



US006884232B1

(12) **United States Patent**
Hagmann et al.

(10) **Patent No.:** **US 6,884,232 B1**
(45) **Date of Patent:** **Apr. 26, 2005**

(54) **LAPAROSCOPIC SPRAY DEVICE AND METHOD OF USE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(21) Appl. No.: **10/698,714**

EP 0 424 068 A2 4/1991

(22) Filed: **Oct. 31, 2003**

(Continued)

(51) **Int. Cl.**⁷ **A61M 37/00**
 (52) **U.S. Cl.** **604/82**; 604/191; 604/83
 (58) **Field of Search** 604/191, 82, 83,
 604/85, 187, 86; 606/213, 214; 222/137,
 222/145, 6, 153.09, 459, 135; 239/399; 141/18,
 141/20; 206/219, 220

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(57)

ABSTRACT

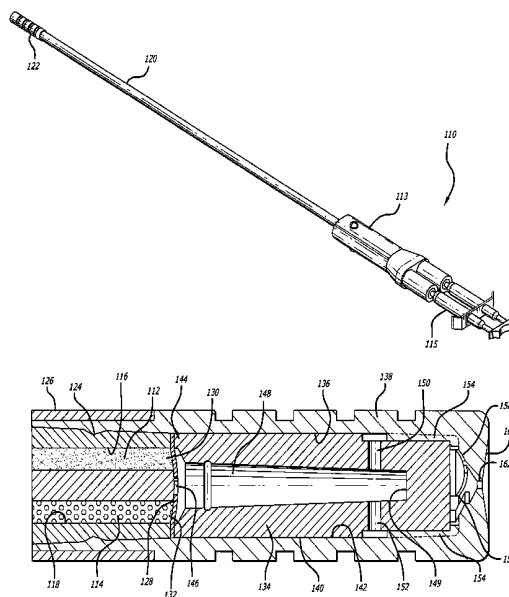
A laparoscopic spray device for selectively applying a multiple component material dispensed from a multiple component material applicator to a surgical site in vivo is disclosed. The device comprises an interface member capable of engaging a multiple component applicator, a body having at least two lumens therein, and a detachable spray tip in fluid communication with the body. The detachable spray tip includes a mixing chamber having at least one flexible mixing member positioned therein which is capable of creating a turbulent flow within a mixing chamber. In addition, the at least one mixing member prevents a back flow of material from the mixing chamber to the at least two lumens. The present invention is particularly useful in remotely applying multiple component tissue adhesives to an internal incision.

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13 Claims, 14 Drawing Sheets

