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(71) Applicant *(for all designated States except US)*: **CRYOLIFE, INC.** [US/US]; 1655 Roberts Boulevard, Kennesaw, Georgia 30144 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **HOFFMAN, Jeffrey, Michael** [US/US]; 17 Boones Ridge Drive, Acworth, Georgia 30102 (US).

(74) Agents: **KING, Kevin, W.** et al.; SUTHERLAND ASBILL & BRENNAN LLP, 999 Peachtree Street, NE, Atlanta, GA 30309-3996 (US).

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(54) Title: APPLICATOR DELIVERY TIP EXTENSION

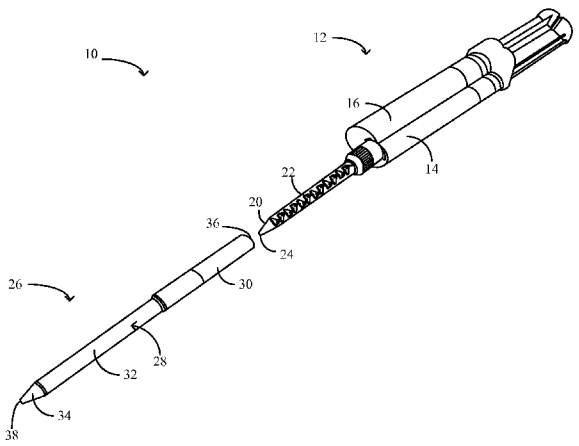

Fig. 1

(57) Abstract: A delivery tip extension communicates an adhesives material from a fluid applicator tip to a site within a patient. The delivery tip extension has an elongated shaft with a proximal end portion, a central body portion, and a tapered distal end portion. The central body portion has a length between about 5 cm and about 45 cm. A lumen is defined within and extends along the elongated shaft from a proximal opening to a distal opening. The elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion. The lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that a dispensing outlet on the fluid applicator tip is in fluid communication with the lumen. The delivery tip extension is sterilized or sterilizable.

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APPLICATOR DELIVERY TIP EXTENSION

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/329,717, filed April 30, 2010, and U.S. Provisional Application No. 61/307,372, filed February 23, 2010, which are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates generally to the field of biomaterial delivery systems, and more particularly to tip extensions for biomaterial delivery systems.

BACKGROUND

[0003] Fluid biomaterials, such as adhesive substances, are frequently used in surgeries and other medical procedures, for example in soft tissue repairs or as a vascular suture sealant. These materials may be applied by the physician with a syringe or other fluid applicator, such as those described in U.S. Patent Nos. 4,538,920 and 4,359,049; however, some tissue sites may not be readily accessible with conventional applicators. For example, the site may not be reachable at all or only with great difficulty in an open surgical procedure. In a laparoscopic procedure, delivery may not be possible with a conventional applicator due to site location or applicator limitations. In still other cases, the physician may be unable to navigate through or around soft tissue without damaging the surrounding tissue or organs with a conventional applicator. Often, large incisions are necessary to accommodate such applicator limitations. Large incisions are undesirable.

[0004] It would be desirable to provide improved systems for targeted delivery of biomaterials to remote sites within a patient that allow for precise navigation through the body and reduce the risk of damaging surrounding tissue or organs while also decreasing the size of the incision site required. It would also be desirable for the delivery system to provide rapid transport of the biomaterial between the fluid applicator tip and the application site, especially where the fluid to be delivered is a quick-setting adhesive.

SUMMARY

[0005] A delivery tip extension is provided for communicating an adhesive material from a fluid applicator tip to a site within a patient. The delivery tip extension has an elongated shaft with a proximal end portion, a central body portion having a length between 5 cm and 45 cm, and a tapered distal end portion. A lumen is defined within and extends along the elongated shaft from a proximal opening on the proximal end portion to a distal opening on the distal end portion. The elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion. The lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that a dispensing outlet on the fluid applicator tip is in fluid communication with the lumen. The delivery tip extension is sterilized or sterilizable.

[0006] In embodiments, the lumen may have a reduced cross-sectional area along the central body and distal end portions relative to the cross-sectional area along the proximal end portion. The reduced cross-sectional area may promote rapid transport of adhesive from the fluid applicator tip to the distal opening. The delivery tip extension also may include a distal end covering positioned about the distal end portion of the elongated shaft. The distal end covering may include a relatively softer material than the elongated shaft, the relatively softer material further reducing trauma to the patient by the distal end portion. For example, the elongated shaft may include a polyurethane material, and the distal end covering may include a polyether block amide material. The delivery tip extension also may include a proximal end connector positioned about the proximal end portion of the elongated shaft. In some embodiments, the elongated shaft has an outer diameter of between about 2 mm and about 8 mm along the central body portion, and the lumen has a diameter of between about 0.5 mm and about 5.0 mm along the central body and distal end portions. For example, the elongated shaft may have an outer diameter of between about 4 mm and about 6 mm along the central body portion, and the lumen may have a diameter of between about 0.8 mm and about 1.6 mm along the central body and distal end portions. The elongated shaft may have a length of about 10 cm, about 27 cm, or about 35 cm. The proximal end portion may include a textured inner surface for

frictional engagement with the fluid applicator tip. The elongated shaft may include a polymer, such as a polyurethane.

[0007] In another aspect, a sterile kit is provided for delivering an adhesive material to a site within a patient. The kit includes a syringe apparatus and at least one delivery tip extension. The syringe apparatus has at least one chamber and a fluid applicator tip. The at least one chamber houses a fluid therein, the fluid comprising an adhesive material or at least one precursor therefor. The fluid applicator tip is in fluid communication with the fluid in the chamber, and the fluid applicator tip includes a dispensing outlet. The delivery tip extension is connectable to the fluid applicator tip of the syringe apparatus for dispensing the adhesive. The delivery tip extension has an elongated shaft with a proximal end portion, a central body portion having a length between 5 cm and 45 cm, and a tapered distal end portion. A lumen is defined within and extends along the elongated shaft from a proximal opening on the proximal end portion to a distal opening on the distal end portion. The elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion. The lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that a dispensing outlet on the fluid applicator tip is in fluid communication with the lumen.

