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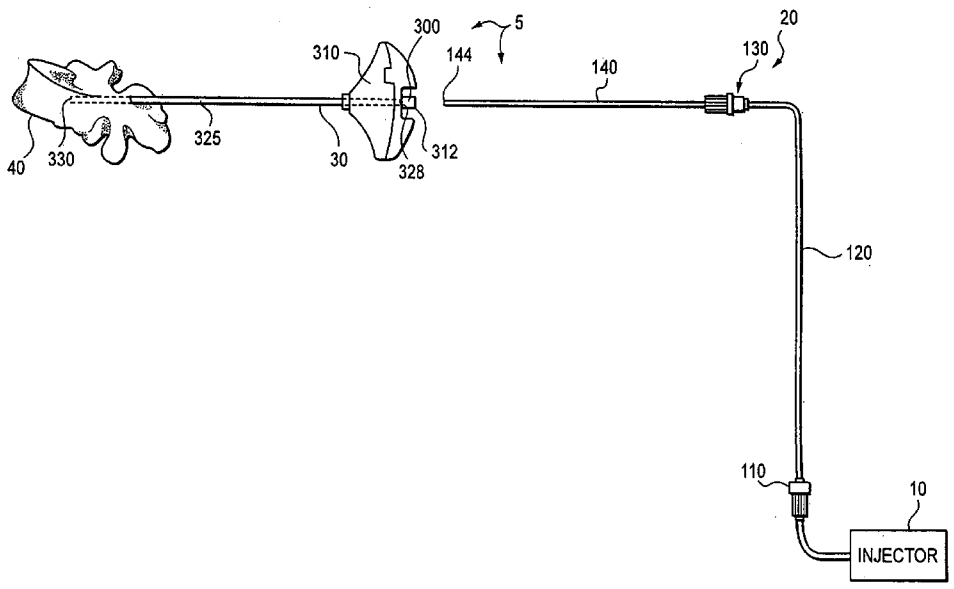

(57) Abstract: An apparatus and method for introducing material into an injection site of a patient is disclosed. The device includes a cannula and a carrier. The cannula is inserted into an injection site of a patient. The carrier is connected to an injector containing a volume of material. Material may be pre-loaded into the carrier so that the material is delivered to a distal end of the carrier from the injector and the carrier is thus pre-loaded with material. A portion of the distal end of the pre-loaded carrier is inserted into the cannula and material is delivered to an injection site. The supply section can be rotatable with respect to the longitudinal axis of the inner section.

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CURABLE MATERIAL DELIVERY DEVICE WITH A ROTATABLE SUPPLY SECTION

TECHNICAL FIELD

[0001] The present invention relates to devices and methods for stabilizing bone structures. More particularly, it relates to devices, systems and methods for delivering a curable, stabilizing material into a bone structure.

BACKGROUND INFORMATION

[0002] Surgical intervention at damaged or compromised bone sites has proven highly beneficial for patients, for example patients with back pain associated with vertebral damage.

[0003] Bones of the human skeletal system include mineralized tissue that can generally be categorized into two morphological groups: "cortical" bone and "cancellous" bone. Outer walls of all bones are composed of cortical bone, which has a dense, compact bone structure characterized by a microscopic porosity. Cancellous or "trabecular" bone forms the interior structure of bones. Cancellous bone is composed of a lattice of interconnected slender rods and plates known by the term "trabeculae."

[0004] During certain bone procedures, cancellous bone is supplemented by an injection of a palliative (or curative) material employed to stabilize the trabeculae. For example, superior and inferior vertebrae in the spine can be beneficially stabilized by the injection of an appropriate, curable material (e.g., polymethylmethacrylate (PMMA) or other bone curable material). In other procedures, percutaneous injection under computed tomography (CT) and/or fluoroscopic guidance of stabilization material into vertebral compression fractures by, for example, transpedicular or parapedicular approaches, has proven beneficial in relieving pain and stabilizing damaged bone sites. Other skeletal bones (e.g., the femur) can be treated in a similar fashion. In any regard, bone in general, and cancellous bone in particular, can be strengthened and stabilized by a palliative injection of bone-compatible material.

[0005] Using a vertebropasty as a non-limiting example, a conventional technique for delivering the bone stabilizing material entails placing a cannula with an internal stylet into the desired injection site. The cannula and stylet are used in conjunction to pierce the cutaneous layers of a patient above the hard tissue to be supplemented, then to penetrate the hard cortical bone of the vertebra, and finally to traverse into the softer cancellous bone underlying the cortical bone. Once positioned in the cancellous bone, the stylet is then removed leaving the cannula in the appropriate position for delivery of curable material to the trabecular space of the vertebra to reinforce and solidify the damaged hard tissue.

[0006] According to one method in the prior art, curable material, is introduced into an end of the cannula for delivery into the vertebra using a 1 cc syringe. A 1 cc syringe is used because it generates the high pressures required to the force curable material through the cannula and into the vertebra. A disadvantage of a 1 cc syringe is that an amount of curable material required for the procedure is larger than 1 cc. As a result, it is required to sterilely reload the syringe several times during the procedure. This increases time and complexity of the procedure and increases the risk of radiation exposure to the physician.

[0007] An improved prior art procedure uses a curable material injector loaded with a relatively larger volume of curable material. The injector is connected to an end of the cannula via a non-compliant supply tube. Pressure created at the injector pushes a column of curable material through the supply tube and into the cannula. Curable material is then delivered from the cannula into the trabecular space of the vertebra. Although an improvement over the use of a syringe, the method has several disadvantages.

[0008] The method results in less control for the physician because the flow of curable material through the cannula has been found to be somewhat unpredictable. A column of curable material is pushed by substantial pressure over a distance, creating a pressure head in the column. When the curable material column reaches the end of the cannula, physicians have experienced that the curable material can burst into the trabecular space, depositing an uncontrolled volume of curable material in an uncontrolled manner. Further, the transfer of

curable material from the injector to the vertebra can only begin after the supply tube is connected to the cannula. A significant amount of time can elapse while the column of curable material is advanced through the supply tube and cannula.

[0009] Moreover, during a long procedure, curable material can begin to solidify inside of the cannula. After the desired amount of curable material is deposited in the vertebra, the cannula is removed at the completion of the procedure. The curable material that was in the cannula that may have begun to set may remain attached to the core of curable material in the bone. As the cannula is removed, the curable material may break inside of the cannula instead of at the tip of the cannula and leave a "spike" of curable material protruding from the vertebra.

[0010] There exists a need in the medical device field for an improved subcutaneous bone material delivery system. The present invention provides an efficient device and method of introducing curable material, or other material, into a bone structure in a controlled manner.

BRIEF SUMMARY

[0011] One aspect of the present invention is directed to an apparatus for introducing material into an injection site of a patient. The apparatus includes a cannula defining a lumen. The apparatus also includes a carrier for delivering material from an injector to an injection site. The carrier defines a lumen and includes a supply section operable to receive curable material, and an inner section having an axis and defining a tip section operable to direct material in a direction that is not coaxial with the axis of the inner section. In the apparatus, the carrier is releasably attachable with the cannula, and at least a portion of the inner section is located within the lumen of the cannula.

[0012] In another aspect of the present invention, an apparatus is provided for introducing material into an injection site of a patient. The apparatus has an injector containing a volume of material, a cannula having an elongated portion defining a lumen wherein an end of the elongated portion is for positioning within the injection site and a carrier defining a lumen between the injector and the

injection site. The carrier further includes a supply tube having a first end adaptable for connecting the supply tube with the injector and receive material from the injector and a second end. The carrier also includes a connector attaching the carrier with the cannula. The connector also defines a chamber. The carrier also includes an inner tube having a first end and a second end, wherein the connector connects the second end of the supply tube with the first end of the inner tube via a chamber such that the supply tube, chamber and inner tube form a lumen having a substantially smooth transition from the supply tube to the inner tube. In the apparatus, at least a portion of the inner tube is located within the lumen of the elongated portion of the cannula.

[0013] In yet another aspect of the present invention, a method of delivering material to the injection site is provided. The method includes a step of inserting a cannula defining an elongated lumen into an injection site. The method also includes a step of connecting a carrier defining a lumen with an injector containing a volume of material. The method further includes a step of pre-loading the lumen of the carrier with the material so that the material is delivered to a distal end of the carrier from the injector, wherein the carrier is thus pre-loaded with material. The method also includes a step of inserting at least a portion of the distal end of the pre-loaded carrier into the elongated lumen of the cannula and delivering material to an injection site.

[0014] In another aspect of the present invention, a method of delivering material to the injection site is provided. The method includes a step of inserting a cannula defining an elongated lumen into an injection site. The method also includes a step of connecting a carrier with an injector containing a volume of material, said carrier defining a lumen and comprising an inner section distal from the injector. The method further includes a step of inserting at least a portion of the distal inner section of the carrier into the elongated lumen of the cannula. The method also includes a step of transmitting material from the injector through the lumen of the carrier wherein curable material is also transmitted through the distal inner section. The method finally includes a step of delivering material to an injection site.

