



US 20090292289A9

(19) **United States**  
(12) **Patent Application Publication**  
**Sand et al.**

(10) **Pub. No.: US 2009/0292289 A9**  
(48) **Pub. Date: Nov. 26, 2009**  
**CORRECTED PUBLICATION**

(54) **SYSTEMS AND METHODS FOR INJECTING FLOWABLE MATERIALS INTO BONES**

(65) US 2004/0024409 A1 Feb. 5, 2004

(75) Inventors: **Paul M. Sand**, San Carlos, CA (US);  
**Mark A. Reiley**, Piedmont, CA (US);  
**Arie Scholten**, Manteca, CA (US);  
**Robert M. Scribner**, Niwot, CO (US);  
**Michael L. Reo**, Redwood City, CA (US)

Correspondence Address:

**Medtronic**  
**Attn: Noreen C. Johnson, IP Legal Department**  
**2600 Sofamor Danek Drive**  
**Memphis, TN 38132 (US)**

**Related U.S. Application Data**

- (60) Division of application No. 09/893,298, filed on Jun. 27, 2001, now Pat. No. 6,645,213.  
Continuation-in-part of application No. 09/496,987, filed on Feb. 2, 2000, now Pat. No. 6,719,761, which is a division of application No. 08/910,809, filed on Aug. 13, 1997, now Pat. No. 6,048,346.
- (60) Provisional application No. 60/214,666, filed on Jun. 27, 2000.

**Publication Classification**

(73) Assignee: **Kyphon Inc.**

(21) Appl. No.: **10/630,519**

(22) Filed: **Jul. 30, 2003**

- (51) **Int. Cl.**  
**A61B 17/58** (2006.01)
- (52) **U.S. Cl.** ..... **606/92**

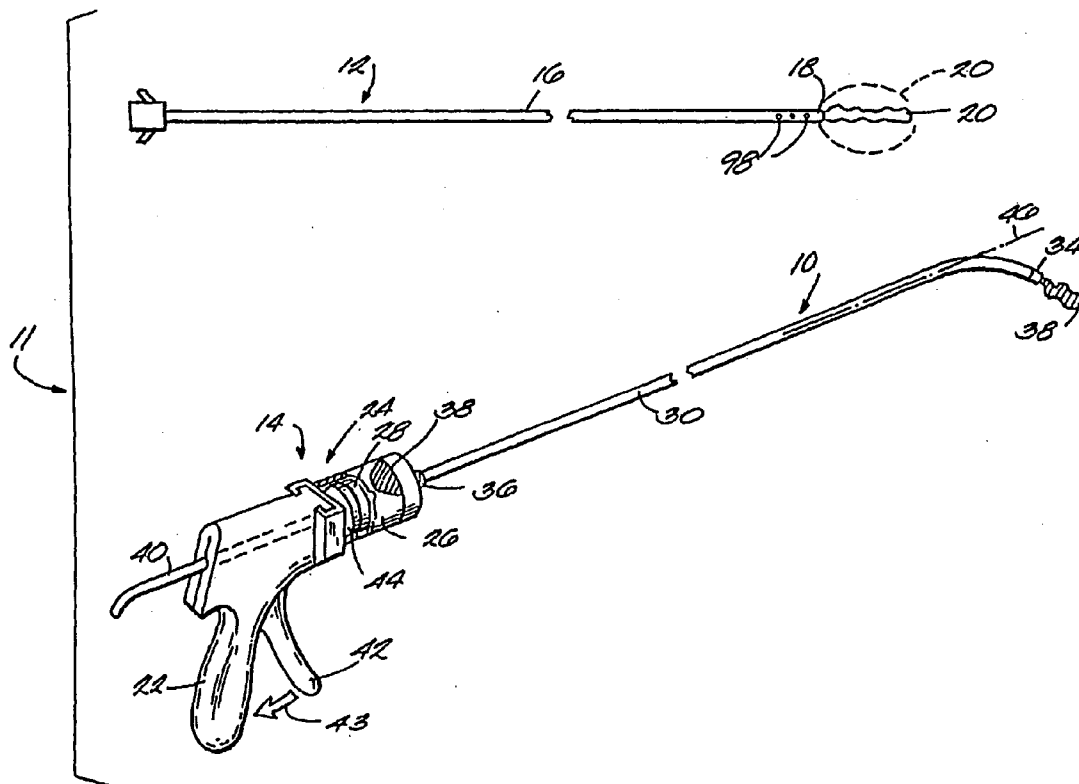
**Prior Publication Data**

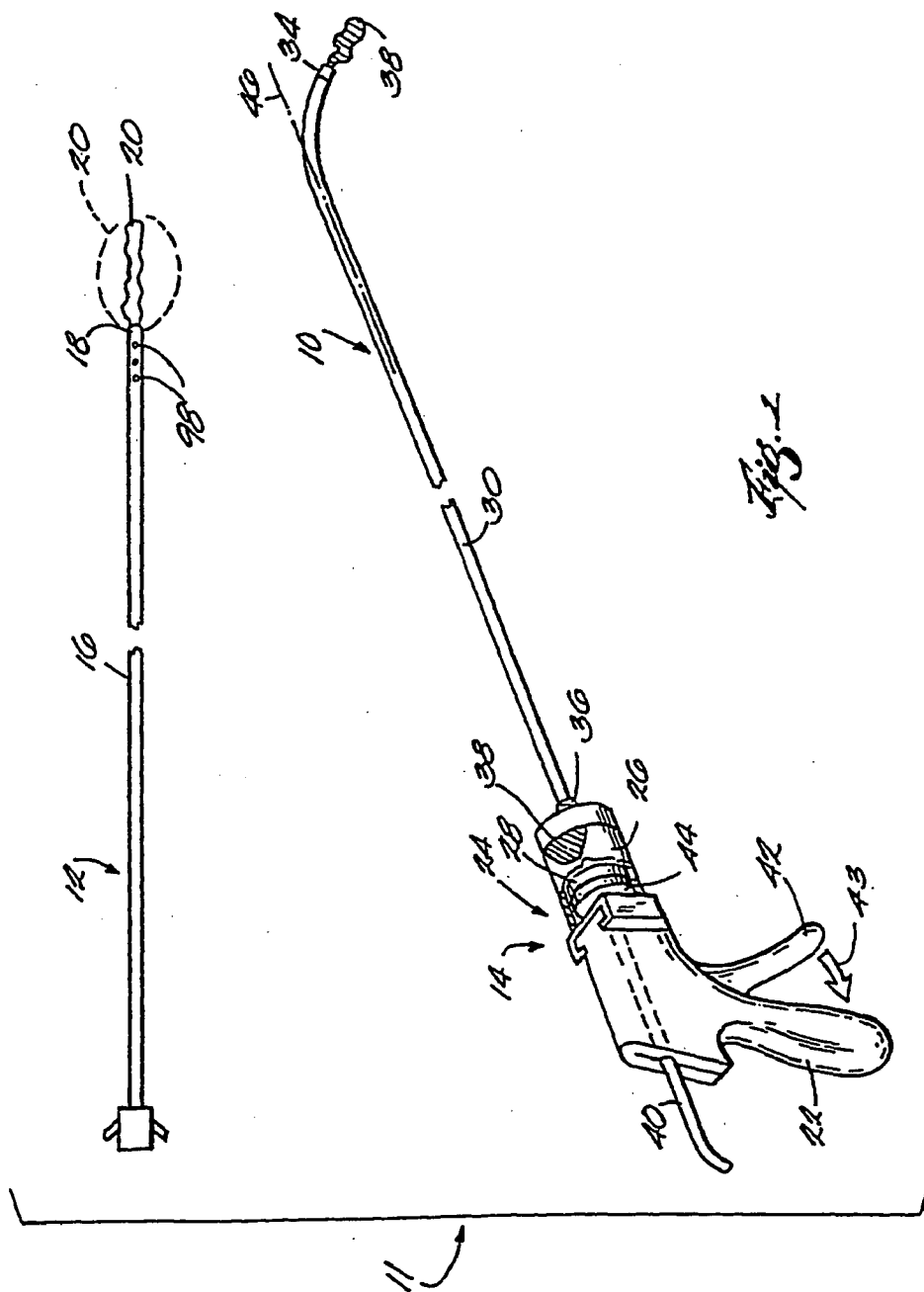
(15) Correction of US 2004/0024409 A1 Feb. 5, 2004