[0008] In embodiments, the syringe apparatus may include a first chamber and a second chamber. The first chamber may house a first fluid that comprises a solution including albumin, and the second chamber may house a second fluid that includes an aldehyde for crosslinking the albumin. The syringe apparatus may include a plunger for driving the first and second fluids from the first and second chambers into the fluid applicator tip. The fluid applicator tip may include a static mixer operable to mix the first and second fluids to form the adhesive.

[0009] In still another aspect, a method of delivering an adhesive to a tissue site within a patent is provided. The method includes flowing an adhesive from a syringe apparatus through a delivery tip extension to a tissue site in a patient. The delivery tip extension has an elongated shaft with a proximal end portion, a central body portion having a length between 5 cm and 45 cm, and a tapered distal end portion. A lumen is defined within and extends along the elongated shaft from a proximal opening on the

proximal end portion to a distal opening on the distal end portion. The elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion. The lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that a dispensing outlet on the fluid applicator tip is in fluid communication with the lumen.

[0010] In embodiments, the delivery tip extension may deliver the adhesive laparoscopically. The delivery tip extension may be inserted through a trocar to deliver the adhesive to the tissue site.

[0011] In yet another aspect, a method of making a delivery tip extension is provided. The method includes molding an elongated shaft having a lumen extending therethrough and a length between 5 cm and 45 cm. The elongated shaft includes a proximal end portion, a central body portion, and a tapered distal end portion. A distal end covering is overmolded about the distal end portion of the elongated shaft. The distal end covering comprises a relatively softer material than the elongated shaft. In embodiments, the delivery tip extension may be sterilized.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** is an exploded perspective view of a system for delivering a biomaterial to a tissue site in a patient in accordance with one or more embodiments of the present invention.

[0013] **FIG. 2** is a plan view of one embodiment of a delivery tip extension device.

[0014] **FIG. 3** is a plan, cross-sectional view of the embodiment of a delivery tip extension device shown in **FIG. 2**.

[0015] **FIG. 4** is a plan view of another embodiment of a delivery tip extension device.

[0016] **FIG. 5** is a plan, cross-sectional view of the embodiment of the delivery tip extension device shown in **FIG. 4**.

DETAILED DESCRIPTION

[0017] The present application will now be described more fully hereinafter with reference to the accompanying drawings, in which several embodiments of the application are shown. Like numbers refer to like elements throughout the drawings.

[0018] Described below are embodiments of systems and methods for delivering a fluid to a location within a patient. The patient may be a human or other mammal, for example. The systems and methods generally employ a fluid dispensing apparatus, such as a syringe, and a delivery tip extension. The fluid dispensing apparatus may dispense a fluid, such as an adhesive, for use within the body of a patient. The delivery tip extension may communicate the fluid from the fluid dispensing apparatus to a location within the patient that is remote from the fluid dispensing apparatus. Thus, the delivery tip extension extends the reach of the fluid dispensing apparatus, so that fluid within the fluid dispensing apparatus can be delivered to a site within a patient that would not be reachable using the fluid dispensing apparatus alone.

[0019] In particular embodiments, the delivery tip extension is configured on its proximal end to receive fluid from the fluid delivery apparatus, on its distal end to release the fluid into the patient, and along its length to deliver the fluid between its proximal and distal ends relatively quickly. A lumen may extend along the length of the delivery tip extension for this purpose, and the lumen may be relatively narrow in width. The narrow width of the lumen facilitates quick delivery of the fluid through the length of the delivery tip extension. Thus, when the fluid dispensing apparatus is positioned outside of the patient and the delivery tip extension extends into the patient with its proximal end is in communication with the fluid dispensing apparatus and its distal end is in communication with the intended delivery site, fluid dispensed from the fluid delivery apparatus may quickly travel through the delivery tip extension to reach the intended delivery site. Rapid delivery may be useful in certain surgical contexts, such as embodiments in which the fluid dispensing apparatus dispenses a surgical glue that begins hardening or setting within or shortly upon exiting the fluid delivery apparatus, as described in further detail below.

[0020] In particular embodiments, the fluid dispensing apparatus includes at least one chamber and a dispensing tip in communication with the chamber. The chamber may house the fluid, or a component thereof, and the dispensing tip may dispense the fluid from the chamber. The delivery tip extension may secure onto the dispensing tip to

receive the fluid therefrom. Thus, when the fluid dispensing apparatus is operated to dispense the fluid from the dispensing tip, the fluid may flow directly into the dispensing tip extension, along its length, and to the intended delivery site.

[0021] In particular embodiments, the fluid dispensing apparatus houses at least two fluid components for forming a biocompatible adhesive. For example, the fluid components may be housed in separate chambers, each of which may be in fluid communication with the dispensing tip. The chambers may be operatively associated with a plunger, or any other suitable mechanism for driving the constituent components from the chambers into the dispensing tip. The dispensing tip may include a static mixer or other suitable mechanism for combining the constituent components to react to form an adhesive. The driving force of the plunger may be sufficient to drive the fluid components and resulting adhesive through both the dispensing tip and the delivery tip extension.

[0022] In some embodiments, the delivery tip extension includes an elongated shaft and a lumen defined within the elongated shaft between its proximal and distal ends. The elongated shaft may be configured along its proximal end to receive and secure to the fluid dispensing apparatus, and the elongated shaft may be configured along its distal end for controlled dispensing of the biomaterial. For example, the distal end may be tapered.