[0015] Advantages of the present invention will become more apparent to those skilled in the art from the following description of the preferred embodiments of the invention which have been shown and described by way of illustration. As will be realized, the invention is capable of other and different embodiments, and its details are capable of modification in various respects. Accordingly, the drawings and description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1 is a perspective view of the curable material delivery device according to a preferred embodiment of the present invention prior to insertion of the inner section into the cannula;

[0017] Figure 2 is a cross-section view of the curable material delivery device according to a preferred embodiment of the present invention after insertion of the inner section into the cannula;

[0018] Figure 3 is a cross-section view of the curable material delivery device according to another preferred embodiment of the present invention after insertion of the inner tube into the cannula;

[0019] Figure 4 is a cross-section of the connection between the supply tube and the cannula according to a preferred embodiment of the present invention;

[0020] Figure 4a is a cross-section of the inner section according to a preferred embodiment of the present invention;

[0021] Figure 5 is a cross-section of the connection between the supply tube and the cannula according to a another preferred embodiment of the present invention;

[0022] Figure 5a is a cross-section view of the curable material delivery device according to another preferred embodiment of the present invention;

[0023] Figure 5b is a cross-section view of the curable material delivery device according to another preferred embodiment of the present invention;

[0024] Figure 5c is a cross-section view of the curable material delivery device according to another preferred embodiment of the present invention;

[0025] Figure 6 is a perspective view of the curable material delivery device according to a preferred embodiment of the present invention after insertion of the inner section into the cannula;

[0026] Figure 7 is a perspective view of the tip portion of the curable material delivery device according to a preferred embodiment of the present invention;

[0027] Figure 8 is a perspective view of the tip portion of the curable material delivery device according to another preferred embodiment of the present invention;

[0028] Figure 9 is a perspective view of the tip portion of the curable material delivery device according to another preferred embodiment of the present invention; and

[0029] Figure 10 is a perspective view of the curable material delivery device according to a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

[0030] FIG. 1 illustrates components of an intraosseous, curable material delivery system **5** according to principles of the present invention. The curable material delivery system **5** according to a preferred embodiment of the present invention has an injector **10**, a carrier assembly **20** connected to the injector **10** via an injection connector **110** and a cannula **30** for insertion into a bone site of interest in a patient. In the embodiment depicted in FIG. 1, the bone site of interest is a vertebra **40**.

[0031] Details on the various components are provided below. In general terms, however, a portion of the carrier assembly **20** is sized to be slidably disposed within the cannula **30** that otherwise serves to form and/or locate a desired injection site within a bone. Once positioned within the cannula, the carrier assembly **20** is employed to inject a curable, bone stabilizing material into the delivery site. The system **5** can be used for a number of different procedures, including, for example, vertebroplasty and other bone augmentation procedures in

which curable material is delivered to a site within bone, as well as to remove or aspirate material from a site within bone.

[0032] The system **5**, and in particular the carrier assembly **20**, is highly useful for delivering a curable material in the form of a bone cement curable material. The phrase "curable material" within the context of the substance that can be delivered by the system/device of the invention described herein is intended to refer to materials (e.g., composites, polymers, and the like) that have a fluid or flowable state or phase and a hardened, solid or cured state or phase. Curable materials include, but are not limited to injectable bone cements (such as polymethylmethacrylate (PMMA) bone curable material), which have a flowable state wherein they can be delivered (e.g., injected) by a cannula to a site and subsequently cure into hardened curable material. Other materials, such as calcium phosphates, bone in-growth material, antibiotics, proteins, etc., could be used in place of or to augment, bone cement (but do not affect an overriding characteristic of the resultant formulation having a flowable state and a hardened, solid or cured state). This would allow the body to reabsorb the curable material or improve the clinical outcome based on the type of filler implant material.

[0033] The injector **10** may typically comprise a chamber filled with a volume of curable material and uses any suitable injection system or pumping mechanism to transmit curable material out of the injector and through the carrier assembly **20**. Typically, a hand injection system is used where a physician applies force by hand to an injector. The force is then translated into pressure on the curable material to flow out of the chamber. A motorized system may also be used to apply force.

[0034] A cannula **30** is provided to be positioned in an injection site for delivery of curable material therein. The cannula **30** is preferably made of a surgical grade of stainless steel, but may be made of known equivalent materials which are both biocompatible and substantially non-compliant at operating pressures described herein. The cannula **30** defines a lumen **325** to allow the stylet (not shown), carrier assembly **20**, and other equipment to pass through the cannula **30.** Preferably, at least a distal end **330** of the cannula **30** is radiopaque. The

cannula **30** has an inside diameter which is only slightly larger than the outside diameter of the stylet. The distal end **330** of the cannula **30** is preferably beveled to ease the penetration of the cannula through the cutaneous and soft tissues, and especially through the hard tissues.

[0035] Surrounding the proximal end **328** of the cannula **30** is a handle **310** for manipulating the cannula **30** and connecting the cannula **30** with carrier assembly **20** via a handle connector **312**. Preferably, handle connector **312** has a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a thread and locking nut arrangement, etc. Cannulas may be of standard lengths and diameters. A cannula may be about 4cm to about 20cm long and is preferably 12cm long. Additionally, with respect to the cannula diameter, the cannula may be about 1.2mm in outer diameter (18 gauge) with a wall thickness of about 0.216mm to about 5.2mm in outer diameter (6 gauge) with a wall thickness of about 0.381mm, and is preferably about 3.1mm in outer diameter (11 gauge) with a wall thickness of about 0.33mm or about 2.1mm in outer diameter (13 gauge) with a wall thickness of about 0.305mm.

[0036] The carrier assembly **20** provides a passageway for curable material to travel from the injector **10** to an injection site, such as a vertebra **40**. With reference to FIG. 2, carrier assembly **20** preferably defines a lumen **100** from the injection connector **110** to its terminal end **144** positioned inside of a patient. According to one preferred embodiment, the carrier assembly **20** comprises an injection connector **110**, a cannula connector **130** and a transfer body **115**. The transfer body **115** further comprises a supply section **120** and an inner section **140.** The injection connector **110** is preferably a Luer-lock type of connector, but other known connecting mechanisms suitable for medical applications may be successfully interchanged.

[0037] The cannula connector **130** is fixedly attached to the transfer body **115** and connects the carrier assembly **20** with the cannula **30** and cannula handle **310**. According to a preferred embodiment, the cannula connector **130** contains a Luer-lock threaded fitting **200** for connection with a Luer-lock threaded fitting **300** of

the cannula **30** to allow the carrier assembly **20** and cannula **30** to be removably detachable.

[0038] The transfer body **115** is preferably a single tubular structure that defines lumen **100**. Due to the operating pressures required to transfer curable material through the carrier assembly **20**, the transfer body **115** is preferably made of a non-compliant material such as polyetheretherketone (PEEK). Other suitable materials include aluminum or wire reinforced plastic. The supply section **120** of the transfer body **115** is operable to receive curable material from the injector **10** and is generally defined by the section of the transfer body **115** between the injector **10** and the cannula connector **130**. The inner section **120** of the transfer body **115** is operable to deliver curable material to an injection site and is generally defined by the section of the transfer body **115** between the cannula connector **130** and the terminal end **144** of the carrier assembly **20** for positioning within the patient. At least a portion of the inner section **140** is adapted to be inserted into the cannula **30**. The inner section **140** must therefore have an outer diameter that is smaller than the inner diameter of the cannula **30**; however, the outer diameter should not be so small so as to allow curable material to travel around the outside of the inner section **140** and back into the cannula **30**. Preferably the clearance between the inner diameter of the cannula **30** and the outer diameter of the inner section **140** is within a range of about 1 to 30 thousandths of an inch and is more preferably no more than about 5 thousands of an inch.

[0039] Additionally, according to a preferred embodiment the distal end **330** of the cannula **30** extends beyond the terminal end **144** of the inner section **140** such that the terminal end **144** of the inner section **140** is at a length from the distal end **330** of the cannula **30** that is less than 50% of the length of the cannula **30.** According to another preferred embodiment, the terminal end **144** of the inner section **140** is substantially even with the distal end **330** of the cannula **30**. One skilled in the art will also understand that an inner section **140** that extends beyond the distal end **330** of the cannula **30** may also be used as long as the inner section **140** fits within the injection site and dispenses curable material effectively.

[0040] One skilled in the art will appreciate that although this embodiment uses a single tube for delivering curable material to the patient, the single tube may be manufactured to have different diameters at different sections of the tube.

[0041] With reference to FIG. 3, in another preferred embodiment, the supply section **120** and inner section **140** may be separate structures that are connected at the cannula connector **130**. In this embodiment, preferably the supply section **120**, cannula connector **130** and inner section **140** define the lumen **100**. The supply section **120** has a first end **122** and second end **124** and is preferably a tubular structure that defines a portion of the lumen **100**. Due to the operating pressures required to transfer curable material through the carrier assembly **20**, the supply section **120** is preferably made of a non-compliant material such as polyetheretherketone (PEEK) or other polymer. Other suitable materials include aluminum or wire reinforced plastic. The second end **124** of the supply section **120** connects with a first end **132** of the cannula connector **130**.

[0042] The inner section **140** comprises a first end **142** connected with the cannula connector **130** and a terminal end **144** for positioning within the patient to deliver curable material to an injection site. The inner section **140** is adapted to be inserted into the cannula and preferably extends from the cannula connector **130** to the injection site. Due to the operational pressures applied with injecting curable material, the inner section **140** is preferable made of a non-compliant material and is more preferably made of polyetheretherketone (PEEK) or aluminum. The inner section **140** must therefore have an outer diameter that is smaller than the inner diameter of the cannula **30**; however, the outer diameter should not be so small so as to allow curable material to travel around the outside of the inner section **140** and back into the cannula **30**. Preferably the clearance between the inner diameter of the cannula **30** and the outer diameter of the inner section **140** is within a range of about 1 to 30 thousandths of an inch and is more preferably no more than about 5 thousands of an inch. The supply section **120** and the inner section **140** may be made of the same or different materials.

[0043] According to one preferred embodiment of the inner section **140**, the interior surface of the inner section **140** is smooth to aid in delivery of material to

a delivery site. Typical medical cannulas or needles in the prior art for introducing curable material contain rough inner surfaces. Rough inner surfaces may have root-mean-square (RMS) values of 50 micro inches and greater. It has been observed that the application of curable material requires relatively less force when the surfaces defining the lumen for introducing the curable material are smooth. Smooth surfaces may have root-mean-square (RMS) values of about 45 and lower. As a result, in a preferred embodiment, the RMS value of the inner section defining lumen **100** has an RMS value of between about 0 and about 45. In another preferred embodiment, the RMS value is preferably between about 0 and about 32, and is more preferably between about 0 and about 16.

