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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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[Continued on next page]

(54) Title: MULTI-SECTIONED CANNULA WITH AT LEAST ONE LUMEN

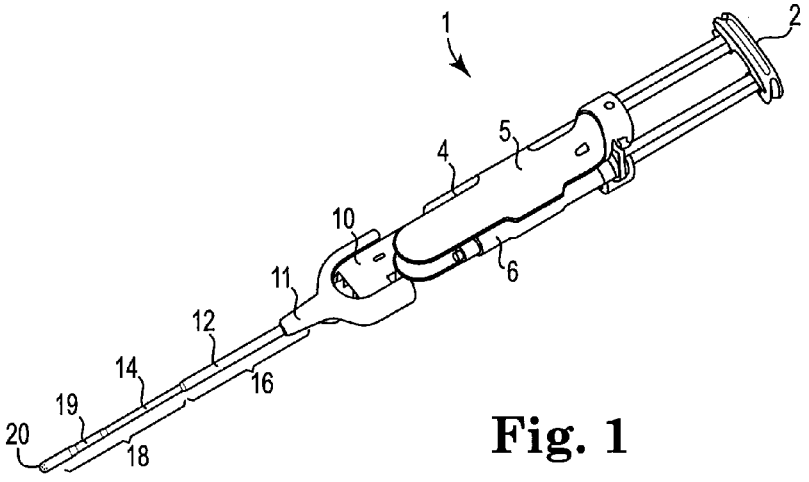

Fig. 1

(57) Abstract: A malleable cannula having multiple lumens, constrained at the proximal end portion to provide rigidity and malleable at the distal end portion. The cannula has a combination of flexibility and stiffness that assists in accessing body passageways without kinking.

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MULTI-SECTIONED CANNULA WITH AT LEAST ONE LUMEN

Cross-Reference to Related Application

[0001] This application claims priority from U.S. Patent Application Serial No. 13/284,387 filed October 28, 2011, the disclosure of which is incorporated herein by reference.

Technical Field

[0002] This invention relates to a medical cannula used to deliver fluids.

Background

[0003] Sinusitis is an inflammation of the mucosal tissue lining of the sinus walls which may lead to nasal passageway blockage, mucous stagnation and bacterial or fungal sinus cavity infection. Typical treatments begin with antibiotics. However, when antibiotics cannot relieve sinusitis, sinus surgery (which involves opening the sinus cavities and removing mucosal tissue) may be an alternative. Post-operative care for such surgery requires temporary and uncomfortable sinus packing or gauze which supports the reopened sinus passage and absorbs excess fluid while the tissues heal. After several days or at the discretion of the physician, the gauze packing is removed. Doing so is painful.

[0004] Sinus sealants and other biological materials have emerged as a promising technique to temporarily seal or otherwise protect the post-operative passageways with less intrusion and pain than that caused by traditional packing techniques.

Summary of the Invention

[0005] Biomaterials have been used in ear, nose, and throat (ENT) procedures for surgical repair and drug delivery. The chemical nature of some biomaterials requires that they be provided in a multi-component form with the components being separated prior to use. The components are mixed together shortly before or during delivery, and the mixture rapidly forms a gel or solid.

[0006] There are, however, potential difficulties when using highly-reactive multi-component biomaterial systems. If the components react too rapidly, the resulting mixture may exhibit poor or erratic performance. Rapid reaction may however be desired for other reasons, such as a need for the biomaterial system to be spray-applied yet quickly form a

gel or solid at a desired application site. An operator also desirably should be able to dispense the biomaterial using a single gloved hand.

[0007] Other concerns encountered using tissue sealants such as sinus sealants include navigating the sealant delivery system within a patient's anatomic structures. For example, sealants may be delivered through a cannula having one or more lumens through which fluids can flow. The cannula requires flexibility for insertion through various pathways that may twist and turn, sometimes abruptly at acute angles. At the same time, the cannula should be able to resist kinking or closing off of the lumen and permit uninterrupted fluid flow.

[0008] The invention provides, in one aspect, a multi-sectioned cannula comprising:

a) a malleable member having a proximal portion and a distal portion;

b) at least one lumen within and extending between the proximal and distal portion; the at least one lumen in fluid communication with a fluid supply; and;

c) a reinforcement member extending along the length of the at least one lumen; the cannula having a durometer such that the cannula does not kink when bent greater than 45 degrees.