[0023] The elongated shaft may be rigid enough to facilitate navigation through the body tissues. The distal end may be soft to reduce damage to surrounding tissue and organs, and yet the distal end may be stiff enough to ensure the delivery tip extension can navigate through tissues or structures that occlude the target site. The stiffness of the distal end may be sufficient to ensure the end is responsive to direction and torque applied at the proximal end and is less affected by sideways pressure from surrounding tissues/structures. The narrow width of the lumen may provide rapid transport of the fluid along the shaft, which may be useful in cases in which the fluid is an adhesive that begins cross-linking or hardening upon mixing or upon exiting the dispensing tip.

[0024] The delivery tip extension may facilitate precise delivery of a fluid or other biomaterial to a delivery site within a patient, even in cases in which the delivery site otherwise is not easily accessible or is inaccessible. The delivery tip extension may be used in an open surgical procedure, a laparoscopic procedure, a video-assisted thoracic surgery, in conjunction with a trocar, or any combination thereof. Examples of open surgeries in which the delivery tip extension may be used include general surgery such as

liver resection or pancreatic resection; cardiac surgery such as valve replacement or aneurysm repair; pulmonary surgery such as lung resection, bullectomy, blebectomy, or lung volume reduction; urologic surgery such as partial nephrectomy or prostatectomy; or neurosurgery such as tumor resection or pituitary gland removal. Examples of laparoscopic or video-assisted thoracic surgeries in which the delivery tip extension may be used include general surgery such as liver resection or pancreatic resection; pulmonary surgery such as lung resection, bullectomy, blebectomy, or lung volume reduction; or urologic surgery such as lap partial nephrectomy or lap prostatectomy.

[0025] The delivery tip extension may facilitate precise delivery of an adhesive or other fluid to a depth below the surface of the skin that would not be reachable using a standard tip alone, which may be desirable in certain applications. One example is surgery on an obese patient, whose organs may be farther from the surface of the skin. Another example is surgery on an occluded area of the body, such as the back of the heart or the underside of another organ. An additional example is a surgery wherein a portion of the body of the patient is inflated, such as a laparoscopic surgery or other procedure in which the abdominal cavity of the patient is insufflated with carbon dioxide causing the abdominal cavity to enlarge. A trocar, which is often used in such surgeries, is essentially a port through which instruments are introduced into the abdomen. The trocar is often associated with a one-way valve, which prevents carbon dioxide from escaping through the port. Yet another example is a video-assisted thoracic surgery wherein the size of the thoracic cavity necessitates reaching a depth below the surface of the skin or a surgery wherein resected tissue is located closer to the medial line of the body and farther from the skin surface. In these and in other cases, the target tissue may be a distance below the skin surface from which the adhesive or other fluid is deployed, and the delivery tip extension may facilitate accessing these locations effectively.

[0026] **FIG. 1** illustrates an embodiment of a system **10** for delivering a fluid, such as an adhesive, to a location within the body of a patient. The system includes a syringe apparatus **12** and a delivery tip extension **26**. The syringe apparatus **12** is configured to dispense a fluid, and the delivery tip extension **26** is configured to deliver the dispensed fluid to a location remote from the syringe apparatus **12**. The delivery tip extension **26** is shown in greater detail in **FIGS. 2** and **3**, which are plan and cross-sectional views.

[0027] In the illustrated embodiment, the syringe apparatus **12** includes a first chamber **14**, a second chamber **16**, and a fluid applicator tip **20** in fluid communication with fluid material contained in the first and second chambers **14**, **16**. The fluid applicator tip **20** also has a dispensing outlet **24** for dispensing the fluid material. It should be noted that the syringe apparatus **12** may include one chamber or more than two chambers in other embodiments, and that the chambers may have a number or orientations including, including concentric, serial, or side-by-side alignment.

[0028] In some embodiments, the fluid material dispensed by the syringe apparatus **12** comprises an adhesive material, such as a bioadhesive material for use within the human body. Each chamber may house an adhesive or an adhesive presursor (e.g., a prepolymer and a crosslinker). The precursors may include a proteinaceous material, such as human or bovine serum albumin, and an aldehyde, including a di- or poly-aldehyde such as gluteraldehyde, as described in U.S. Patents No. 5,385,606 and No. 7,621,969. The chambers **14, 16** may house these adhesive precursors that can be combined to form an adhesive. For example, one chamber **14** may house a solution that includes albumin, and the other chamber **16** may house an aldehyde for crosslinking the albumin. One example of such an adhesive is BioGlue® surgical adhesive, available from CryoLife, Inc. of Kennesaw, Georgia. Such an adhesive may create a bond in thirty seconds or less. Alternatively, the fluid may be another bioadhesive substance known in the art, a biopolymer for tissue augmentation or embolic therapy, a rapid-gelling composition, or the like.

[0029] As shown in **FIG. 1**, the fluid applicator tip **20** may optionally include a static mixer **22** for mixing the fluid material prior to delivery via the dispensing outlet **24**. For example, in a dual chamber syringe apparatus **12** wherein each of the two chambers **14**, **16** includes an adhesive precursor, the fluid applicator tip **20** may include a static mixer **22** to combine the two adhesive precursors to form an adhesive immediately prior to delivery via the dispensing outlet **24**. The adhesive precursors may be driven from the chambers **14, 16** and into the fluid applicator tip **20** with a plunger that is operatively associated with the chambers **14, 16**. Upon mixing, such adhesive precursors may immediately begin cross-linking or hardening. In such embodiments, the adhesive may be delivered to the delivery site before it solidifies using a delivery tip extension **26**.

