0030] The container 18 also may comprise measurement indicia, which allow a user to determine a quantity of the therapeutic agent 33 that is held within the container 18, as explained in commonly assigned pending U.S. Application Number 12/435,574 ("the '574 application"), filed May 5, 2009. Optionally, a valve member may be disposed between the reservoir of the container 18 and the catheter 46 to selectively permit and inhibit fluid communication between the container 18 and the catheter 46, as further described in the '574 application.

[0031] Referring now to FIGS. 1 and 10-12, an actuator, such as a button, may be used to selectively actuate the pressure source 70. The pressurized fluid may flow from the pressurized fluid cartridge 72, and subsequently through the regulator valve 73 using an adapter, as explained in the '574 application. The adapter may be configured to be sealingly coupled to the pressurized fluid cartridge 72, as further explained in the '574 application. Further, the adapter may be coupled to tubing, which allows the pressurized fluid to flow into the regulator valve. A proximal end of a different tubing may be adapt-

ed to be coupled to the regulator valve 73, as shown in the '574 application, thereby enabling the pressurized fluid to flow through the regulator valve 73 and into the tubing at the lower, second predetermined pressure.

[0032] The pressure source 70 optionally may comprise one or more commercially available components. Solely by way of example, the pressurized fluid cartridge 72 may comprise a disposable carbon dioxide cartridge, such as the Visage® commercial dispenser manufactured by Helen of Troy®, El Paso, Texas. The pressure source 70 therefore may comprise original or retrofitted components capable of providing a fluid or gas into the tubing at a desired regulated pressure.

[0033] One or more catheters may be used to deliver the therapeutic agent 33 to a target site. Referring to FIGS. 1, 11, and 12, the catheter 46 comprises a proximal end that may be placed in fluid communication with the distal end 30 of the container 18 using a suitable coupling mechanism or arrangement. The catheter 46 further comprises a distal end that may facilitate delivery of the therapeutic agent 33 to a target site, as set forth below. The catheter 46 may comprise a flexible, tubular member that may be formed from one or more semi-rigid polymers. For example, the catheter may be manufactured from polyurethane, polyethylene, tetrafluoroethylene, polytetrafluoroethylene, fluorinated ethylene propylene, nylon, PEBAX or the like.

[0034] Referring to FIG. 13, the apparatus for delivering the therapeutic agent may further comprise an endoscope 150 and a needle 95 suitable for penetrating tissue, or just a needle without the endoscope (not shown). The needle 95 may be coupled to a distal end 94 of the catheter 46 to form a sharp, distal region configured to pierce through a portion of a patient's tissue, or through a lumen wall to perform a transluminal procedure. In FIG. 13, the needle 95 may be formed as an integral component with the catheter 46, i.e., such that distal movement of the catheter 46 causes distal advancement of the needle 95. In this embodiment, a relatively sharp needle tip may be affixed to the distal tip of the catheter 90, e.g., using an adhesive, to form a needle-shaped element at the distal end of the catheter. Alternatively, a separate needle configured to be inserted through a lumen of the catheter 90 may be employed.

[0035] In addition, end-viewing and side-viewing endoscopes may be used, as described in the '574 application. The endoscopes may be advanced through a bodily lumen such as the alimentary canal to a position proximate the target location. The catheter 46 then may be advanced through the working lumen of the endoscope. If the needle 95 is employed, a sharpened tip 96 of the needle 95 may extend distal to the endoscope, and may be used to puncture through an organ or a gastrointestinal wall or tissue. At this time, the therapeutic agent 33 may be delivered through the catheter 46, then through a bore 97 in the needle 95, in the manner described above and in the '574 application.

[0036] In operation, the apparatus of FIGS. 1 and

10-13 may be used to deliver the therapeutic agent 33 to a target site within a patient's body. In a first step, the distal end of the catheter 46 may be positioned in relatively close proximity to the target site. The catheter 46 may be advanced to the target site using an open technique, a laparoscopic technique, an intraluminal technique, using a gastroenterology technique through the mouth, colon, or using any other suitable technique.

[0037] The catheter 46 may comprise one or more markers (not shown), which may be disposed near the distal end of the catheter 46. The markers may be configured to be visualized under fluoroscopy or other imaging techniques to facilitate location of the distal end of the catheter 46. If the needle 95 is integral to the catheter 46, the needle 95 also may be visualized using the imaging techniques, thereby allowing placement of the distal end of the catheter 46 in close proximity to the target site. If desired, the catheter 46 may be advanced through a working lumen of an endoscope, as explained in further detail in the '574 application.

[0038] When the catheter 46 is positioned at the desired location, the pressure source 70 may be actuated. As noted above, a button or other actuator may be coupled to the pressurized fluid cartridge 72 to release a relatively high pressure fluid. As noted above, the pressurized fluid may flow through a regulator valve 73 and through the container 18 at a desired pressure and rate. For example, the regulator valve may automatically set the pressure for fluid flow, or alternatively, a control mechanism coupled to the pressurized fluid cartridge and/or the regulator valve may be activated by a user to set the desired pressure for fluid flow into the container 18. Such a control mechanism also may be used to variably permit fluid flow into the container 18, e.g., fluid from the pressurized fluid cartridge 72 may flow into the container 18 at a desired time interval, for example, a predetermined quantity of fluid per second. Moreover, the control mechanism may be pre-programmed to deliver a predetermined amount of the therapeutic agent, depending on the type, viscosity, and other properties of the agent. Empirical information, such as a table of pressure, time and delivered quantity, may be stored and used for the different agents or procedures.

[0039] Fluid from the pressure source 70 flows through the proximal end 32 of the container 18, around the obstruction flow member 26 and into the tube member 22, through the distal end 30 and then through a lumen of the catheter 46. Fluid may exit the distal end of the catheter 46, for example, through a bore formed in the needle 95. In addition, the orientation of container 18 in regards to the pressure source 70 may vary. For example, the container 18 may be aligned parallel to the pressure source 70 as described in U.S. Application Number 61/182,463 filed May 29, 2009.

[0040] As noted above, a valve member optionally may be disposed between the reservoir of the container 18 and a connecting member, as shown in the '574 application. A user may selectively actuate the valve member

to periodically permit and inhibit fluid communication between the container and the connecting member. The valve member also may serve as a "shut-off" safety mechanism to inhibit withdrawal of the therapeutic agent from the reservoir, even when pressurized fluid is flowing through the connecting member.

[0041] As noted above and depicted in the '574 application, a control mechanism coupled to the pressure source 70 may variably permit fluid flow into the tubing from the pressurized fluid cartridge 72 at a desired time interval, for example, a predetermined quantity of fluid per second. In this manner, pressurized fluid may flow through the catheter periodically, and the therapeutic agent 33 may be delivered to a target site at a predetermined interval or otherwise periodic basis.

[0042] The apparatus may be used to deliver the therapeutic agent 33 in a wide range of procedures and the therapeutic agent 33 may be chosen to perform a desired function upon ejection from the distal end of the catheter 46. Solely by way of example, and without limitation, the provision of the therapeutic agent 33 may be used for providing hemostasis; closing perforations; performing lithotripsy; delivering drugs; treating tumors and cancers; and treating renal dialysis fistulae stenosis, vascular graft stenosis, and the like. The size of the catheter 46 used to deliver the therapeutic agent 33 may vary depending upon the procedure for which it is being used; for example, a short catheter may be used for external use on irregularly shaped lacerations. The size of the therapeutic agent 33 may also vary, although a preferred embodiment of a therapeutic agent 33 for hemostasis has a 325 mesh size.

[0043] The therapeutic agent 33 can be delivered during procedures such as coronary artery angioplasty, renal artery angioplasty and carotid artery surgery, or may be used generally for treating various other cardiovascular, respiratory, gastroenterology or other conditions. The above-mentioned systems also may be used in transvaginal, umbilical, nasal, and bronchial/lung related applications.

