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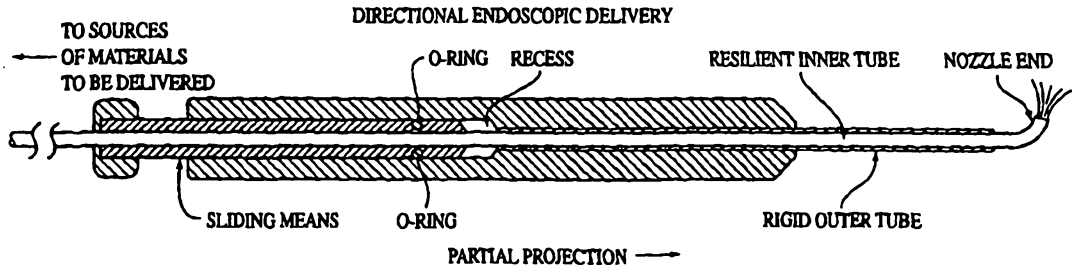

(57) Abstract

A directional application system for applying one or more components to a desired internal site in a human or animal within a range of angular directions comprises a source of the components; means for fluid communication integral at a first end with the source of components, and at a second end with a directional nozzle; and a directional nozzle comprising an inner tube of resilient material integral at a first end with the second end of the fluid communication means, having a nozzle at a second end, the second end being bent to the maximum angle within the desired range of directions; and an outer tube of a material more rigid than the inner tube having an opening at one end to allow the inner tube to slidably project through the opening.

Directional Endoscopic Delivery of Material

Field of the Invention

This invention relates to an applicator for the directional delivery of one or more materials to a desired internal site in a human or animal.

SUMMARY OF THE INVENTION

In accordance with the present invention a directional application system for applying one or more components to a desired internal site in a human or animal within a range of angular directions is disclosed. The present system comprises a source of the components; means for fluid communication integral at a first end with the source of components and at a second end with a directional nozzle; and a directional nozzle comprising an inner tube of resilient material integral at a first end with the second end of the fluid communication means and having a nozzle at a second end, the second end being bent to the maximum angle within the desired range of directions; and an outer tube of a material more rigid than the inner tube and having an opening at one end to allow the inner tube to slidably project through the opening, whereby the amount of projection of the bent end o the inner tubing through the opening determines the angular direction of the nozzle.

Brief Description of the Drawings

Figure 1 shows a section of resilient tube with the bent or curved nozzle end.

Figures 2-4 illustrate the different range of angular delivery possible depending upon the extent to which the resilient tube is projected out of or retracted into the second end of the rigid tube. Sliding means (or projecting/retracting means) can be provided at or near the first end of the rigid tube.

Throughout the description and claims of the specification the word "comprise" and variations of the word, such as "comprising" and "comprises", is not intended to exclude other additives, components, integers or steps.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Thus, the device of the present invention may be used to

deliver materials endoscopically, i.e., via a body opening or duct to an organ, or through a surgical opening typically fitted with a trocar, e.g., laparoscopically or thorascopically, that is, into the abdominal or thoracic cavity. The invention comprises a directional dispensing or delivery device comprising an inner tube of a resilient material integral at a first end with a source or sources of the one or more materials to be delivered and having a nozzle at a second end. The second or nozzle end of the resilient material is bent or curved to the maximum angle within a desired range of angular directions for delivery of the materials. The inner tube is positioned slidably within an outer tube of a more rigid material such that the user can hold a first end of the rigid outer tube (which may be formed into a convenient handle) and such that the second end of the resilient tube can extend out of an opening at a second end of the rigid tube. The second end of the more rigid tube is positioned in the vicinity of the site to receive the desired materials, e.g., through the trocar. Means are provided to slide the resilient tube within the rigid tube so as to vary the length of the resilient tube projecting beyond the second end of the rigid tube. In doing this, the bent or curved nozzle (second) end of the resilient tube will assume, or be positioned at, varying angles to deliver or dispense the materials to a desired internal location.