[0044] FIG. 4a depicts an inner section **140** having a smooth interior surface **141** defining a portion of lumen **100**. In one preferred embodiment, the interior surface **141** of the inner section **140** is coated with a dry lubricant, such as Teflon®. In another preferred embodiment, a smooth-surface liner having a smooth interior surface **141** may be placed within the inner section **140** such the smooth-surface liner covers the interior surface of the inner section **140**. According to one preferred embodiment, the smooth-surface liner is made of Teflon®. In another preferred embodiment, the interior surface **141** of inner section **140** is manufactured to have a polished or mirror surface finish such that the interior surface **141** of the inner section **140** has a substantially smooth surface finish having an RMS value of 49 or lower. In this embodiment, the inner section **140** is preferably made of metal and is more preferably made of stainless steel.

[0045] Additionally, according to a preferred embodiment the distal end **330** of the cannula **30** extends beyond the terminal end **144** of the inner section **140** such that the terminal end **144** of the inner section **140** is at a length from the distal end **330** of the cannula **30** that is less than 50% of the length of the cannula **30.** According to another preferred embodiment, the terminal end **144** of the inner section **140** is substantially even with the distal end **330** of the cannula **30**. One skilled in the art will also understand that an inner section **140** that extends beyond the distal end **330** of the cannula **30** may also be used as long as the inner section **140** fits within the injection site and dispenses curable material effectively.

[0046] In this embodiment, in addition to connecting the carrier assembly **20** with the cannula **30**, the cannula connector **130** also connects the supply section **120** with the inner section **140**. According to a preferred embodiment, the supply tube **120** connects with the cannula connector **130** via a Luer-lock type of connector **210**, but other known connecting mechanisms suitable for medical applications may be successfully interchanged. The cannula connector **130** further comprises a second Luer connection **312** for connecting the inner section **140** with the cannula connector **130**.

[0047] With reference to FIG. 4, the cannula connector **130** preferably comprises a flangeless adapter **220**. Flangeless adapter **220** provides a precise and smooth transition from the supply section **120** to the inner section **140**. It has been found that disruptions in the walls defining the lumen **100**, such as at abrupt transitions in fittings or connections, can cause curable material within the lumen **100** to prematurely set and potentially plug the line. As a result, a smooth transition at fittings or connections between lines advantageously delivers curable material to the patient.

[0048] Preferably, flangeless adapter **220** defines a first radial lip **230**, a chamber **240**, and a second radial lip **250**. The chamber **240** further defines an input end **242,** an output end **244** and a transition region **246**. To effect a precise and smooth transition from the supply section **120** to the chamber **240**, the second end of the supply section **124** abuts with the first radial lip **230** at the input end **242** of the chamber **240**. The input end **242** of the chamber has an inner diameter that is substantially the same inner diameter of the supply section **120**. Similarly, the first end **142** of the inner section **140** abuts with the second radial lip **250** at the output end **244** of the chamber **240**. The output end **244** of the chamber **240** has an inner diameter that that is substantially the same as the inner diameter of the inner section **140**. It will thus be appreciated that a precise and smooth transition between the supply section and the inner section is achieved.

[0049] In the embodiment depicted in FIG. 4, the supply section **120** and the inner section **140** have the same inner diameter. As a result the input end **242**, transition region **246** and output end **244** of the chamber also have the same

diameter. In another preferred embodiment, the supply section **120** and the inner section **140** may have different inner diameters. Accordingly, the input end **242** and output end **244** of the chamber **240** will also have different inner diameters. In this embodiment, the transition region **246** of the chamber **240** is tapered to smoothly transition the chamber **240** from one diameter to the other.

[0050] It has been observed that the application of curable material is more controllable where the downstream pathway of the curable material is more narrow than the upstream pathway. As a result, according to a preferred embodiment, the inner diameter of the inner section **140** is smaller than the inner diameter of the supply section **120**. In this preferred embodiment, the transition region **246** will preferably smoothly transition the chamber **240** from a larger diameter at the input end **242** of the chamber to a smaller diameter at the output end **244** of the chamber. It is important to keep in mind that abrupt transitions in connections should be avoided to prevent plugging by the curable material. The flangeless adapter **220** is preferably made of a material that can withstand the operational pressures such as polyetheretherketone (PEEK) or other polymers.

[0051] With reference to FIG. 5, another embodiment of the cannula connector is presented. In this embodiment the supply section **120** and the inner section **140** are conveniently detachable from each other such that different inner sections **140** may be attached and detached from the supply section **120**. In this embodiment, the inner section **140** comprises an inner section connector **480**. The inner section connector **480** connects with the cannula connector **130** via the Luer-lock connection **200** that was used to connect to the cannula handle **310** in the previous embodiment. The inner section connector **480** also comprises another Luer-lock connection **475** for connection to the cannula handle **310**. The inner section connector **480** further comprises a second flangeless adapter **420** to provide a precise and smooth transition from the cannula connector **130** to the inner section **140**. With reference to FIG. 5, preferably the second flangeless adapter **420** defines a chamber **440** and a radial lip **450**. The chamber **440** further defines an input end **442**, an output end **444** and a transition region **446**. To effect a precise and smooth transition from the cannula connector **130** to the chamber **440**, the

output end **477** of the chamber **240** of the cannula connector **130** abuts with the input end **442** of the second chamber **440**. The input end **442** of the second chamber **440** has an inner diameter that is substantially the same inner diameter of the output end **477** of the chamber **240** of the cannula connector **130**. It will be appreciated that multiple sizes of inner sections may be attached to a single sized supply section because each inner section connector contains a particularly tapered transition region **446** that is suitable to smoothly transition the supply section **120** with an inner section **140**.

[0052] With reference to FIG. 5a, another embodiment of the cannula connector is presented. In this embodiment the supply section **120** (not shown) and the inner section **140** are conveniently detachable from each other such that different inner sections **140** may be attached and detached from the supply section **120**. Additionally, in this embodiment the supply section **120** is conveniently rotatable with respect to the inner section **140** such that the material injector and supply section **140** may be rotated around the longitudinal axis of the inner section **140** to achieve a preferred orientation for ease of use. In this embodiment, the inner section **140** is connected with a connector body **680**. The connector body **680** connects via a Luer-lock connection **682** to the cannula handle **310** (see FIG. 1). The connector body **680** also comprises fixed adapter **690** and a rotating adapter **620**. The rotating adapter **620** allows a rotatable transition from the supply section **120** to the inner section **140** via the connecter body **680**. In this embodiment, the rotating adapter **620** is operative to rotate with respect to the fixed adapter **690** and to rotate about the longitudinal axis of the inner section **140**. The rotating adapter **620** is operative to interface with the supply section **120** and allow the supply section **120** to rotate during use. In a preferred embodiment, the rotating adapter is operative to rotate the supply section preferably about 90 degrees and more preferably about 360 degrees.

[0053] With reference to FIG. 5a, according to one preferred embodiment the rotating adapter **620** defines a grip section **622**, a holder section **624** and a cap **626**. In one preferred embodiment the grip section **622** and holder section **624** are connected with each other by an adhesive; however, in another embodiment, the

grip and holder sections may be integrally formed. The holder **624** section is inserted into a cavity in the fixed adapter **690** and the cap **626** is placed over the end of the fixed adapter **690** to secure the holder section **624** within the fixed adapter **690**. According to one preferred embodiment, the cavity of the fixed adapter **690** also contains an O-ring **692** to interface with the holder section **624**. The grip section **622** preferably contains one or more fin-like projections **630** to aid in rotating the rotating adapter **620**. The grip section **622** also contains a Luer threading **628** operative to connect the supply section **120** to the connecter body **680**. When assembled, the connecter body **680**, inner section **140** and supply section **120** form a lumen to allow material to be delivered from the material injector to the material delivery site.

[0054] In another embodiment of the connector body **680**, connector body **680** further comprises a flangeless adapter (not shown) in accordance with the flangeless adapters described herein to provide a precise and smooth transition from the supply section **120** to the inner section **140**. It will also be appreciated that because the inner section is detachable from the supply section, multiple sizes of inner sections may be attached to a single sized supply section.

[0055] According to another preferred embodiment, the inner section **140** also rotates as the rotating adapter **620** is rotated. In this embodiment, rotation of the supply section **120** causes the inner section **140** to rotate to provide for directional delivery of curable material within the injection site. With reference to FIG. 5b, according to one preferred embodiment the inner section **140** is connected to the rotating adapter **620.** As can be seen in FIG. 5b, the inner section **140** extends through the fixed adapter **680** to the rotating adapter **620.** The inner section **140** and rotating adapter **620** may be connected by an adhesive; however, other connection means may be used. According to one preferred embodiment, an end **691**of the inner section **140** may be flared to correspond with a surface of the rotating adapter **620** to aid in manufacturing of the invention and to increase surface area for an adhesive. In this embodiment, the supply section **120** is connected with the rotating adapter as described above. As the supply section is rotated about the longitudinal axis of the inner section **140**, the inner section is

also rotated within and relative to the fixed adapter **690.** Thus, rotation of the inner section **140** is dependant on rotation of the supply section. When used with various inner section tip configurations, rotation of the supply section will cause rotation of inner section and provide for directional application of curable material within the injection site.

[0056] According to yet another preferred embodiment, the inner section **140** and the supply section **140** can rotate independently of each other. In this embodiment, the supply section **120** may be rotated about a the longitudinal axis of the inner section **140** without causing the inner section **140** to rotate. Additionally, the inner section **140** may be rotated to provide directional cement delivery without rotating the supply section **120**. With reference to FIG. 5c, in this embodiment rotating adapter **620** is connected with a second connector body **780**. The second connector body **780** connects to the rotating adapter **620** via Luer thread **628**. The second connector body **780** also comprises a second fixed adapter **790** and a second rotating adapter **720.** The second rotating adapter **720** allows an independent rotatable transition from the supply section **120** to the inner section **140**. In this embodiment, the second rotating adapter **720** is operative to rotate with respect to the second fixed adapter **790** and to rotate about the longitudinal axis of the inner section **140**. The second rotating adapter **720** is operative to interface with the supply section **120** and allow the supply section **120** to rotate during use.