[0009] The invention provides, in another aspect, a method of dispensing fluids to a target site, the method comprising:

A) providing a spray delivery system comprising:

(i) at least one fluid supply; and

(ii) a cannula, the cannula comprising:

a) a malleable member having a proximal portion and a distal portion;

b) at least one lumen within and extending between the proximal and distal portion; the at least one lumen in fluid communication with a fluid supply; and;

c) a reinforcement member extending along the length of the at least one lumen; the cannula having a durometer such that the cannula does not kink when bent greater than 45 degrees; and

(iii) a spray head through which the at least one fluid supply exits;

B) dispensing fluid from the fluid supply into the at least one such lumen and through the spray head.

[0010] The disclosed apparatus and method have particular use for accessing various anatomical locations such as sinus cavities and for applying tissue sealants at these anatomical locations.

Brief Description of the Drawing

[0011] **Fig. 1** is a perspective view of a partially assembled spray delivery system including an exemplary cannula;

[0012] **Fig. 2** is a perspective, exploded view of the cannula of **Fig. 1**;

[0013] **Fig. 3A** is a perspective view of a shroud and support member;

[0014] **Fig. 3B** is a perspective view, partially in cross-section of the **Fig. 3A** shroud;

[0015] **Fig. 4A** is a perspective view of a distal portion of the cannula;

[0016] **Fig. 4B** is a perspective, exploded view of components in the **Fig. 4A** cannula;

[0017] **Figs. 5A-B** are perspective views, partially in phantom, of the **Fig. 4A** and **4B** cannula.

[0018] **Fig. 6** is a perspective view of an embodiment of a distal portion of the cannula.

[0019] Like reference symbols in the various figures of the drawing indicate like elements. The elements in the drawing are not to scale.

Detailed Description

[0020] The recitation of a numerical range using endpoints includes all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc.).

[0021] The present invention provides, in one aspect, a malleable, kink-resistant cannula and, in other aspects, a method of delivering tissue sealants using such cannula. The cannula can be bent to desirable configurations that are maintained during use and without the cannula or its lumen(s) kinking or closing off and thereby provide uninterrupted fluid delivery through the lumen(s). This kink-resistant feature permits the cannula to be shaped and reshaped during a sealant delivery process while fluid is flowing through the cannula.

[0022] The cannula may be assembled to a delivery system and spray head that may be used to apply multi-component fluid compositions. Such delivery systems and spray heads, for example, include those described in U.S. Patent Application Ser. No. 13/284,600 and Attorney Docket No. 151-P-41646.WO04 and U.S. Patent Application Ser. No. 13/284,421 and Attorney Docket No. 151-P-41646.WO02, respectively, filed even date herewith and each of which is incorporated herein by reference in its entirety.

[0023] The apparatus and method may be used to apply compositions containing multiple agents, such as a multiple component tissue sealant (e.g. two components) to a variety of bodily passageways or cavities including nasal cavities and sinus cavities (e.g. maxillary, frontal or sphenoid sinuses). Exemplary multi-component tissue sealants may include reactive polysaccharides, for example, chitosan and starch. Other exemplary multi-component tissue sealants are provided in U.S. patent application Ser. No.12/429,141, now published as U.S. Patent Application Publication No. 2009/0270346A1 and U.S. Patent Application Ser. No.12/429,150, now published as U.S. Patent Application Publication No. 2009/0291912 A1.

[0024] **FIG. 1**, which shows a partially assembled spray delivery system **1,** includes an actuating member **2**, and a body **5** capable of receiving and capturing syringes **4, 6**. The actuating member **2** operates upon syringes **4, 6** to provide simultaneous delivery of fluids housed in syringes **4, 6**. The spray delivery system **1**, as shown in **FIG. 1**, further includes cannula **14** and spray head **20**.

[0025] Cannula **14** may be a flexible or malleable member that may be assembled to include a rigid proximal end portion **16** and a malleable distal end portion **18**. The rigid proximal end portion **16** may be constrained at the proximal end by support shaft **12** and shroud **11**, which prevents or discourages cannula bending. The rigid proximal end portion **16** also includes the portion of cannula **14** surrounded by support shaft **12**. Cannula **14** may be bent at the malleable distal end portion **18,** which extends from the end of the support shaft **12** up to the proximal portion of the spray head **20**.

[0026] Cannula **14** and spray head **20** are connected to body **5** through manifold **10**. Manifold **10** may be surrounded by a shroud **11** with support shaft **12** constraining the proximal end of cannula **14**. Manifold **10** may be configured to receive portions of syringes **4, 6** without requiring threaded or rotating engagement of the syringe to manifold **10** to provide a liquid tight connection. Spray head **20** is connected to malleable distal end

portion **18**. Covering the interface between the malleable distal end portion **18** and spray head **20** is a sheath **19** which provides a smooth transitional interface at the joint between cannula **14** and spray head **20**.