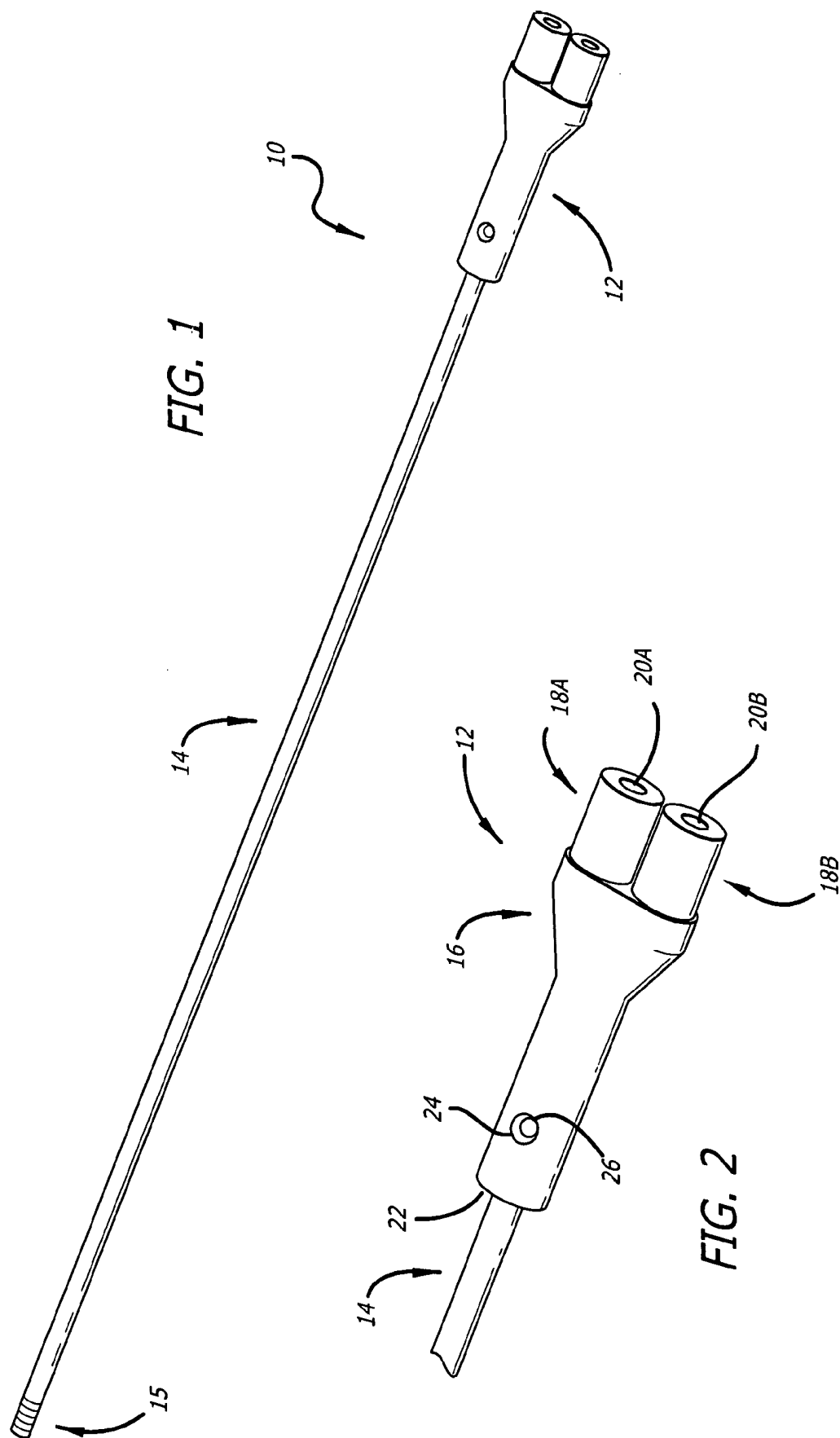


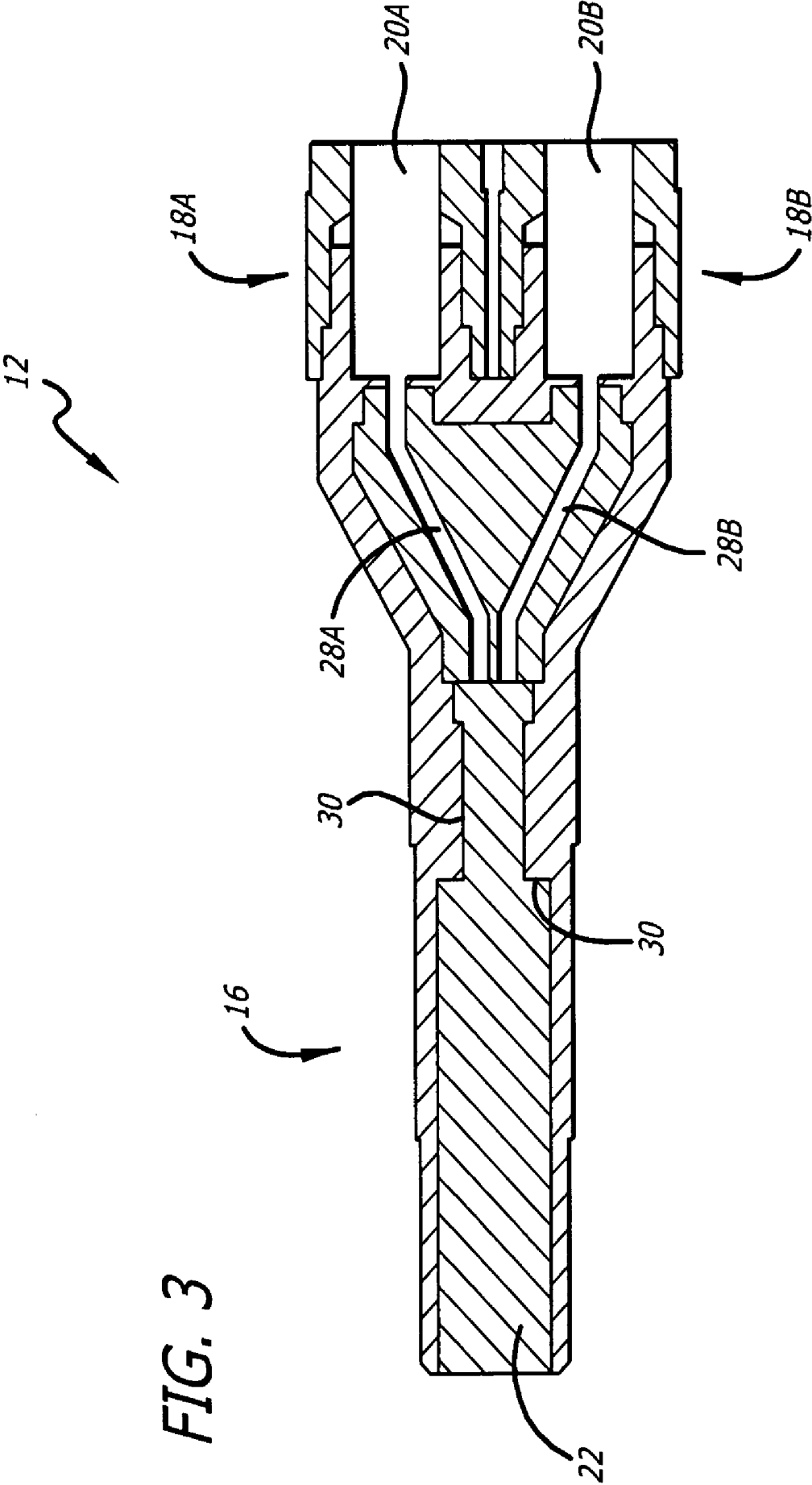
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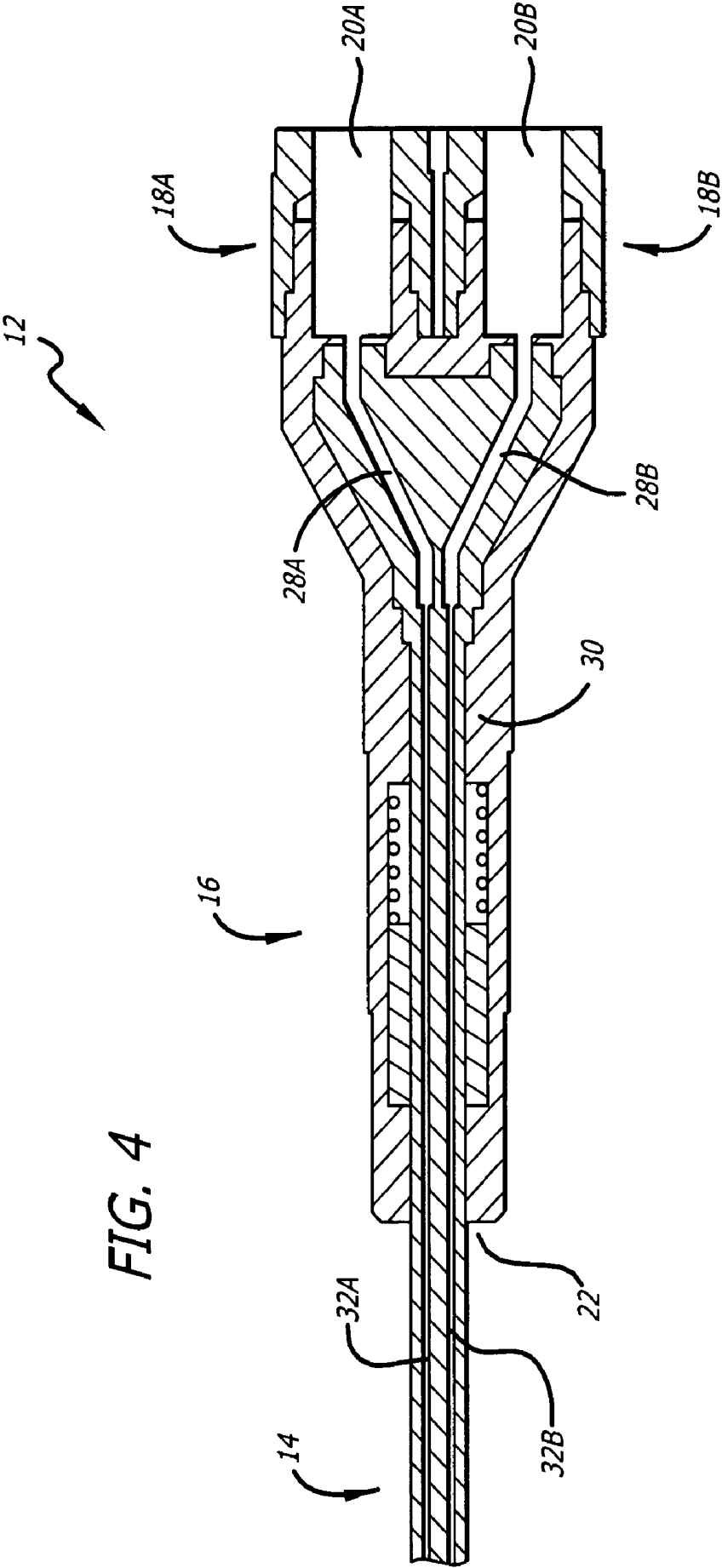
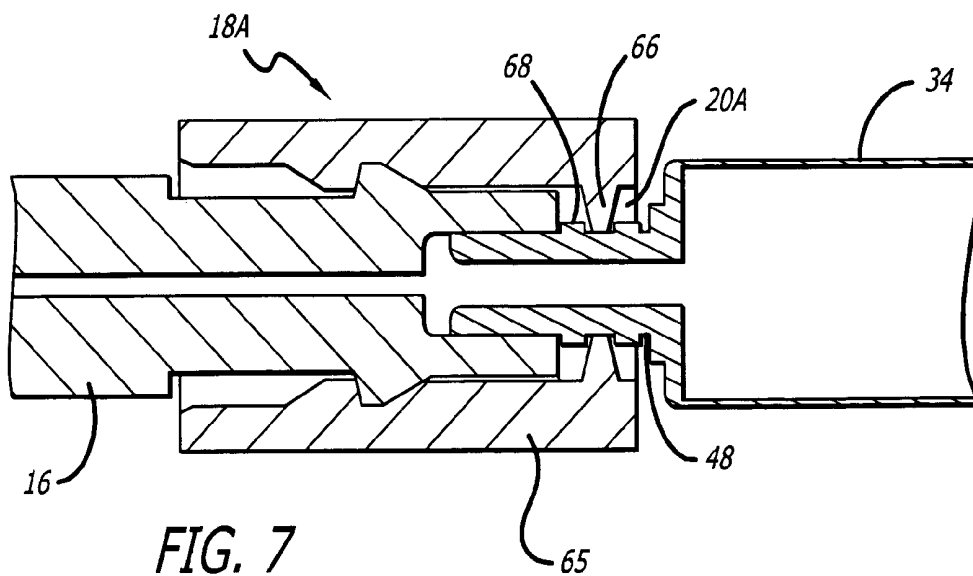
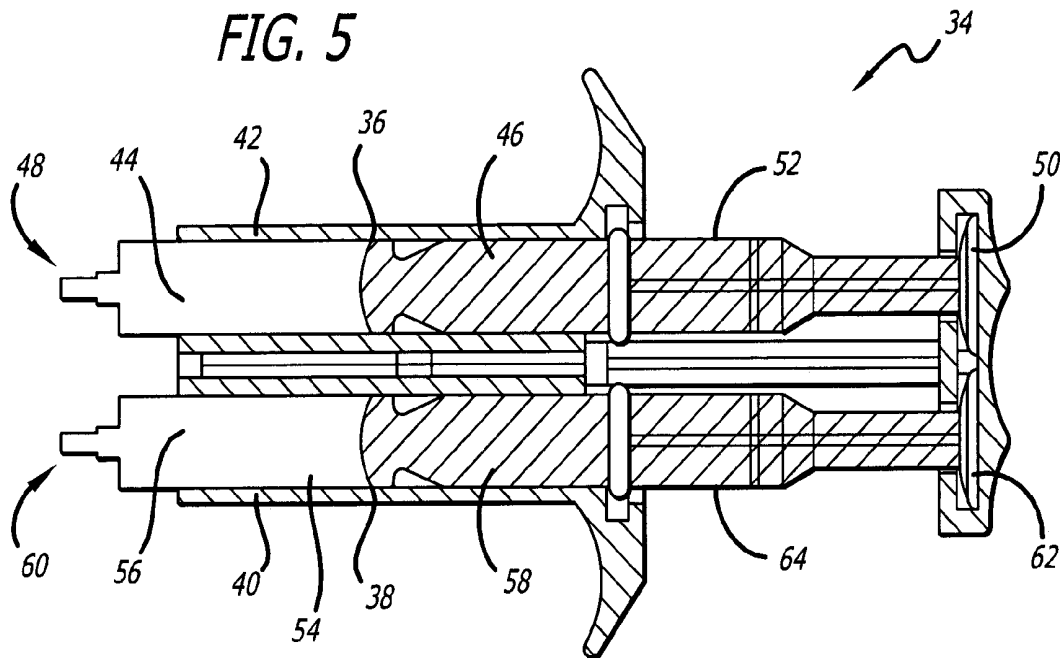


FIG. 5



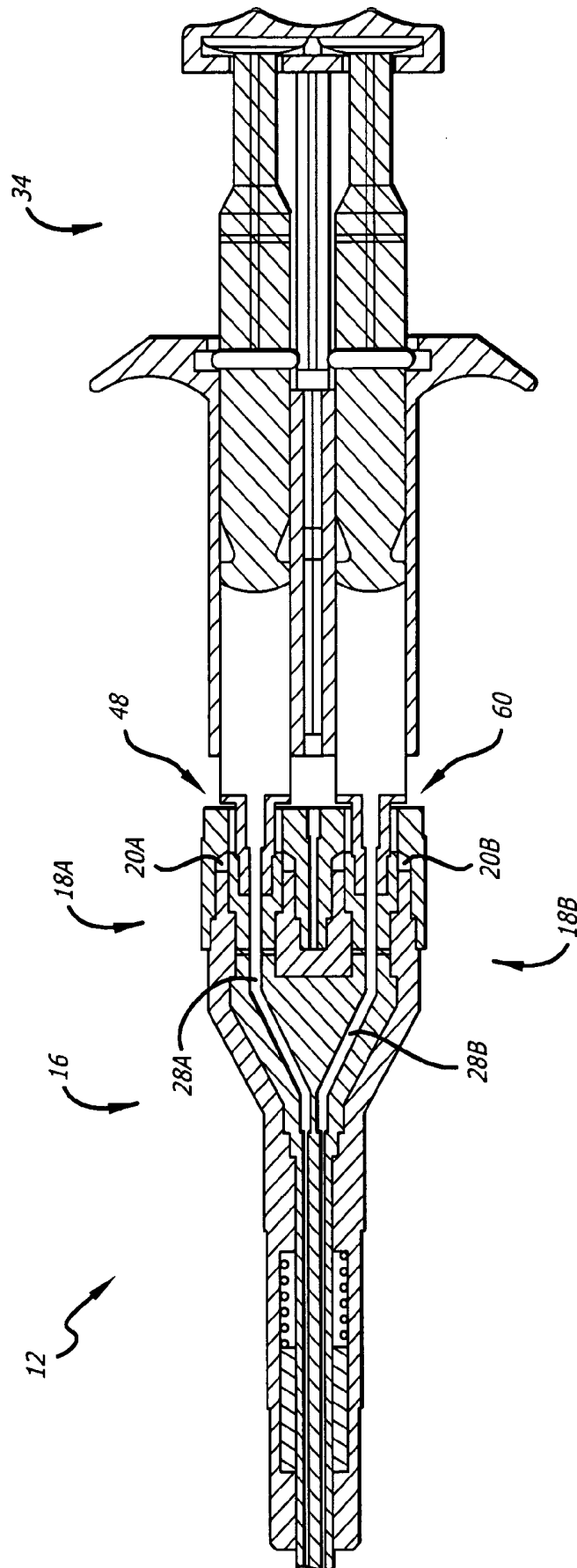
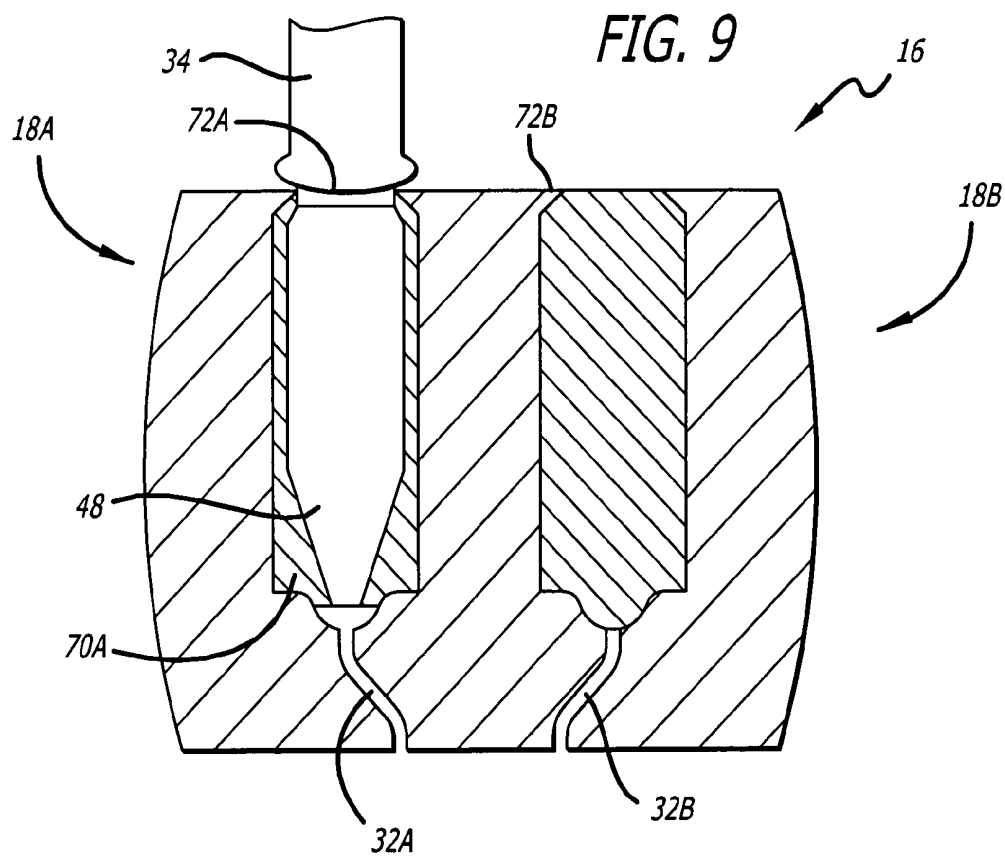
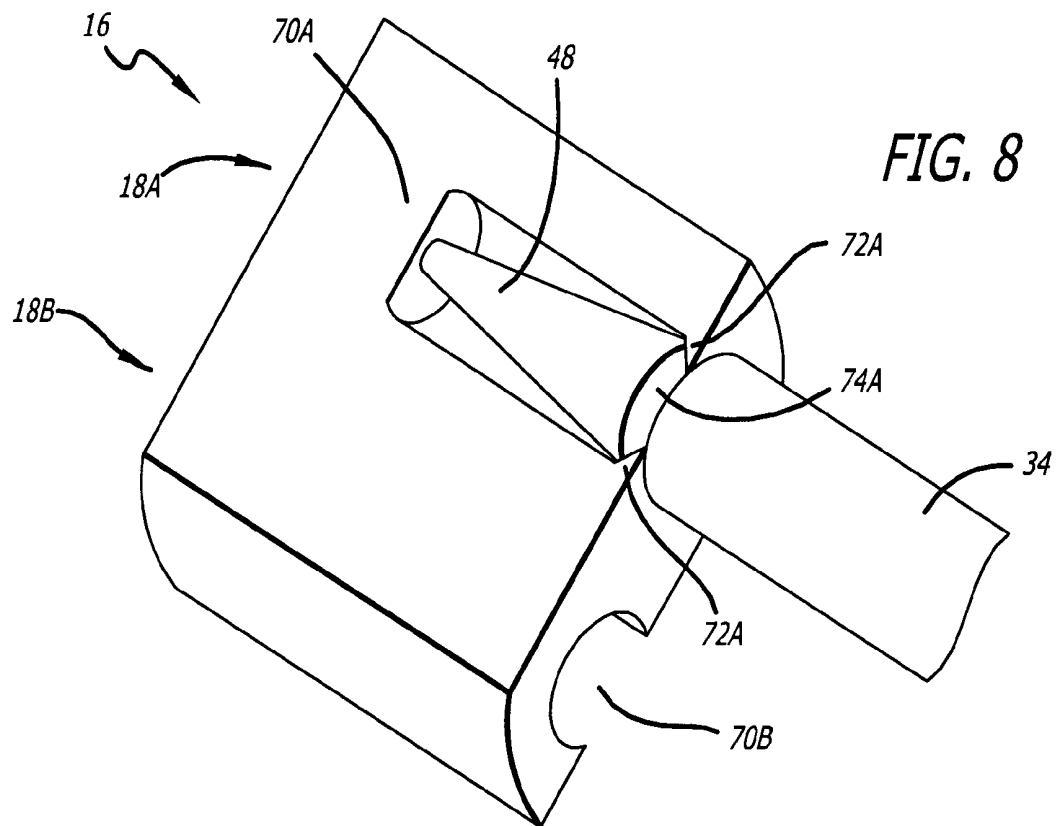