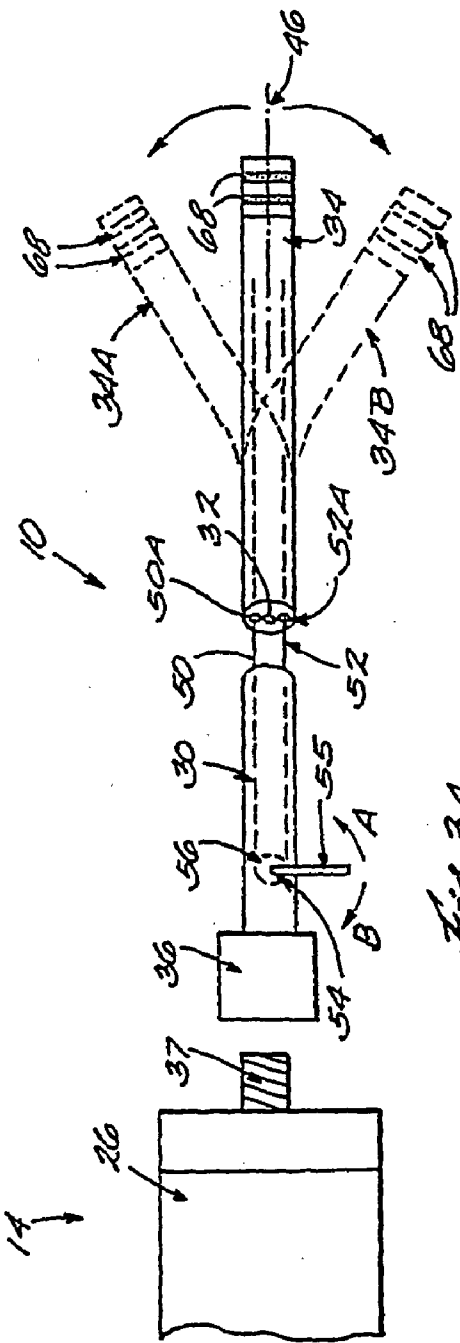
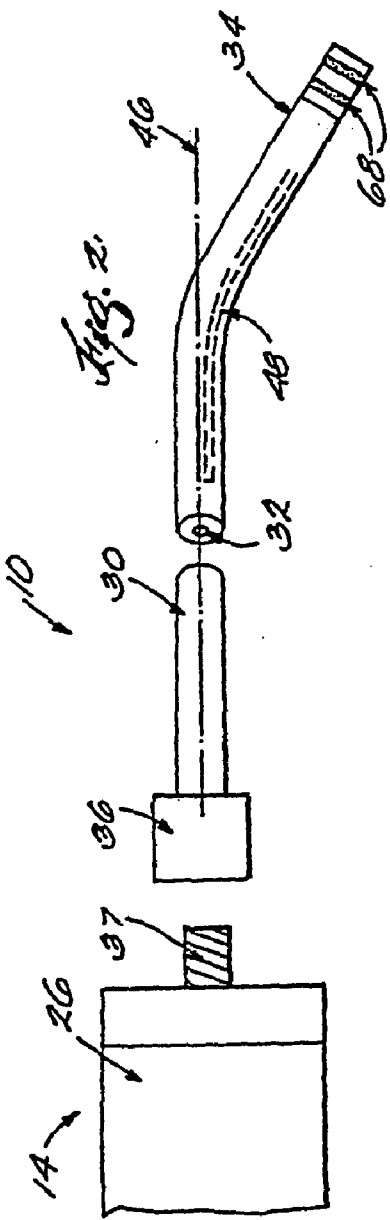
See (60) Related U.S. Application Data.

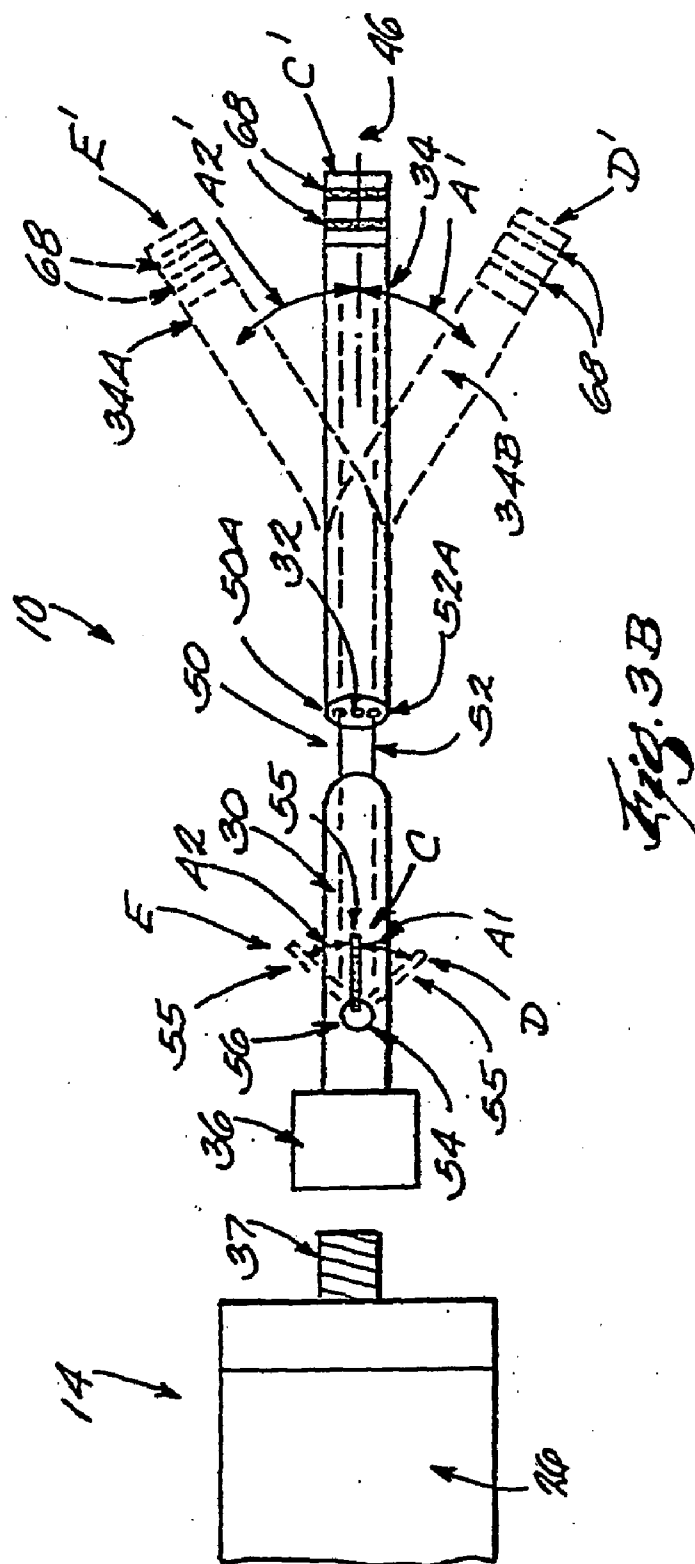
(57) **ABSTRACT**

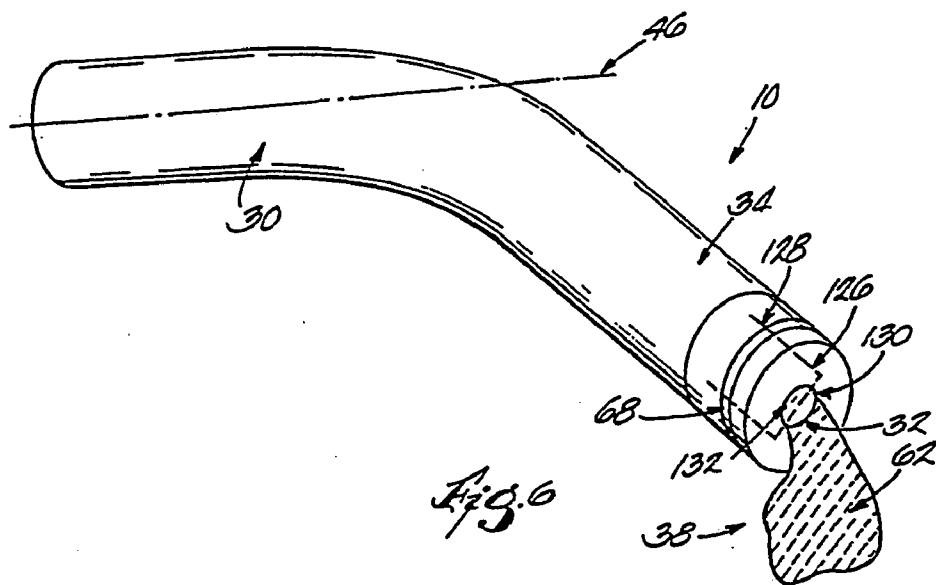
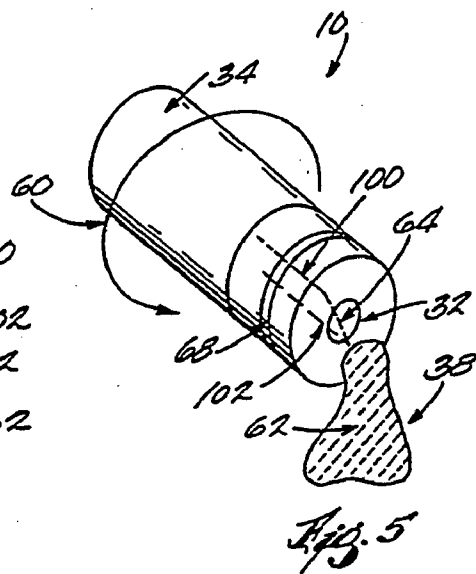
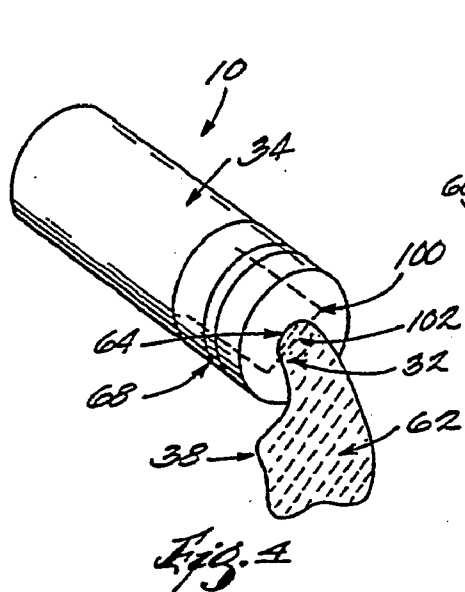
Systems and methods provide greater control over the placement of cement and other flowable liquids into bone.