[0027] When used to deliver a tissue sealant to a sinus cavity, cannula **14** preferably has an overall length of about 10 cm to 15 cm, more preferably about 12 to 13 cm. The rigid proximal end portion **16** may have a length in the range from about 4 cm to 8 cm, preferably about 5 cm to 7 cm, and the malleable distal end portion **18** may have a length, for example, in the range from about 4 cm to 8 cm, preferably about 5 cm to 7 cm. The outer diameter of cannula **14** may be from about 0.1 cm to 1.0 cm, preferably about 0.3 cm to 0.4 cm. The ratio of the rigid proximal end portion **16** to the malleable distal end portion **18** may be in a ratio of about 2:1 or about 1:2, and preferably about 1:1.

[0028] Depending on the specific cannula use, other dimensions are also acceptable. For example, cannula **14** may be used in laparoscopic anatomical or gynecological surgery, neural surgery, pulmonary surgery or the like.

[0029] The cannula **14** may be formed of a material acceptable for use inside the human body and of a selected durometer (hardness). The selected durometer aids in preventing the cannula from kinking when bent greater than 45 degrees, greater than 90 degrees, or greater than 180 degrees with respect to a straight, unbent configuration. The selected material may include for example, thermoplastic or thermoset polymers such as polyolefins, silicones, polyvinyl chlorides, polyurethanes, polyesters and the like. To attain a desired durometer, fillers or plasticizers may be used. The amount and type of filler or plasticizer is determined by the selected thermoplastic or thermoset polymers used. Cannula **14** may have a durometer (Shore A) in the range, for example, from 60 to 95, preferably from about 85 to 95.

[0030] Referring to **FIG. 2**, support member **12** may be in the form of a cylindrical metal or plastic tube surrounding cannula **14** and molded within or otherwise connected to the distal end portion of shroud **11**, for example, by adhesive or welding. The support member **12** preferably is made of stainless steel. Other exemplary materials include, for example, metals such aluminum and plastics such as thermoplastic or thermoset polymers. The support member **12** desirably has a thickness and length such that it minimizes physical obstruction during anatomic insertion and resists sideways deflection of proximal end portion **16** so as to provide improved control when maneuvering and navigating

cannula **14** through bodily passageways. The support member **12** may, for example, have a thickness of about 0.01 cm to about 0.1 cm, preferably from about 0.02 cm to 0.03 cm; and a length, for example, of about 3 cm to 10 cm, preferably from about 4.5 cm to 5.5 cm.

[0031] As illustrated in **FIGS. 2** and **3A-B**, shroud or casing **11** surrounds outer portions of manifold **10**. The shroud **11** also engages the support member **12**, and when assembled to cannula **14**, provides additional proximal rigidity to the cannula **14**. Shroud **11** may be permanently attached to the manifold **10**, for example, by adhesives, welding or injection molding or may be optionally removable.

[0032] As illustrated in **FIGS. 4A-B**, sheath **19** may, for example, surround the proximal portion of spray head **20** and the distal end portion **18** producing a smooth interface between the spray head **20** and cannula **14**. Sheath **19** also helps keep spray head **20** firmly attached to cannula **14** when withdrawing spray head **20** from a confined location.

[0033] Desirable lengths of sheath **19** may for example, range from about 10 mm to 50 mm, preferably from about 20 mm to 25 mm. A thickness for sheath **19** desirably may be selected such that it minimizes interference with anatomical features during cannula insertion. The sheath thickness may, for example, range from to 0.001 cm to 0.010 cm, preferably 0.001 cm to 0.003 cm. The sheath **19** may be a heat shrink tube, a mechanically expanded tube, or an extruded plastic tube, and may be made from a variety of materials, for example, polyester, polyolefin, and fluoropolymers.

[0034] As shown in **FIGS. 5A-B**, an exemplary cannula **14** may enclose multiple lumens that extend the entire cannula length, from the rigid proximal end portion **16** to the malleable distal end portion **18** and maintains the separation of each lumen. The individual lumen diameters are dependent on a number of factors, including the spray head opening diameters, the desired pressure and flow rate. The lumens may, for example, all be of the same diameter and cross sectional shape. The lumen shape may be, for example, circular, oval, square or D-shaped in cross-section, with the flat portions of neighboring D-shapes being adjacent to one another.