The device and method of the present invention can be used for the endoscopic, laparoscopic or thorascopic delivery of any materials. They are conveniently employed to deliver components, e.g., liquid components, to a surgical site to form or deposit a polymer, e.g., a biopolymer. The present invention is particularly useful in the delivery of fibrin sealant components. Accordingly, the resilient inner tube may comprise separate tubes or one tube with multiple discrete channels to deliver a fibrinogen component and a component capable of converting fibrinogen to a fibrin polymer

(sealant). Such a component is thrombin or another enzyme which catalyzes the cleavage of fibrinopeptides A and/or B from fibrinogen. According to U.S. 5,739,288 the fibrin sealant forming components (which are delivered in discrete tubes or channels) may also be a fibrin monomer component (which can be fibrin I, fibrin II or des ββ fibrin) and a component which will polymerize the fibrin component to form the sealant. In the case where the fibrin component is at low pH, i.e., pH4, the second component can be, for example, a pH10 buffer which facilitates the fibrin polymerization. The inner tube can be of a plastic material which can be bent or curved and which will strive to retain such a bend or curve. That is, the material of the inner tube needs to have some "memory" such that if it is initially bent or deformed to a desired maximum angle by known means, it will substantially return to that angle after being forced straight. Polyethylene multilumen tubing such as low density polyethylene tubing commercially available from the Putnam Company is suitable. Those multilumen tubings are preferably (each lumen) below about 500 microns in diameter, i.e., more preferably at or below 300 microns in diameter and most preferably the tubing has a reduced diameter portion such as described in WO 98/20931, incorporated herein by reference, such that the lumen diameters are about 120-150 microns in diameter. This involves heating and drawing the end of the tubing to produce a reduced diameter.

The resilient inner tube is in fluid communication directly or indirectly with sources of the components to be delivered. By indirectly is meant that the resilient tubing is in fact connected to a separate tubing or conduit which is, in turn, connected to the sources. Preferably the source of components are at a remote location and connected by tubing. This means that the user does not have to hold the sources of components in his/her hand and greater ease of use is provided. This is disclosed in WO 98/20931 and WO 97/20585

incorporated herein by reference. As mentioned in those patents, the sources of components are in a remote location as part of a mechanical or electromechanical drive unit to deliver the components from the sources to, and out the nozzle of, the present device. Delivery of the components from the sources, through the means for fluid communication and out of the directional nozzle, can be accomplished using a foot pedal which signals the drive unit. Alternatively, the present device may incorporate a handle for the user which may further include an actuator, button or trigger to actuate dispensing of the components.

Of course, the device of the present invention can be incorporated onto the delivery end of any medical component applicator, such as double barreled syringes, known in the art to apply fibrin sealants.

The more rigid outer tubing can be any material more rigid than the resilient inner tube. For example, medical grade plastics can be used and these are well known in the art. Examples include polypropylene or polycarbonate but can be any plastic so long as the outer tube is sufficiently rigid so that the inner bent resilient tube is "straightened" when drawn back into the outer tube. The outer tube can also be metal, e.g., stainless steel or other metal useful for internal medical devices.

The dimensions of the outer tube are adapted for their intended purpose. For endoscopic use the outer tube needs to be comparable to other endoscopic tubing for insertion into canals, e.g., esophagus, colon, etc., or into other body apertures or cavities. The laparoscopic use the outer tube needs to fit through a trocar. In practice, generally, the outer tube (with the inner tube withdrawn as in Figure 2) is inserted into the area where component delivery is desired. Thereafter, the inner tube is extended sufficiently to provide the desired angular directional spray or delivery of components as shown in Figures 3 and 4. This can be used in

conjunction with known endoscopic or laparoscopic cameras or optical equipment to observe/confirm the procedure.

As can be seen from Figures 2-4, in a preferred embodiment the present device includes a handle which can be a hollow tube-like part, cylindrical or otherwise. The rigid outer tube extends from a first end of the handle as shown in the figures. A means for sliding (or extending and withdrawing) the resilient inner tube within the outer tube is also a rigid material which is secured to the resilient tube, for example, by O-rings or other convenient fastening means. The means for sliding is adapted to slide in and out of a recess within a second end of the handle. This provides that when the means for sliding is slid in or out of the recess of the handle, the nozzle end of the resilient tube will extend or withdraw from the rigid outer tube as shown.