[0030] More particularly, a delivery tip extension **26** is provided for communicating an adhesive material from a fluid applicator tip **20** of a syringe apparatus **12** to a site within a patient by extending the fluid delivery length of the syringe apparatus **12**. The delivery tip extension **26** includes an elongated shaft **28** and a lumen **40**. The elongated shaft has a proximal end portion **30,** a central body portion **32**, and a tapered distal end portion **34**. The lumen **40** is defined within and extends along the elongated shaft **28** from a proximal opening **36** on the proximal end portion **30** to a distal opening **38** on the distal end portion **34**. The elongated shaft **28** is advantageously relatively more rigid along the central body portion **32** than along the distal end portion **34** to facilitate driving the elongated shaft **28** through/between tissues in the patient. The elongated shaft **28** is relatively less rigid along the distal end portion **34** than along the central body portion **32** to reduce trauma to the patient by the distal end portion **34**. The lumen **40** is sized and shaped along the proximal end portion **30** for securely receiving the fluid applicator tip **20** when inserted through the proximal opening **36** such that the dispensing outlet **24** is in fluid communication with the lumen **40**.

[0031] The distal end portion **34** is relatively less rigid than the central body portion **32**, for example, as a result of the reduced wall thickness due to the tapering of the distal end portion **34**. The decreased rigidity at the distal end portion **34** reduces the risk of puncturing or tearing surrounding tissue or organs when the delivery tip extension **26** is guided through the patient. In one embodiment, the delivery tip extension **26** is sterilized or sterilizable for use in medical procedures.

[0032] In one embodiment, the elongated shaft **28** is made from one or more USP Class VI compliant, clear resins. For example, the elongated shaft **28** may be made from a single gamma-irradiation stable, biocompatible, USP Class VI polymer. In one embodiment, the polymer is a polyurethane, such as Isoplast® 2510. Isoplast® brand polymers are available from Lubrizol Corp. of Wickliffe, Ohio. In another embodiment, the elongated shaft **28** may be made from multiple biocompatible, USP Class VI polymers and resins that are ionizing radiation stable (e.g., gamma-irradiation or electron beam), chemical stable (e.g., glutaraldehyde, ethylene oxide, hydrogen peroxide or plasma), or heat sterilization stable (e.g., autoclaving). Other suitable polymeric materials may be used. Examples of suitable materials include Isoplast® 2530, Pebax® 7033, or Pebax®

7233. Pebax® brand polymeric materials are available from Arkema, Inc. of Philadelphia, Pennsylvania.

[0033] The elongated shaft **28** may be made from rigid polymers to facilitate easy steering of the delivery tip extension **26** within the body. In an exemplary embodiment, these rigid polymer resins may comprise polyethylene (e.g., low-, high-, or ultrahigh-density), polypropylene, polyurethane, or liquid-crystalline polymers. These resins may include fillers or modifiers. Fillers or modifiers may comprise glass fibers, glass beads, talc, calcium carbonate, or other suitable materials. In certain embodiments, these polymer resins may comprise Vectra® liquid crystal polymers, Isoplast® 2510, Isoplast® 2530, Pebax® 7033, or Pebax® 7233. Vectra® brand polymeric materials are available from Celanese, Inc., Dallas, Texas. Alternatively, the elongated shaft **28** may be made from soft polymer resins for ease of bending or shaping by the end user.

[0034] In one embodiment, the tapered distal end portion **34** is conical to provide pointed adhesive application and easy introduction into surgical ports, as shown in **FIG. 1**. The distal end portion **34** may also be rounded to further minimize tissue damage. In another embodiment, the tapered distal end portion is flattened and flared to dispense a ribbon of the adhesive over the tissue surface. Alternatively, the distal end portion may have other configurations, including those described in U.S. Patent No. 7,325,995, which is incorporated by reference herein in its entirety.

[0035] In particular embodiments, the proximal end portion **36** is configured to engage the fluid applicator tip **20**. The engagement may be by frictional engagement, mating threads, snap-fit connection, or the like. The proximal end portion **36** may form a fluid tight connection with the fluid applicator tip **20**. In one case, the proximal end portion **36** may include a textured inner surface to promote frictional engagement with the fluid applicator tip **20**. The proximal end portion **36** also may be secured to the fluid applicator tip via one or more suitable mechanical fasteners known in the art. Other methods of forming a sealed connection may be used. In some embodiments, the proximal end portion **36** may include a textured outer surface to aid in gripping. For example, the texture may comprise product or brand name, company name, or size identifiers. Alternatively, the texture may comprise random, ordered, or periodic ridges and valleys or shapes.

[0036] In certain embodiments, the distal and proximal end portions **30**, **34** are made from transparent or translucent polymer resins. The transparent or translucent polymer resins may allow visualization of the fluid being delivered or the fluid applicator tip **20** or static mixer **22** being inserted through the proximal opening **36**.

[0037] As shown in **FIG. 3**, the lumen **40** has a reduced cross-sectional area along the central body and distal end portions **32**, **34** relative to the cross-sectional area along the proximal end portion **30**, to promote rapid transport of adhesive from the fluid applicator tip **20** to the distal opening **38**. While the lumen **40** has a cross-sectional area sized along the proximal end portion **36** to securely receive the fluid applicator tip **20** of the syringe apparatus **12**, the lumen **40** has a cross-sectional area sized along the central body and distal end portions **32**, **34** to provide rapid delivery along the length of the delivery extension tip **26**, such as from the dispensing outlet **24** of the fluid applicator tip **20** to the distal opening **38** of the delivery extension tip **26** for application at the tissue site within the patient. In cases in which the adhesive is one that solidifies quickly, the reduced diameter of the lumen **40** provides almost immediate communication of the adhesive from the fluid applicator tip to the site of application, thereby reducing adhesive hardening within the delivery tip extension **26**. Also, in some embodiments, the lumen **40** is smooth and has a low coefficient of friction to further expedite fluid transport along the lumen **40**.