[0044] For example, if used for purposes of hemostasis, thrombin, epinephrine, or a sclerosant may be provided to reduce localized bleeding. Similarly, if used for closing a perforation, a fibrin sealant may be delivered to a localized lesion. In addition to the hemostatic properties of the therapeutic agent 33, it should be noted that the relatively high pressure of the fluid and therapeutic agent, by itself, may act as a mechanical tamponade by providing a compressive force, thereby reducing the time needed to achieve hemostasis.

[0045] The therapeutic agent 33 may be selected to perform one or more desired biological functions, for example, promoting the ingrowth of tissue from the interior wall of a body vessel, or alternatively, to mitigate or prevent undesired conditions in the vessel wall, such as restenosis. Many other types of therapeutic agents 33 may be used in conjunction with the apparatus.

[0046] The therapeutic agent 33 may be delivered in

any suitable form. For example, the therapeutic agent 33 may comprise a powder, liquid, gel, aerosol, or other substance. Advantageously, the pressure source 70 may facilitate delivery of the therapeutic agent 33 in any one of these forms.

[0047] The therapeutic agent 33 employed also may comprise an antithrombogenic bioactive agent, e.g., any bioactive agent that inhibits or prevents thrombus formation within a body vessel. Types of antithrombotic bioactive agents include anticoagulants, antiplatelets, and fibrinolytics. Anticoagulants are bioactive materials which act on any of the factors, cofactors, activated factors, or activated cofactors in the biochemical cascade and inhibit the synthesis of fibrin. Antiplatelet bioactive agents inhibit the adhesion, activation, and aggregation of platelets, which are key components of thrombi and play an important role in thrombosis. Fibrinolytic bioactive agents enhance the fibrinolytic cascade or otherwise aid in dissolution of a thrombus. Examples of antithrombotics include but are not limited to anticoagulants such as thrombin, Factor Xa, Factor VIIa and tissue factor inhibitors; antiplatelets such as glycoprotein IIb/IIIa, thromboxane A₂, ADP-induced glycoprotein IIb/IIIa, and phosphodiesterase inhibitors; and fibrinolytics such as plasminogen activators, thrombin activatable fibrinolysis inhibitor (TAFI) inhibitors, and other enzymes which cleave fibrin.

[0048] Additionally, or alternatively, the therapeutic agent 33 may include thrombolytic agents used to dissolve blood clots that may adversely affect blood flow in body vessels. A thrombolytic agent is any therapeutic agent that either digests fibrin fibers directly or activates the natural mechanisms for doing so. Examples of commercial thrombolytics, with the corresponding active agent in parenthesis, include, but are not limited to, Abbokinase (urokinase), Abbokinase Open-Cath (urokinase), Activase (alteplase, recombinant), Eminase (anistreplase), Retavase (reteplase, recombinant), and Streptase (streptokinase). Other commonly used names are anisoylated plasminogen-streptokinase activator complex; APSAC; tissue-type plasminogen activator (recombinant); t-PA; rt-PA. While a few exemplary therapeutic agents 33 have been listed, it will be apparent that numerous other suitable therapeutic agents may be used in conjunction with the apparatus and delivered through the catheter 46.

[0049] Advantageously, the apparatus permits localized delivery of a desired quantity of the therapeutic agent 33 at a desired pressure via the pressure source 70. Since the distal end of the catheter 46 may be placed in relatively close proximity to a target site, the apparatus provides significant advantages over therapeutic agents delivered orally or through an IV system and may reduce accumulation of the therapeutic agent 33 in healthy tissues, thereby reducing side effects. Moreover, the delivery of the therapeutic agent 33 to the target site is performed in a relatively fast manner due to the relatively high pressure of the fluid, thereby providing a prompt

delivery to the target site compared to previous devices.

[0050] Further, if the optional needle 95 is employed, the apparatus advantageously may be used both to perforate tissue at or near a target site, and then deliver the therapeutic agent 33 at a desired pressure in the manner described above. For example, the needle 95 may comprise an endoscopic ultrasound (EUS) needle. Accordingly, in one exemplary technique, a sharpened tip of the needle 95 may be capable of puncturing through an organ or a gastrointestinal wall or tissue, so that the therapeutic agent 33 may be delivered at a predetermined pressure in various bodily locations that may be otherwise difficult to access. One or more delivery vehicles, such as an endoscope or sheath, may be employed to deliver the catheter 46 to a target site, particularly if the distal end of the catheter 46 comprises the optional needle 95.

[0051] Referring now to FIGS. 6 and 7, in this embodiment, a switch 40 may be used to selectively open and close the proximal end 32 of the container 18, and a switch 42 may be used to selectively open and close the distal end 37 of the tube member 22. Each of the switches 40 and 42 contain an opening 44 therein. When the switches 40 and 42 are depressed into the open position as depicted in FIG. 7, fluid from the pressure source 70 will enter the proximal end 32 of the container 18 and will propel at least some therapeutic agent 33 within the container 18 through the tube member 46 to be delivered to a target site. In the closed position depicted in FIG. 6, no fluid from the pressure source 70 will be able to enter the container 18, and therefore no therapeutic agent will be delivered to the target site.

[0052] In the embodiment depicted in FIGS. 6 and 7, the switches 40 and 42 may be used with or without the sealing members 25. When the switches 40 and 42 are used in conjunction with the sealing members 25, they perforate the sealing members 25 when depressed into the open position for the first time, thereby allowing at least some therapeutic agent 33 to travel through the distal end 37 of the tube member 22 and into the catheter 46 to be delivered to a target site. When returned to the closed position depicted in FIG. 6, the switches 40 and 42 prevent therapeutic agent from entering the catheter 46 even after the sealing members 25 have been perforated. In an alternative embodiment, stopcocks or valves that are typically used with catheters could substitute for the switches 40 and 42. In yet another embodiment, threaded luers with male and female ends could be used wherein the distal end 37 of the tube member 22 is the male end of a threaded luer.

[0053] Referring again to FIGS. 11 and 12, a clearing valve 60 may be used. In the "on" position, a piston 61 having an opening 64 formed therein is located in the valve 60 so that the opening 64 is in fluid communication with a proximal end of a first hollow tube 62, such as a catheter. A distal end of the hollow tube 62 is in fluid communication with a container holding therapeutic agent 33. In this embodiment, fluid from the pressure source 70 travels through the valve 60 and the hollow

tube 62 and into the container 18, where it can propel therapeutic agent 33 through the distal end 30 of the container 18 and deliver the therapeutic agent 33 through the catheter 46 to a target site within a patient. In the "off" position depicted in FIG. 12, the piston 61 is located so that the opening 64 is aligned with a second hollow tube 63 that is not in fluid communication with the container 18. In this embodiment, fluid from the pressure source 70 passes through the catheter 46 and forces any therapeutic agent 33 that may have accumulated in the catheter 46 to exit the catheter 46. A check valve 65, or a one-way valve-located at a position distal to the container and proximal to the catheter 46-prevents any therapeutic agent 33 from traveling into the catheter 46. This ensures that when the valve 60 is in the "on" position, a uniform amount of therapeutic agent 33 is delivered to a target site within a patient.

[0054] Referring now to FIG. 14, an alternative embodiment for containing therapeutic agent 33 and delivering a uniform amount of therapeutic agent 33 is shown. Instead of one flow obstruction member and a tube member of the embodiment shown in FIG. 1, the embodiment of FIG. 14 comprises multiple flow obstruction members 50 aligned along an interior surface 17 of a container 16. Each flow obstruction member 50 has a preferred annular shape comprising a base 52 secured to the interior surface 17 of the container 16, a peak 54, a convex proximal side 56, and a concave distal side 58, although the proximal side 56 and the distal side 58 may also be concave and convex, respectively.