FIG. 6



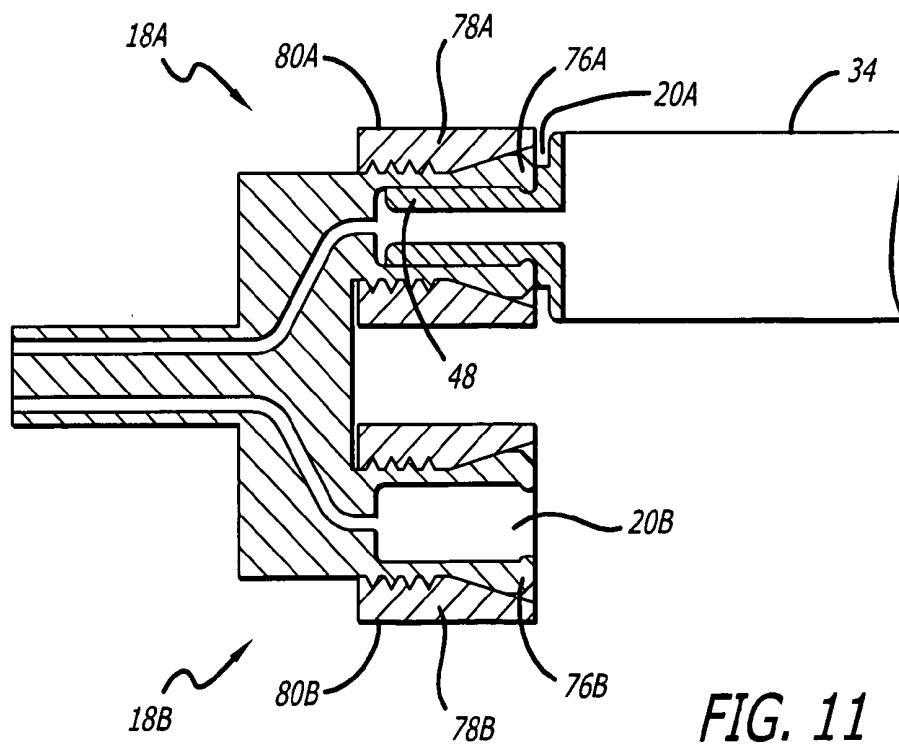
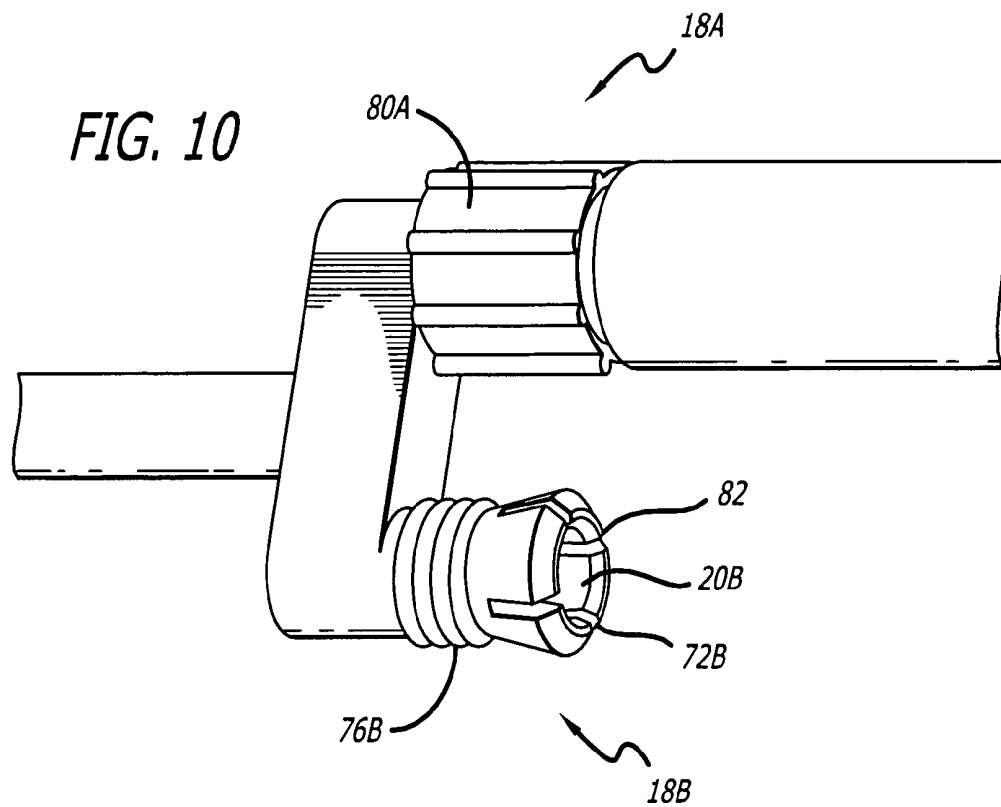


FIG. 11

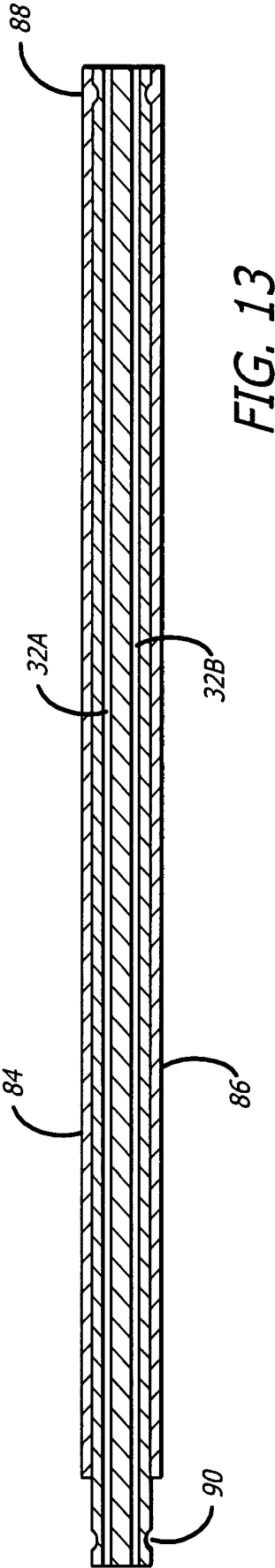
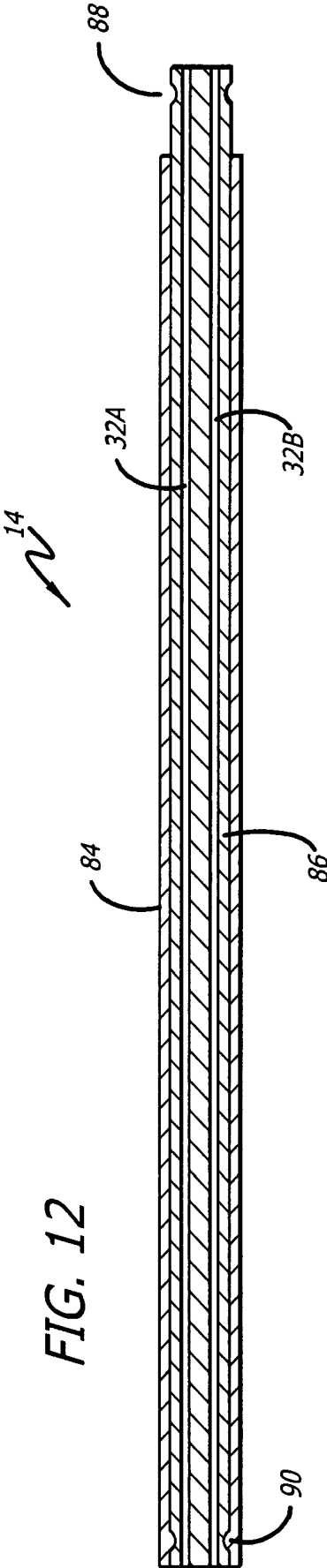