[0057] With continued reference to FIG. 5c, according to one preferred embodiment the second rotating adapter **720** defines a second grip section **722,** a second holder section **724** and a second cap **726**. In one preferred embodiment the second grip section **722** and second holder section **724** are connected with each other by an adhesive; however, in another embodiment, the grip and holder sections may be integrally formed. The second holder section **724** is inserted into a cavity in the second fixed adapter **790** and the second cap **726** is placed over the end of the second fixed adapter **790** to secure the second holder section **724** within the second fixed adapter **790**. According to one preferred embodiment, the cavity of the fixed adapter **690** also contains a second O-ring **792** to interface with the

second holder section **724**. The second grip section **622** preferably contains one or more fin-like projections **730** to aid in rotating the second rotating adapter **720**. The second grip section **722** also contains a Luer threading **728** operative to connect the supply section **120** to the second connecter body **780**. When assembled, the connecter body **680**, second connecter body **780,** inner section **140** and supply section **120** form a lumen to allow material to be delivered from the material injector to the material delivery site.

[0058] In this embodiment, the inner section **140** may be rotated using the rotating adapter **620** independently of rotation of the supply section **120**. When used with various inner section tip configurations, rotation of the inner section **140** will provide for directional application of curable material within the injection site.

[0059] Regardless of an exact configuration, the assembled curable material delivery system (such as the curable material delivery system **5** of FIG. 1) in accordance with principles of the present invention is highly useful in performing a wide variety of bone stabilizing procedures as part of an overall curable material delivery system. Using a vertebroplasty as a non-limiting example, in operation, the cannula **30** and stylet (not shown) are driven into the vertebra **40** to reach the trabecular cavity of the vertebra **40**. The stylet is removed, leaving an open lumen **325** within the cannula **30**. Curable material is mixed and loaded into the injector **10**. Preferably, curable material is transferred under pressure from the injector **10** to the terminal end **144** of the inner section **140** prior to insertion of the inner section **140** into the lumen **325** of the cannula **30**. In practice, an operator may advance curable material beyond the terminal end **144** of the inner section **140** in order to completely fill the inner section **140** and then wipe the terminal end **144** of the inner section **140** of excess curable material before insertion into the cannula **30**. The carrier assembly is thus preloaded with curable material before the carrier assembly **20** is connected with the cannula **30** and the inner section **140** is inserted into the cannula **30**. Once the inner section **140** is inserted into the cannula **30** and the carrier assembly **20** is connected with the cannula **30**, curable material is immediately available to be delivered into the vertebra **40**. This preloading step advantageously reduces the time required to deliver curable

material into a patient because it can be done at substantially the same time the cannula **30** is being driven into the vertebra. In the prior art, the transfer of curable material from the injector can begin only after a supply tube is connected with the cannula. Time is thus required to transfer curable material from the injector to the supply tube, through the cannula tube, and into the patient. In the preferred embodiment of the present invention, however, curable material is preloaded to the terminal end **144** of the inner section **140** and the inner section **140** is then inserted into the cannula **30**, thus making curable material immediately available to be delivered to the patient. One skilled in the art will realize, however, that curable material need not be preloaded into the carrier assembly to realize other advantages on the present invention.

[0060] It has been observed that during the initial preloading of the delivery device with curable material, a "dry plug" forms at the end of the curable material column as it advances through the device. The dry plug is formed when monomer is extracted from the leading end of the column of curable material as it coats the inner surface of the delivery device lumen. As monomer is extracted from the curable material the end of the column becomes dry and increases friction against the inner surface. The dry plug becomes longer as the column of curable material is advanced which, in turn, further increases friction.

[0061] The dry plug thus requires the injector to exert greater pressure to advance the column of curable material when compared with a column that does not have a dry plug. As a result, according to one preferred embodiment a preferred method may be employed to reduce the effects of the dry plug during preloading. According to this preferred method of preloading the curable material delivery device, the inner section **140** is detached from the supply section **120** and curable material is loaded to the distal end of the supply section **120**. The curable material is then further advanced so that the dry plug is dispelled from the distal end of the supply section **120**. The distal end of the supply section **120** is then wiped clean of any excess curable material and the inner section **140** is attached to the supply section **120**. Preloading of the curable material continues as described above.

[0062] At this point in the procedure, the inner section **140** is inserted into the cannula **30** and locked into place with the Luer-lock that connects the carrier assembly **20** to the cannula **30** in order to prohibit ejection of the carrier assembly **20** from the cannula **30** under pressure. The present invention permits burst-free injection of the curable material into an injection site at the beginning of the procedure because the carrier assembly **20** is primed prior to insertion into the cannula **30**. When the physician activates the injector **10**, the curable material is already going into the injection site and hence the flow is more predictable. The injector will then allow transfer of finely controlled amounts of curable material into the patient.

[0063] Following the delivery of a predetermined amount of curable material into the vertebra, the carrier assembly **20** may be detached from the cannula **30** and removed. It will be appreciated by one skilled in the art that when the carrier assembly **20** is removed, the inner section **140**, which is loaded with curable material, is also removed and thus removes the column of curable material from the cannula **30**. Several advantages are therefore realized in this embodiment. First, because the inner section **140** functions as a liner between the curable material and the cannula **30**, there is no residual curable material inside of the cannula **30**. The cannula **30** may therefore again be used to deliver additional material to the vertebra. Second, in the prior art, curable material may begin to set within the cannula **30** before completion of the procedure. When the procedure is complete and the cannula is removed, the resulting curable material column may break at a point inside the cannula **30** and not at the tip of the distal end **330** of the cannula **30**. This results in a "spike" of curable material that is still attached to the curable material that has been deposited inside of the vertebra and the "spike" may extend outside of the vertebra. In the present invention, it has been observed that the curable material more uniformly breaks at the tip of the terminal end **144** of the inner section **140** when the inner section **140** is removed, thus minimizing the opportunities for curable material "spikes." Additionally, it is understood in the art that curable material will begin to set more quickly when exposed to body temperature. In the present invention, if delivery of curable material needs to be

interrupted for a period of time, the inner section **140** can be conveniently temporarily removed from the cannula **30** and cooled by the relatively cooler room temperature, slowing the setting of the curable material. This is not possible under the prior art where curable material filled within the cannula **30** cannot be removed during the operation.

[0064] The present invention also allows a physician to conveniently fill multiple cannulas in one or more vertebra with curable material in the same operation. It is understood that a physician may enter a vertebral body with two basic approaches: uni-pedicular and bi-pedicular. In the uni-pedicular approach, the physician attempts to place the cannula in such a way that it traverses the midline of the vertebral body. This is done so that the entire vertebra can be filled through one entry point and one cannula. This technique can provide faster curable material filling, thus reducing procedure time. The technique, however, can be technically more challenging for the physician and may not always be possible to use. The bi-pedicular approach relies on placing a cannula through each pedicle of a vertebra. Because there is no need to traverse the midline of the vertebral body, the bi-pedicular approach is considered technically easier and safer. It permits equal filling on both sides of the vertebra, thus providing more uniform distribution of curable material.

[0065] The present invention can be used with both the uni-pedicular and bi-pedicular approaches. In the bipedicular approach the same carrier assembly **20** can be used to fill a first side of a vertebral body through a first cannula until the first side is satisfactorily filled. The inner section **140** of the carrier assembly **20** can then be removed from the first cannula and positioned within a second cannula to the other side of the vertebral body. It will be appreciated that upon removal of the carrier assembly **20**, the first cannula is substantially free of curable material. It will also be appreciated that the inner section **140** is still filled with curable material and is thus "preloaded" with respect to the second procedure. Filling of the second side of the vertebral body can therefore immediately begin while the curable material begins to set on the first side. If the physician so desires, he or she can return to the first cannula and resume filling the first side. In a preferred

embodiment, the physician can alternate between first and second cannula in a procedure, keeping both clean.

[0066] In another preferred embodiment, the physician may fill two different vertebral bodies in one procedure. The technique allows the physician to work between cannulas at various times while keeping the cannulas clean. In this embodiment, the physician drives cannulas into two or more vertebra. The carrier assembly **20** is preloaded with curable material as described above. The carrier assembly **20** is connected with the first cannula **30** for the first procedure and curable material is immediately delivered to the vertebra. At the completion of the first procedure, the carrier assembly **20** is removed from the first cannula **30**. It will be appreciated that the inner section **140** is still filled with curable material and is thus "preloaded" with respect to the second procedure. The carrier assembly **20** is connected to the second cannula **30** and curable material is ready to be immediately delivered to the vertebra.

[0067] Alternative structures may be employed within the scope of the present invention. With reference to FIG. 6, in another preferred embodiment, the terminal end **144** of the inner section extends beyond the distal end **330** of the cannula **30**. The tip portion **550** of the terminal end **144** can contain different configurations to deliver curable material to an injection site.

[0068] In a preferred embodiment shown in FIG. 7, the tip portion **550** contains a closed, blunt end **518** such that the terminal end **144** is axially closed to the lumen **100** (i.e., material cannot be axially expelled from the terminal end **144** relative to an axis of the lumen **100**). That is to say, material in the lumen **100** cannot be forced distally therefrom in an axial fashion. Further, the terminal end **100** defines or includes a blunt end **518**. In one embodiment, the blunt end **518** defines a hemispherical surface, although other blunt (i.e., curved or curvilinear) shapes or contours are also acceptable. The blunt end **518** is adapted to provide a non-traumatic surface suitable for accessing, contacting and probing bone or tissue while minimizing the risk of puncture and/or coring of the tissue or damage to the bone.