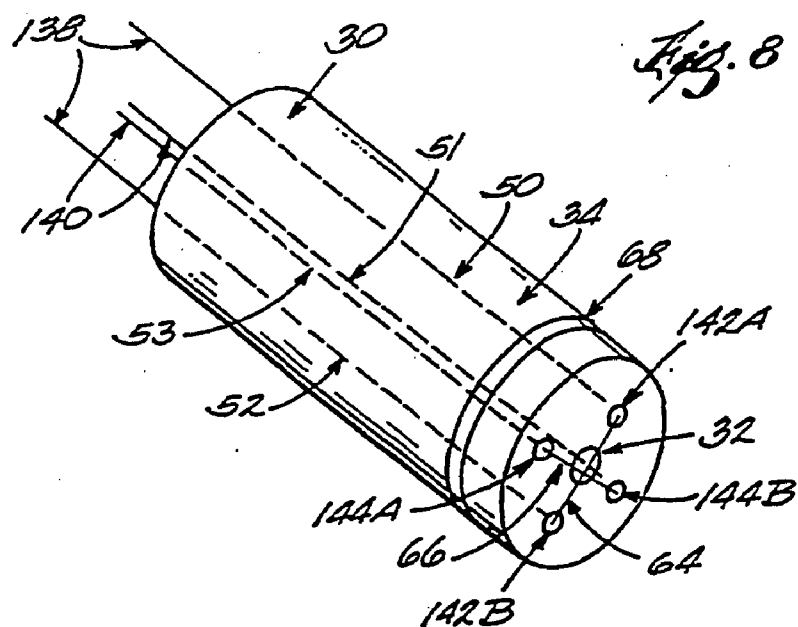
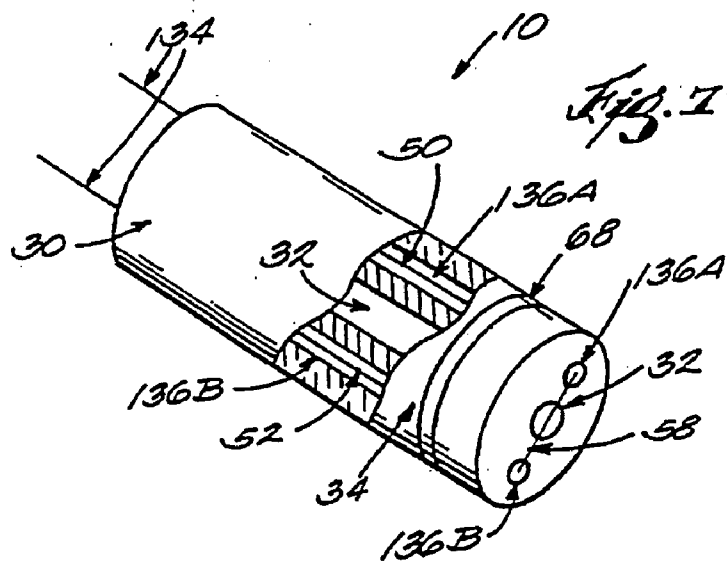


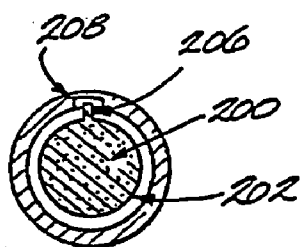
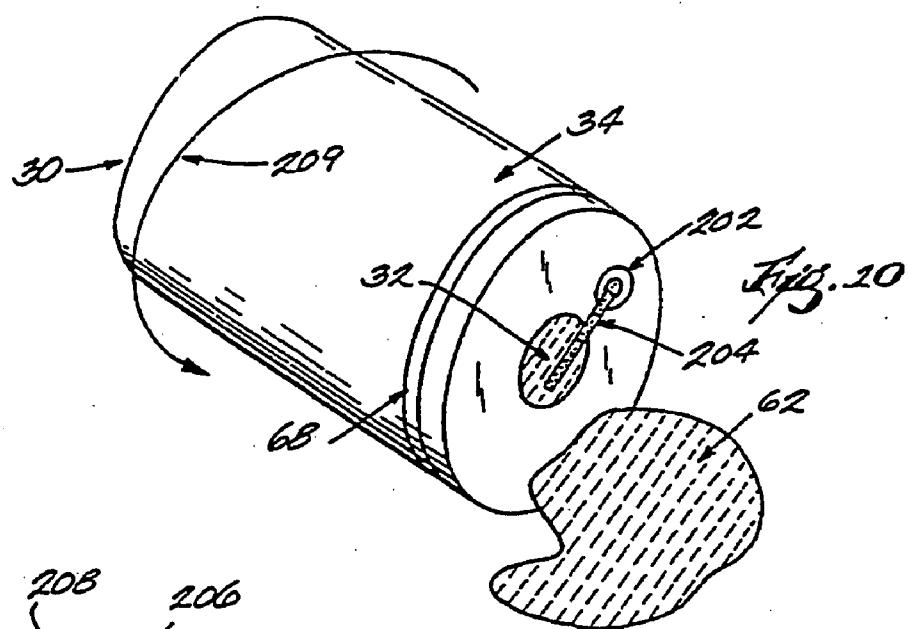
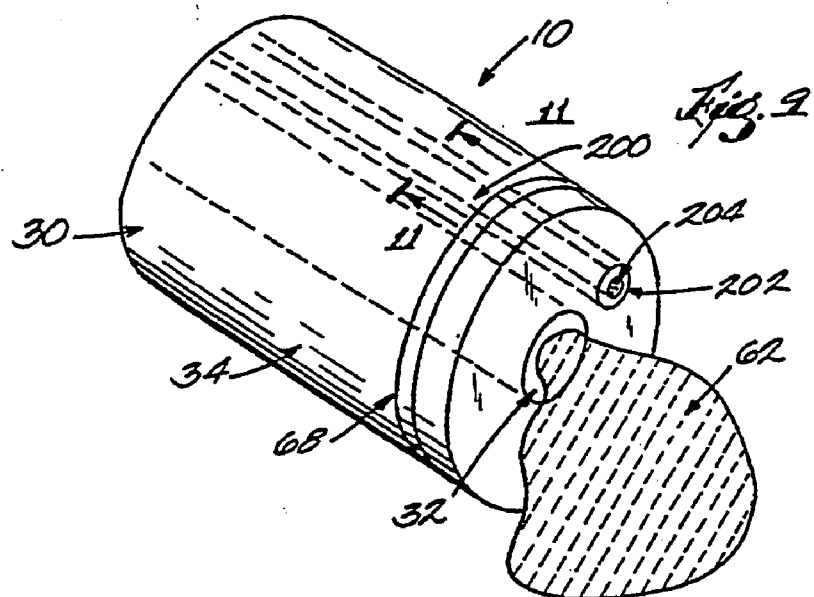


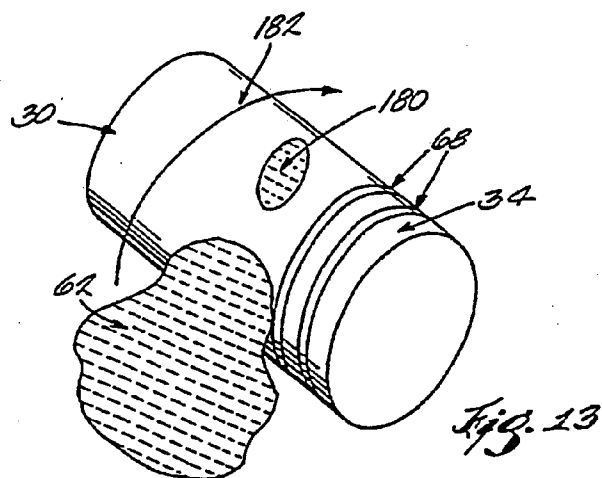
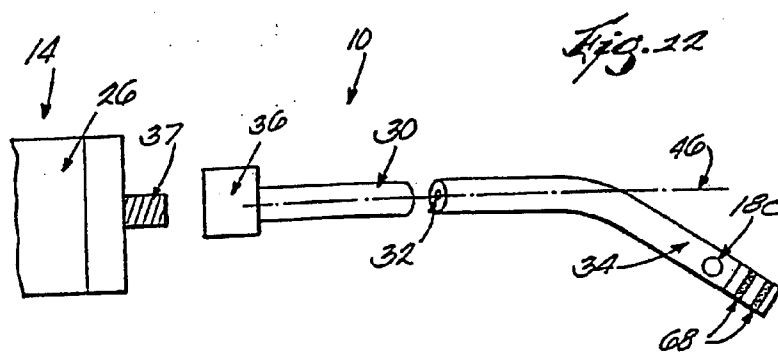