FIG. 14

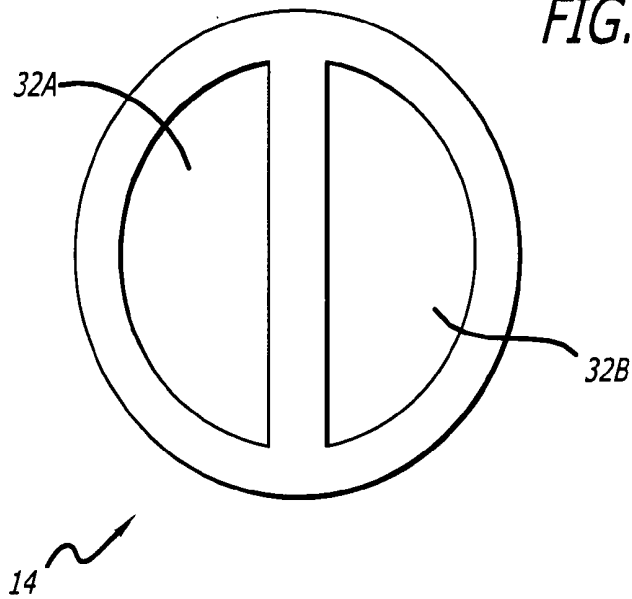


FIG. 15

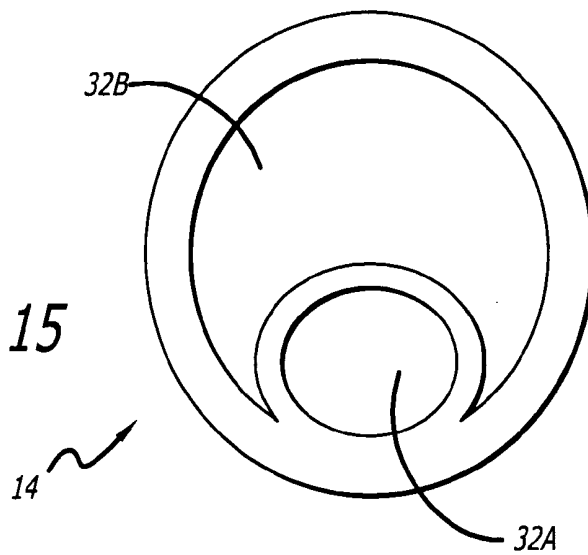
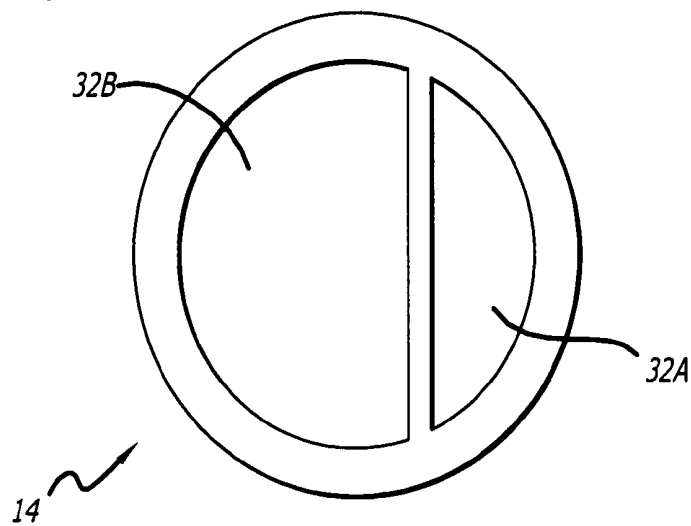