[0038] In some embodiments, the elongated shaft **28** has an outer diameter of between about 0.1 mm and about 20 mm, and the lumen **40** has a diameter of between about 0.01 mm and about 19 mm along the central body and distal end portions **32**, **34**. In particular embodiments, the elongated shaft **28** has an outer diameter of between about 1 mm and about 10 mm, and the lumen **40** has a diameter of between about 0.5 mm and about 4.5 mm along the central body and distal end portions **32**, **34**.

[0039] In one embodiment, the elongated shaft **28** is constructed of a clear polyurethane, e.g., Isoplast® 2510 and has an outer diameter between about 2 mm and about 8 mm along the central body portion and the lumen has a diameter of between about 0.5 mm and about 5.0 mm along the central body and distal end portions. In one particular embodiment, the elongated shaft **28** has an outer diameter between about 4 mm and about 6 mm (e.g., about 5 mm) along the central body portion and the lumen has a diameter of between about 0.8 mm and about 1.6 mm (e.g., about 1.2 mm) along the central body and distal end portions. However, in other embodiments the elongated shaft

28 may have a larger outer diameter, such as a diameter that is as much as 20 mm or more, so that the entire delivery tip extension is somewhat stiffer or more rigid. A stiffer or more rigid delivery tip extension may be useful in certain surgical applications.

[0040] In one embodiment, the elongated shaft **28** has a length between 5 cm and 45 cm. In exemplary embodiments, the elongated shaft **28** has a length of about 10 cm, about 27 cm, or about 35 cm. Other lengths of the elongated shaft **28** are also envisioned.

[0041] **FIGS. 4** and **5** illustrate another embodiment of a delivery tip extension **126.** In this embodiment, the delivery tip extension **126** includes a distal end covering **142** positioned about the distal end portion **134** of the elongated shaft **128**. The distal end covering **142** comprises a relatively softer material than the elongated shaft **128**, to further reduce trauma to the patient by the distal end portion **134**. In some embodiments, the relatively softer material of the distal end covering **142** is a soft polymer resin, such as a polyether block amide, polyurethane, or polyethylene. In one embodiment, the distal end covering **142** comprises Pebax® 4033 SA01. The delivery tip extension **126** may be formed with a step or indent along the distal end portion **134** so that a smooth surface is formed when the distal end covering **142** is positioned thereabout. For example, the distal end covering **142** may be formed by overmolding.

[0042] In some embodiments, the delivery tip extension **126** also includes a proximal end connector **144** positioned about the proximal end portion **130** of the elongated shaft **128**, as shown in **FIGS. 4** and **5**. The proximal end connector **144** may be separately formed from the elongated shaft **128** and attached thereto, such as by overmolding or with an adhesive, so that the proximal end connector **144** can be formed from a different material than the elongated shaft **128**. For example, the elongated shaft **128** may be relatively rigid or stiff, so that the elongated shaft can be directed to the area of application, while the proximal end connector **144** may have a certain flexibility or give so that it can stretch about and flexibly mate with the applicator tip. As another example, the elongated shaft **128** may have a relatively lower coefficient of friction so that it can slide into and out of a trocar without excessive frictional engagement, while the proximal end connector **144** may exhibit a higher coefficient of friction. The higher coefficient of friction for the proximal end connector **144** may facilitate grasping the connector to place it on the applicator tip. The higher coefficient of friction also may facilitate retaining the proximal end connector **144** on the applicator tip. These various design parameters may

be achieved by forming different portions of the delivery tip extension **126** from different materials, with different diameters, with different wall thicknesses, or any combination thereof. Thus, the elongated shaft **128** may be associated with a separate proximal end connector **144** to form the delivery tip extension **126** in some embodiments.

[0043] In another aspect, a system is provided for delivering an adhesive material to a site within a patient. The system includes the syringe apparatus and the delivery tip extension. The syringe apparatus is operably connected to the delivery tip extension by inserting the fluid applicator tip through the proximal opening and securing it within the proximal end portion such that the dispensing outlet is in fluid communication with the lumen.

[0044] The system may be used to deliver adhesive, sealant or tissue augmentation compositions to bond, coat, or augment a variety of tissue sites. The adhesive may bond to living tissues, including muscle, skin, connective tissue, nerve tissue, vascular and cardiac tissues, cartilage, bone, and the like, as well as to corresponding cadaver tissues, which may be preserved or otherwise chemically treated. Bonds may also be formed to natural or synthetic materials such as rubber, polyethylene terephthalate, polytetrafluoroethylene, and the like, as well as to metals, enabling the use of these compositions for the attachment of surgical grafts and devices, as well as for wound closure, trauma repair, and the like in the practice of human or veterinary medicine. Non-medical applications of the adhesive delivery system are also envisioned.

[0045] In another aspect, a method is provided for delivering an adhesive to a tissue site in a patient. The method includes flowing an adhesive from a syringe apparatus through a delivery tip extension to a tissue site in a patient. In some embodiments, the delivery tip extension delivers the adhesive laparoscopically. In an exemplary embodiment, the delivery tip extension is used in conjunction with a trocar to deliver the adhesive to the tissue site.

[0046] In another aspect, a method is provided for making a delivery tip extension. The method includes a first step of molding, extruding, thermoforming, or a combination thereof, an elongated shaft having a lumen extending therethrough and a length between 5 cm and 45 cm. The elongated shaft includes a proximal end portion, a central body portion, and a tapered distal end portion. In some embodiments, the method includes a next step of overmolding a distal end covering about the distal end portion of the

elongated shaft, the distal end covering comprising a relatively softer material than the elongated shaft. In some embodiments, the method for making a delivery tip extension also includes a step of overmolding a proximal end connector about the proximal end portion of the elongated shaft. Overmolding distal and proximal end portions on an elongated shaft may facilitate forming different portions of the delivery tip extension from different materials. Thus, the materials of the different portions may be specifically selected based on the desired function of the different portions. Additionally, overmolding may facilitate varying the diameter of the delivery tip extension along its length with improved quality control and less waste.