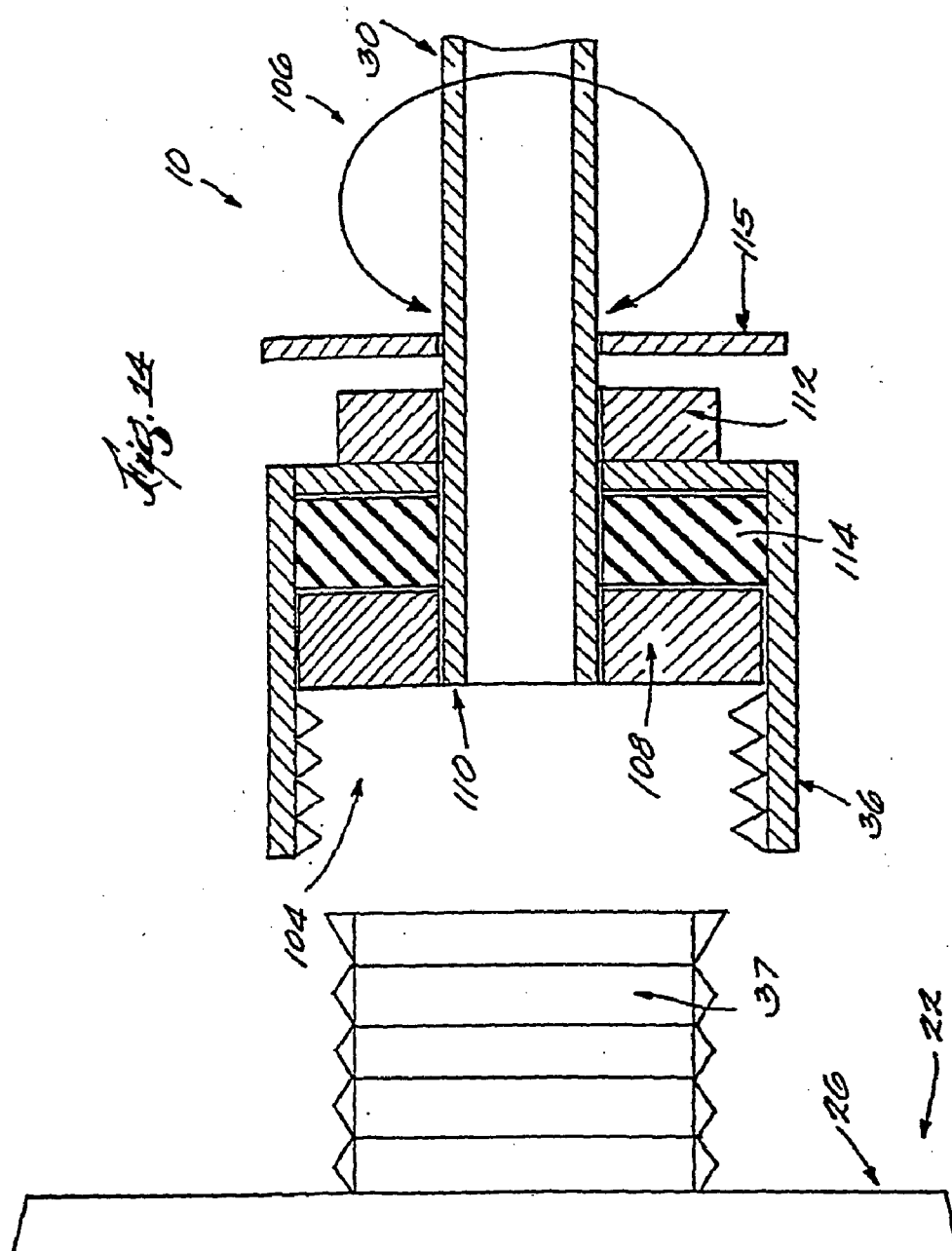


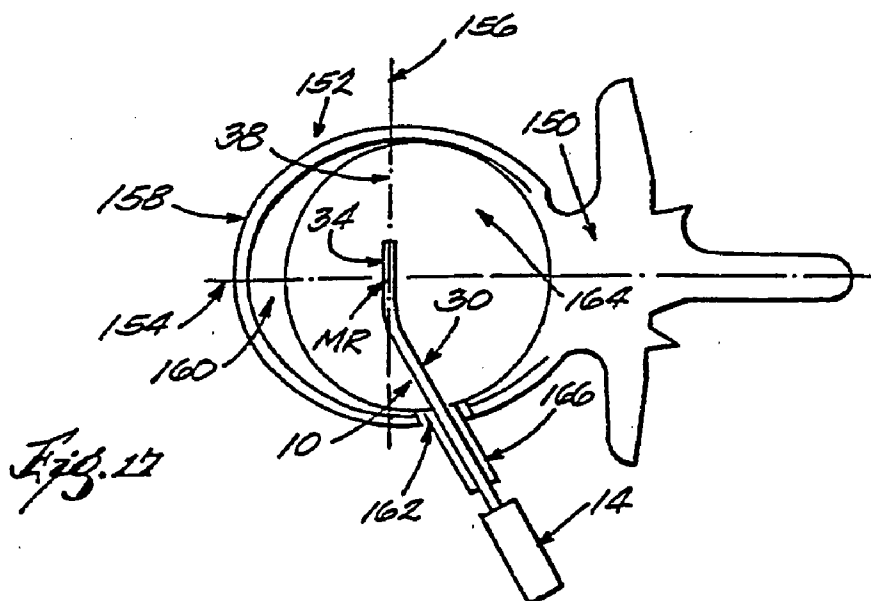
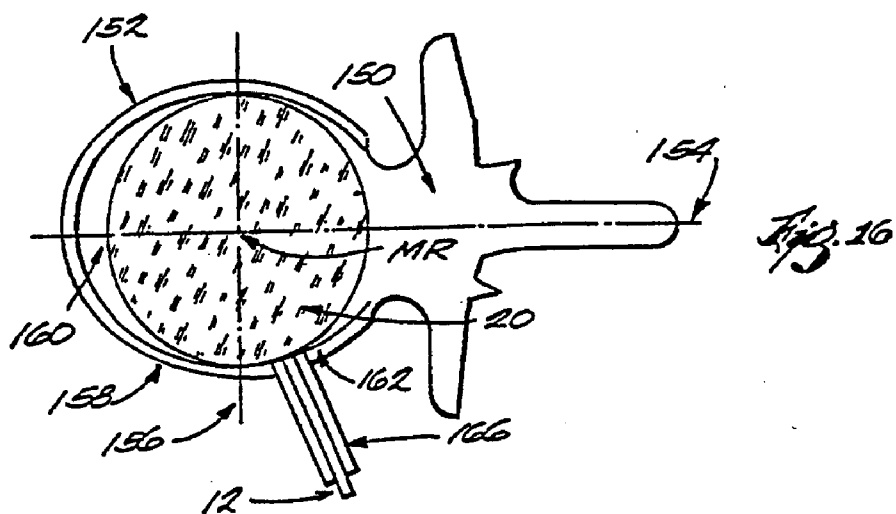
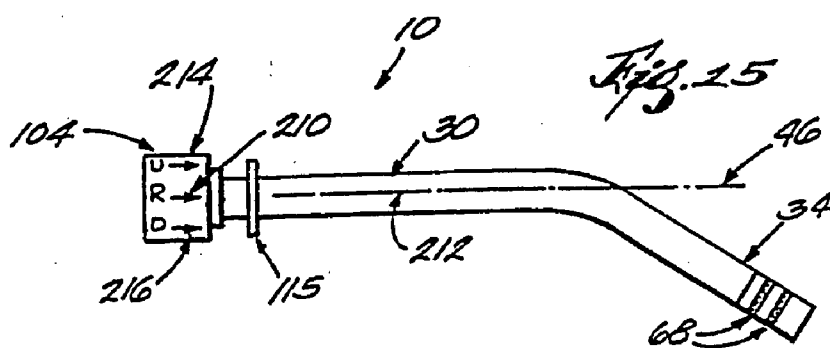