FIG. 16



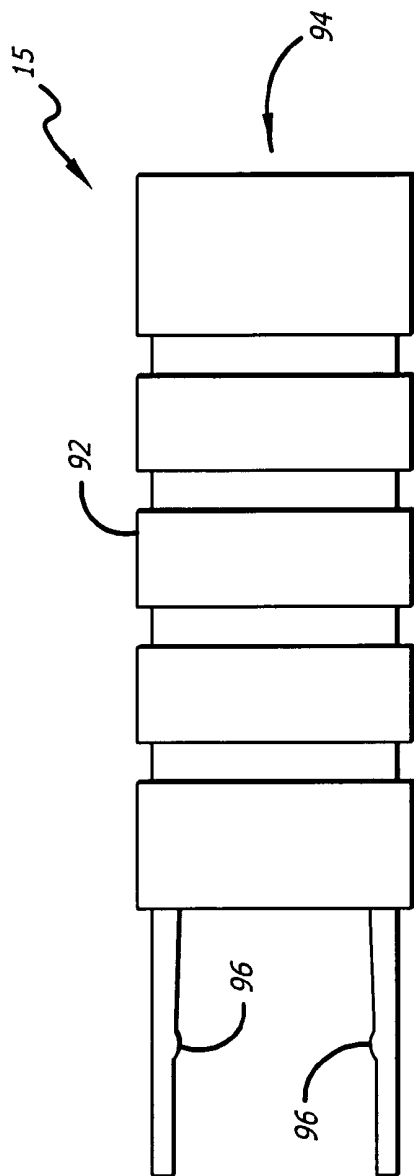


FIG. 17

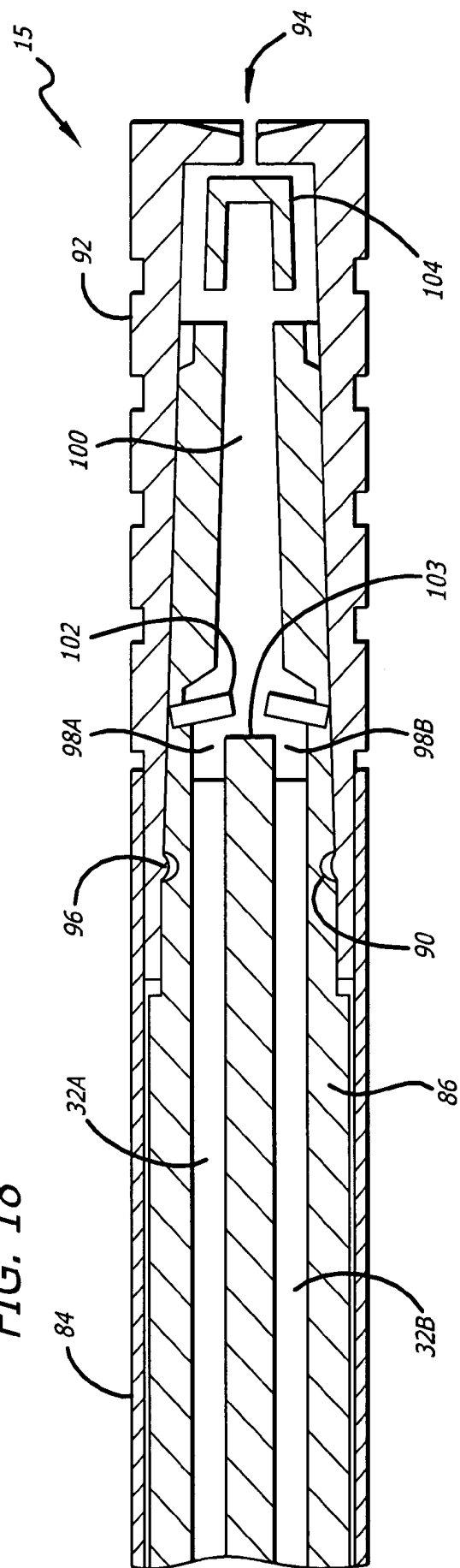


FIG. 18

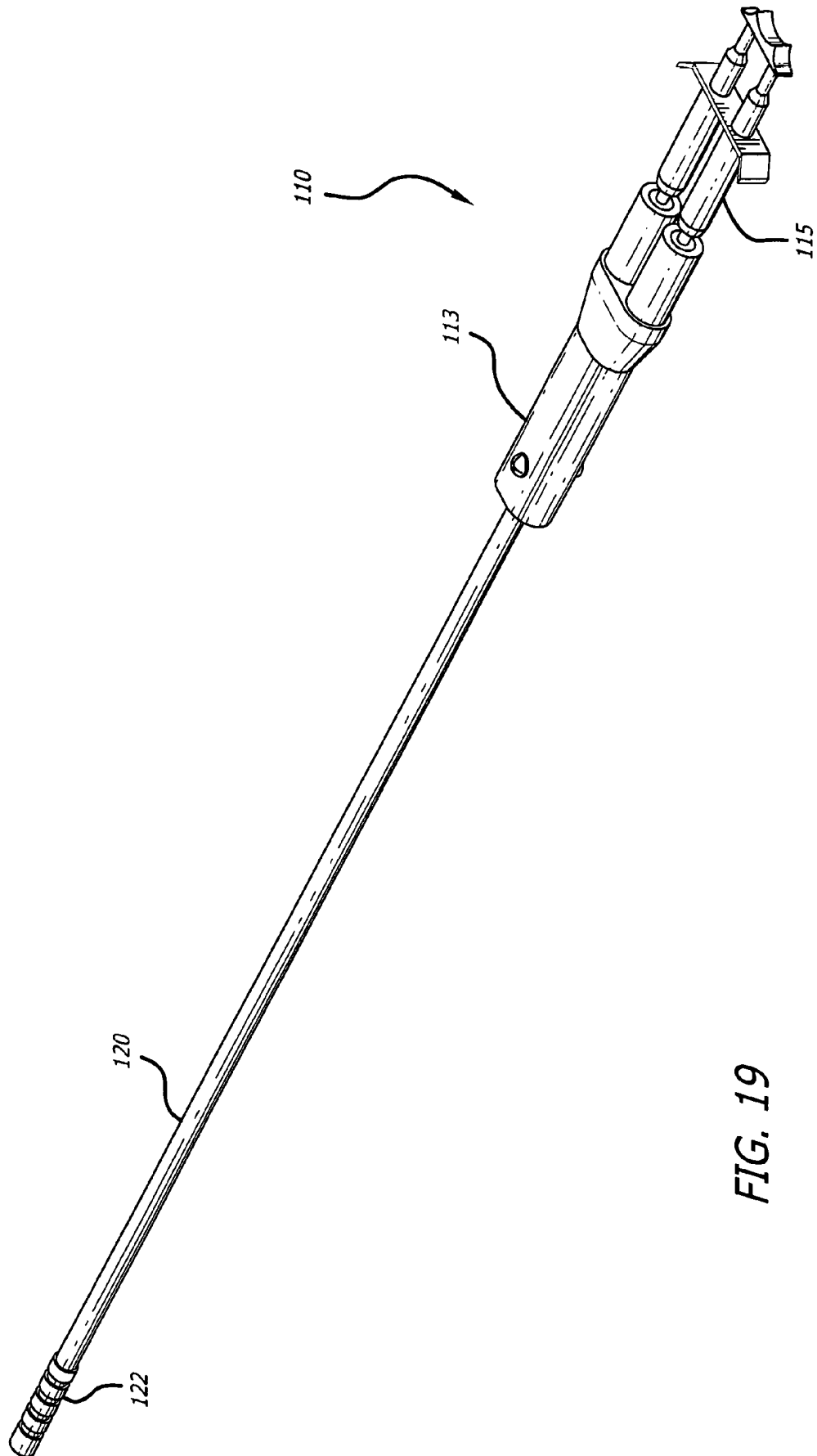


FIG. 19

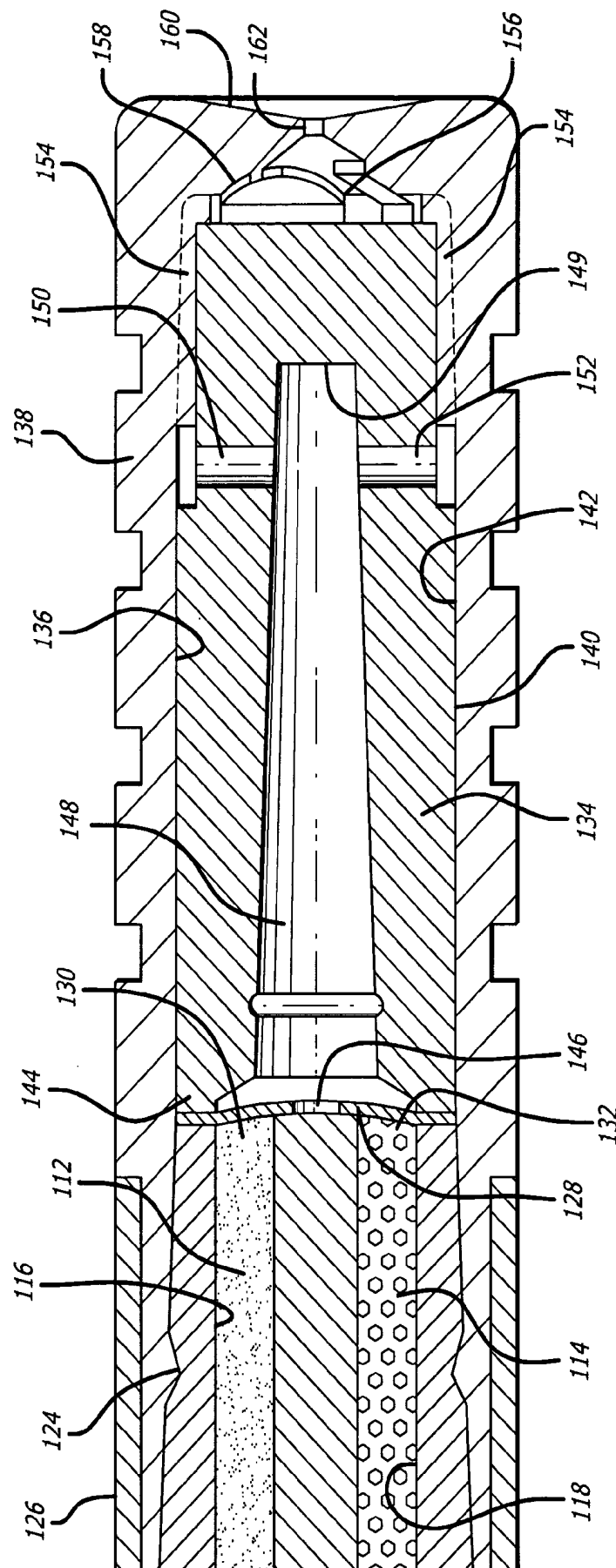


FIG. 20

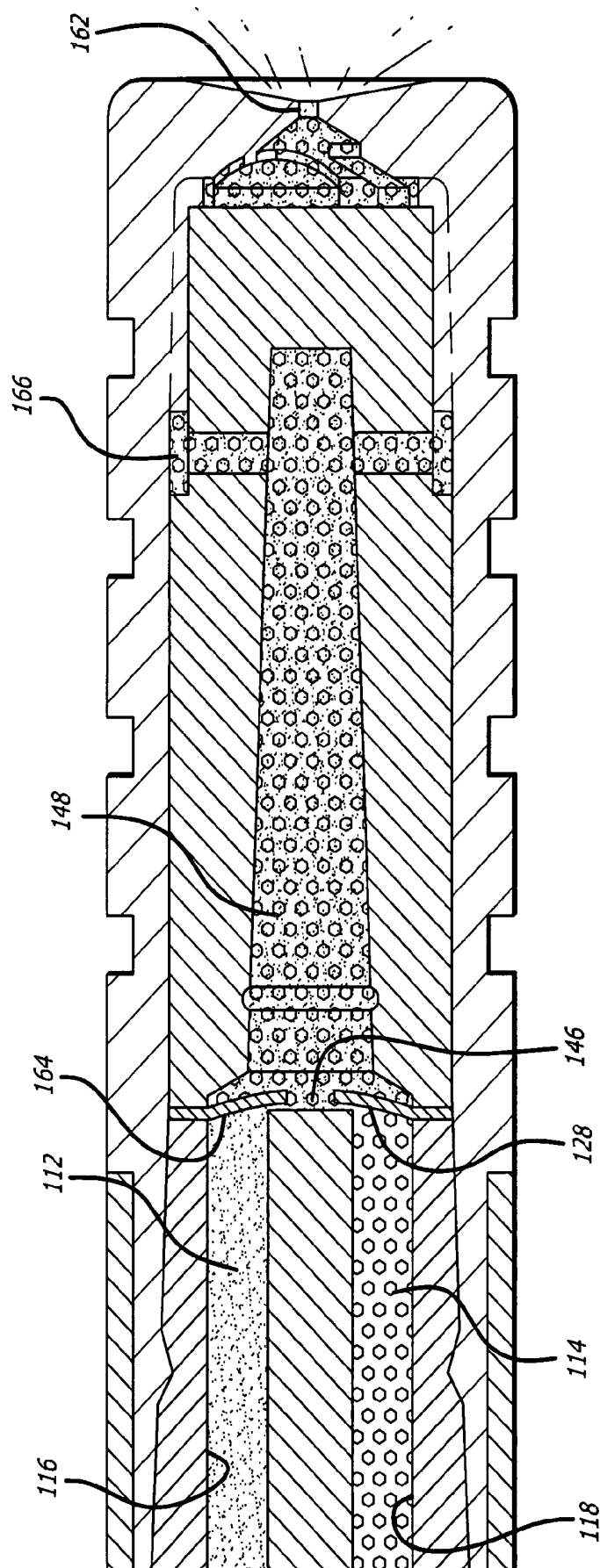
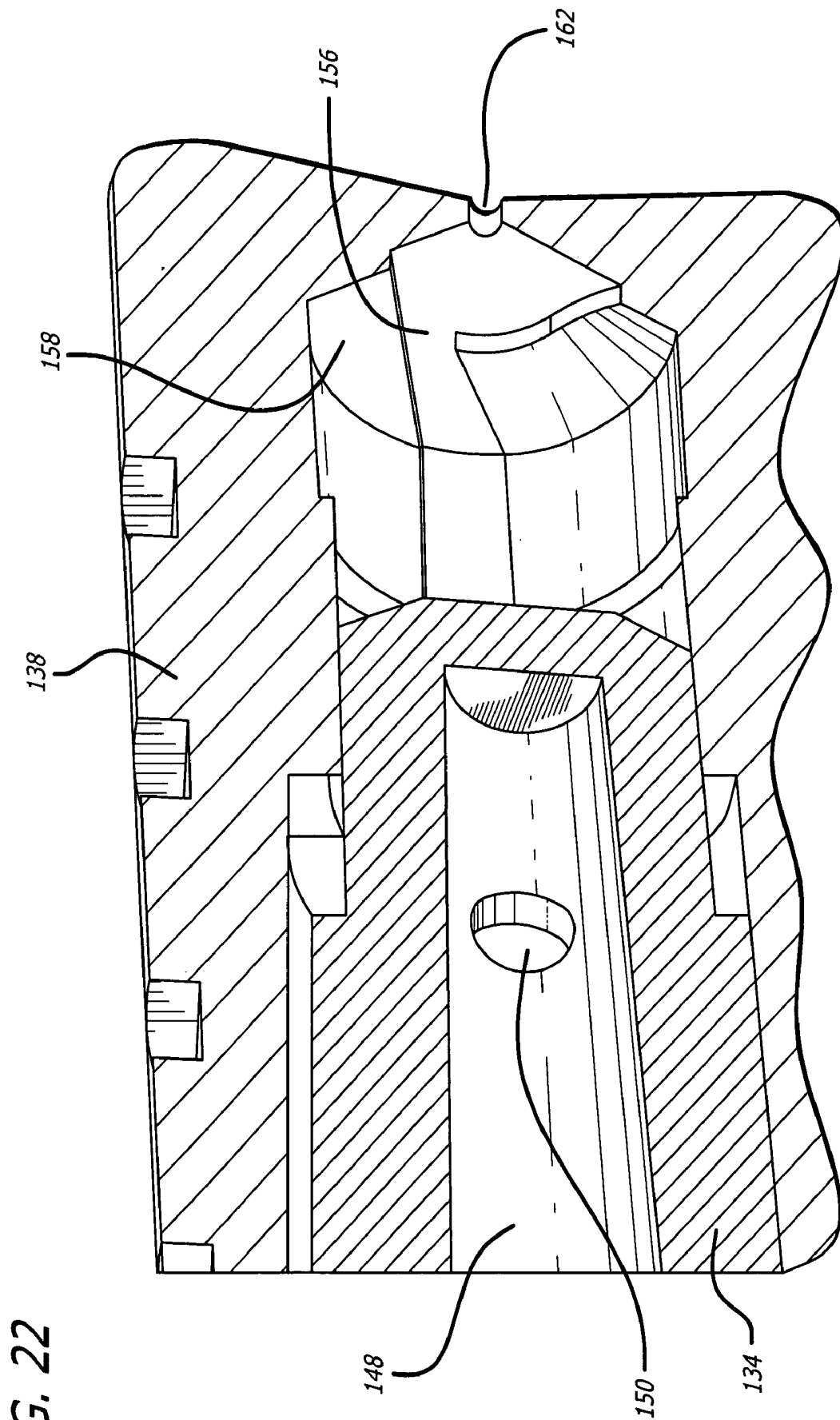


FIG. 21



LAPAROSCOPIC SPRAY DEVICE AND METHOD OF USE

BACKGROUND

In recent years, minimally invasive surgical techniques have emerged as an alternative to conventional surgical techniques to perform a plurality of surgical procedures. Minimally invasive procedures differ from conventional surgical procedures in that a plurality of devices may be introduced into the body through a small incision. As a result, trauma to the body is greatly reduced, thereby decreasing the recovery time of the patient.

One example of a common minimally invasive surgery involves laparoscopic surgical procedures. Laparoscopic procedures may be used to treat hernias, colon dysfunctions, gastroesophageal reflux disease, and gallbladder disorders. Typically, the patient undergoing the procedures will return home hours after undergoing surgery.

Generally, laparoscopic procedures require making at least one small incision in the patient's abdomen near the area of interest. A cannula or trocar may be inserted into the incision to limit blood loss and reduce the likelihood of infection. Thereafter, various surgical instruments are introduced into the patient's body through the incision. Generally, these instruments enable the surgeon to visualize the inside of the patient's body and access the internal organs of the patient. Current laparoscopic surgical instruments include cameras, scissors, dissectors, graspers and retractors. Generally, these instruments include a handle attached to an elongated body having a distal tip used to execute the particular procedure. The handle, which remains outside the patient's body, is used by the surgeon to control the operation of the instrument during the procedure.