[0069] The tip portion **550** also defines a side orifice **520** formed adjacent the terminal end **144**, extending through a thickness of a sidewall of the tip portion **550**. The side orifice **520** can assume a wide variety of shapes and sizes. For example, the side orifice **520** can be oval, circular, curvilinear, etc. In one embodiment, a chamfered region **570** can be formed about the side orifice **520** to eliminate sharp edges along an exterior of the tip portion **550** as well as to promote consistent flow of curable material from the side orifice **520** (via the expanding orifice size effectuated by the chamfered region **570**). Although the tip portion **550** has been described as including or otherwise forming one side orifice **520,** two, circumferentially aligned side orifices can be provided

[0070] With reference to FIGS 8-9, a variety of other configurations for the tip portion **550** are also acceptable. FIG. 8 shows a tip portion **550** having three side orifices **522** having consecutively smaller side orifices. This reduction in side orifice size proximal the terminal end **144** promotes consistent distribution of curable material otherwise being forced through the tip portion **550**. While three of the side orifices **522** are shown, other configurations are also acceptable. For example, multiple side orifices (i.e., more than three side orifices) can be formed longitudinally along the length of the tip portion **550**, and in addition, the side orifices can include more than one longitudinally aligned series of side orifices. In an exemplary embodiment, the side orifices that are visible in FIG. 8 are matched by another column of longitudinally aligned side orifices formed on an opposing side of the tip portion **550** (and therefore not visible in the view of FIG. 8). Aspects of the present invention provide for the side orifices **522** to define circular side orifices, non-circular side orifices, or a set of circular and non-circular side orifices.

[0071] FIG. 9 shows another preferred embodiment of the tip portion **550**. In this embodiment, the tip portion **550** is bent to provide about a 90 degree opening **560** with respect to the axis of the inner section **140**. In the exemplary embodiment, the angle between the opening **560** and the axis of the inner section, represented by θ, is 90 degrees. Aspects of the present invention contemplate that the angle θ may be between 0 and 90 degrees and are preferably substantially 90 degrees. Preferably, the leading edge of the tip portion **550** should be substantially rounded so that the tip

portion **550** does not easily cut into tissue. In one embodiment, the inner section comprises a rotatable hub that rotates the inner section **140.** The hub would comprise a visual indicator corresponding to the orientation of the opening **560** so that the clinician may visualize the opening at the terminal end of the inner section. Preferably, the hub of the inner section has a seal to allow the hub to be rotated 360 degrees. Therefore, the clinician can orient cement injection in any direction based upon the architecture of the area that the bone cement in injected into.

[0072] With reference to FIG. 10, another preferred embodiment of the present invention comprises a curved portion **510** at the terminal end **505** of the inner section that extends beyond the distal end of the cannula **30** during a procedure. In this embodiment, the curved portion **510** is a resilient preformed curved section capable of being straightened for insertion through the elongated tubular portion of the cannula. The curved portion also has a shape memory feature which allows it to return to its curved shape after exiting the distal end of the elongated tubular portion. The curved portion **510** may be formed integrally with the inner section or may be a separate structure that is bonded with the inner section. In a preferred embodiment, a visual indicator, such as a symbol or color indicator on the cannula connector, for example, is provided to indicate to the physician the orientation of the curved portion **510** relative to the cannula connector. The inner section **140** includes indicia **517** adjacent the terminal end **144**. The indicia **517** is indicative of a location of the terminal end **144** relative to the distal end of the cannula **30.** The indicia **517** can assume a wide variety of forms differing from that shown in FIG. 10, and in some embodiments can be eliminated. The end portion **550** may be any of the tip configurations described above.

[0073] In operation, a cannula is positioned within a vertebral body as described above. The carrier assembly having the curved portion **510** is preloaded with curable material and inserted into the elongated tubular portion of the cannula. Depth indicia **517** on the inner section may be used by the physician to determine how far the curved portion **510** has traveled beyond the distal end of the cannula **30.** After the desired depth is achieved, curable material may be delivered to the vertebral body. Using the visual indicator of the orientation of the curved

portion **517**, the curved portion **515** may be repositioned so that curable material may be delivered to different areas within the vertebral body. Following the delivery of a predetermined amount of curable material into the vertebra, the carrier assembly **20** is removed from the cannula **30**.

[0074] It is also contemplated that according to another preferred embodiment, the invention may be used with a tamping operation using an inflatable device. Tamping operations using a balloon are known in the prior art and are disclosed at, for example, U.S. 4,969,888, titled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device" and U.S. 5,108,404, titled "Surgical Protocol For Fixation of Bone Using Inflatable Device." In those procedures in which physicians believe a clinical advantage can be gained by tamping the internal bone, the present invention may be used in the following manner. First, a physician gains entry into the bone using a cannula and stylet combination. After gaining entry, the trabecular bone is morcellated to create a void for the tamping device. The tamping device is inserted into this space and expanded, thus enlarging the void in the bone. After the tamping device is removed, the preloaded inner section is inserted into the cannula and curable material is delivered into the site as already described.

[0075] It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention. In this regard, it should be understood that although reference to bone sites and curable material has been made, the devices and methods disclosed herein are not limited in application to bone sites and curable materials. One skilled in the art will understand that the devices and methods disclosed herein may be used at non-bone sites such as spinal discs and may be used to inject material other than curable material.

INDUSTRIAL APPLICABILITY

[0076] The system and method answers a long felt need for increasing safety and control in the administration of curable material to a bone site by providing an inner section of tubing within a cannula that may be preloaded with curable

material. The inner section of tubing allows a cannula to remain free of the curable material so that it may be reused during the procedure. Additionally, preloading the inner section of tubing with curable material allows for reduced time to deliver curable material to a patient and increases control over the curable material delivery.

CLAIMS

What is claimed is:

1. An apparatus for introducing material into an injection site of a patient comprising:

a cannula defining a lumen;

a carrier for delivering material from an injector to an injection site, the carrier defining a lumen and the carrier comprising

a supply section operable to receive curable material, and

an inner section proximal to the patient having a longitudinal axis,

wherein the supply section is rotatable with respect to the longitudinal axis of the inner section and at least a portion of the inner section is located within the lumen of the cannula.

2. The apparatus of claim 1 wherein the inner section is rotatable and rotation of the inner section is dependant on rotation of the supply section.

3. The apparatus of claim 1 wherein the inner section is rotatable and rotation of the inner section is independent of rotation of the supply section.

4. The apparatus of claim 1 wherein the carrier further comprises a connector for connecting an end of the supply section with an end of the inner section wherein the connector defines a chamber between the end of the supply section and the end of the inner section.

5. The apparatus of claim 4 wherein the connector further comprises a rotating adapter that connects with the end of the supply section.

6. The apparatus of claim 5 wherein the rotating adapter is operative to rotate the supply section at least about 90 degrees.

7. The apparatus of claim 6 wherein the supply section, chamber and inner section form a lumen having walls defining a substantially smooth transition from the supply section to the inner section.

8. An apparatus for introducing material into an injection site of a patient comprising:

a tubular section having an interior surface defining a lumen for transporting curable material wherein the interior surface of the lumen is smooth.

9. The apparatus of claim 8 wherein the smooth interior surface has an RMS value of about 0 to about 45.

10. The apparatus of claim 8 wherein the smooth interior surface has an RMS value of about 0 to about 36.

11. The apparatus of claim 8 wherein the interior surface has an RMS value of about 0 to about 16.

12. The apparatus of claim 8 wherein the interior surface is coated with a dry lubricant.

13. The apparatus of claim 12 wherein the dry lubricant is Teflon®.

14. The apparatus of claim 8 wherein a liner within the tubular section defines the smooth interior surface.

15. The apparatus of claim 14 wherein the liner is made of Teflon®.

16. The apparatus of claim 10 wherein the tubular section is metallic.

17. The apparatus of claim 8 further comprising a cannula defining a second lumen wherein at least a portion of the inner section is located within the second lumen of the cannula during delivery of the material.

18. A method of delivering material to an injection site comprising the steps of:

inserting a cannula defining an elongated lumen into an injection site;

connecting a tubular supply section of a carrier defining a lumen with an injector containing a volume of material;

advancing material through the tubular supply section from the injection to dispel a dry plug of material from the tubular supply section;

connecting a tubular inner section of the carrier with the supply section;