[0055] In the embodiment of FIG. 14, when the fluid from a single blast of the pressure source 70 enters the container 16 through the proximal end 36, a relatively uniform amount of the therapeutic agent 33 contained within the container 16 is propelled longitudinally through the container 16 and out through the distal end 34. The relatively uniform amount is obtained, because some therapeutic agent 33 becomes obstructed by and accumulates behind and around the flow obstruction members 50 after the fluid from the pressure source enters and moves toward the distal end 34 of the container 16. During each blast, a certain amount of therapeutic agent 33 that has accumulated behind each flow obstruction member 50 is picked up by the longitudinally advancing fluid and is circulated towards the distal end 34 of the container 16. In FIG. 14, the flow obstruction members 50 are depicted as being peak-shaped, but they may comprise any shape suitable for obstructing or halting the flow of some of the therapeutic agent 33 in order to assure that a relatively uniform amount of therapeutic agent 33 is allowed out of the container 16 per blast from the pressure source 70.

[0056] Referring now to FIGS. 15 and 16, an alternative embodiment of the catheter 46 is shown, which may be substituted for any embodiments of the catheter 46 previously described herein. In this embodiment, the catheter 46 is comprised of a shape-memory material and is enclosed within an outer sheath 79. When covered by

the sheath 79, the catheter 46 remains in the delivery state as depicted in FIG 15. When the outer sheath 79 is retracted, a distal end 47 of the catheter 46 expands in a radial direction in the deployed state as depicted in FIG. 16. The distal end 47 of the catheter 46 may comprise nitinol or any other suitable shape-memory material such as those described in U.S. Application Number 12/428,226 filed April 22, 2009. The distal end 47 may be coated with a fabric or lubricious polymer such as ethylene tetrafluoroethylene ("ETFE"). When used in conjunction with an endoscope 150, the sheath 79 and the catheter 46 within may pass through the lumen 161 of the endoscope 150. The catheter 46 of this embodiment may allow for the therapeutic agent to be delivered in a more precise manner to the target site. By using the sheath 79 to maintain the catheter 46 and the distal end 47 in the delivery state, other items may be passed through the endoscope 150 or lumen 161 simultaneously with the catheter 46.

[0057] While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

Claims

1. Apparatus suitable for facilitating delivery of a therapeutic agent, the apparatus comprising:

- a pressure source (70);
- a container (18) having proximal (32) and distal (30) ends with an inlet port (35) at the proximal end for receiving a fluid from the pressure source (70);
- a therapeutic agent (33) disposed within the container (18); and
- a tube member (22) having proximal and distal (37) ends,

characterized in that:

the proximal end of the tube member is positioned within the container (18); and
the apparatus further comprises a flow obstruction member (26) positioned within the container (18) between the inlet port (35) and the proximal end of the tube member (22), the flow obstruction member structured to direct fluid around the flow obstruction member (26) and towards the proximal end of the tube member (22), the flow obstruction member (26) and the tube member (22) being spaced relative to each other to cause the fluid to flow around the obstruction member (26) and draw the therapeutic

- agent (33) into the tube member (22) and direct the therapeutic agent distally there-through.
2. The apparatus of claim 1 further comprising at least one sealing member (25) located at the proximal end of the container (32) and at least one sealing member (25) located at the distal end of the container.
 3. The apparatus of claim 1 further comprising:
 - a switch (40) located at the proximal end (32) of the container (18) and a switch (42) located at the distal end (30) of the container (18);
 - an opening (44) located in the interior of each switch;
 - the switches (40, 42) having a first position wherein the openings (44) are not in fluid communication with the proximal (32) and distal (30) ends of the container (18); and
 - the switches (40, 42) having a second position wherein the switches are in fluid communication the proximal (32) and distal (30) ends of the container (18).
 4. The apparatus of claim 1 wherein the flow obstruction member (26) comprises a sphere shape.
 5. The apparatus of claim 1 wherein the flow obstruction member (26) comprises a tear drop shape oriented with a rounded end facing the inlet port (35).
 6. The apparatus of claim 1 further comprising a support structure (24) connected to the container (18) and having a support member (28) projecting radially inwardly, the support structure (24) being connected to the flow obstruction member (26) via said support member (28), preferably wherein a plug (20) maintains the tube member (22) in about the radial center of the container (18).
 7. The apparatus of claim 1 wherein the flow obstruction member (26) is sized according to the container (18) in order to create a pressure differential whereby the resulting lower pressure within the tube member draws therapeutic agent (33) into the tube member.
 8. The apparatus of claim 1 wherein the flow obstruction member (26) is configured so as in use to result in a laminar flow of the therapeutic agent (33).
 9. The apparatus of claim 1 wherein the container (18) has an outer diameter ranging from about 23mm to about 28mm, the flow obstruction member (26) has a diameter ranging from about 6.4mm to about 8.9mm, the tube member (22) has an inner diameter ranging from about 4.8mm to about 5.6mm, and a distance between the flow obstruction member (26)

and the tube member (22) ranging from about .25 mm to about .35 mm.

10. The apparatus of claim 1 so configured that in use the fluid and the therapeutic agent (33) are mixed together within the tube member to form a mixture, the mixture having a generally uniform dispersion of the therapeutic agent (33) within the fluid.
11. The apparatus of claim 1 further comprising:
 - a first hollow tube (62) having proximal and distal ends, wherein the distal end of the first hollow tube is in fluid communication with the proximal end of the container;
 - a second hollow tube (63) having proximal and distal ends, wherein the distal end of the second hollow tube is in fluid communication with the proximal end of a catheter (46); and
 - the apparatus operable in at least two states including,
 - a first state wherein the pressure source (70) is in fluid communication with the proximal end of the first hollow tube (62) and the container (18), wherein the provision of a fluid from the pressure source (70) through at least a portion of the container (18) is adapted to urge the therapeutic agent (33) towards the distal end of the container and through the catheter (46) in a distal direction towards a target site;
 - a second state wherein the pressure source (70) is in fluid communication with the proximal end of the second hollow tube (63) and communicates with the proximal end of the catheter (46), wherein the provision of a fluid from the pressure source (70) bypasses the container (18) and flows through the catheter (46).
12. The apparatus of claim 11 further comprising:
 - a valve (60) placed between the pressure source (70) and the first (62) and second (63) hollow tubes;
 - the valve (60) maintaining fluid communication between the pressure source (70) and the first (62) and second (63) hollow tubes; and
 - the valve (60) comprising a piston (61) with an opening (64) located in the interior of the piston that controls whether the pressure source is in fluid communication with the first hollow tube (62) or the second hollow tube (63).

Patentansprüche

1. Vorrichtung, die zur Erleichterung der Abgabe eines therapeutischen Mittels geeignet ist, wobei die Vorrichtung das Folgende umfasst:

- eine Druckquelle (70);
 einen Behälter (18) mit einem proximalen (32) und einem distalen (30) Ende mit einer Einlassöffnung (35) am proximalen Ende zur Aufnahme eines Fluids von der Druckquelle (70);
 ein therapeutisches Mittel (33), das im Behälter (18) angeordnet ist; und
 ein Schlauchelement (22) mit einem proximalen und einem distalen (37) Ende,
dadurch gekennzeichnet, dass:
- das proximale Ende des Schlauchelements im Behälter (18) angeordnet ist; und die Vorrichtung ferner ein Durchflussobstruktionselement (26) umfasst, das im Behälter (18) zwischen der Einlassöffnung (35) und dem proximalen Endes des Schlauchelements (22) angeordnet ist, wobei das Durchflussobstruktionselement so strukturiert ist, dass es Fluid um das Durchflussobstruktionselement (26) und zum proximalen Ende des Schlauchelements (22) leitet, wobei das Durchflussobstruktionselement (26) und das Schlauchelement (22) in Bezug aufeinander beabstandet sind, um zu verursachen, dass das Fluid um das Obstruktionselement (26) fließt und das therapeutische Mittel (33) in das Schlauchelement (22) zieht und das therapeutische Mittel distal dort hindurch leitet.
2. Vorrichtung nach Anspruch 1, ferner umfassend mindestens ein Dichtungselement (25), das am proximalen Ende des Behälters (32) angeordnet ist, und mindestens ein Dichtungselement (25), das am distalen Ende des Behälters angeordnet ist.
 3. Vorrichtung nach Anspruch 1, ferner umfassend:

einen Schalter (40), der am proximalen Ende (32) des Behälters (18) angeordnet ist, und einen Schalter (42), der am distalen Ende (30) des Behälters (18) angeordnet ist;
 eine Öffnung (44), die im Inneren jedes Schalters angeordnet ist;
 wobei die Schalter (40, 42) eine erste Position aufweisen, in der die Öffnungen (44) mit dem proximalen (32) und distalen (30) Ende des Behälters (18) nicht in Fluidverbindung stehen; und
 wobei die Schalter (40, 42) eine zweite Position aufweisen, in der die Schalte mit dem proximalen (32) und distalen (30) Ende des Behälters (18) in Fluidverbindung stehen.
 4. Vorrichtung nach Anspruch 1, wobei das Durchflussobstruktionselement (26) eine Kugelgestalt umfasst.
 5. Vorrichtung nach Anspruch 1, wobei das Durchflussobstruktionselement (26) eine tränenförmige Gestalt umfasst, die so orientiert ist, dass ein abgerundetes Ende der Einlassöffnung (35) zugewandt ist.
 6. Vorrichtung nach Anspruch 1, ferner umfassend eine Stützstruktur (24), die mit dem Behälter (18) verbunden ist und ein radial einwärts vorragendes Stützelement (28) aufweist, wobei die Stützstruktur (24) mit dem Durchflussobstruktionselement (26) über das Stützelement (28) verbunden ist, wobei vorzugsweise ein Pfropfen (20) das Schlauchelement (22) ungefähr in der radialen Mitte des Behälters (18) hält.
 7. Vorrichtung nach Anspruch 1, wobei das Durchflussobstruktionselement (26) eine dem Behälter (18) entsprechende Größe aufweist, um eine Druckdifferenz zu erzeugen, wodurch der resultierende niedrigere Druck innerhalb des Schlauchelements therapeutisches Mittel (33) in das Schlauchelement zieht.
 8. Vorrichtung nach Anspruch 1, wobei das Durchflussobstruktionselement (26) so ausgelegt ist, dass es bei Benutzung zu einer laminaren Strömung des therapeutischen Mittels (33) führt.
 9. Vorrichtung nach Anspruch 1, wobei der Behälter (18) einen Außendurchmesser im Bereich von ungefähr 23 mm bis ungefähr 28 mm aufweist, das Durchflussobstruktionselement (26) einen Durchmesser im Bereich von ungefähr 6,4 mm bis ungefähr 8,9 mm aufweist, das Schlauchelement (22) einen Innendurchmesser im Bereich von ungefähr 4,8 mm bis ungefähr 5,6 mm aufweist und ein Abstand zwischen dem Durchflussobstruktionselement (26) und dem Schlauchelement (22) im Bereich von ungefähr 0,25 mm bis ungefähr 0,35 mm liegt.
 10. Vorrichtung nach Anspruch 1, die so ausgelegt ist, dass bei Benutzung das Fluid und das therapeutische Mittel (33) innerhalb des Schlauchelements zur Bildung eines Gemischs miteinander vermischt werden, wobei das Gemisch eine allgemein gleichmäßige Dispersion des therapeutischen Mittels (33) im Fluid aufweist.
 11. Vorrichtung nach Anspruch 1, ferner umfassend:

einen ersten hohlen Schlauch (62) mit einem proximalen und einem distalen Ende, wobei das distale Ende des ersten hohlen Schlauchs mit dem proximalen Ende des Behälters in Fluidverbindung steht;
 einen zweiten hohlen Schlauch (63) mit einem proximalen und einem distalen Ende, wobei das distale Ende des zweiten hohlen Schlauchs mit

dem proximalen Ende eines Katheters (46) in Fluidverbindung steht;
und

wobei die Vorrichtung in mindestens zwei Zuständen bedienbar ist, einschließlich
einem ersten Zustand, in dem die Druckquelle (70) mit dem proximalen Ende des ersten hohlen Schlauchs (62) und dem Behälter (18) in Fluidverbindung steht, wobei die Bereitstellung eines Fluids von der Druckquelle (70) durch zumindest einen Teil des Behälters (18) dazu ausgelegt ist, das therapeutische Mittel (33) zum distalen Ende des Behälters und durch den Katheter (46) in einer distalen Richtung zu einem Zielort zu drängen;
einem zweiten Zustand, in dem die Druckquelle (70) mit dem proximalen Ende des zweiten hohlen Schlauchs (63) in Fluidverbindung steht und mit dem proximalen Ende des Katheters (46) in Verbindung steht, wobei die Bereitstellung eines Fluids von der Druckquelle (70) den Behälter (18) umgeht und durch den Katheter (46) fließt.

12. Vorrichtung nach Anspruch 11, ferner umfassend:

ein Ventil (60), das zwischen der Druckquelle (70) und dem ersten (62) und zweiten (63) hohlen Schlauch angeordnet ist;
wobei das Ventil (60) eine Fluidverbindung zwischen der Druckquelle (70) und dem ersten (62) und zweiten (63) hohlen Schlauch aufrechterhält; und
wobei das Ventil (60) einen Kolben (61) mit einer Öffnung (64) im Inneren des Kolbens umfasst, die kontrolliert, ob die Druckquelle mit dem ersten hohlen Schlauch (62) oder dem zweiten hohlen Schlauch (63) in Fluidverbindung steht.

Revendications

1. Appareil convenant à faciliter l'administration d'un agent thérapeutique, l'appareil comprenant :

une source (70) de pression ;
un récipient (18) comportant des extrémités proximale (32) et distale (30) avec un orifice d'entrée (35) à l'extrémité proximale pour recevoir un fluide provenant de la source (70) de pression ;
un agent thérapeutique (33) disposé à l'intérieur du récipient (18) ; et
un élément de tube (22) comportant des extrémités proximale et distale (37),
caractérisé en ce que :

l'extrémité proximale de l'élément de tube est placée à l'intérieur du récipient (18) ; et

l'appareil comprend en outre un élément (26) d'obstacle à l'écoulement placé à l'intérieur du récipient (18) entre l'orifice d'entrée (35) et l'extrémité proximale de l'élément de tube (22), l'élément d'obstacle à l'écoulement étant structuré pour diriger le fluide autour de l'élément (26) d'obstacle à l'écoulement et vers l'extrémité proximale de l'élément de tube (22), l'élément (26) d'obstacle à l'écoulement et l'élément de tube (22) étant espacés l'un de l'autre pour faire s'écouler le fluide autour de l'élément (26) d'obstacle à l'écoulement, aspirer l'agent thérapeutique (33) dans l'élément de tube (22) et le faire traverser distalement l'élément de tube.

2. Appareil selon la revendication 1, comprenant en outre au moins un élément d'étanchéité (25) situé à l'extrémité proximale (32) du récipient et au moins un élément d'étanchéité (25) situé à l'extrémité distale du récipient.

3. Appareil selon la revendication 1, comprenant en outre :

un commutateur (40) situé à l'extrémité proximale (32) du récipient (18) et un commutateur (42) situé à l'extrémité distale (30) du récipient (18) ;
une ouverture (44) située à l'intérieur de chaque commutateur ;
les commutateurs (40, 42) ayant une première position dans laquelle les ouvertures (44) ne sont pas en communication fluïdique avec les extrémités proximale (32) et distale (30) du récipient (18) ; et
les commutateurs (40, 42) ayant une seconde position dans laquelle les commutateurs sont en communication fluïdique avec les extrémités proximale (32) et distale (30) du récipient (18).

4. Appareil selon la revendication 1, dans lequel l'élément (26) d'obstacle à l'écoulement présente une forme de sphère.

5. Appareil selon la revendication 1, dans lequel l'élément (26) d'obstacle à l'écoulement présente une forme de larme orientée avec l'extrémité arrondie tournée vers l'orifice d'entrée (35).