One challenge presented when performing minimally invasive surgical procedures relates to closing an incision made within the patient's body by a cutting laparoscopic instrument. As opposed to conventional surgical procedures, the surgeon's access to the site of the incision is greatly reduced during minimally invasive procedures. As a result, several knot pushing devices capable of advancing suture knots formed outside the patient's body to an area of interest in vivo have been developed. Typically, a suturing laparoscopy device is inserted into the patient's body and advanced to the incised area.

A needle is advanced through the various tissue portions proximate the incision, thereby securing the suture material to the tissue. Thereafter, the suturing device is removed from the patient's abdomen leaving the suture material attached to the tissue. A knot is formed in the suture material and advanced along the suture material by the knot pusher to the incision, thereby applying the suture knot. The extraneous suture material is trimmed with laparoscopic scissors once the incision is adequately sutured. Occasionally, the suture knot becomes entangled in the suture material during the advancement process. The surgeon is then required to remove the entangled suture material from the incision area and reattach new suture material, thereby increasing the likelihood of infection and the patient's exposure to anesthesia.

Recently, the use of tissue sealants and other biological adhesive materials has emerged as an alternate technique of closing incisions. Preferred tissue sealants include fibrin, which is comprised of thrombin and a fibrinogen material, although other multiple component materials are available. Typically, the individual components of the adhesive material are stored in isolated reservoirs. When mixed, these

components may coagulate very quickly, yielding an adhesive gel within perhaps 10 or 20 seconds. When applied to the exterior of the body, or when considerable access to the application site is possible, the rapid coagulative properties of the tissue sealant are welcomed. Though desirable for use during minimally invasive procedures, such fast-acting properties of conventional tissue sealants and adhesive have presented potential problems of fouling or clogging during the application of tissue sealants through laparoscopic devices, which typically results in the destruction of the device.

Thus, there is a need for a device capable of effectively delivering a multiple component tissue sealant to a location in vivo through from a remote location.

SUMMARY

Embodiments of the present invention enable a user to apply a multiple component material to an incision site within the patient's body from a remote location without the fouling or clogging problems associated with prior art devices. In one aspect, the present invention provides a laparoscopic spray device comprising an interface member or manifold capable of detachably coupling to a multiple component material applicator, an elongated body or delivery shaft having at least two lumens formed therein in fluid communication with the interface member, and a detachable spray tip having a mixing chamber therein coupled to the elongated body useful in generating a spray to apply the material in vivo. The spray tip assembly may also include a flexible mixing member adjacent the mixing chamber. The flexible mixing member may generate a turbulent flow within the mixing chamber, thereby resulting in impingement mixing of the components of the multiple component material. In addition, the at least one flexible mixing member may be used to prevent a back flow of material from the mixing chamber to the at least two lumens within the elongated body. Those skilled in the art will appreciate that a material applicator may be coupled to the present invention in a plurality of ways, including, without limitation, in slip-fit relation, in Luer-lock relation, and in screw-like relation.

In another embodiment, the laparoscopic spray device comprises an interface member capable of detachably coupling to a material applicator, an elongated body having at least two lumens therein in fluid communication with the at least two transport lumens within the interface member, and a spray tip having a mixing chamber containing at least one mixing member therein detachably coupled to and in fluid communication with the elongated body. The interface member further comprises at least two coupling members having at least two receiving apertures formed therein. The receiving apertures are capable of coupling to the material applicator and are in fluid communication with at least two transport lumen positioned within the interface member.

The elongated body comprises a stationary inner body member positioned within a longitudinally slide-able outer body member. The stationary inner body includes a spray tip receiver adapted to receive a detachable spray tip. The slide-able outer body is capable of being advanced and retracted to cover and expose, respectively, the spray tip receiver. The at least one flexible mixing member of the present invention is capable of generating turbulent flow within the mixing chamber, thereby resulting in impingement mixing of the components of the multiple component material. In addition, the at least one flexible mixing mem-

ber may be used to prevent a back flow of material from the mixing chamber to the at least two lumens within the elongated body.

Embodiments of the present invention also provide a method of mixing a multiple component material with at least one flexible mixing member. To practice the present invention the user positions at least one flexible mixing member proximate to the entrance of a material mixing chamber. The mixing chamber is attached to at least two component lumens which are in fluid communication with a multiple component source. The individual components are advanced through the separate lumens towards the mixing chamber. Thereafter, the at least one flexible mixing member engages the individual components and forces the components together, thereby generating turbulent flow within the mixing chamber. The generation of turbulent flow within the mixing chamber results in impingement mixing of the components which yields a mixed material. In addition to enhancing the impingement mixing effects, the at least one flexible mixing member prevents the back flow of material from the mixing chamber to the at least two component lumens. Thereafter, the mixed material is advanced through an aperture formed in the mixing chamber and applied to a work surface.

Another embodiment includes a laparoscopic spray device for mixing and applying a multiple component agent to a target site having a first fluid reservoir containing a first component and a second fluid reservoir containing a second component. An elongated delivery shaft has a proximal end, a distal end, and at least two fluid delivery channels in fluid communication with the first and second fluid reservoirs. A spray tip assembly is detachably coupled to the distal end of the elongated delivery shaft and has a sealing member disposed at a proximal end of the spray tip assembly that seals distal ports of the fluid delivery channels of the elongated delivery shaft when the sealing member is in a relaxed state. The sealing member is configured to allow fluid flow from the distal ports when pressure is applied to the sealing member. An elongated mixing chamber is in fluid communication with the fluid delivery channels when pressure is applied to the first and second components in the fluid delivery channels.

Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The apparatus of the present invention will be explained in more detail by way of the accompanying drawings, wherein:

FIG. 1 shows a perspective view of the laparoscopic spray device of the present invention;

FIG. 2 shows a perspective view of the interface member of the present invention;

FIG. 3 shows a cross-sectional view of the interface member of the present invention;

FIG. 4 shows a cross-sectional view of the interface member attached to the elongated body of the present invention;

FIG. 5 shows a cross-sectional view of a multiple syringe material applicator useful in applying a multiple component material to a work surface;

FIG. 6 shows a cross-sectional view of a multiple syringe material applicator coupled to the interface member of the present invention;

FIG. 7 shows an expanded cross-sectional view of an embodiment of the interface member of the present invention engaging a dispensing tip of a multiple syringe material applicator;

FIG. 8 shows a perspective of another embodiment of the interface member of the present invention engaging a dispensing tip of a multiple syringe material applicator;

FIG. 9 shows a cross-sectional view of the embodiment of FIG. 8 wherein the interface member of the present invention is engaging a dispensing tip of a multiple syringe material applicator;

FIG. 10 shows a perspective of yet another embodiment of the interface member of the present invention engaging a dispensing tip of a multiple syringe material applicator;

FIG. 11 shows a cross-sectional view of the embodiment of FIG. 10 wherein the interface member of the present invention is engaging a dispensing tip of a multiple syringe material applicator;

FIG. 12 is a cross-section view of the elongated body of the present invention wherein the slidable outer sleeve is positioned over the spray tip receivers;

FIG. 13 is a cross-section view of the elongated body of the present invention wherein the slidable outer sleeve is positioned over the attachment channel;

FIG. 14 is a cross-section view of the at least two lumens located within the elongated body of the present invention;

FIG. 15 is a cross-section view of an alternate embodiment of the at least two lumens located within the elongated body of the present invention;

FIG. 16 is a cross-section view of another embodiment of the at least two lumens located within the elongated body of the present invention;

FIG. 17 is a side view of the detachable spray tip of the present invention; and

FIG. 18 is a cross-section view of the detachable spray tip of the present invention;

FIG. 19 is a perspective view of another embodiment of a laparoscopic spray device;

FIG. 20 is an elevational view in partial section of a spray tip assembly of the laparoscopic spray device of FIG. 19;

FIG. 21 depicts the spray tip assembly of FIG. 20 in use; FIG. 22 is an enlarged view in section of a distal portion of the spray tip assembly of FIG. 19.

DETAILED DESCRIPTION

Embodiments of a laparoscopic spray device having features of the present invention are used in conjunction with a multiple component applicator to dispense a multiple component fluid to a work surface located within the body of a patient. Embodiments may be used to dispense a multiple component tissue sealant, such as Fibrin, which is capable of effecting hemostasis or achieving other therapeutic results. Embodiments are designed to permit the remote application of a multiple component fluid and may be adapted to functionally couple to a plurality of applicators, including, for example, multiple reservoir syringe-type applicators such as the DUPLOJECT™ syringe-type applicator manufactured by the Baxter Healthcare Corporation. Embodiments may also include a laparoscopic spray device capable of functionally coupling with a plurality of applicators in a plurality of sizes. Some of the exemplary embodiments disclosed herein may be similar to or the same as embodiments disclosed in co-pending U.S. application Ser. No. 09/972,495, titled "Laparoscopic Spray Device and Method of Use", filed Oct. 5, 2001, by Spero et al., which is incorporated by reference herein in its entirety.

FIG. 1 shows a perspective view of an embodiment of the present invention. As shown, the laparoscopic spray device 10 comprises an interface member 12 in fluid communication with an elongated body 14 having a spray head 15 attached thereto. Those skilled in the art will appreciate that the present invention may be manufactured from a plurality of materials, including, without limitation, polyethylene, polypropylene, polystyrene, or a like material. A plurality of materials having different physical properties may be used to manufacture various portions of the present invention. For example, the interface member 12 and elongated body 14 may be made rigid, while the spray tip 15 is resilient. In an alternate embodiment, the interface member 12 may be manufactured from a rigid material while the elongated body 14 and spray tip 15 is resilient.

FIG. 2 shows a perspective view of the interface member 12 of the present invention. The interface member 12 comprises a member body 16 in communication with at least two coupling members 18A, 18B. A first receiving aperture 20A is formed within the first coupling member 18A. Similarly, a second receiving aperture 20B is formed within the second coupling member 18B. The receiving apertures 20A, 20B are sized to receive a material applicator (not shown). Those skilled in the art will appreciate that the interface member 12 may be manufactured in a plurality of sizes to receiving a plurality of material applicators. The interface member 12 further includes an elongated body receiver 22 which is in communication with an attachment device aperture 24 sized to receive an attachment device 26 therein. The attachment device 26 removably couples the interface member 12 to the elongated body 14. The exemplary attachment devices 26 may include, without limitation, screws and buttons.

FIGS. 3-4 show several cross sectional views of the interface member 12. The receiving apertures 20A, 20B located within the coupling members 18A, 18B are in fluid communication with at least two transport lumens 28A, 28B located within the member body 16. As shown, the transport lumens 28A, 28B have a uniform diameter. In an alternate embodiment the transport lumens 28A, 28B may have different diameters. The transport lumens 28A, 28B terminate within the elongated body receiver 22. As shown in FIGS. 3 and 4, the elongated body receiver 22 includes at least one aligning member 30 therein. The aligning member 30 ensures that the at least two lumens 32A, 32B formed in the elongated body 14 are aligned with and are in fluid communication with the transport lumens 28A, 28B within the interface member 12. In addition, the aligning member 30 may apply a constrictive force to the elongated body 14, thereby assisting in the retention thereof.

FIG. 5 shows a cross-sectional view of an exemplary material applicator 34 capable of coupling to the present invention. As shown, the material applicator 34 comprises at least a first syringe device 36 and a second syringe device 38 coupled by a syringe coupler 40. It should be understood that the material applicator 34 of the present invention may comprise a plurality of material reservoirs, and the present embodiment should not be construed as limiting.