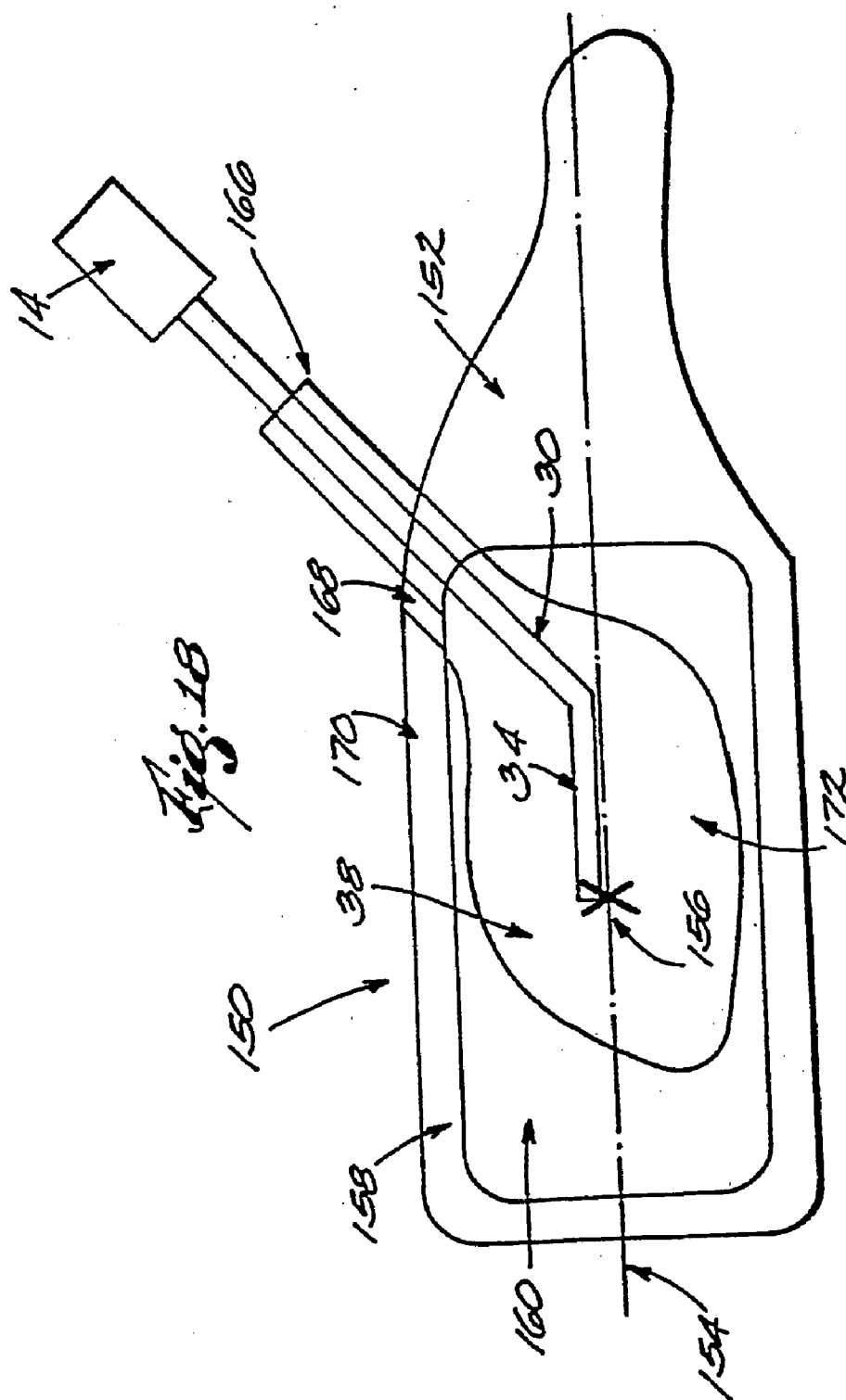


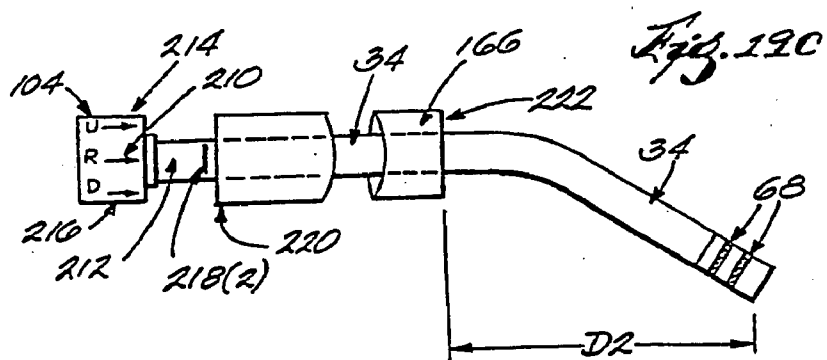
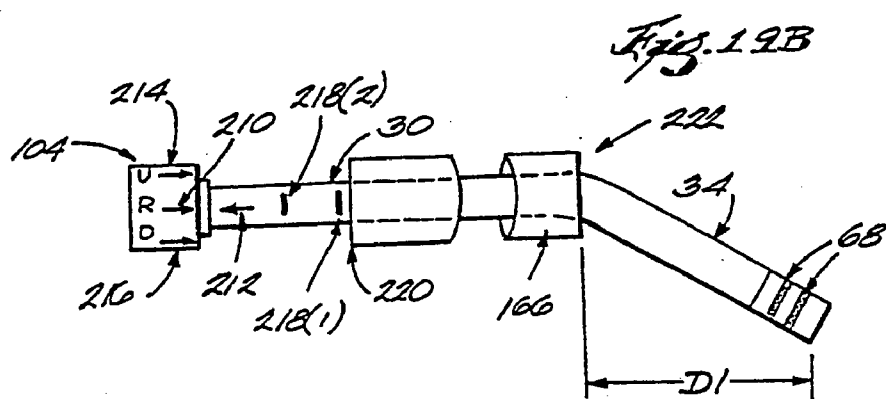
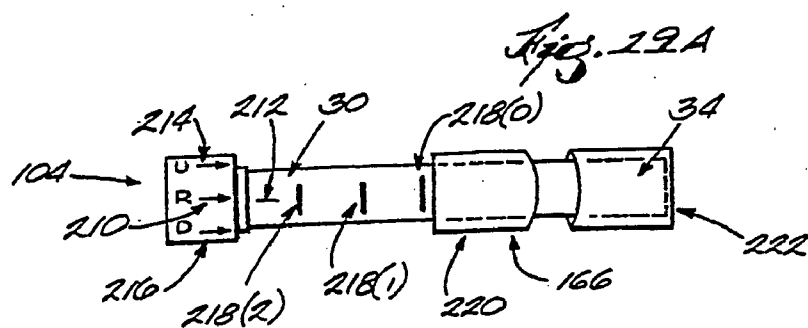


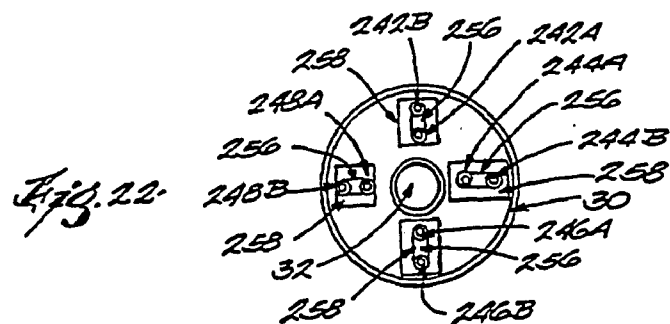
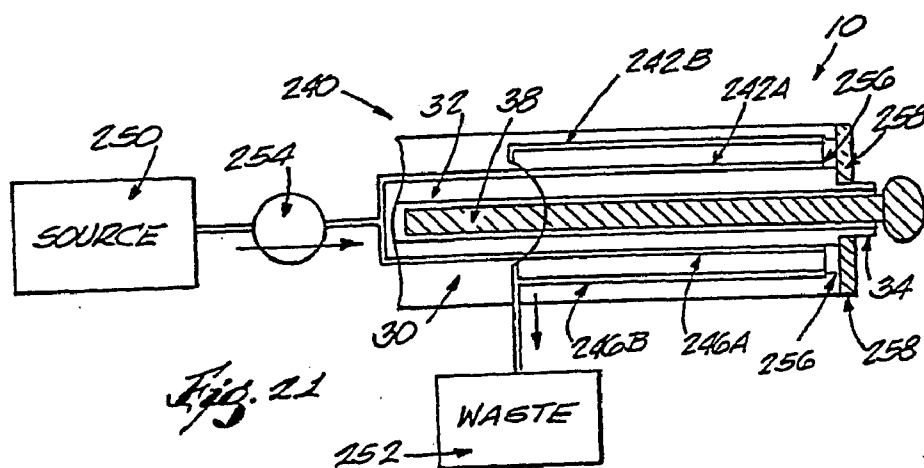
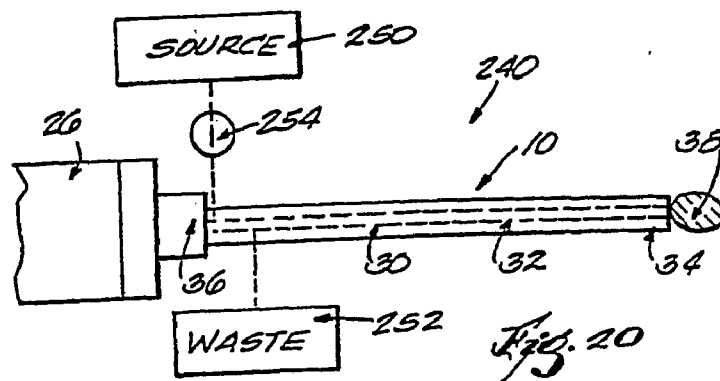