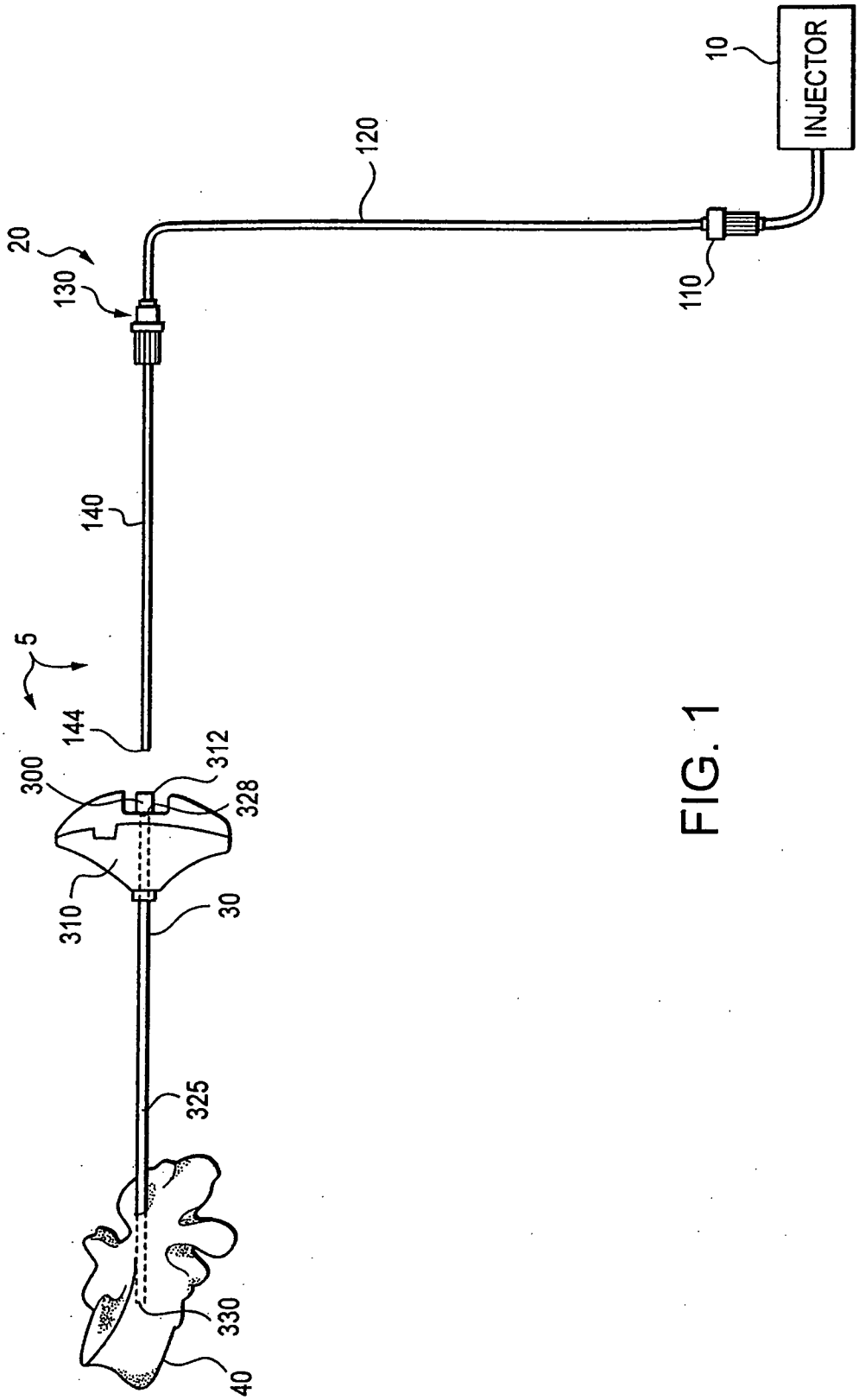
pre-loading the lumen of the carrier with the material so that the material is delivered to a distal end of the tubular inner section from the injector, wherein the carrier is thus pre-loaded with material;

inserting at least a portion of the distal end of the pre-loaded tubular inner section into the elongated lumen of the cannula; and

delivering material to an injection site.

19. The method of claim 18 wherein the injection site and second injection site are within a vertebra.

20. The method of claim 19 wherein the tubular supply section and the tubular inner section are of different diameters.


INJECTOR
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120
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130
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144
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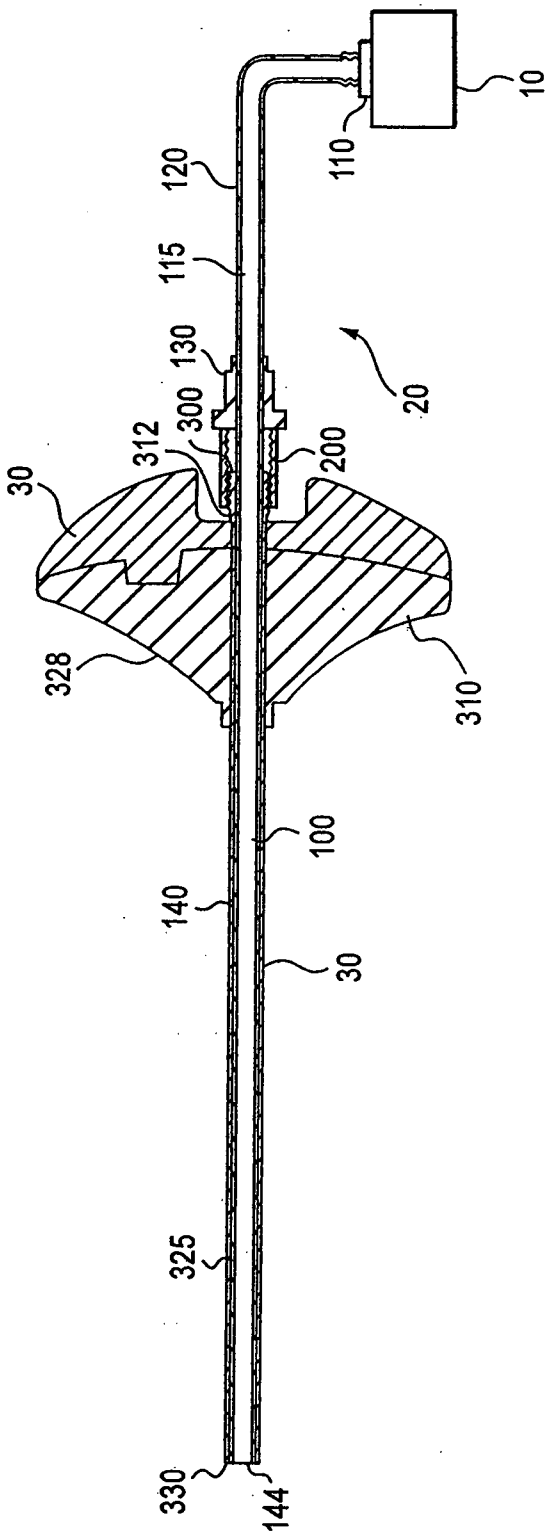
310
30
325
330
40

FIG. 1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310
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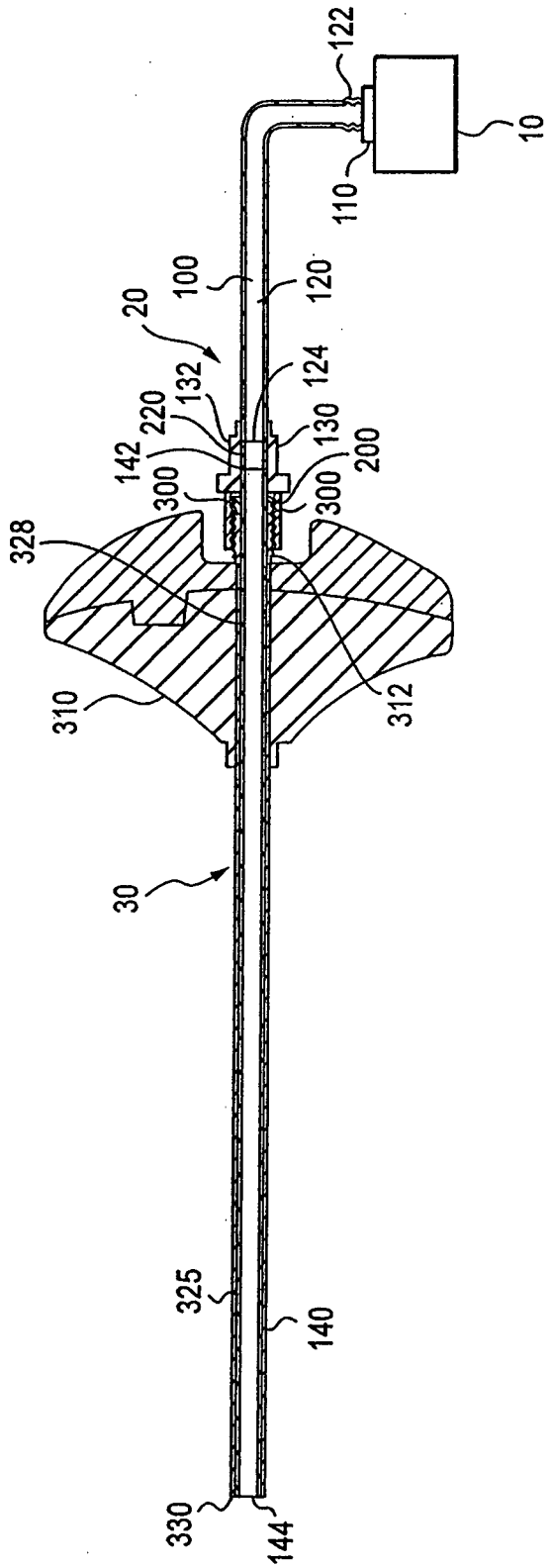
140
30
325
330
144