The first syringe device 36 comprises a first syringe reservoir 42 storing a first component 44 and a first syringe piston 46, positionable within the first syringe reservoir 42. The first syringe device 36 has a first syringe dispensing tip 48 connected to the first syringe reservoir 42 extending beyond the syringe coupler 40 and a first syringe pusher 50, which is attached to the first piston rod 52.

Likewise, second syringe device 38 comprises a second syringe reservoir 54 storing a second component 56 and a

second syringe piston 58, positionable within the second syringe reservoir 54. The second syringe device 38 has a second syringe dispensing tip 60 connected to the second syringe reservoir 54 extending beyond the syringe coupler 40, and a second syringe pusher 62, which is attached to the second piston rod 64.

The coupling members 18A, 18B of the present invention may couple to the material applicator 34 in a plurality of ways, including, in screw-able relation or snap-fit relation. FIG. 6 shows one embodiment of the interface member 12 of the present invention coupled to a material applicator 34. As shown, the syringe dispensing tips 48, 60 are slidably positioned within the coupling members 18A, 18B, in a luer-lock relation. In one embodiment the coupling members 18A, 18B are manufactured from a resilient material such as a biologically compatible elastomer, thereby permitting the coupling members 18A, 18B to resiliently receive the dispensing tips 48, 60. Those skilled in the art will appreciate that the receiving apertures 20A, 20B formed in the coupling members 18A, 18B may be tapered to ensure that a sealable interface between the interface member 16 and the applicator 34 is obtained. In an alternate embodiment, the receiving apertures 20A, 20B is not tapered.

An alternate embodiment of the coupling members 18A, 18B is shown in FIG. 7. A coupling member 18A is shown, which comprises a rotate-able threaded sleeve 65 and includes a lock member 66 positioned within the receiving aperture 20A. The lock member 66 engages a tip thread 68 located on the dispensing tip 48 in a screw-like relation.

FIGS. 8 and 9 show an alternate embodiment of the coupling members of the present invention. As shown, the coupling members 18A, 18B may comprise engaging channels 70A, 70B formed in the member body 16. The receiving channels 70A, 70B include at least one lock ridge 72A, 72B positioned within each receiving channel 70A, 70B. The lock ridge 72A, 72B slide-ably engages at least one engaging channel 74A, 74B formed on the dispensing tips 48, 60 of the material applicator 34.

FIGS. 10 and 11 show yet another embodiment of the coupling members 18A and 18B. As shown, the coupling members 18A, 18B each include a compressible collet 76A, 76B therein. Each collet 76A, 76B, which defines a receiving aperture 20A, 20B sized to be a slightly larger diameter than the inside diameter of the threaded outer sleeve 80A, 80B, includes a threaded base 78A, 78B. As shown, each collet 76A, 76B is tapered and includes a plurality of compression slits 82 positioned radially around the collet. During use each dispensing tip 48, 60 is inserted into the receiving aperture 20A, 20B defined by the individual collet 76A, 76B. Thereafter, the threaded outer sleeve 80A, 80B is positioned to engage the threaded base 78A, 78B and rotated. As a result, the threaded outer sleeve 80A, 80B forcibly compresses the collet 76A, 76B thereby decreasing the diameter of the receiving aperture 20A, 20B and applying a retentive force to the dispensing tips 48, 60 of the material applicator 34 positioned therein. Those skilled in the art will appreciate the dispensing tips 48, 60 of the material applicator 34 may, but need not, include a retaining channel (not shown) thereon.

FIG. 12 shows a cross-sectional view of the elongate body 14. As shown, the elongated body 14 includes a longitudinally slide-able outer sleeve 84 positioned around a stationary inner body 86. At least two elongated body lumens 32A, 32B are positioned within the inner body 86. The at least two elongated body lumens 32A, 32B are capable of engaging the transport lumens 28A, 28B positioned within the interface member 12. An attachment channel 88 is formed on the

elongated body **14** thereby enabling the elongated body to engage attachment device **26** positioned on the interface member **12**. The distal portion of the elongated body **14** includes a spray tip receiver **90** capable of receiving a detachable spray tip (not shown) thereon. As shown in FIG. **13**, the outer sleeve **84** may be slidably retracted towards the attachment channel **88** thereby exposing the spray tip receiver **90**.

The elongated body lumens **32A**, **32B** positioned within the elongated body **14** may be formed in a plurality of shapes, including, without limitation, circular lumens and D-shaped lumens. FIG. **14** shows one embodiment wherein the elongated body lumens **32A**, **32B** are D-shaped. Those skilled in the art will appreciate that the D-shaped elongated body lumens **32A**, **32B** of the present embodiment allow a larger cross sectional area for the lumen in a smaller overall diameter shaft. As a result, less force is required to advance the individual components through the device with a flow rate sufficient to permit the sprayed application of the multiple component material.

As shown in FIG. **14**, the elongated body lumens **32A**, **32B** positioned within the elongated body **14** may have uniform diameters. Commonly, the individual components comprising the multiple component materials may have different viscosities and flow rates, or may require a disproportionate amount of one component in relation to another component. As such, in an alternate embodiment of the present invention the elongated lumens **32A**, **32B** may be different diameters to accommodate the different viscosities and flow rates of the component materials, or to account for the uneven distribution of one component in relation to another component. FIGS. **15** and **16** show cross-sectional views of alternate embodiments of the present invention wherein the elongated lumens **32A**, **32B** have different diameters to account for different viscosities and flow rate of individual components, or to dispense a disproportionate amount of one component in relation to another component. Similarly, the transport lumens **28A**, **28B** may also have different diameters or shapes as well. As shown in FIG. **15**, the first elongated body lumen **32A** has a diameter considerably smaller than the diameter of the second elongated body lumen **32B**. Therefore, the device **10** will transport a greater volume of component material through the second elongated body lumen **32B** with respect to the first elongated body lumen **32A**. Similarly, FIG. **16** shows another embodiment of the present invention wherein the second elongated body lumen **32B** is capable of transporting a larger volume of material therethrough with respect to the first elongated body lumen **32A**.

FIGS. **17** and **18** show various views of the detachable spray tip **15**. As shown in FIG. **17**, the exterior of the spray tip **15** includes a tip body having a spray aperture **94** formed therein. The spray tip **15** further includes at least one low-profile mounting member **96** attached thereto, thereby enabling the spray tip **15** to detachably mount to the elongated body **14**. The spray tip may be manufactured from a plurality of materials, including, for example, biologically-compatible elastomers, plastics, and metals.

FIG. **18** shows a cross sectional view of the detachable spray tip **15** coupled to the elongated body **14**. As shown, the at least one mounting member **96** is located between the outer body **84** and the stationary inner body **86** of the elongated body **14**, and is engaging the spray tip receiver **90**. The detachable spray tip **15** of the present invention may detachably couple to the elongated body **14** in a plurality of

ways, including, in snap-fit relation. At least two lumen receivers **98A**, **98B** receive the elongated body lumens **32A**, **32B**.

The spray tip **15** further includes a mixing chamber **100** which is in communication with the at least two lumen receivers **98A**, **98B**. At least one flexible mixing member **102** is positioned within the mixing chamber **100**, proximate to the at least two lumen receivers **98A**, **98B**. The at least one flexible mixing member **102** assists in causing impingement mixing of the at least two material components by forming a turbulent flow within the mixing chamber **100**. During use, the individual components are advanced through the elongated body lumens **32A**, **32B** and individually engage the at least one mixing member **102** positioned within the mixing chamber **100**. The force applied by the advancement of the individual components forces the at least one flexible mixing member **102** to flex in response thereto. The at least flexible mixing member **102** provides sufficient resistance to the applied force so as to form a narrowing element within the mixing chamber **100** and thereby force the individual components together within the mixing chamber **100**. The resistance applied by the at least one flexible mixing member **102** in addition to the forward advancement of the material results in generation of turbulent flow within the mixing chamber **100**. In addition to forming turbulent flow within the mixing chamber **100**, the resilient nature of the at least one flexible mixing member **102** prevents a backflow of material from the mixing chamber **100** into the elongated body lumens **32A**, **32B** thereby acting as a directional flow valve. As shown in FIG. **18**, the at least one mixing member **102** is capable of engaging the elongated body support member **103**, thereby restricting access of the material to the elongated body lumens **31A**, **32B** from the mixing chamber **100** and preventing a backflow of material. The at least one flexible mixing member **102** may be manufactured in a plurality of shapes, including, for example, washer-like shapes.

A spray regulator **104** is positioned within the mixing chamber **100** proximate to the spray aperture **94**. The spray regulator **104** further ensures that the material located within the mixing chamber **100** are adequately mixed and provides an impedance within the mixing chamber **100** to aid in forming a material spray. Those skilled in the art will appreciate that the position and size of the spray regulator, in cooperation with the size of the spray aperture **94**, effects the emitted spray volume.

In use, a multiple component fluid may be applied by the laproscopic spray device **10** to a work surface located within the body of a patient. The illustrated embodiment shows a syringe-type material applicator **34**, although other applicators may be used.

Initially, the user attaches the spray tip **15** to the elongated body **14** by sliding the outer sleeve **84** of the elongated body **14** towards the interface member **12**, thereby exposing the spray tip receiver **90**. Thereafter, the user attaches the spray tip **15** to the elongated body **14**, wherein the at least one mounting member **96** of the spray tip **15** engages the exposed spray tip receiver **90** on the elongated body **14**. The outer sleeve **84** is then slid towards the spray tip **15**, thereby locking the spray tip **15** in place. The user may then insert the dispensing tips **48**, **60** of the syringe-type material applicator **34** into the receiving apertures **20A**, **20B** formed on the coupling members **18A**, **18B** of the interface member **12**. Thereafter, the coupling members **18A**, **18B** are actuated to engage and retain the dispensing tips **48**, **60**. Syringe-type material applicators **34** may be single-use disposable devices constructed of inexpensive plastics and polymers. The appli-

cation of force to the first piston rod **52** and second piston rod **64** of the syringe-type material applicator **34** will result in the application of the fluid components.

The spray tip **15** may then be inserted into the patient's body and advanced to the area of interest. Once suitably positioned the user applies force to the first piston rod **52** and second piston rod **64** of the syringe-type material applicator **34**. Material stored within the syringe reservoirs **42**, **54** is advanced through the dispensing tips **48**, **60** and into the transport lumens **28A**, **28B**. The continued application of force advances the material into the elongated body lumens **32A**, **32B**, which are in communication with the spray tip **15**. Thereafter, the material encounters the flexible mixing member **102** positioned within the mixing chamber **100** of the spray tip **15**. The mixing member **102** forces the individual materials together and forms a turbulent flow within the mixing chamber **100**. The continued application of force expels the mixed material as a spray mixture through the spray aperture **94**. The disclosed configuration permits the user to easily detach and apply the spray tip **15** to the elongated body **14**, thereby permitting the user to easily replace the spray tip **15** should the device foul or clog.