The present device is extremely useful in any endoscopic, laparoscopic, thorascopic or similar procedure where directional angular applications of components, e.g., fibrin sealant components, is required. It can be used in nearly all "minimally" invasive procedures and provides a great benefit by providing a comfort level to the surgeon, regarding fluid and air leakage, which is comparable to that realized in standard open surgical procedures.

A particular advantage is realized in thorascopic surgery especially video-assisted thorascopic surgery (VATS). For example, spontaneous pneumothorax (collapsed lung) is extremely difficult to treat due to the aperture, surgical cut or resection lines in the lung which have caused the collapse. Staples and/or sutures do not adequately seal air leak to reinflate the lung. Using standard, minimally invasive thorascopic procedures, the compromised lung is resealed using staples and/or sutures and the device of the present invention is utilized to apply fibrin sealant over the resection lines and staple lines. The ports used can be standard thorascopic ports of 10-16 mm and the application of sealant is preferably

under direct thorascopic supervision (VATS). Thereafter, the lung can be reinflated.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A directional application system for applying one or more components to a desired internal site of a human or animal within a desired range of angular directions, said system comprising:

a) a source of said components;

b) means for fluid communication integral at a first end with said source of components and at a second end with a directional nozzle; and

c) a directional nozzle comprising

i) an inner tube of resilient material integral at a first end with the second end of said fluid communication means and having a nozzle at a second end, said second end being bent to the maximum angle within said desired range of directions;

ii) an outer tube of a material more rigid than said inner tube and having an opening at one end to allow said inner tube to slidably project through said opening, whereby the amount of projection of said bent end of said inner tubing through said opening determines the angular direction of said nozzle.

2. An application system according to claim 1 wherein said one or more components form a fibrin sealant.

3. An application system according to claim 1 or claim 2 wherein said components comprise a fibrinogen component and component comprising an enzyme which catalyzes the cleavage of fibrinopeptides A and/or B from fibrinogen.

4. An application system according to claim 2 wherein said components comprise a fibrin monomer component.

5. An application system according to any one of the preceding claims wherein said directional nozzle is inserted through a direct, orifice, passageway and/or canal of a human or animal so that said components can be directionally applied to the inside of said direct, orifice, passageway or canal or an organ integral therewith.

6. An application system according to any one of the preceding claims wherein said directional nozzle is adapted to fit through a trocar or port through the abdominal or thoracic wall of said human or animal.

7. An application system according to any one of the preceding claims wherein said inner tube of a resilient material is a multilumen tubing with discrete lumen for each of said one or more components.

8. A system according to claim 7 wherein said lumen are about 500 microns or less in diameter.

9. A system according to claim 7 wherein the nozzle end of said tubing is of a reduced diameter.

10. A system according to claim 7 wherein said lumen are about 150 microns or less in diameter.

11. A system according to any one of the preceding claims wherein said resilient tubing is of a plastic material.

12. A system according to claim 11 wherein said material is polyethylene.

13. A system according to claim 12 wherein said outer tube is of a medical grade plastic which is more rigid than polyethylene.

14. A system according to any one of claims 1-12 wherein said outer tube is of stainless steel.

15. A device according to any one of the preceding claims further comprising a handle integral with said outer tube.

16. A device according to any one of the preceding claims wherein said resilient inner tube is in fluid communication with remote sources of said components.

17. A device according to any one of the preceding claims further comprising a foot pedal for dispensing said components.

18. A device according to claim 15 further comprising a button, trigger or actuator on said handle to control the dispensing of said components.

19. A method for the treatment of spontaneous pneumothorax comprising

a) stapling or suturing an aperture or defect in a lung;

b) using the device of claim 1 to apply a fibrin sealant to the staple line or suture line; and

c) reinflating the lung.

20. A directional application system for applying one or more components to a desired internal site of a human or animal within a desired range of angular directions, said system comprising

a) a source of said components;

b) an inner tubing of resilient material integral, and in fluid communication, at a first end with said source of components and having a nozzle at a second end, said second end being bent to the maximum angle within said desired range of directions; and

c) an outer tube of a material more rigid than said inner tube and having an opening at one end to allow said inner tube to slidably project through said opening, whereby the amount of projection of said bent end of said inner tubing through said opening determines the angular direction of said nozzle.