6. Appareil selon la revendication 1, comprenant en outre une structure (24) de support raccordée au récipient (18) et comportant un élément (28) de support faisant une saillie radiale vers l'intérieur, la structure (24) de support étant raccordée à l'élément (26) d'obstacle à l'écoulement par l'intermédiaire dudit élément (28) de support, de préférence dans lequel

un bouchon (20) maintient l'élément de tube (22) à peu près au centre radial du récipient (18).

7. Appareil selon la revendication 1, dans lequel l'élément (26) d'obstacle à l'écoulement est dimensionné en fonction du récipient (18) afin de créer une pression différentielle moyennant quoi la pression plus faible qui en résulte à l'intérieur du tube aspire l'agent thérapeutique (33) dans l'élément de tube. 5
8. Appareil selon la revendication 1, dans lequel l'élément (26) d'obstacle à l'écoulement est configuré de façon à entraîner, lors de l'utilisation, un écoulement laminaire de l'agent thérapeutique (33). 10
9. Appareil selon la revendication 1, dans lequel le récipient (18) a un diamètre extérieur allant d'environ 23 mm à environ 28 mm, l'élément (26) d'obstacle à l'écoulement a un diamètre allant d'environ 6,4 mm à environ 8,9 mm, l'élément de tube (22) a un diamètre intérieur allant d'environ 4,8 mm à environ 5,6 mm, et la distance entre l'élément (26) d'obstacle à l'écoulement et l'élément de tube (22) va d'environ 0,25 mm à environ 0,35 mm. 20
10. Appareil selon la revendication 1, configuré de sorte que lors de l'utilisation le fluide et l'agent thérapeutique (33) se mélangent l'un à l'autre à l'intérieur de l'élément de tube pour constituer un mélange, le mélange présentant une dispersion dans l'ensemble uniforme de l'agent thérapeutique (33) dans le fluide. 25
11. Appareil selon la revendication 1, comprenant en outre : 30

un premier tube creux (62) comportant des extrémités proximale et distale, dans lequel l'extrémité distale du premier tube creux est en communication fluïdique avec l'extrémité proximale du récipient ; 35

un second tube creux (63) comportant des extrémités proximale et distale, dans lequel l'extrémité distale du second tube creux est en communication fluïdique avec l'extrémité proximale d'un cathéter (46) ; et 40

dans lequel l'appareil est utilisable dans au moins deux états parmi lesquels : 45

un premier état dans lequel la source (70) de pression est en communication fluïdique avec l'extrémité proximale du premier tube creux (62) et le récipient (18), dans lequel la fourniture d'un fluide provenant de la source (70) de pression par au moins une partie du récipient (18) est apte à pousser l'agent thérapeutique (33) vers l'extrémité distale du récipient et par le cathéter (46) dans une direction distale vers un site cible ; 50

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un second état dans lequel la source (70) de pression est en communication fluïdique avec l'extrémité proximale du second tube creux (63) et communique avec l'extrémité proximale du cathéter (46), dans lequel la fourniture d'un fluide provenant de la source (70) de pression contourne le récipient (18) et s'écoule par le cathéter (46).

12. Appareil selon la revendication 11, comprenant en outre :

une valve (60) placée entre la source (70) de pression et les premier (62) et second (63) tubes creux, 5

la valve (60) maintenant une communication fluïdique entre la source (70) de pression et les premier (62) et second (63) tubes creux ; et 10

la valve (60) comprenant un piston (61) ayant une ouverture (64) située à l'intérieur du piston qui contrôle si la source de pression est en communication fluïdique avec le premier tube creux (62) ou le second tube creux (63). 20

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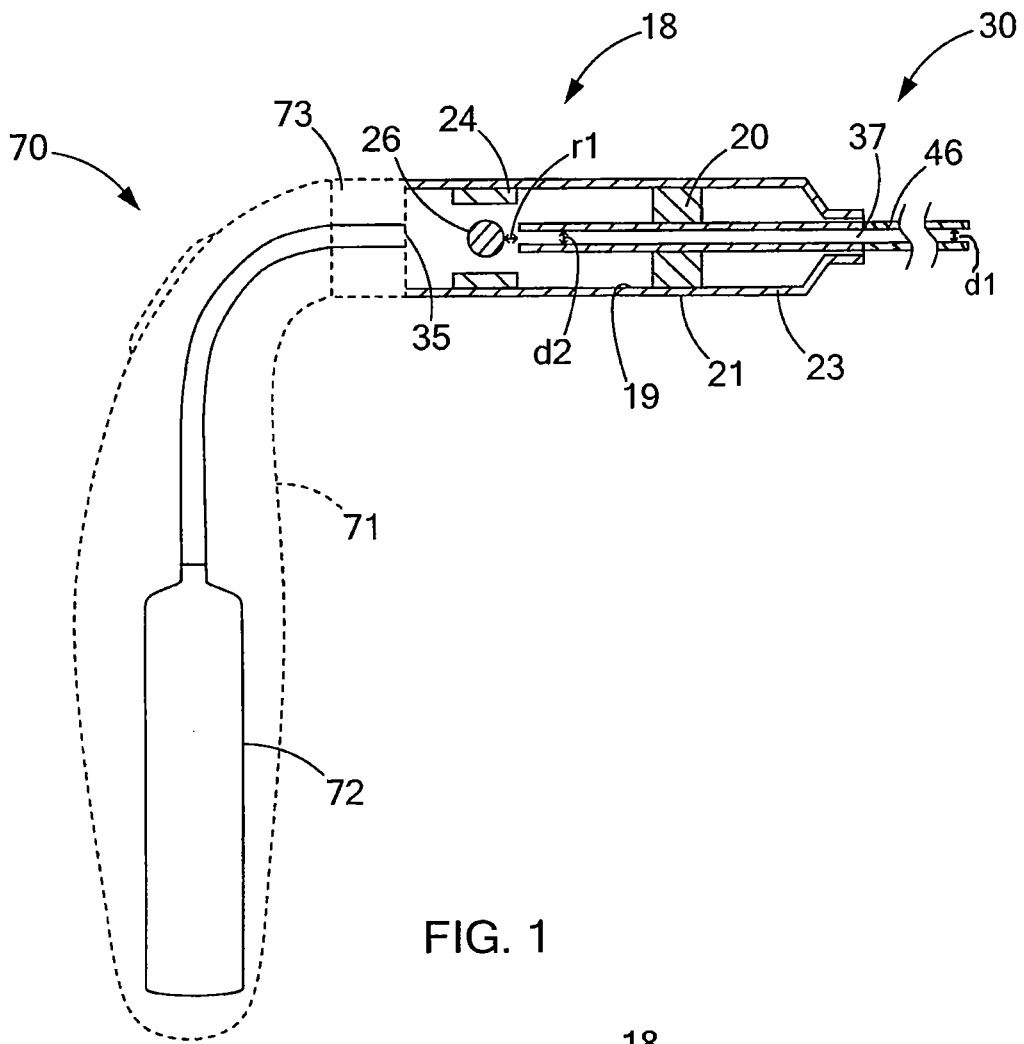