[0035] As illustrated in **FIG. 5A**, at least one of the lumens may include a reinforcement member **22** to allow selective bending of the cannula **14** to fit different orientations. The reinforcement member **22** may, for example, be in the form of a wire

located within and extending along the length of a lumen. The reinforcement member **22** may, but need not be centrally located in the multi-lumen cannula **14**. In such embodiments, the cannula **14** may be formed with at least two lumens, one of which will become occupied by the reinforcement member **22**. The cannula **14** may also be formed by extruding or molding it over the reinforcement member **22** and by providing at least one lumen through which fluid may flow.

[0036] The reinforcement member **22** may be made of, for example, metal or a metal alloy such as stainless steel, copper, aluminum or the like. In other examples, reinforcement member **22** may be made of a shape memory metal such as Nitinol. The diameter of the reinforcement member **22**, may, for example, range from 0.001 cm to 0.10 cm, preferably 0.03 cm to 0.05 cm. The shape of the reinforcement member **22** may be, for example, circular, oval, square or D-shaped in cross-section. The stiffness of the reinforcement member **22** may be full hard, half hard, quarter hard, annealed, soft or any other desired stiffness depending on the desired application.

[0037] The cannula **14**, illustrated in **FIGS. 5A-B**, includes four lumens, one of which is occupied by reinforcement member **22**. Remaining lumens **24, 26, 28** are in fluid communication with one or more fluid supplies such as syringes **4, 6** and a source of pressurized air (not shown) that may be introduced into lumen **28** via port **30**, which is shown in **FIG. 2**.

[0038] In some aspects, the cannula **14**, illustrated in **FIG. 6** shows at least a portion of the distal tip of cannula **14** as a beveled or tapered distal end **32**. The beveled end **32** is positioned to be centered with respect to the four lumens, three lumens, two lumens or one lumen. The bevel end **32** may, for example, extend through all the lumens, four lumens, three lumens, two lumens or one lumen. As illustrated in **FIG. 6**, bevel **32** extends over three lumens. As shown in **FIG. 6**, the distal tip of the cannula **14** that does not include bevel **32** has the longest lumen. In some embodiments, the longest lumen is occupied by reinforcement member **22**. As seen in **FIG. 6**, lumens **34, 36** and **38** are part of the tapering. In some embodiments, the shortest lumen **38** allows air passage and lumens **34** and **36** allow fluid passage. In such an arrangement (as depicted in **FIG. 6**), exiting of air before fluids results in better mixing of the lumen contents as it enters spray head **20**. As will be appreciated, variations on the lumen arrangement and reinforcement member may be envisioned. The bevel angle may, for example, range from about 35 degrees to about

75 degrees. In other embodiments, the bevel angle may range from about 40 degrees to 45 degrees. Bevel **32** may be formed at any desired angle that allows insertion into a spray head and results in better homogeneous mixing of the lumen contents as it moves into spray head **20**.

[0039] In one exemplary assembly process for the disclosed device, an operator first inserts the actuating member **2** into body **5.** Alternatively, actuating member **2** may be preassembled with body **5**. Syringes **4, 6** are positioned against body **5** and actuating member **2** so that body **5** and actuating member **2** can receive and capture syringes **4, 6**. In this manner, syringes **4, 6** are held substantially parallel in body **5**.

[0040] Once the syringes are received and captured by body **5**, cannula **14** and spray head **20** are assembled to body **5** through manifold **10**. Cannula **14** and spray head **20** may if desired be preassembled to manifold **10** during manufacturing.

[0041] The operator then connects manifold **10** to syringe outlets to provide an unthreaded, liquid-tight connection such that the syringe contents in syringe barrels are in fluid communication with cannula **14** through manifold **10**.

[0042] When the delivery device **1** is fully assembled, the operator shapes the cannula **14** to a desired shape. Cannula **14** desirably is sufficiently stiff so that it will retain its shape until bent into a new shape. The shaped cannula **14** and spray head **20** are then maneuvered or navigated into a desired treatment site within the patient's body, for example, a nasal or sinus cavity or other opening, recess or passageway. Once satisfactorily positioned, an operator may, for example, depress actuating member **2** to move the plunger of syringe **4, 6** toward the syringe outlets, advancing the fluid syringe contents substantially at the same time through the separate syringe barrels and out into respective fluid channels in manifold **10** which maintain the fluid separation. Continued force will advance the fluids through the multi-lumen cannula **14** and into a region within spray head **20** where they mix before the mixed fluids exit spray head **20**. If compressed gas is used, it may be supplied through a gas inlet (not shown). The gas stream passes through a lumen of multi-lumen cannula **14** into the mixing region of spray head **20**. The gas stream helps atomize the mixed syringe contents resulting in much smaller droplets. In some embodiments, a beveled cannula may be used. Overall, a smoother manipulation and easier control of the device through passageways is provided.