FIG. 2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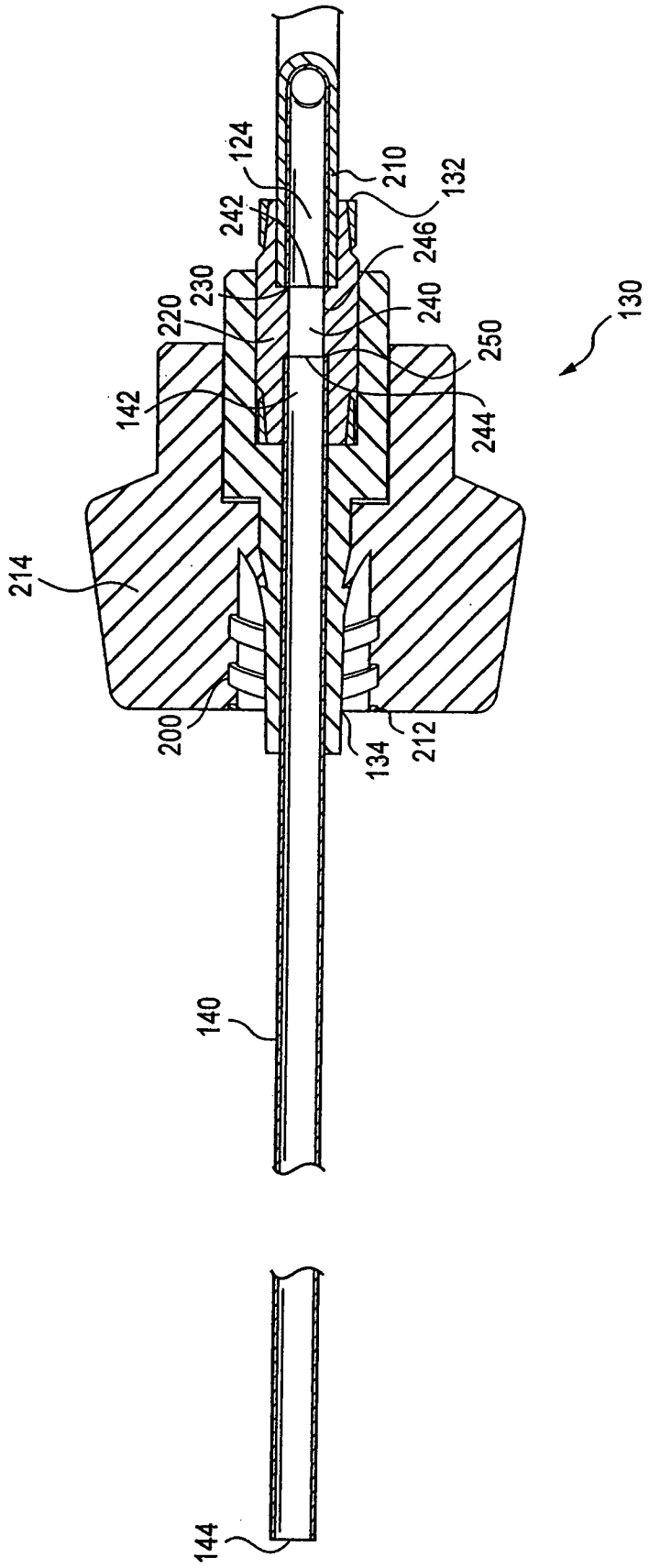
330
144

FIG. 3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130
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142
244
214
200
134
212
140
144