Another embodiment of a laproscopic spray device **110** is depicted in FIGS. **19–22**. In this embodiment, at least two adhesive components **112** and **114** can be delivered simultaneously from a dual syringe assembly **115** through an interface member in the form of a manifold assembly **113** in a manner that is similar to or the same as the delivery of components discussed above with regard to the applicators **34** and interface member **12**. The adhesive components may include any suitable biological materials for delivery to a desired target site. Two such suitable components include fibrinogen and thrombin, which when appropriately combined, form a useful biological adhesive. The manifold assembly is in fluid communication with isolated fluid channels **116** and **118** extending the length of an elongated delivery shaft **120**. The manifold assembly may have features that are similar to or the same as the interface member **12** discussed above. A spray tip assembly **122** is detachably snapped onto a distal end of the elongated delivery shaft **120** by means of a locking ring **124** which is radially constrained by a rigid outer sleeve **126** of the elongated delivery shaft **120**. The spray tip assembly **122** may have features, dimensions and materials which are similar to or the same as those of the spray tip **15** discussed above, and vice versa. A sealing member in the form of a flexible disc **128** is disposed over distal ports **130** and **132** of the fluid channels **116** and **118**, respectively. The flexible disc **128** in a relaxed state covers and seals the distal ports **130** and **132**. This sealed configuration prevents backflow of components **112** and **114** into the fluid channels **130** and **132** when positive pressure urging the components in a distal flow is not present.

The spray tip assembly **122** can have an outer diameter of about 2 mm to about 10 mm, more specifically, about 4 mm to about 8 mm. The spray tip assembly can have an axial length of about 10 mm to about 25 mm.

The spray tip assembly **122** also includes an elongated chamber body **134** disposed within an internal cavity **136** of an outer spray tip body member **138**. The elongated chamber body **134** may be made from a high strength resilient material, such as stainless steel and the outer spray tip body member can be formed of an injection molded polymer. The elongated chamber body **134** has an outer surface **140** that mates with an inner surface **142** of the internal cavity **136** of the spray tip body member **138**. The flexible disc **128** is

disposed within a recess of the proximal end **144** of the elongated chamber body **134**, and has a central passage **146** to allow a flow of components therethrough. The diameter or transverse dimension of the central passage **146** can be about 0.01 inches to about 0.04 inches.

The central passage **146** is in fluid communication with an elongated mixing chamber **148** of the spray tip assembly **122**. The elongated mixing chamber **148** is in fluid communication with lateral ports **150** and **152** which in turn communicate with longitudinal channels **154** formed into the inside surface **142** of the outer spray tip body member **138**. The lateral ports **150** and **152** are disposed proximally of a distal end **149** of the elongated mixing chamber. The longitudinal channels **154** terminate distally in spiral mixing channels **156** on an inside surface **158** of the distal face **160** of the outer spray tip body member **138**. The spiral mixing channels **156** converge axially inward to an aperture **162** which is configured to spray an atomized mixture of the components delivered from the dual syringe assembly **115** as depicted in FIG. **21**. The mixing chamber **148** can have an axial length of about 5 mm to about 25 mm, more specifically about 10 mm to about 20 mm. The mixing chamber **148** can have an inner diameter or transverse dimension of about 1 mm to about 3 mm. The inner diameter of the mixing chamber **148** may taper distally to a smaller transverse dimension relative to a transverse dimension of the proximal end of the mixing chamber.

During use, as shown in FIG. **21**, the individual components **112** and **114** are advanced by pressure from the dual syringe assembly **115** through the fluid channels **116** and **118** to a distal end of the elongated delivery shaft **120** where the components **112** and **114** then contact a proximal surface **164** of the flexible disc **128**. Force from the pressurized component flow then pushes the proximal surface **164** of the flexible disc **128** from the distal ports **130** and **132** of the fluid delivery channels **116** and **118** and breaks the seal between the distal end of the fluid delivery channels and the flexible disc **128**. The components **112** and **114** then flow radially inward and converge and begin to mix together as they pass through the central passage **146** of the flexible disc **128** and thereafter, into the elongated mixing chamber **148** disposed within the elongated chamber body **134**.

Turbulent flow of the components through the elongated mixing chamber **148** serves to mix the components **112** and **114** substantially before the components are then expelled radially outwardly through the lateral ports **150** and **152** of the elongated chamber **148**. The components **112** and **114** then flow into a gap **166** between an outer surface **140** of the elongated chamber body **134** and an inside surface **142** of the outer spray tip body member **138**, and then into the longitudinal channels **154** of the outer spray tip body member **138**. The flow of components **112** and **114** then continues into the spiral mixing channels **156** on the inside surface **158** of the distal face **160** of the outer spray tip body member **138**. Thereafter, the mixed components **112** and **114** are expelled from the aperture **162** in atomized form onto a target site.

Embodiments disclosed herein are illustrative of the principles of the invention. Other modifications may be employed which are within the scope of the invention; thus, by way of example but not of limitation, alternative coupling devices, alternative spray tips, and alternative material applicator devices. Accordingly, the present invention is not limited to that precisely as shown and described in the present invention.

What is claimed is:

1. A laparoscopic spray device for mixing and applying a multiple component agent to a target site, comprising:

- a first fluid reservoir containing a first component and a second fluid reservoir containing a second component;
- an elongated delivery shaft having a proximal end, a distal end, and at least two fluid delivery channels in fluid communication with the first and second fluid reservoirs, the fluid delivery channels having distal ports;
- a spray tip assembly having a proximal end, a distal end, and a discharge aperture disposed at the distal end, the spray tip assembly detachably coupled to the distal end of the elongated delivery shaft and having a sealing member disposed at the proximal end of the spray tip assembly that seals the distal ports of the fluid delivery channels of the elongated delivery shaft when the sealing member is in a relaxed state and which allows fluid flow from the distal ports when pressure is applied to the sealing members;
- an elongated mixing chamber having a proximal end and a distal end, the elongated mixing chamber in fluid communication with the fluid delivery channels when pressure is applied to the first and second components in the fluid delivery channels;
- at least one lateral port disposed proximally of the distal end of the elongated mixing chamber and in fluid communication with the elongate mixing chamber; and
- at least one spiral mixing channel proximal to the discharge aperture of the spray to assembly, the at least one spiral mixing chamber in fluid communication with the elongated mixing chamber via the at least one lateral port and in fluid communication with the discharge aperture of the spray tip assembly.

2. The device of claim 1 wherein the elongated mixing chamber of the spray tip assembly comprises an elongated cylindrical cavity that tapers distally to a transverse dimension that is less than a transverse dimension of the proximal end of the elongate mixing chamber.

3. The device of claim 1 wherein the first and second fluid reservoirs comprise syringes and wherein the device further comprises a manifold disposed between and in fluid communication with the syringes and the fluid delivery channels of the elongated delivery shaft.

4. The device of claim 3 wherein the syringes are detachably coupled to the manifold by a Luer-lock configuration.

5. The device of claim 1 wherein the sealing member comprises a flexible disc having an aperture therein for mixing and constraining the flow of components there-through.

6. The device of claim 5 wherein the flexible disc is comprised of a silastic polymer.

7. A laparoscopic spray device for mixing and applying a multiple component agent to a target site, comprising:

- an elongated delivery shaft having a proximal end, a distal end, and at least two fluid delivery channels in fluid communication with the first and second fluid reservoirs, the fluid delivery channels having distal ports;
- a spray tip assembly detachably coupled to the distal end of the elongated delivery shaft having a sealing member disposed at a proximal end of the spray tip assembly that seals the distal ports of the fluid delivery channels of the elongated delivery shaft when the sealing member is in a relaxed state and which allows fluid flow from the distal ports when pressure is applied to the

sealing member, and having a discharge aperture disposed at a distal end of the spray tip assembly;

an elongated mixing chamber having a proximal end and a distal end, the elongated mixing chamber in fluid communication with the fluid delivery channels when pressure is applied to the first and second components in the fluid delivery channels;

at least one lateral port disposed proximally of a distal end of the elongated mixing chamber and in fluid communication with the elongate mixing chamber; and

at least one spiral mixing channel proximal to the discharge aperture of the spray tip assembly, the at least one spiral mixing chamber in fluid communication with the elongated mixing chamber via the at least one lateral port and in fluid communication with the discharge aperture of the spray tip assembly.

8. The device of claim 7 wherein the elongated mixing chamber of the spray tip assembly comprises an elongated cylindrical cavity that tapers distally to a transverse dimension that is less than a transverse dimension of the proximal end of the elongate mixing chamber.

9. The device of claim 7 wherein the sealing member comprises a flexible disc having an aperture therein for mixing and constraining the flow of components there-through.

10. The device of claim 7 wherein the flexible disc is comprised of a silastic polymer.

11. A method of mixing and spraying a multiple component agent, comprising:

- providing a laparoscopic spray device having a first fluid reservoir containing a first component and a second fluid reservoir containing a second component, an elongated delivery shaft having a proximal end, a distal end, and at least two fluid delivery channels in fluid communication with the first and second fluid reservoirs, a spray tip assembly detachably coupled to the distal end of the elongated delivery shaft having a sealing member disposed at a proximal end of the spray tip assembly that seals distal ports of the fluid delivery channels of the elongated delivery shaft when the sealing member is in a relaxed state and which allows fluid flow from the distal ports when pressure is applied to the sealing member and an elongated mixing chamber in fluid communication with the fluid delivery channels when pressure is applied to the first and second components in the fluid delivery channels;

advancing the components by pressure from the fluid reservoirs through the fluid delivery channels to a distal end of the elongated delivery shaft where the components then contact a proximal surface of the sealing member;

pushing a proximal surface of the sealing member from distal ports of the fluid delivery channels so as to break the seal between the distal end of the fluid delivery channels and the sealing member;

flowing the components into a mixing chamber of the spray tip assembly where the components are at least partially mixed;

flowing the at least partially mixed components laterally outward from the mixing chamber and into a spiral mixing chamber; and

discharging the mixed components from a discharge aperture of the spray spiral mixing chamber onto a target site.

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12. The method of claim 11 wherein the mixed components are discharged from the discharge aperture in atomized form.

13. The method of claim 11 wherein the sealing member comprises a flexible disc having a central passage disposed 5
in a center portion thereof and the components flow radially

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inward from discharge ports of the fluid delivery channels and converge and begin to mix together as they pass through the central passage of the flexible disc and thereafter, into the elongated mixing chamber.

* * * * *

专利名称(译)	腹腔镜喷雾装置和使用方法		
公开(公告)号	US6884232	公开(公告)日	2005-04-26
申请号	US10/698714	申请日	2003-10-31
[标]申请(专利权)人(译)	海格曼ADAM SPERO RICHARD YARDIMCI ATIF 中号		
申请(专利权)人(译)	海格曼ADAM SPERO RICHARD YARDIMCI ATIF M.		
当前申请(专利权)人(译)	百特国际有限公司. 百特医疗用品SA		
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发明人	HAGMANN, ADAM SPERO, RICHARD YARDIMCI, ATIF M.		
IPC分类号	A61M37/00 A61B17/00 A61M25/00		
CPC分类号	A61B17/00491 A61M25/003 A61M25/0032 A61B2017/00495 A61B2017/00473 A61M2025/0037 B05C17/00506 B05C17/00516		
审查员(译)	门德斯MANUEL		
其他公开文献	US20050096588A1		
外部链接	Espacenet USPTO		

摘要(译)

公开了一种腹腔镜喷射装置，用于选择性地将从多组分材料涂敷器分配的多组分材料施加到体内手术部位。该装置包括能够接合多组件涂敷器的接口构件，其中具有至少两个腔的主体，以及与主体流体连通的可拆卸喷嘴。可拆卸的喷嘴包括混合室，混合室具有至少一个位于其中的柔性混合构件，该混合构件能够在混合室内产生湍流。另外，至少一个混合构件防止材料从混合室回流到至少两个腔。本发明特别适用于将多组分组织粘合剂远程应用于内部切口。