[0043] The invention is further illustrated in the following non-limiting examples.

Example 1

[0044] Delivery device **1** was clamped into a suitable fixture and evaluated using an air flow rate meter to determine rate of air flow through cannula **14** at different user configurations. The air flow rate was measured at least 14 times for each user configuration.

Test	Average Air Flow Rate (L/min)	STDEV
Air Flow Rate (Straight Cannula)	10.02	0.47
Air Flow Rate (90° Bent Cannula)	10.05	0.43
Air Flow Rate (180° Bent cannula)	10.29	0.88
Air Flow Rate (Greater than 180° Bent Cannula	9.89	0.30

Example 2

[0045] Delivery device **1** was clamped into a suitable fixture and evaluated using a calibrated force gauge to determine the force in Lbf units to bend the cannula 90 degrees. The required force was measured at least 14 times with the cannula bent at 90 degrees.

Test	Average (Lbf)	STDEV
Cannula Bend Force (90°)	1.53	0.11

We claim:

1. A cannula comprising:
   a) a malleable member having a proximal portion and a distal portion;
   b) at least one lumen within and extending between the proximal and distal portion; the at least one lumen in fluid communication with a fluid supply; and;
   c) a reinforcement member extending along the length of the at least one lumen; the cannula having a durometer such that the cannula does not kink when bent greater than 45 degrees.

2. The cannula of claim 1 wherein the cannula does not kink when bent 90 degrees.

3. The cannula of claim 1 wherein the cannula does not kink when bent 180 degrees.

4. The cannula of claim 1 wherein the durometer is about 60-95 Shore A.

5. The cannula of claim 1 wherein the cannula comprises polyvinyl chloride.

6. The cannula of claim 1 wherein the proximal portion includes a rigid support member.

7. The cannula of claim 6 wherein the support member comprises stainless steel.

8. The cannula of claim 1 wherein the distal portion includes a spray head.

9. The cannula of claim 8 wherein the distal portion includes a sheath that provides a smooth transitional interface between the cannula and spray head.

10. The cannula of claim 1 wherein the proximal end portion is rigid and the distal end portion is flexible with the ratio of the proximal end portion to distal end portion is about 1:2 to about 2:1.

11. The cannula of claim 1 wherein the cannula includes four lumens.

12. The cannula of claim 1 wherein the cannula includes at least two lumens configured to be in fluid communication with separate fluid supplies.

13. The cannula of claim 1 wherein the reinforcement member comprises a stainless steel wire.

14. The cannula of claim 1 wherein the cannula comprises a beveled end.

15. A method of dispensing fluids to a body cavity target site, the method comprising:

A) providing a spray delivery system comprising:

(i) at least one fluid supply; and

(ii) a cannula, the cannula comprising:

a) a malleable member having a proximal portion and a distal portion;

b) at least one lumen within and extending between the proximal and distal portion; the at least one lumen in fluid communication with a fluid supply; and;

c) a reinforcement member extending along the length of the at least one lumen; the cannula having a durometer such that the cannula does not kink when bent greater than 45 degrees; and

(iii) a spray head through which the at least one fluid supply exits; and

B) dispensing fluid from the fluid supply into the at least one such lumen and through the spray head.