[0047] In particular embodiments, the elongated shaft is extruded from rigid polyurethane (e.g., Isoplast® 2530) and the distal and/or proximal end coverings are made from soft polyether block amide (e.g., Pebax® 4033 SA01) which is overmolded onto the elongated shaft.

[0048] In some embodiments, the delivery tip extension components may be formed separately and then assembled or combined together. In other embodiments, one or more preparation steps may be included between the component formation and combination steps. The preparation step may be of a physical or mechanical nature, for example shaving, thermoforming, crimping, cutting, flaring, or other steps known in the art. Alternatively, the preparation step may be of a chemical nature, for example solvent application, degreasing, priming, or other steps known in the art. The combination step may be accomplished by one or more steps that include gluing the components or surfaces together, bonding by chemical means, bonding by physical techniques (e.g., heat, laser, ultrasound, radio frequency, or friction), thermoforming or overmolding, or other suitable means.

[0049] The delivery tip extension may be packaged for shipping and storage. It may be sterilized once manufactured/assembled, either before or after packaging. Sterilization may be achieved either by ionizing radiation sterilization, chemical sterilization, or heat sterilization. Suitable examples includes gamma or electron beam ionizing radiation or elthylene oxide (EtO) gas sterilization. Other suitable irradiation processes may be used. As used herein, the term "sterilizable" in reference to the delivery tip extension means that the device is constructed of one or more materials that are stable when subjected to an effective sterilization process.

[0050] One or more delivery tip extensions may be packaged together with one or more applicators to provide a kit. In one embodiment, the kit contains different sizes of delivery tip extensions together with an applicator syringe containing BioGlue™ (CryoLife, Inc., Kennesaw, Georgia USA) or another surgical adhesive. In one embodiment, the delivery tip extension is packaged in a double pouch, such as one having an inner pouch and an outer pouch. The delivery tip extension is packaged two tips per pouch and ten pouches per box. The box preferably includes an Instruction For Use (IFU) insert, in the appropriate languages.

[0051] Publications cited herein and the materials for which they are cited are specifically incorporated by reference. Modifications and variations of the methods and devices described herein will be obvious to those skilled in the art from the foregoing detailed description. Such modifications and variations are intended to come within the scope of the appended claims.

CLAIMS

We claim:

1. A delivery tip extension for communicating an adhesive material from a fluid applicator tip to a site within a patient, comprising:

an elongated shaft comprising a proximal end portion, a central body portion having a length between 5 cm and 45 cm, and a tapered distal end portion; and

a lumen defined within and extending along the elongated shaft from a proximal opening on the proximal end portion to a distal opening on the distal end portion;

wherein the elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion,

wherein the lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that a dispensing outlet on the fluid applicator tip is in fluid communication with the lumen, and

wherein the delivery tip extension is sterilized or sterilizable.

2. The delivery tip extension of claim 1, wherein the lumen has a reduced cross-sectional area along the central body and distal end portions relative to the cross-sectional area along the proximal end portion, the reduced cross-sectional area promoting rapid transport of adhesive from the fluid applicator tip to the distal opening.

3. The delivery tip extension of claim 1, further comprising a distal end covering positioned about the distal end portion of the elongated shaft, the distal end covering comprising a relatively softer material than the elongated shaft, the relatively softer material further reducing trauma to the patient by the distal end portion.

4. The delivery tip extension of claim 3, wherein:

the elongated shaft comprises a polyurethane material; and

the distal end covering comprises a polyether block amide material.

5. The delivery tip extension of claim 1, further comprising a proximal end connector defining the proximal end portion of the elongated shaft, the proximal end connector comprising a relatively softer material than the elongated shaft.

6. The delivery tip extension of claim 1, wherein:

the elongated shaft has an outer diameter of between about 2 mm and about 8 mm along the central body portion; and

the lumen has a diameter of between about 0.5 mm and about 5.0 mm along the central body and distal end portions.

7. The delivery tip extension of claim 4, wherein:

the elongated shaft has an outer diameter of between about 4 mm and about 6 mm along the central body portion; and

the lumen has a diameter of between about 0.8 mm and about 1.6 mm along the central body and distal end portions.

8. The delivery tip extension of claim 1, wherein the elongated shaft has a length of about 10 cm, about 27 cm, or about 35 cm.

9. The delivery tip extension of claim 1, wherein the proximal end portion comprises a textured inner surface for frictional engagement with the fluid applicator tip.

10. The delivery tip extension of claim 1, wherein the elongated shaft comprises a clear polymer.

11. The delivery tip extension of claim 9, wherein the polymer comprises a polyurethane.

12. A sterile kit for delivering an adhesive material to a site within a patient, comprising:

a syringe apparatus comprising:

at least one chamber housing a fluid that comprises an adhesive or at least one precursor therefor;

a fluid applicator tip in fluid communication with each fluid in each chamber, the fluid applicator tip having a dispensing outlet; and

at least one delivery tip extension connectable to the fluid applicator tip of the syringe apparatus for dispensing the adhesive, the delivery tip extension comprising:

an elongated shaft comprising a proximal end portion, a central body portion having a length between 5 cm and 45 cm, and a tapered distal end portion; and

a lumen defined within and extending along the elongated shaft from a proximal opening on the proximal end portion to a distal opening on the distal end portion;

wherein the elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion, and

wherein the lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that the dispensing outlet is in fluid communication with the lumen.