21. A system according to claim 1 or claim 20 substantially as hereinbefore described with reference to any of the drawings.

DATED: 24 October, 2000

PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
BRISTOL-MYERS SQUIBB COMPANY

RESILIENT INNER TUBE WITH BENT NOZZLE END

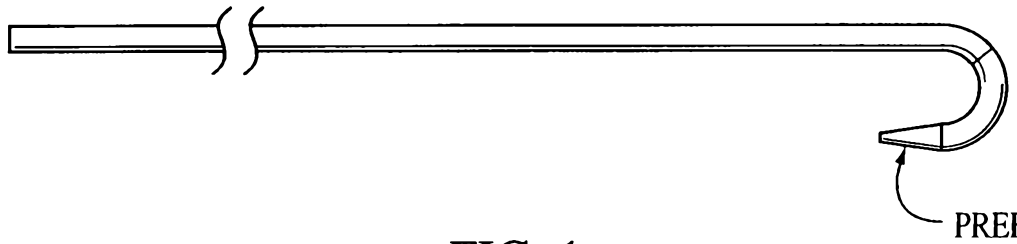

FIG. 1

DIRECTIONAL ENDOSCOPIC DELIVERY

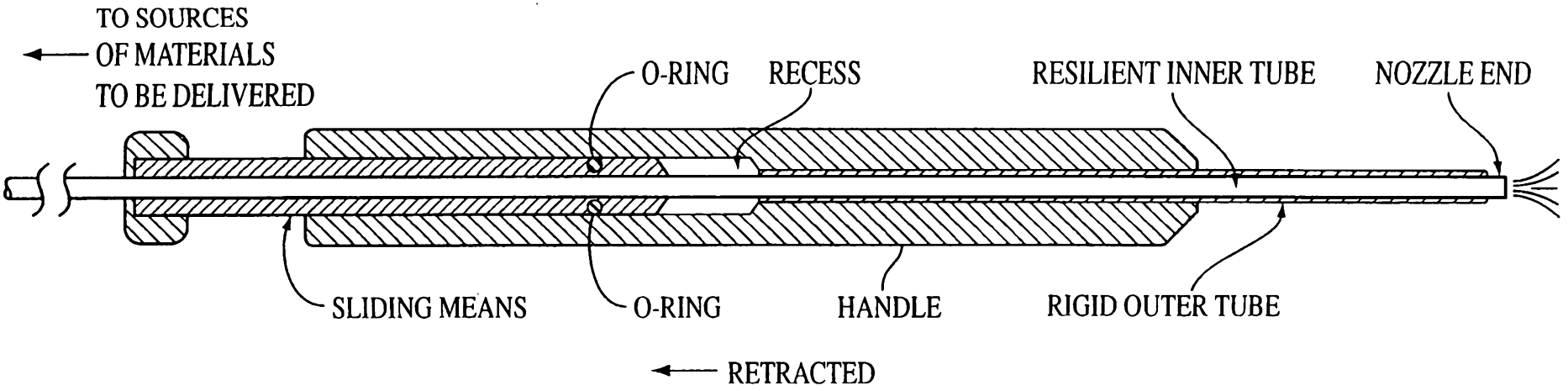

FIG. 2