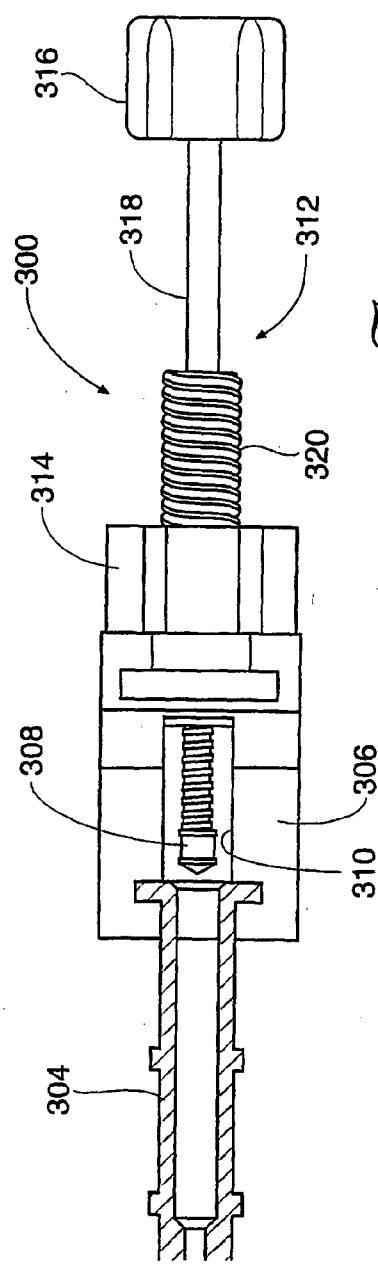


Fig. 23

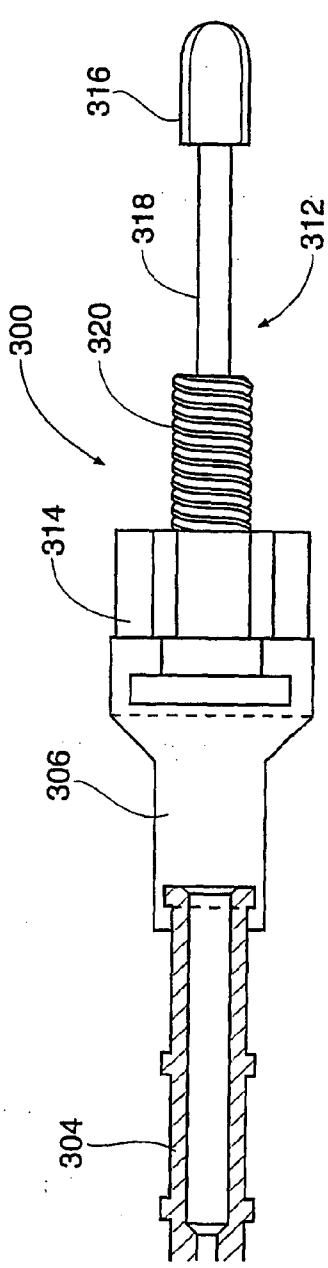


Fig. 24

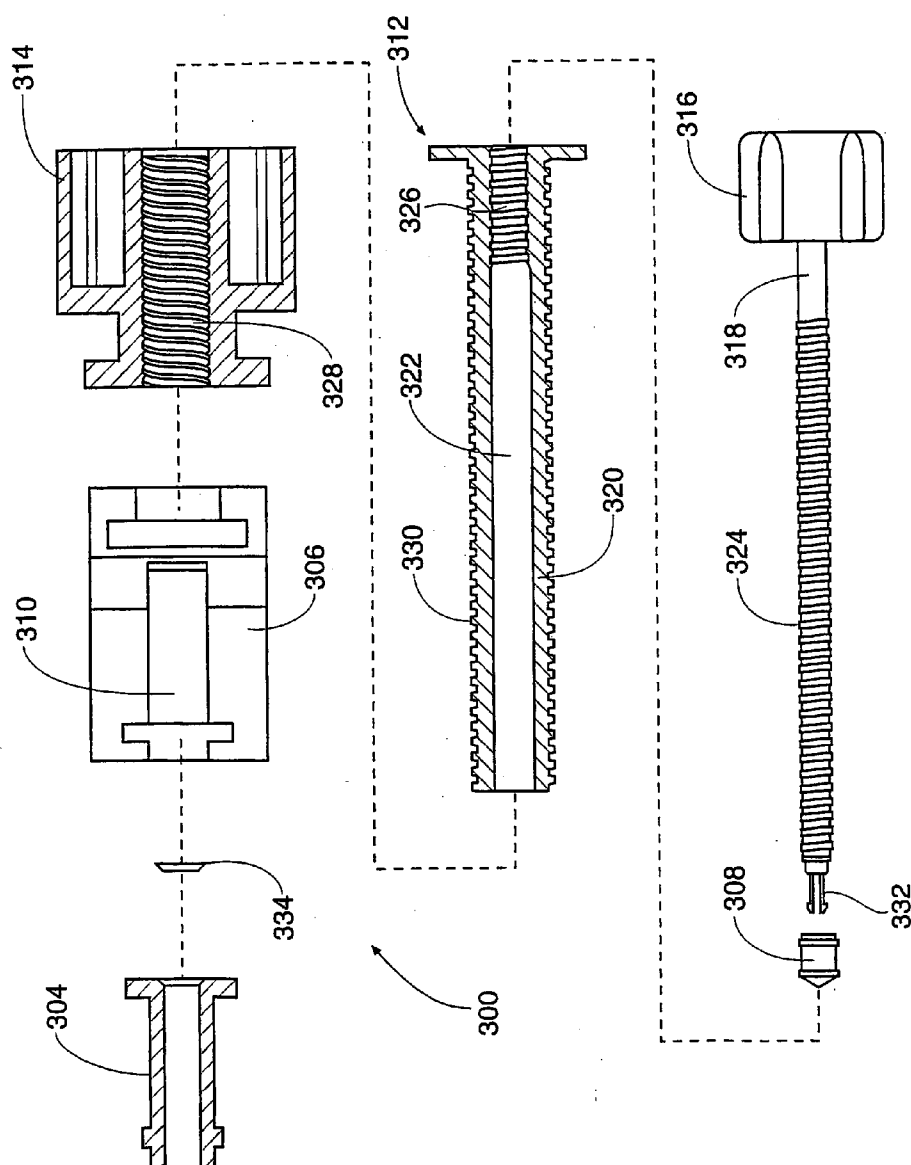
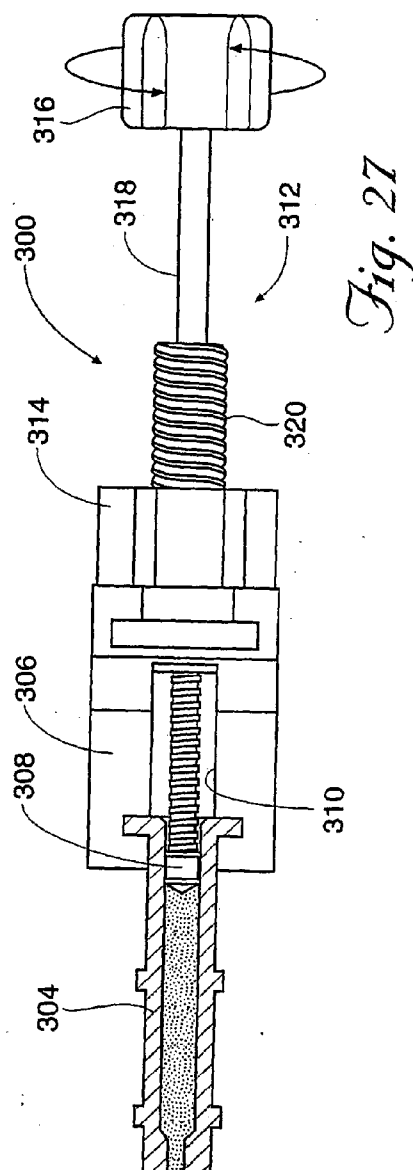
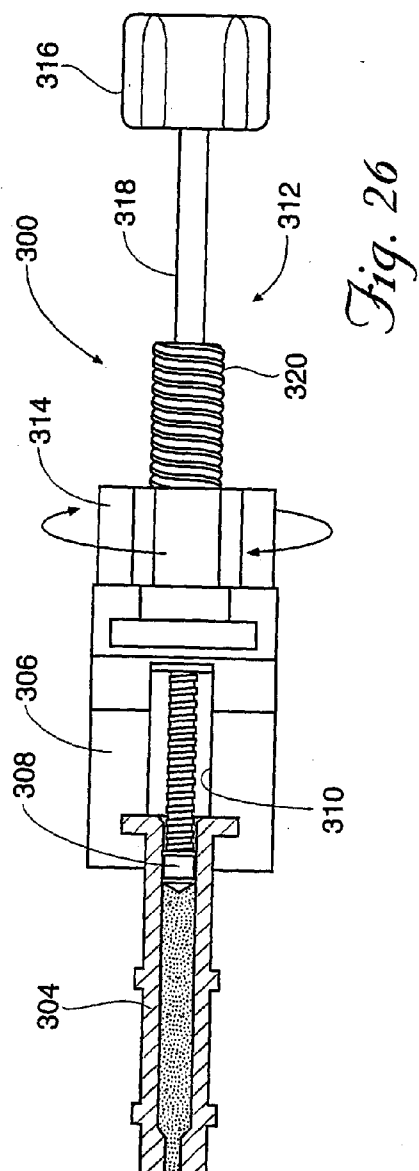