13. The system of claim 12, wherein the at least one chamber comprises a first chamber and a second chamber.

14. The system of claim 13, wherein:

the first chamber houses a first fluid that comprises a solution including albumin; and

the second chamber houses a second fluid that comprises an aldehyde for crosslinking the albumin.

15. The system of claim 13, wherein the syringe apparatus further comprises a plunger for driving the first and second fluids from the first and second chambers into the fluid applicator tip.

16. The system of claim 14, wherein the fluid applicator tip comprises a static mixer operable to mix the first and second fluids to form the adhesive.

17. The system of claim 12, wherein the fluid applicator tip comprises a static mixer.

18. A method for delivering an adhesive to a tissue site in a patient, comprising:

flowing an adhesive from a syringe apparatus through a delivery tip extension to a tissue site in a patient, the delivery tip extension comprising:

an elongated shaft comprising a proximal end portion, a central body portion having a length between 5 cm and 45 cm, and a tapered distal end portion; and

a lumen defined within and extending along the elongated shaft from a proximal opening on the proximal end portion to a distal opening on the distal end portion;

wherein the elongated shaft is relatively more rigid along the central body portion than along the distal end portion to facilitate driving the elongated shaft through the patient with reduced trauma to the patient by the distal end portion;

wherein the lumen is sized and shaped along the proximal end portion for securely receiving the fluid applicator tip inserted through the proximal opening such that a dispensing outlet on the fluid applicator tip is in fluid communication with the lumen.

19. The method of claim 18, wherein the delivery tip extension delivers the adhesive laparoscopically.

20. A method of making a delivery tip extension, comprising:

molding an elongated shaft having a lumen extending therethrough and a length between 5 cm and 45 cm, the elongated shaft comprising:

a proximal end portion,

a central body portion, and

a tapered distal end portion; and

overmolding a distal end covering about the distal end portion of the elongated shaft, the distal end covering comprising a relatively softer material than the elongated shaft, to form the delivery tip extension.