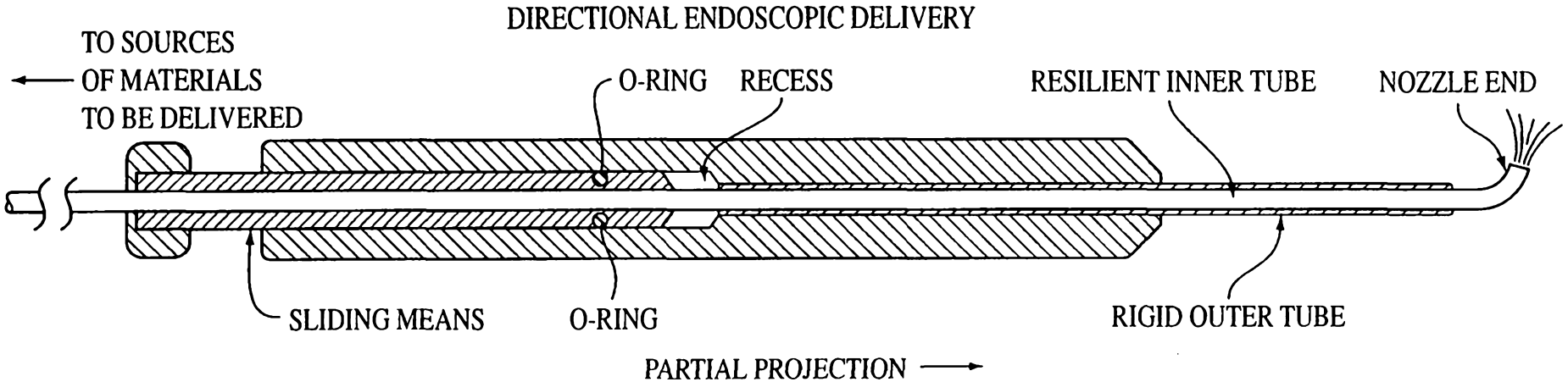
DIRECTIONAL ENDOSCOPIC DELIVERY
TO SOURCES
OF MATERIALS
TO BE DELIVERED
O-RING
RECESS
RESILIENT INNER TUBE
NOZZLE END
SLIDING MEANS
O-RING
RIGID OUTER TUBE
PARTIAL PROJECTION

FIG. 3

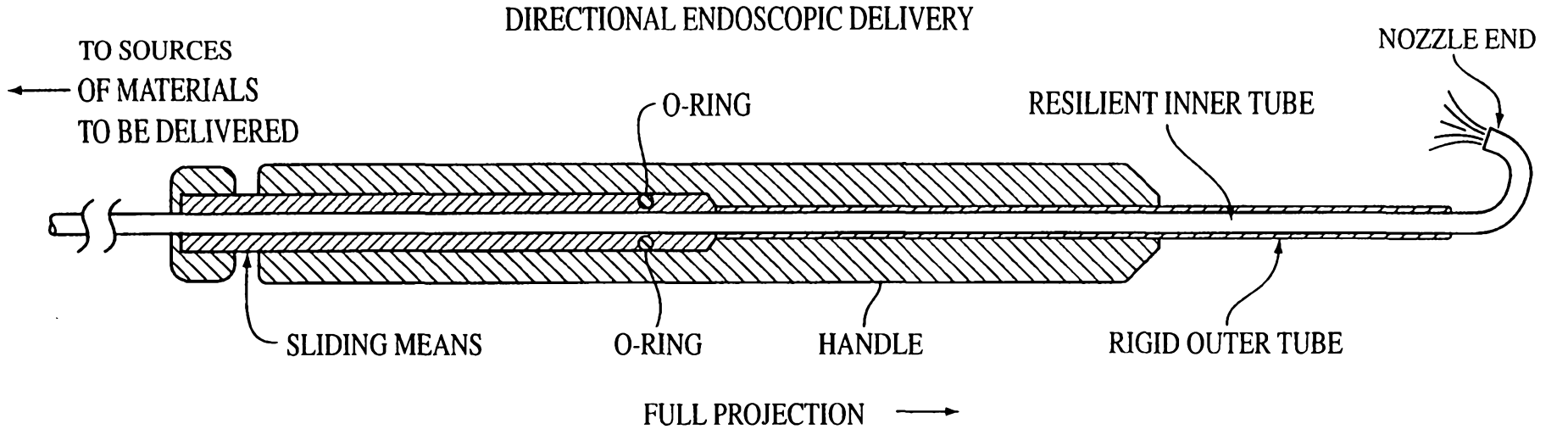
DIRECTIONAL ENDOSCOPIC DELIVERY
TO SOURCES
OF MATERIALS
TO BE DELIVERED
O-RING
RESILIENT INNER TUBE
NOZZLE END
SLIDING MEANS
O-RING
HANDLE
RIGID OUTER TUBE
FULL PROJECTION

FIG. 4