Fig. 25





## SYSTEMS AND METHODS FOR INJECTING FLOWABLE MATERIALS INTO BONES

### RELATED APPLICATION

[0001] This application is a divisional application of co-pending U.S. patent application Ser. No. 09/893,298, filed Jun. 27, 2001. This application claims the benefit of provisional application Serial No. 60/214,666 filed Jun. 27, 2000. This application is a continuation-in-part of co-pending U.S. patent application Ser. No. 09/496,987, filed Feb. 2, 2000, and entitled "Systems and Methods for Injecting Flowable Materials into Bones," which is incorporated herein by reference.

### FIELD OF THE INVENTION

[0002] The invention relates to the treatment of bone conditions in humans and other animals.

### BACKGROUND OF THE INVENTION

[0003] Several companies offer mechanical bone cement injection devices. These devices are similar to a household caulking gun. Typically, the injection device has a pistol-shaped body, which supports a cartridge containing bone cement. The cement is typically in two-parts and must be mixed in a mixer and transferred into the cartridge for injection.

[0004] Just after mixing, and prior to curing, the cement is in a flowing, viscous liquid state, similar to a syrup or watery pancake batter in consistency. The injection device has a ram, which is actuated by a manually movable trigger or screwing mechanism for pushing the viscous bone cement out the front of the cartridge through a suitable nozzle and into the interior of a bone targeted for treatment.

[0005] Once injected into the targeted bone, the cement undergoes a curing cycle of perhaps 6 to 8 minutes. While curing, the cement passes from a viscous liquid to a putty-like consistency and finally to a hard rigid block.

### SUMMARY OF THE INVENTION

[0006] The invention provides, in its various aspects, greater control over the placement of cement and other flowable liquids into bone.

[0007] One aspect of the invention provides an assembly for injecting flowable material into bone. The assembly comprises a tubular body including an interior bore to carry a material flow. The tubular body has a longitudinal axis and includes a dispensing end. An opening in the dispensing end communicates with the bore to dispense the material flow. A plunger is located at least partially within the tubular body. The plunger is adapted to be displaced along the longitudinal axis of the tubular body. The assembly includes an advancement mechanism that is attached to the plunger. The advancement mechanism displaces the plunger a first longitudinal displacement in response to a first delivery impulse, and a second longitudinal displacement in response to a second delivery impulse.

[0008] Features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a view of a system for treating bone, which includes an injector nozzle assembly embodying features of the invention;

[0010] FIG. 2 is an enlarged side view of the dispensing end of one embodiment of the injector nozzle assembly shown in FIG. 1, in which the dispensing end is prebent in a desired geometry to facilitate its deployment;

[0011] FIG. 3A is an enlarged side view of the dispensing end of another embodiment of the injector nozzle assembly shown in FIG. 1, in which the dispensing end is steerable to facilitate its deployment within bone;

[0012] FIG. 3B is an enlarged side view of an alternative embodiment of a steerable dispensing end for the injector nozzle assembly shown in FIG. 1;

[0013] FIG. 4 is an enlarged end view of the dispensing end of one embodiment of the injector nozzle assembly shown in FIG. 1, which carries a loop formed for cutting cement free from the dispensing end;

[0014] FIG. 5 is an enlarged end view of the dispensing end shown in FIG. 4, illustrating the rotation of the cement cutting loop to cut free an ejected cement bolus;

[0015] FIG. 6 is an enlarged end view of the dispensing end of one embodiment of the injector nozzle assembly shown in FIG. 1, which carries two crisscrossing loops formed for cutting cement free from the dispensing end;

[0016] FIG. 7 is an enlarged end view of the dispensing end of one embodiment of the injector nozzle assembly shown in FIG. 1, in which the dispensing end is steerable and also carries a loop formed for cutting cement free from the dispensing end;

[0017] FIG. 8 is an enlarged end view of the dispensing end of another embodiment of the injector nozzle assembly shown in FIG. 1, in which the dispensing end is steerable and also carries two loops formed for cutting cement free from the dispensing end;

[0018] FIG. 9 is an enlarged end view of the dispensing end of one embodiment of the injector nozzle assembly shown in FIG. 1, which carries a prebent stylet, which is shown in a retracted and straightened condition prior to use;

[0019] FIG. 10 is an enlarged end view of the dispensing end shown in FIG. 9, illustrating the rotation of the prebent stylet after advancement to cut free an ejected cement bolus;

[0020] FIG. 11 is a section view of the prebent stylet taken generally along line 11-11 in FIG. 9, showing a mating tab and keyway that prevents rotation of the stylet out of a desired orientation during use;

[0021] FIG. 12 is a side view of one embodiment of the injector nozzle assembly shown in FIG. 1, which includes a side port for dispensing cement;

[0022] FIG. 13 is an enlarged end view of the injector nozzle assembly shown in FIG. 12, illustrating the rotation of the dispensing end to cut free an ejected cement bolus from the side dispensing port;

[0023] FIG. 14 is an enlarged side section view of an injector nozzle assembly which includes a rotating fitting that allows the injector tube to be rotated independent of the cement injecting tool;

[0024] FIG. 15 is a side view of an injector nozzle assembly with a rotating fitting like that shown in FIG. 14, which includes index markers for ascertaining the orientation of the

dispensing end and the extent to which the dispensing end is rotated, without need of direct visualization;

[0025] FIG. 16 is a coronal view of a vertebral body, partially cut away and in section, illustrating the deployment, by postero-lateral access, of an expandable body to compress cancellous bone and form an interior cavity;

[0026] FIG. 17 is a coronal view of the vertebral body shown in FIG. 16, illustrating the deployment of the injector nozzle assembly shown in FIG. 1 by postero-lateral access;

[0027] FIG. 18 is a lateral view of a vertebral body, partially cut away and in section, illustrating the deployment of the injector nozzle assembly shown in FIG. 1 by transpedicular access into a cavity previously formed by an expanded body;

[0028] FIGS. 19A, 19B, and 19C are side views of an injector nozzle assembly, which also includes index markers for ascertaining the extent to which the dispensing end is extended into the targeted treatment site, without the need for direct visualization;

[0029] FIG. 20 is a side view of a system which includes an injector nozzle assembly coupled to a source of cooling fluid to mediate the increase in temperature of curing cement dispensed by the assembly;

[0030] FIG. 21 is a somewhat diagrammatic side section view of the injector nozzle assembly shown in FIG. 20;

[0031] FIG. 22 is an end view of the injector nozzle assembly shown in FIG. 20;

[0032] FIG. 23 is a side view, with portions broken away and in section, of an alternative injector nozzle assembly providing variable rates of delivery;

[0033] FIG. 24 is a top view, with portions broken away and in section, of the injector nozzle assembly shown in FIG. 23;

[0034] FIG. 25 is an exploded view, with portions broken away and in section, of the injector nozzle assembly shown in FIG. 23;

[0035] FIG. 26 is a side view, with portions broken away and in section, of the injector nozzle assembly shown in FIG. 23, being operated to provide a fast rate, high volume delivery of flowable material; and

[0036] FIG. 27 is a side view, with portions broken away and in section, of the injector nozzle assembly shown in FIG. 23, being operated to provide a slower, metered delivery rate of flowable material.

[0037] The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0038] FIG. 1 shows an injector nozzle assembly 10 for conveying a flowable material into bone. The assembly 10 is capable of carrying diverse types of flowable materials, e.g., bone cement or a suspension of one or more therapeutic substances, or both at the same time. The assembly 10 can

likewise be used for diverse therapeutic purposes, as well, e.g., to treat a diseased bone, or to prevent or treat fracture or collapse of a bone, or both at the same time.