FIG. 1

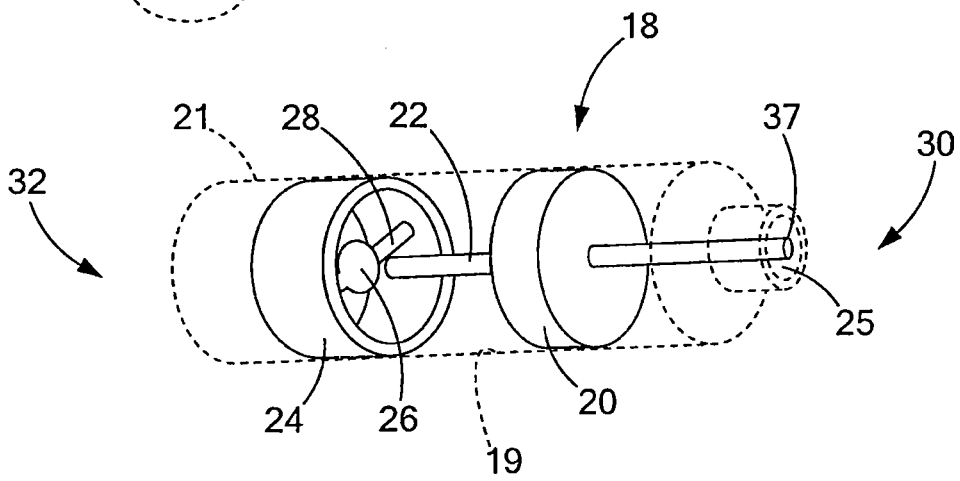


FIG. 2

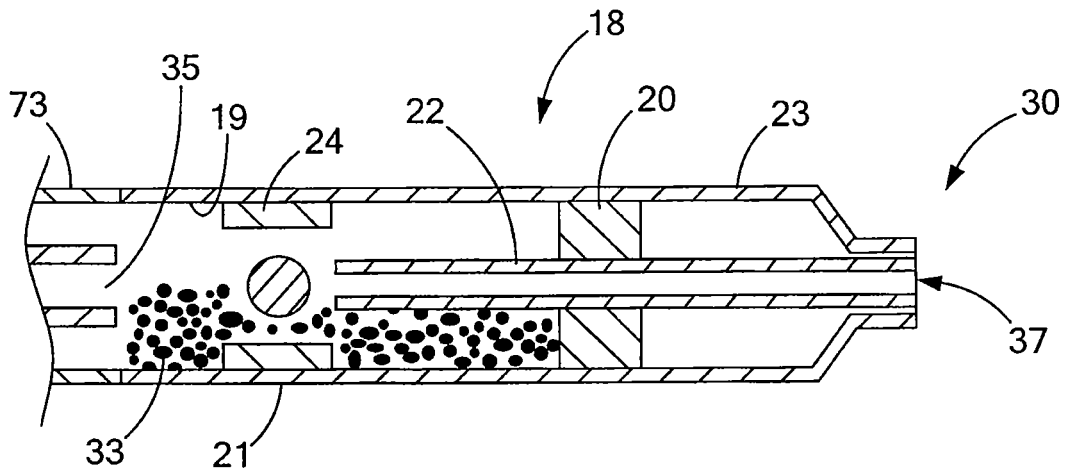


FIG. 3

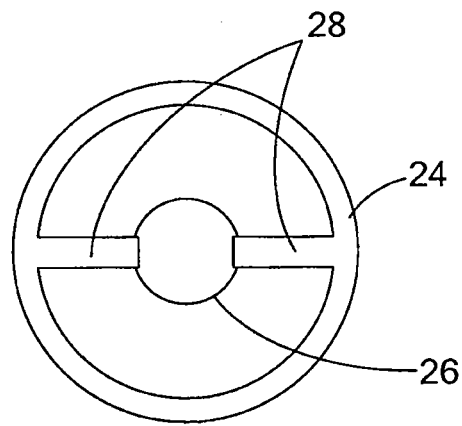


FIG. 4

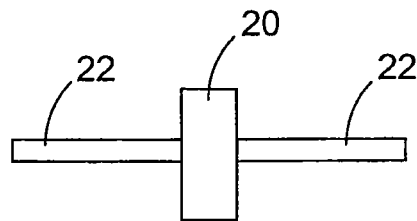


FIG. 5

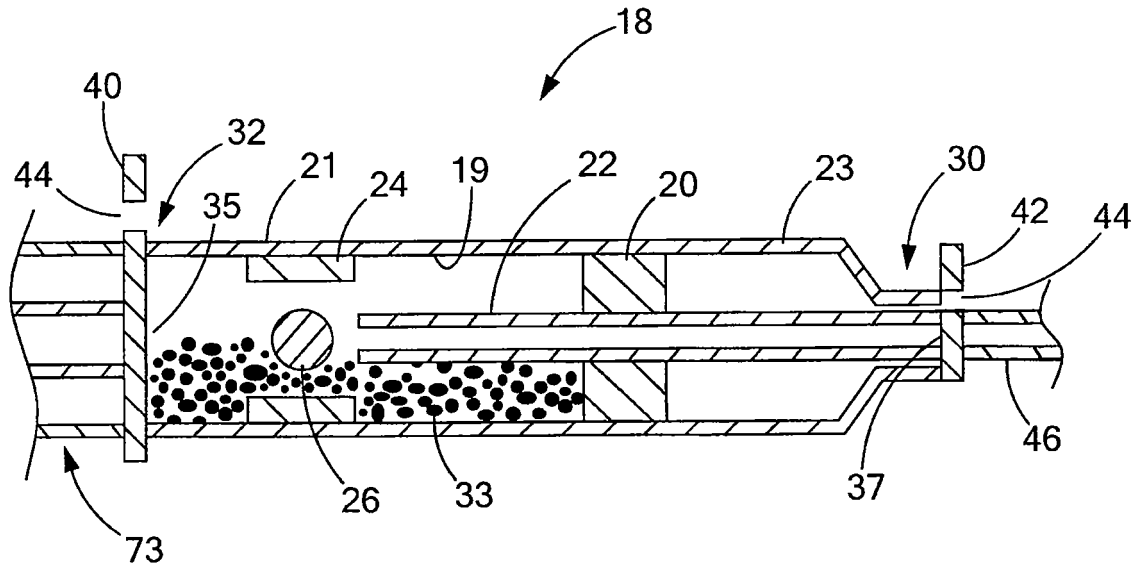


FIG. 6

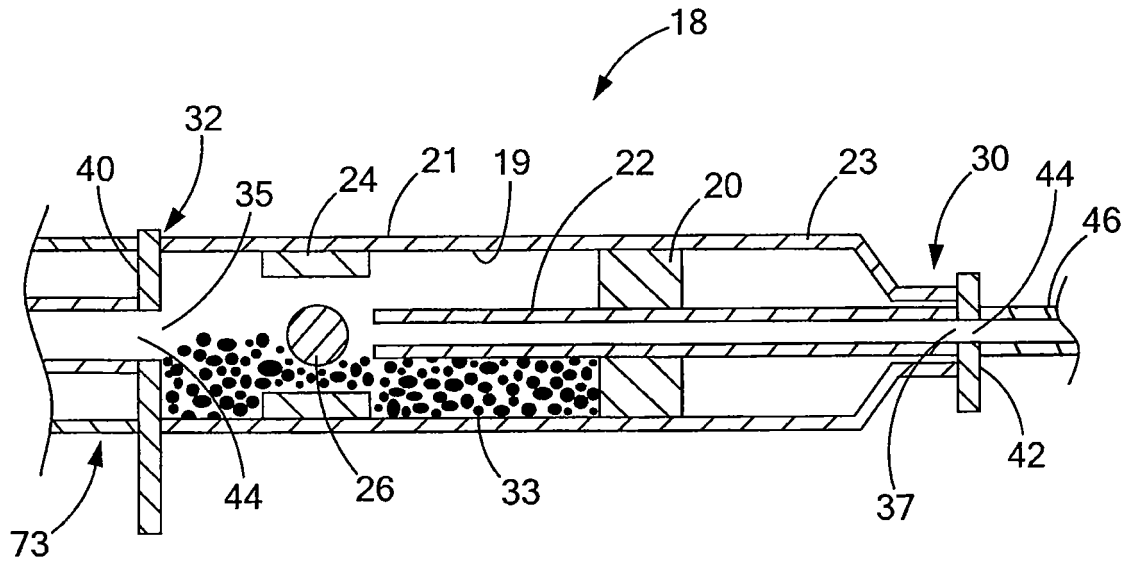


FIG. 7

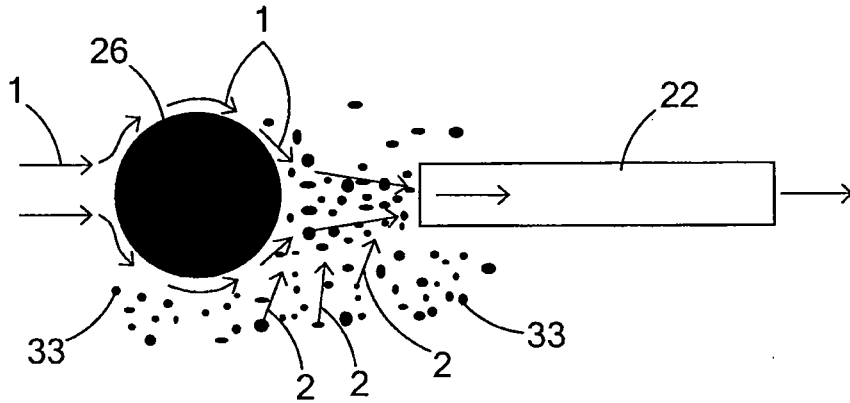


FIG. 8