21. The method of claim 20, further comprising sterilizing the delivery tip extension.

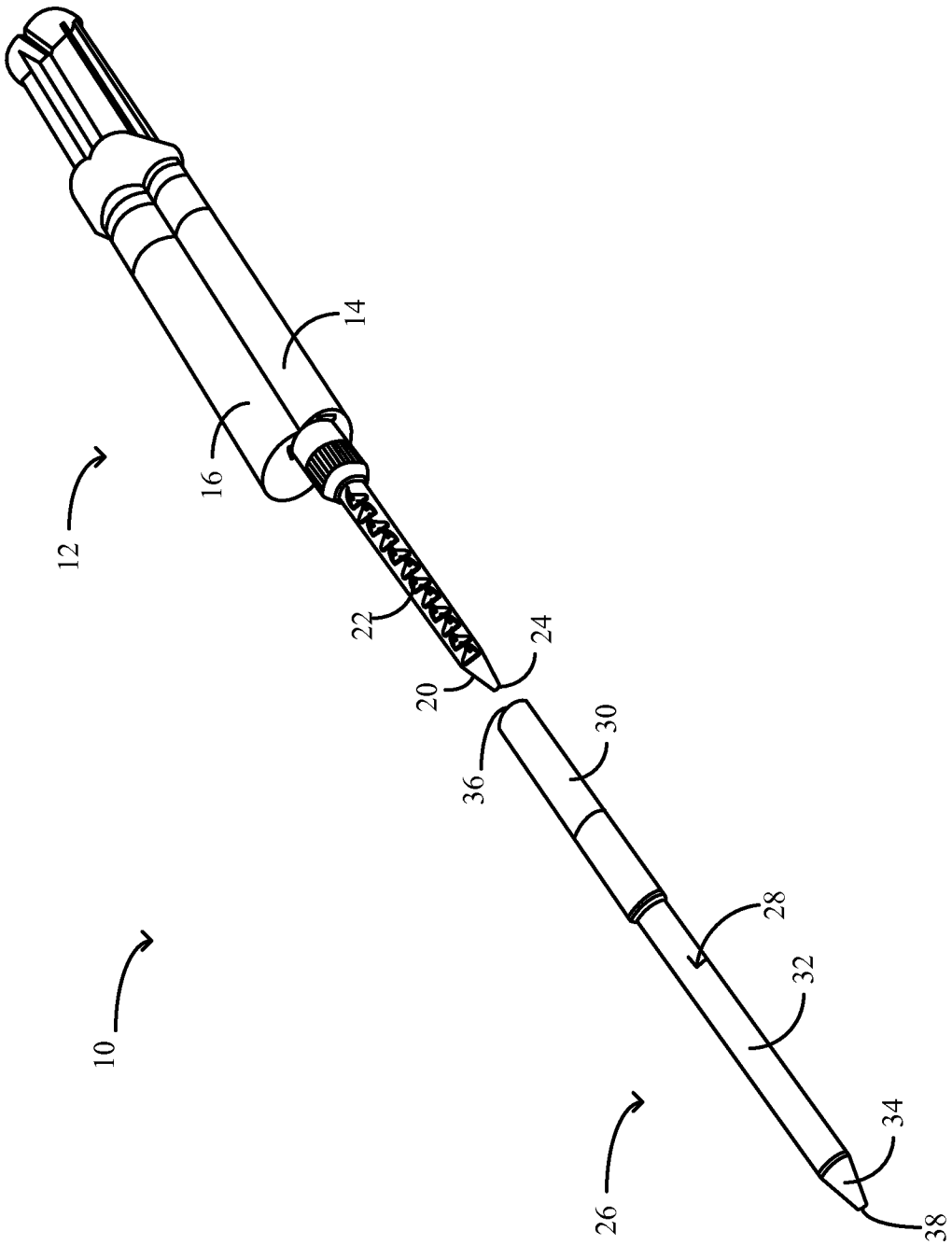

Fig. 1

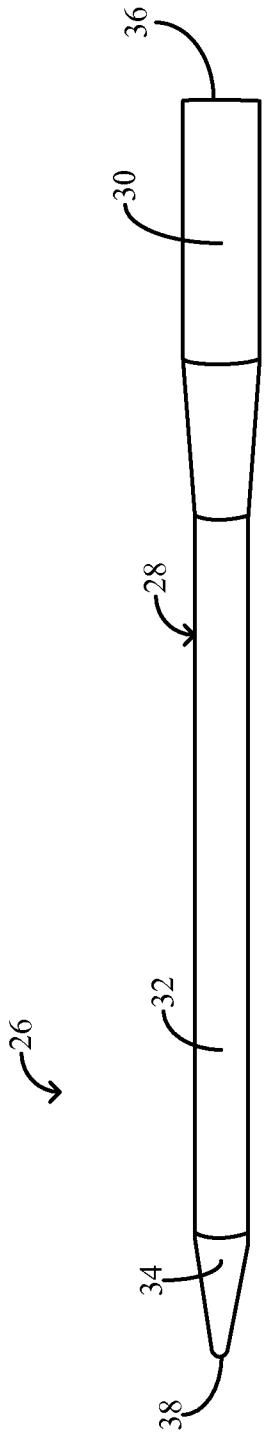

Fig. 2

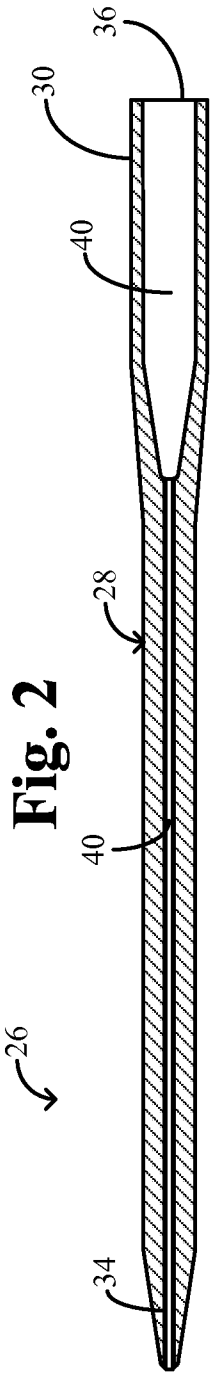

Fig. 3

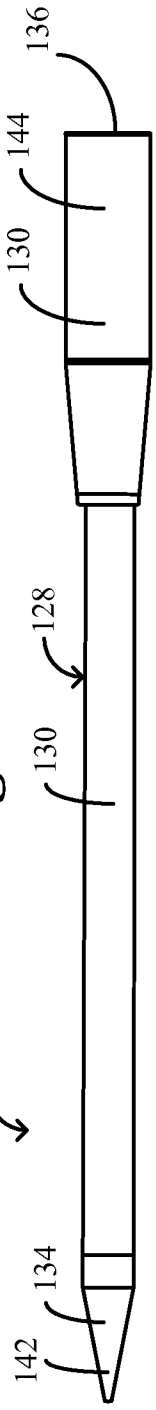

Fig. 4

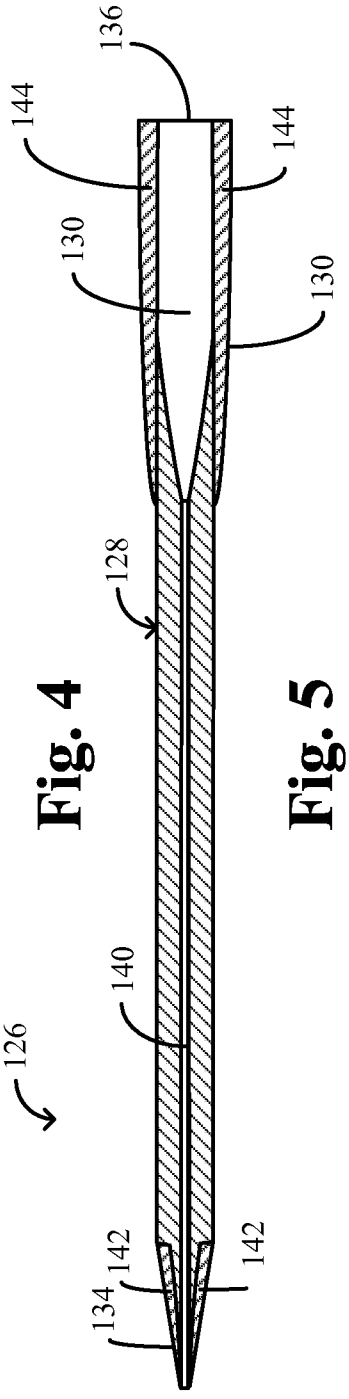

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/025940

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 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 practical, 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 99/17827 A2 (SCIMED LIFE SYSTEMS INC [US]) 15 April 1999 (1999-04-15) the whole document -----	1-17,20, 21 12-17
Y	US 4 979 942 A (WOLF STEPHEN J [US] ET AL) 25 December 1990 (1990-12-25) the whole document -----	12-17
X	WO 2008/014144 A2 (ETHICON INC [US]; FEINBERG MARC [US]; LIBERATORE JESSICA [US]; KOCHARI) 31 January 2008 (2008-01-31) figures -----	1-17,20, 21

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 June 2011	20/06/2011

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	Held, Günter

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/025940

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

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

1. [X] Claims Nos.: 18, 19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

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

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

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

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/025940

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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