FIG. 4

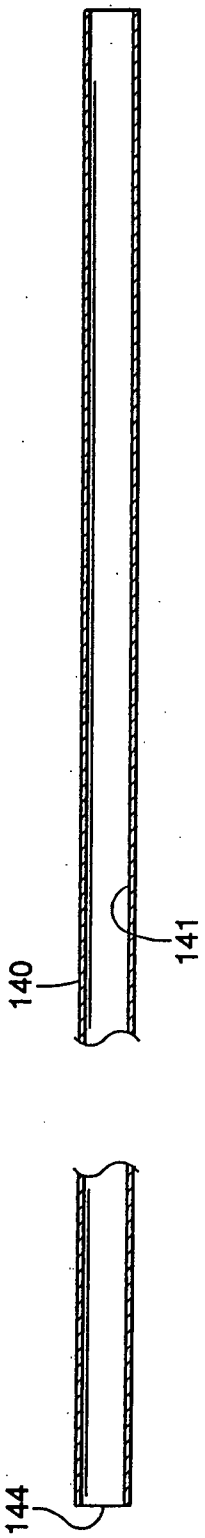


FIG. 4a

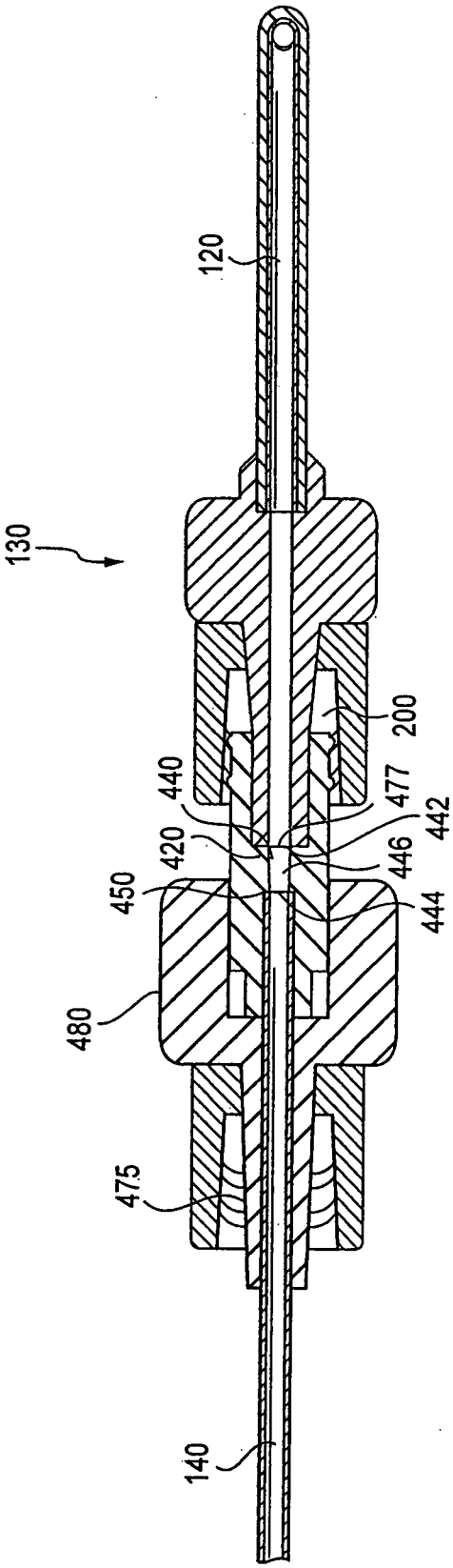


FIG. 5

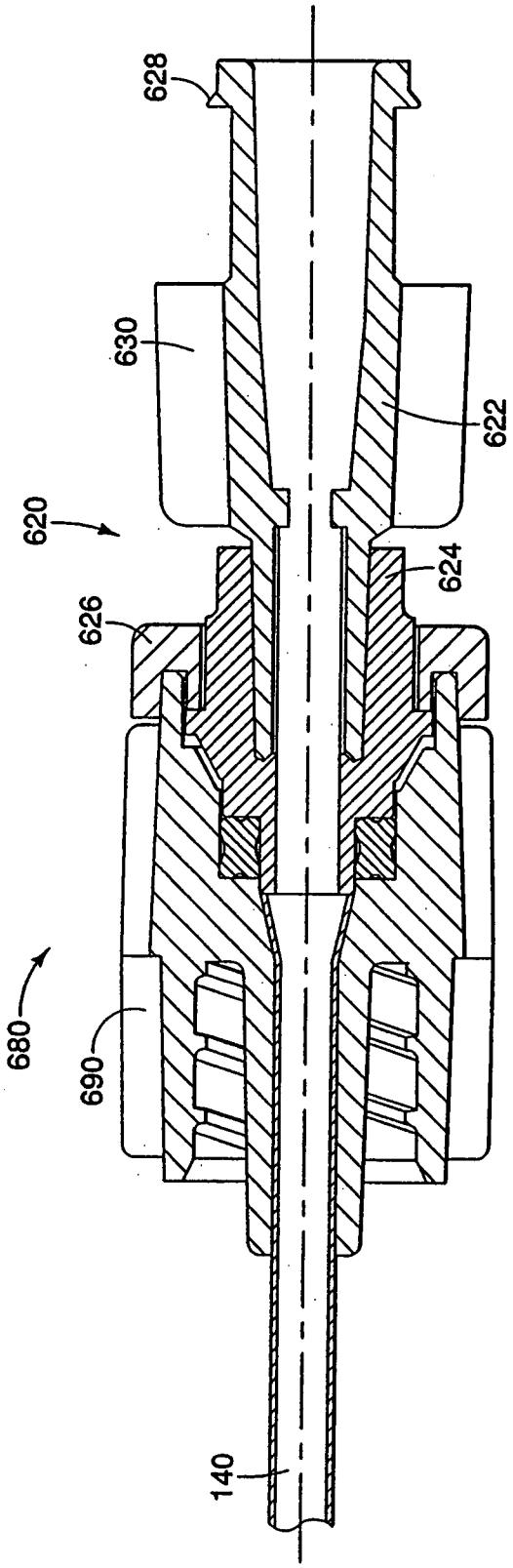


FIG. 5a

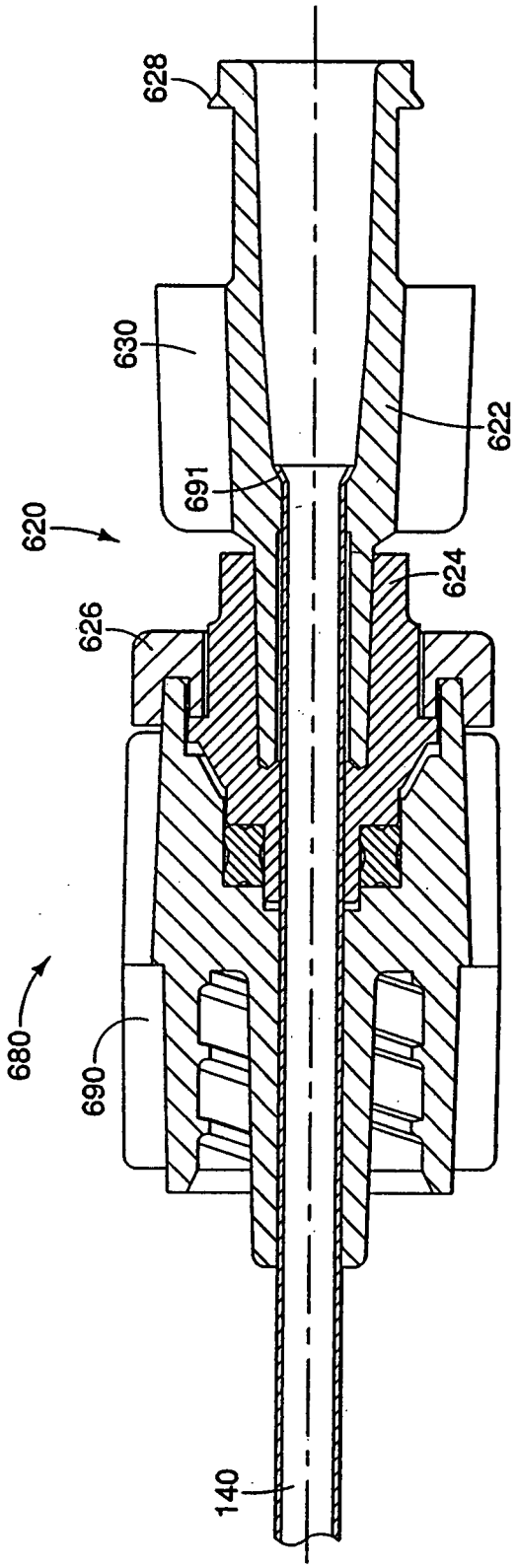
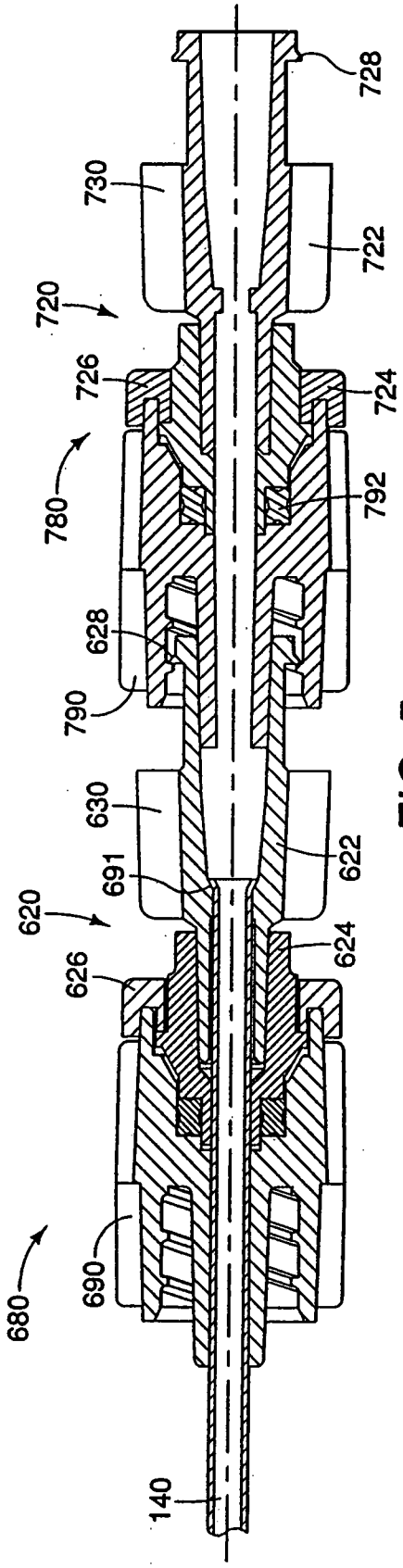


FIG. 5b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622
691
620
624
626
690
680
140

FIG. 5c

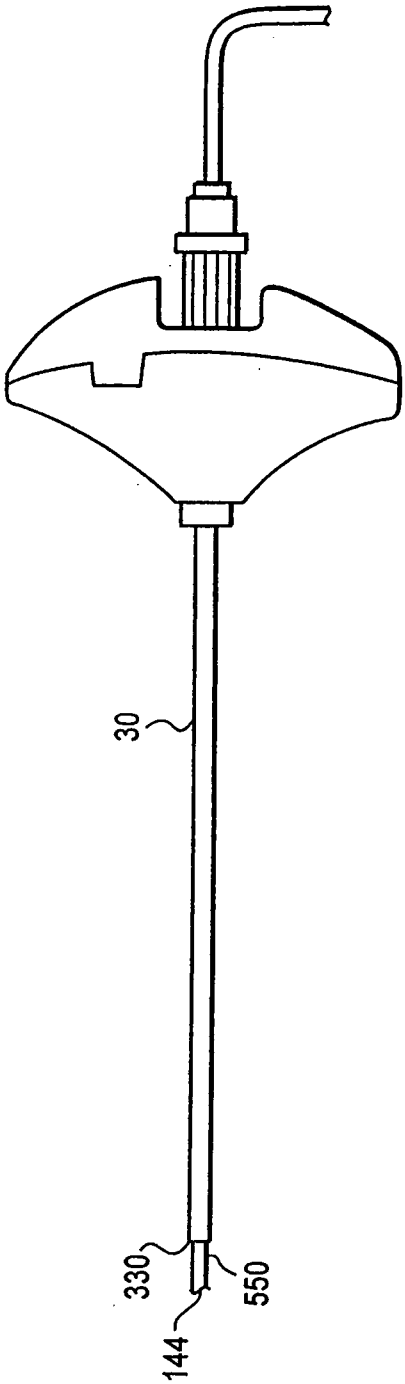

FIG. 6

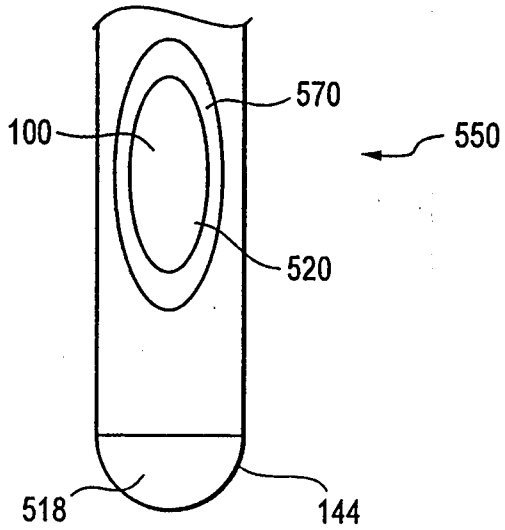

FIG. 7

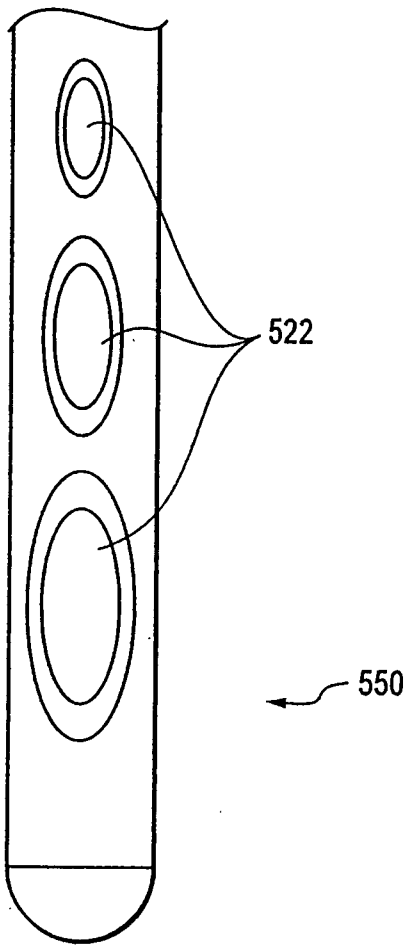

FIG. 8

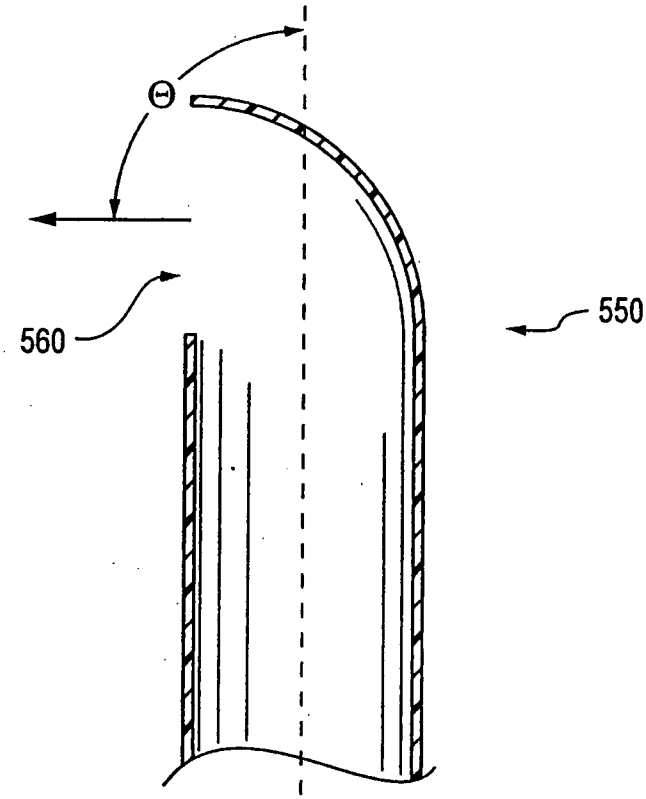

FIG. 9

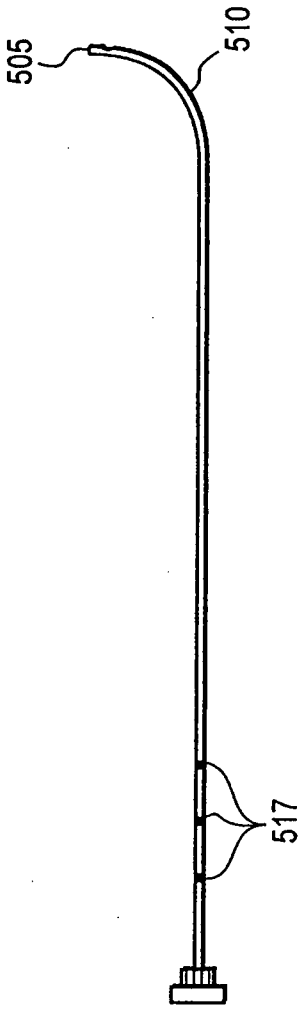

FIG. 10