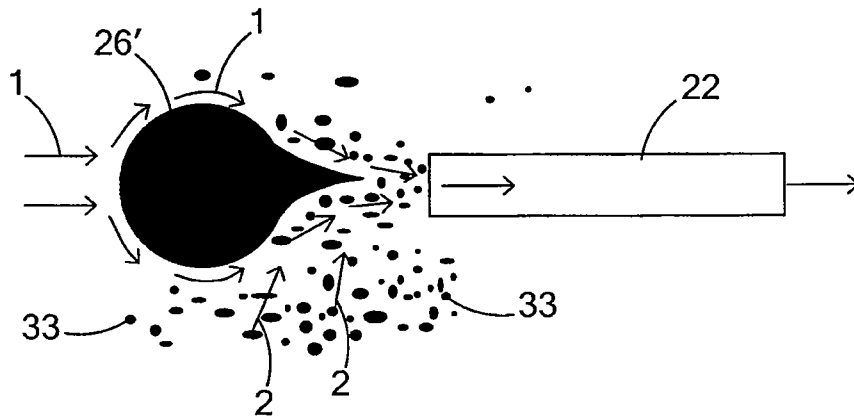


FIG. 9

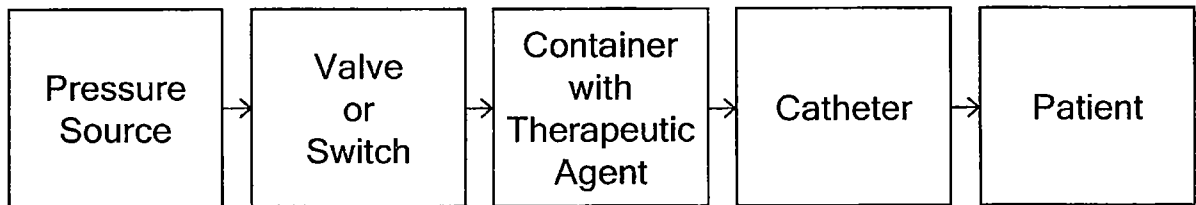


FIG. 10

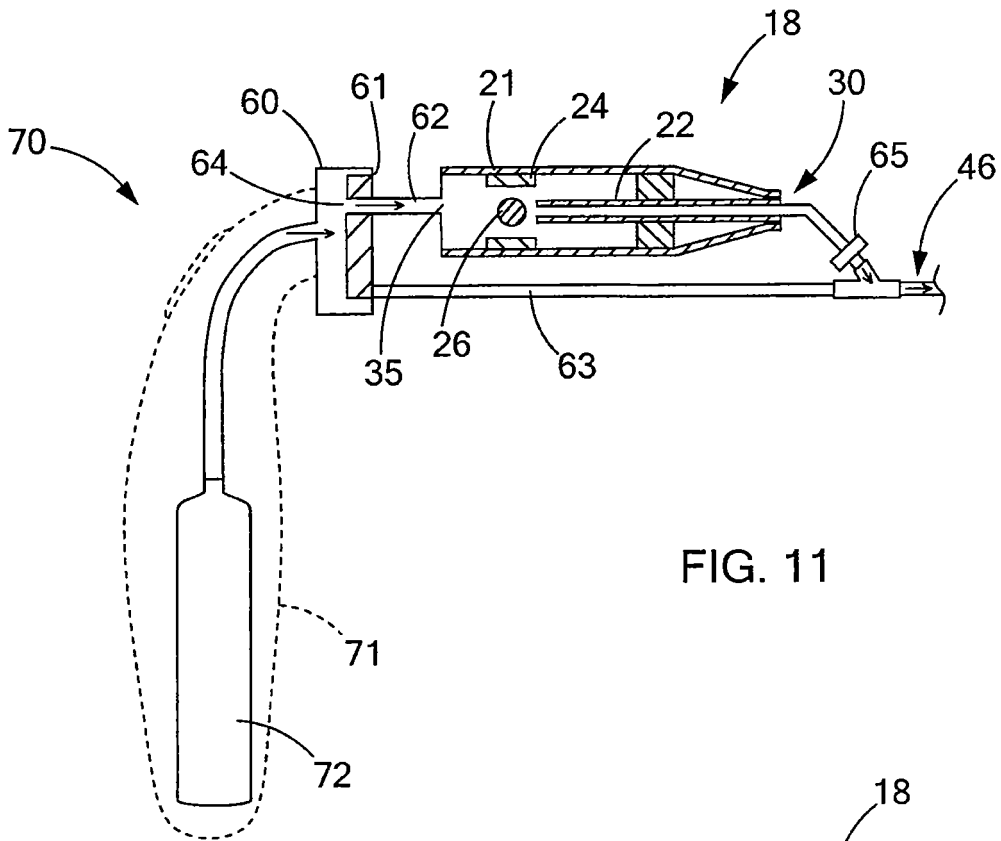


FIG. 11

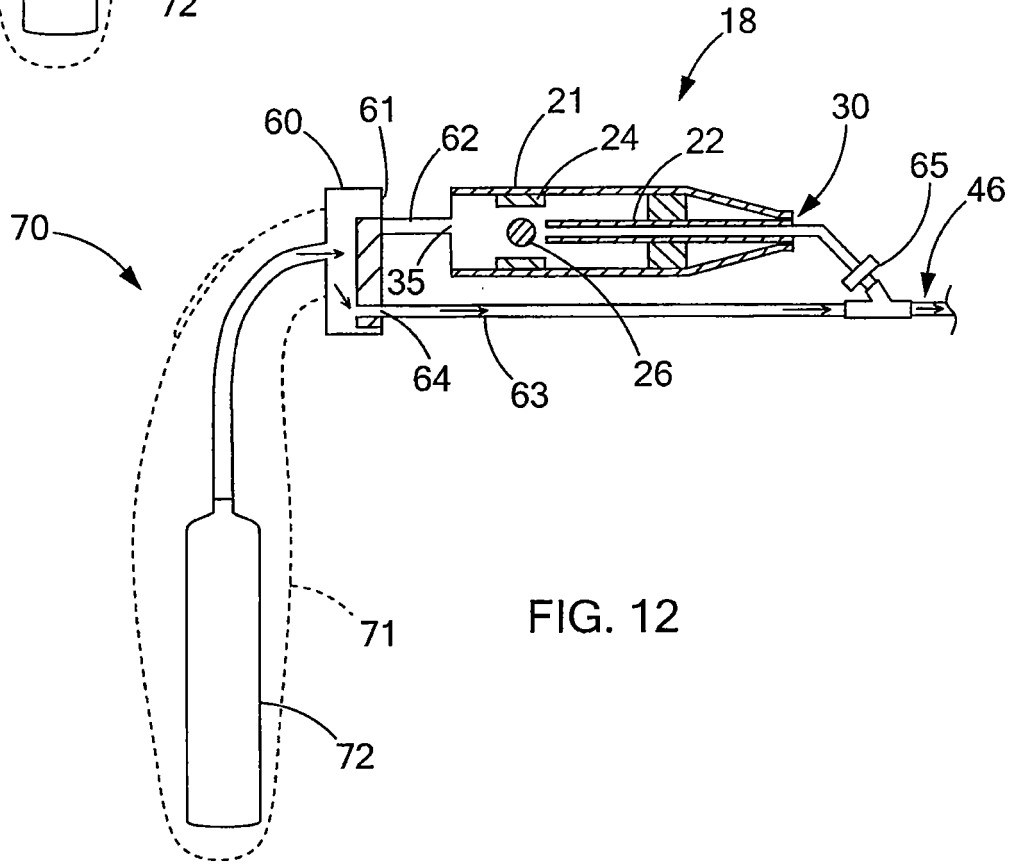
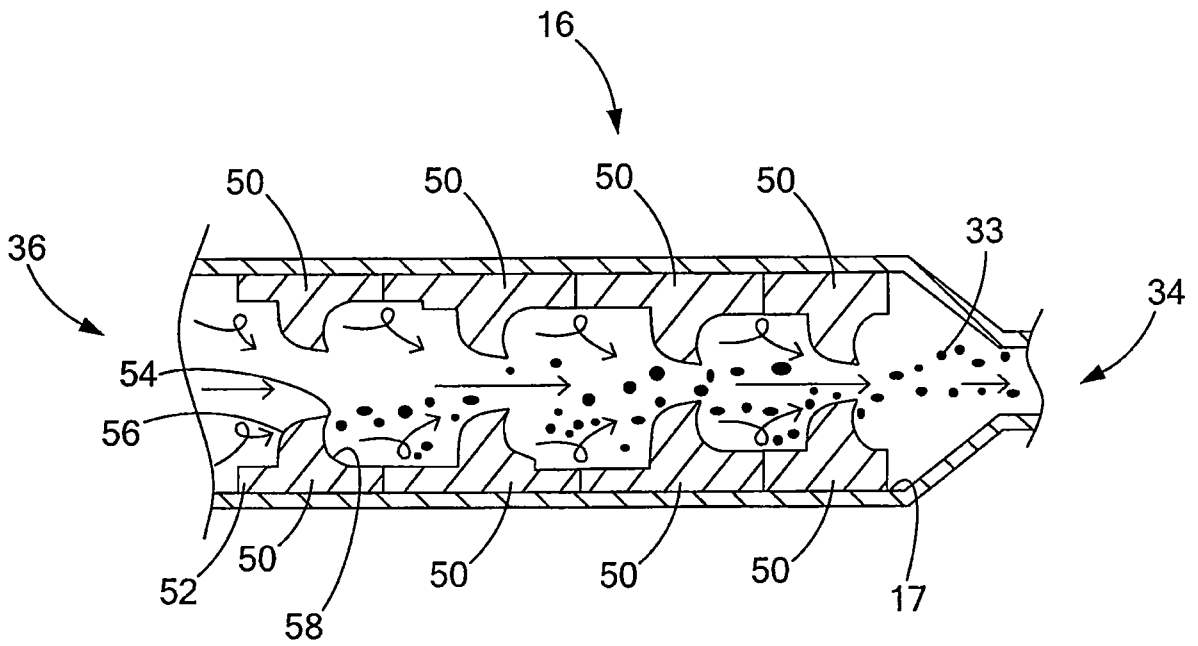
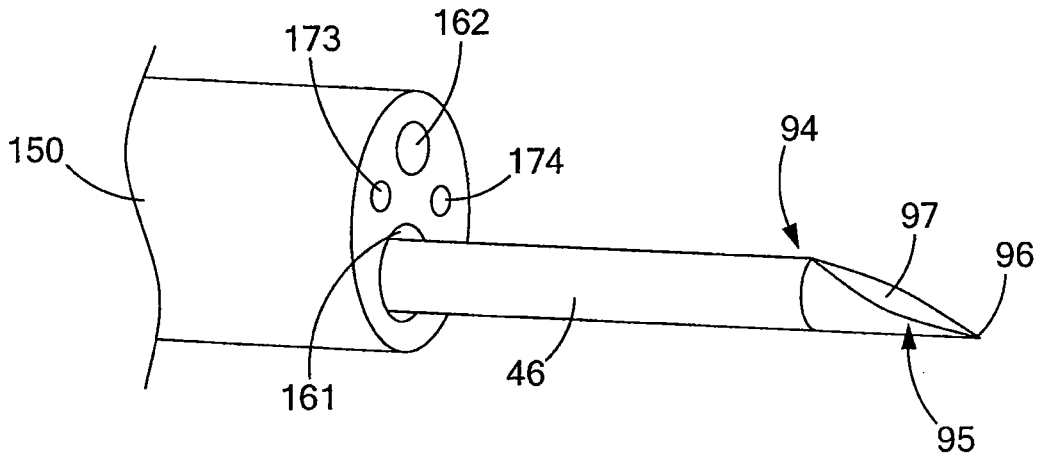


FIG. 12



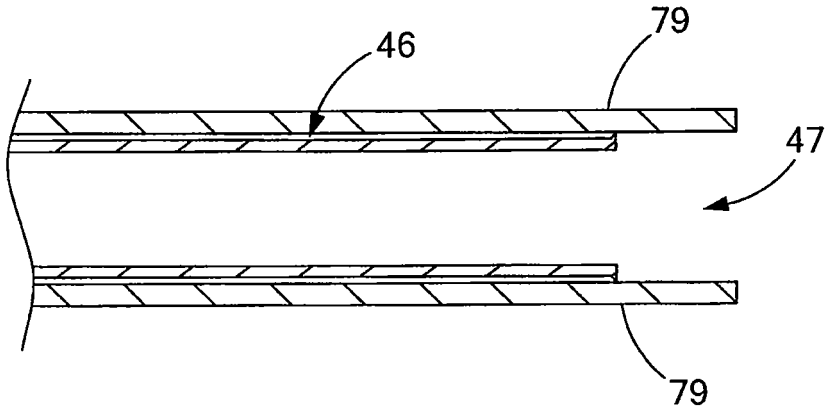


FIG. 15

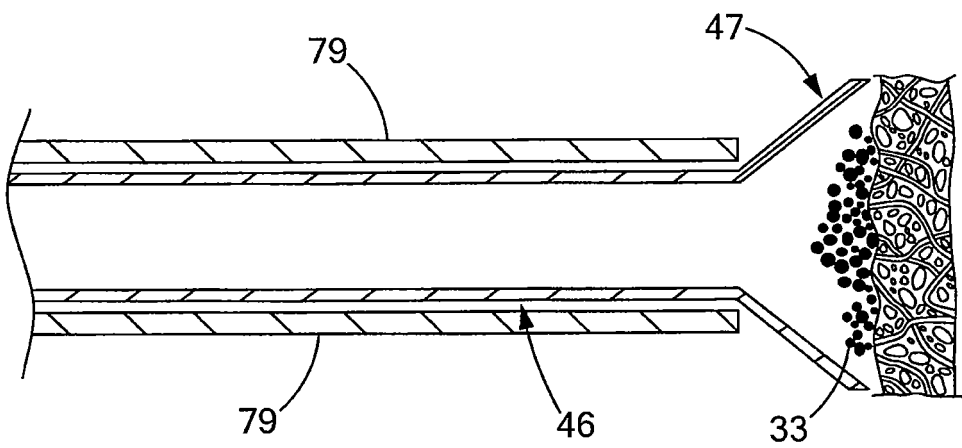


FIG. 16

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于容纳和递送治疗剂的装置和方法		
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摘要(译)

本实施方案提供适合于将治疗剂包含和递送至靶位点的装置和方法。该装置通常包括至少一个用于容纳治疗剂的容器，以及用于促进治疗剂递送的压力源。在一个实施例中，压力源可以与容器的近端区域选择性地流体连通，并且来自压力源的流体可以流过容器的至少一部分，以迫使治疗剂通过容器朝向目标部位。在替代实施例中，压力源可以选择性地与第一中空管和容器流体连通，使得治疗剂被推入导管，或者与第二中空管和导管一起，使得来自压力源的流体绕过容器并进入导管。