16. The method of claim 15 wherein the cannula has a durometer (Shore A) from 60-95.

17. The method of claim 15 wherein the cannula does not kink when bent 90 degrees

18. The method of claim 15 wherein the cannula does not kink when bent 180 degrees.

19. The method of claim 15 comprising dispensing a tissue sealant.

20. The method of claim 15 comprising dispensing a mixture of chitosan and starch.

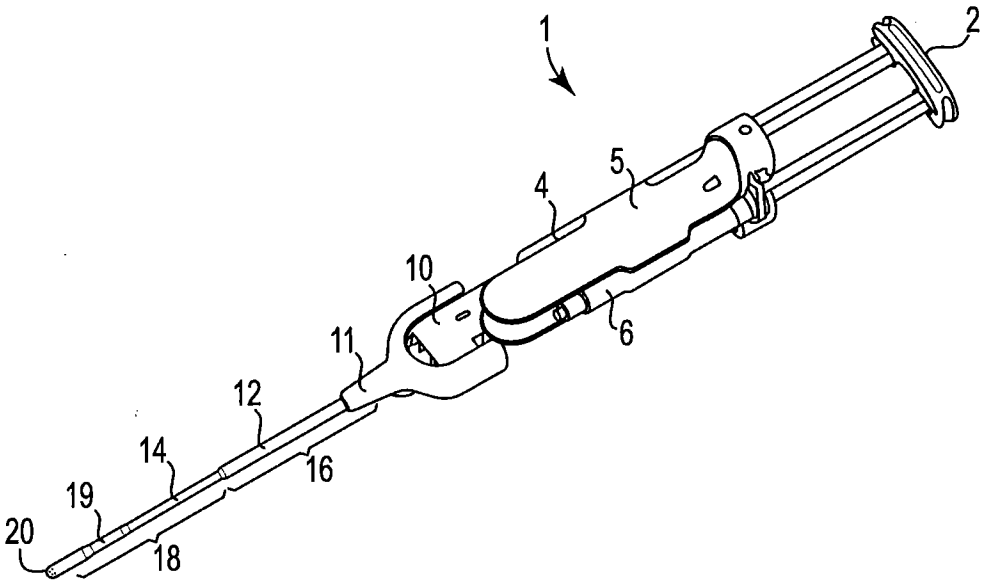

Fig. 1

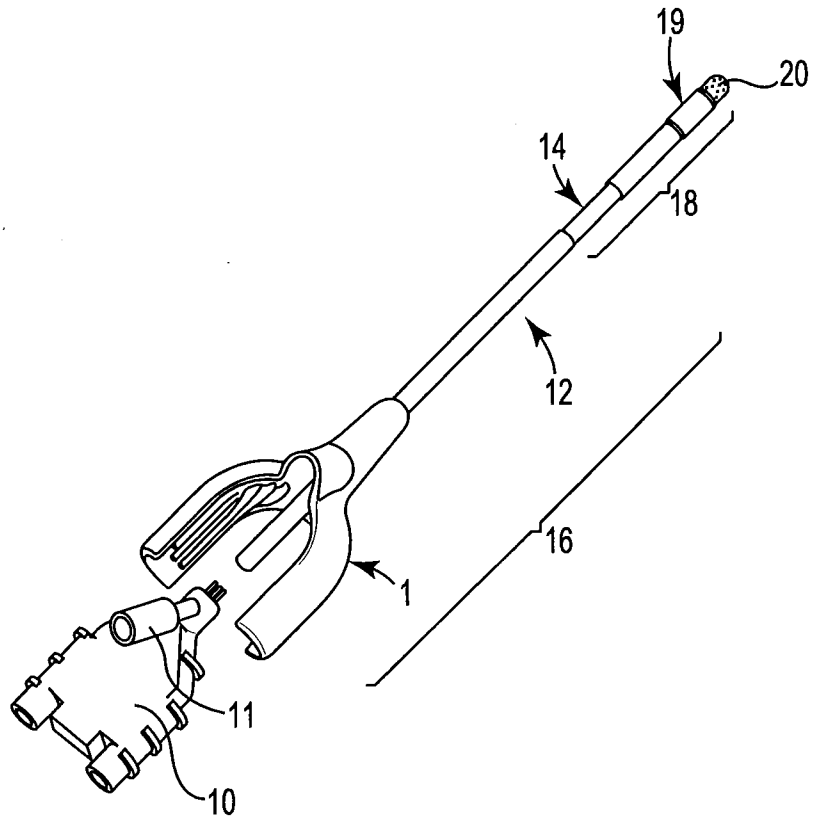

Fig. 2

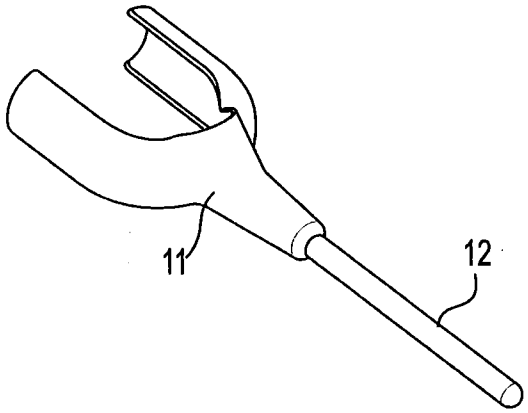

Fig. 3A

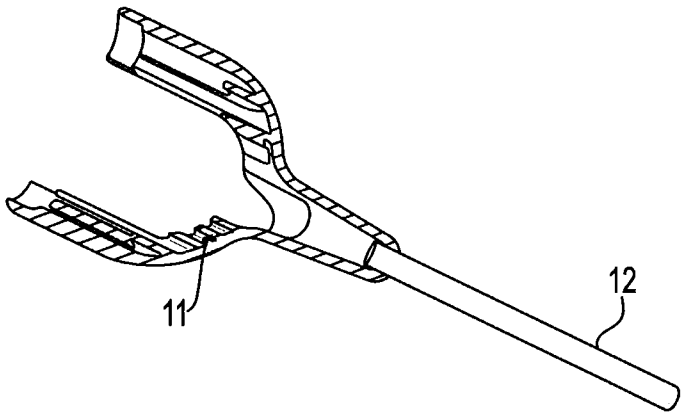

Fig. 3B

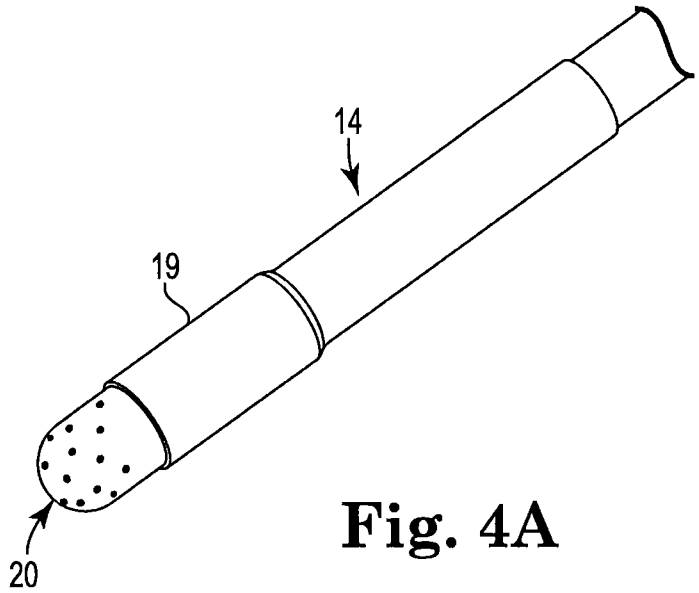

Fig. 4A

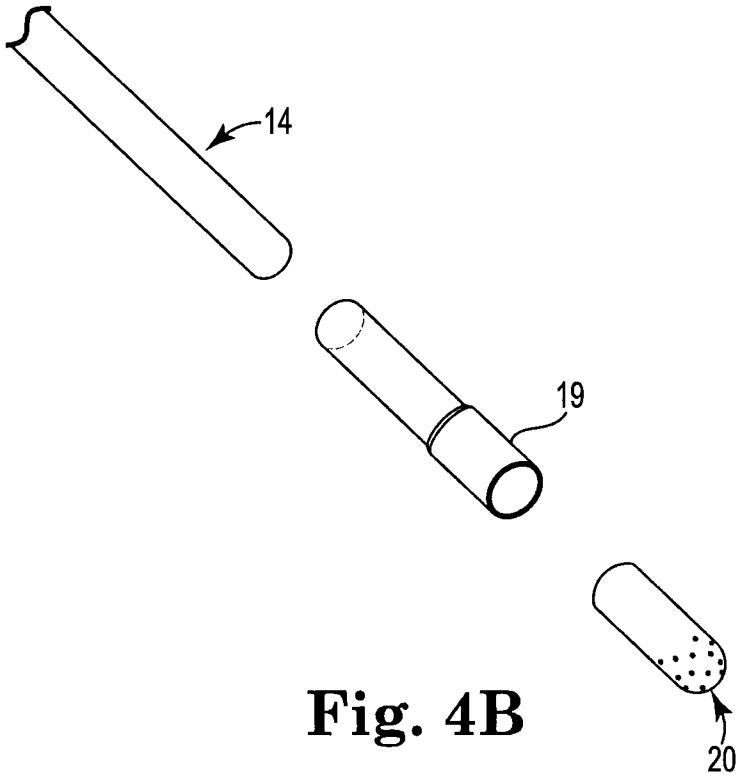

Fig. 4B

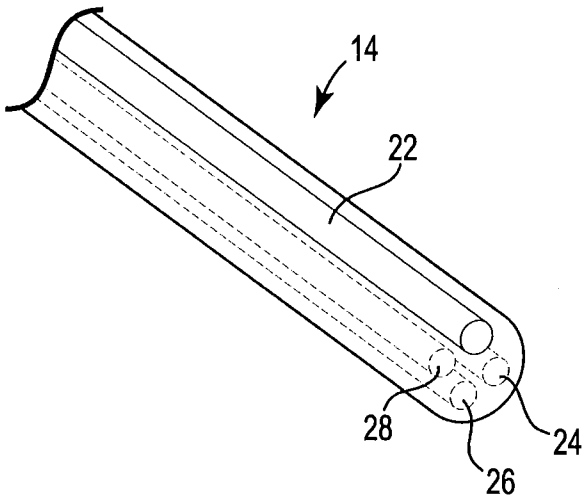

Fig. 5A

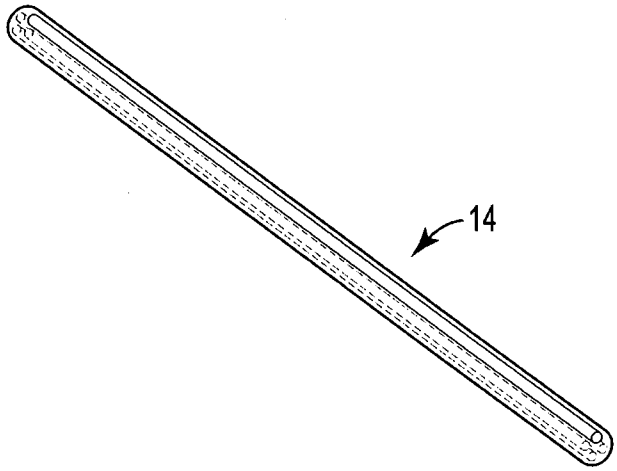

Fig. 5B

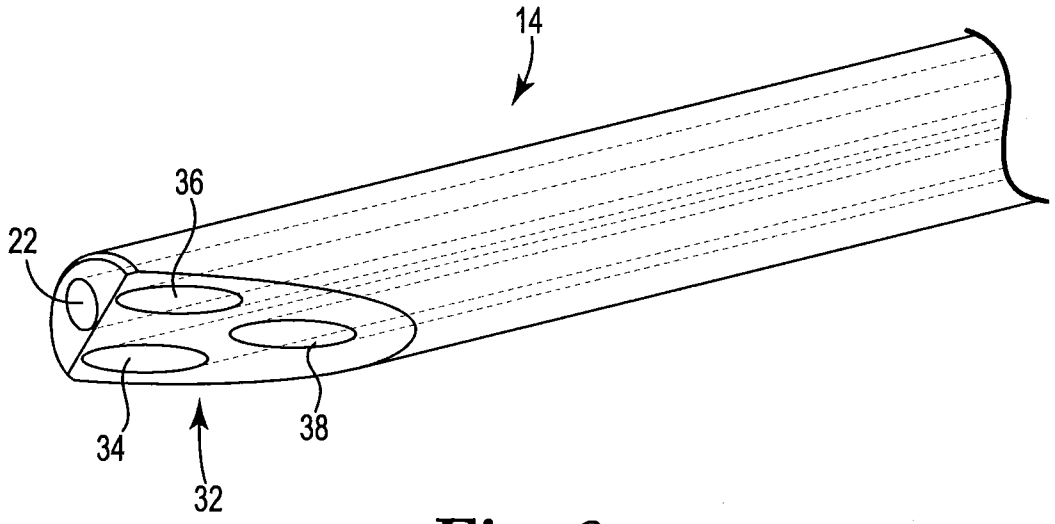

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/062126

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B1/005 A61M3/02 A61B1/00 A61M25/00
ADD.

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)
A61B A61M

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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 00/71016 A1 (SCIMED LIFE SYSTEMS INC [US]) 30 November 2000 (2000-11-30) page 2, lines 47-51; figures 1,3a page 4, lines 90-96,105-113 page 8, lines 1,2,197-204 -----	1-3,6,7, 13,15-20 12
X	WO 2005/094665 A2 (BOSTON SCIENT SCIMED INC [US]) 13 October 2005 (2005-10-13) page 12, lines 27-33 page 13, lines 11,2 page 17 figures 1,3,4,13a,13b,14a,28 -----	1-4,6,7, 11,13,14
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 February 2013	19/02/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Bielsa, David

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/062126

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/298642 A1 (TRUSTY ROBERT M [US] ET AL) 25 November 2010 (2010-11-25) paragraphs [0057], [0085]; figures 1,3,6	1-3,5-7, 11,13,14
Y	WO 96/19940 A1 (OMRIX BIOPHARM SA [BE]; ZINGER FREDDY [IL]) 4 July 1996 (1996-07-04) the whole document	12

INTERNATIONAL SEARCH REPORT

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