[0039] The illustrated embodiment shows the injector nozzle assembly 10 as part of a system 11, which injects cement for treating bone fracture or collapse, which is a purpose for which the assembly 10 is particularly well adapted. It should be appreciated, however, that the nozzle assembly 10 is not limited to use in the treatment of bone fractures or collapse.

[0040] FIG. 1 shows the system 11 to include a tool 12 that forms a cement-receiving cavity in cancellous bone and a tool 14, to which the assembly 10 is releasably attached to convey cement into the formed cancellous bone cavity.

[0041] In FIG. 1, the first tool 12 includes a catheter tube 16 having a distal end 18, which carries an expandable body 20. FIG. 1 shows the body 20 in a collapsed geometry, which permits the physician to insert the body 20 into the interior volume of a targeted bone. Once inserted into bone, the physician can convey fluid to expand the body 20, as shown in phantom lines in FIG. 1.

[0042] As will be described in greater detail later, expansion of the body 20 creates a cavity in cancellous bone. The use of expandable bodies to treat bones in this fashion is disclosed in U.S. Pat. Nos. 4,969,888 and 5,108,404, which are incorporated herein by reference.

[0043] The nozzle assembly 10 is deployed into the formed cavity to dispense bone cement, as will also be described in greater detail later. The cement cures and hardens to provide renewed interior structural support for cortical bone surrounding the cancellous bone.

[0044] Further details of the injection nozzle assembly 10 will now be described.

#### I. The Injection Nozzle Assembly

[0045] The injection nozzle assembly 10 is intended to be component that can be removably connected to a conventional injection tool 14, e.g., by a threaded connector 36 (see FIG. 2). As FIG. 1 shows, the tool 14 comprises a pistol-shaped grip, which will be referred to as a gun 22. The gun 22 includes an end fitment 24, to which a cartridge 26 is removably attached, for example, by threaded screw engagement (not shown). The cartridge 26 includes an interior, movable piston 28.

[0046] As FIG. 2 best shows, the nozzle assembly 10 comprises an injection tube 30. The injection tube is releasably coupled to the front end of the cartridge 26 by the threaded connector 36, which mates with a screw connector 37 on the cartridge.

[0047] The injection tube 30 includes a center lumen 32. The nozzle assembly 10 also includes a distal dispensing end 34, through which the center lumen 32 extends.

[0048] In use (see FIG. 1), the cartridge 26 contains bone cement 38. The cartridge 26 can be loaded with bone cement 38 in various ways. For example, bone cement 38 is typically mixed in an external mixing device (not shown) from two components. Upon mixing, the two components begin to cure from a low viscosity, relatively free flowing liquid, like a thin pancake batter, to a substantially less flowable, putty like

character. Eventually the cement **38** hardens to a rigid state within the targeted bone cavity formed by the expandable body **20**.

[0049] Because of the increasing viscosity (lessening flow) of the bone cement **38**, it should preferably be injected within a few minutes following mixing. For this purpose, a ram rod **40** extends within the gun **22**. The rod **40** carries a ram disk **44**. The rod **40** is coupled to a finger trigger **42**.

[0050] When the physician pulls the trigger **42** rearward (as arrow **43** shows in FIG. 1), the rod **40** advances the ram disk **44** into contact with the cartridge piston **28**. Advancement of the cartridge piston **28**, in turn, pushes the bone cement **38** through the screw connector **37** into the lumen **32** of the injection tube **30** and out through the dispensing end **34**, as FIG. 1 shows.

[0051] Details of the gun **22** can be conventional and are not essential to the invention. The gun **22** can comprise a cement gun made, for example, by Stryker Corporation (Kalamazoo, Mich.). This particular gun has a manually operated trigger with a mechanical advantage of about 9 to 1. Other injection guns may be used, having more or less mechanical advantage. Non-manually operated injection guns can also be used.

[0052] The nozzle assembly **10** can be constructed in various ways. For example, the injector tube **30**, including its dispensing end **34**, can be made of a plastic material, such as polyethylene or other suitable polymer. The diameter and length of the nozzle assembly **10** will vary according to the nature of the procedure. For example, for delivering cement in the hip region, the nozzle assembly **10** can be about 10 to 30 cm long with an outer diameter of about 4 to 12 mm. For delivering cement to a vertebral body, the nozzle assembly **10** can be about 18 to 30 cm long with an outer diameter of about 3 to 8 mm in diameter.

#### [0053] A. Deflecting the Dispensing End

[0054] As FIGS. 1 and 2 show, the dispensing end **34** of the nozzle assembly **10** is either deflected or is otherwise capable of being deflected outside the main axis **46** of the tube **30**. The deflection defines a radius of curvature, which aids in the deployment of the dispensing end **34** within the targeted region. The advantages of the deflected dispensing end **34** will be discussed in greater detail later, as illustrated in the context of its deployment in a vertebral body.

[0055] The deflection of the distal tube end **36** can be accomplished in various ways, which the following description exemplifies.

##### i. Fixed Deflection

[0056] In the embodiment shown in FIG. 2, the dispensing end **34** is normally biased into a prescribed deflected condition. The bias can be thermally set, using, for example, polyurethane or nylon material for the tube. Alternatively (as FIG. 2 shows), the dispensing end **34** can carry a length of prebent memory wire material **48**, made from, e.g., a nickel-titanium alloy, which biases the dispensing end **34** toward the desired deflected geometry. The angle of the deflection can vary, according to the geometry at the intended treatment site.

[0057] As will be described in greater detail later, the bias is overcome by passage of the dispensing end **34** through a guide sheath, which temporarily straightens the dispensing end **34** during its deployment in the intended treatment site.

When free of the confines of the guide sheath, the bias returns the dispensing end **34** to its pre-established deflected condition.

##### ii. Adjustable Deflection

[0058] In an alternative embodiment, as FIG. 3A shows, the injection tube **30** carries steering wires **50** and **52**. The steering wires **50** and **52** extend through side lumens, respectively **50A** and **52A** in the tube **30** and are coupled to the dispensing end **34**.

[0059] In FIG. 3A, two steering wires **50** and **52** are shown for the purpose of illustration, but it should be realized that more or fewer steering wires may be used. The steering wires **50** and **52** are coupled to a steering mechanism **54** located on the proximal end of the tube **30** near the gun cartridge **26**, for manipulation by the physician. In FIG. 3A, the steering mechanism **54** comprises a rotatable wheel **56** with a control lever **55**, to which the steering wires **50** and **52** are coupled. Other types of steering mechanisms **54**, such as pull tabs or linear actuators, can be used.

[0060] Counterclockwise rotation of the wheel **56** (arrow direction A) pulls on the first steering wire **50**, deflecting the dispensing end **34** upward (phantom line position **34A** in FIG. 3A). Clockwise rotation of the wheel **56** (arrow direction B) pulls on the second steering wire **52**, deflecting the dispensing end **34** downward (phantom line position **34B** in FIG. 3A). Multi-directional steering is thereby achieved.

[0061] In an alternative embodiment (see FIG. 3B), position of the control lever **55** corresponds with the angular orientation of the dispensing end **34**. When the control lever **55** is located in the center position C, the dispensing end **34** is in a straightened condition C'. When the control lever **55** is moved down or clockwise (for example, to phantom line position D) the dispensing end **34** is likewise moved to phantom line position D', and the rotation angle A1 between position C and D generally corresponds with the deflection angle A1' between position C' and D'. Likewise, when the control lever **55** is moved up or counterclockwise (for example, to phantom line position E) the dispensing end **34** is likewise moved to phantom line position E', and the rotation angle A2 between position C and E generally corresponds with the deflection angle A2' between position C' and E'.

#### [0062] B. Cutting the Expelled Cement Bolus

##### i. Cutting Wires

[0063] As FIG. 4 shows, one embodiment of the nozzle assembly **10** includes a length of wire **100** carried by the dispensing end **34**. The wire **100** extends across the central opening **32**, forming a loop **102** for cutting loose the cement bolus **62** expelled through the lumen **32**.

[0064] As FIGS. 4 and 5 show, rotation of the injection tube **30** (as arrow **60** in FIG. 5 shows) rotates the dispensing end **34** and, with it, the loop **102**. The loop **102** rotates within the expelled bolus **62** of cement adjacent the terminal end of the lumen **32**. Rotation of the loop **102** through 180° cuts loose the expelled cement bolus **62** from the unexpelled cement mass **64**, which resides within the dispensing end **34**. The loop **102**, integrally carried by the dispensing end **34**, creates a consistent and clean break between the expelled bolus **62** and the unexpelled mass **64**.

[0065] In the embodiment shown in FIG. 6, the nozzle assembly **10** includes two lengths of wire **126** and **128** carried

by the dispensing end 34. The wires 126 and 128 cross over the center lumen 32, forming two cement cutting loops 130 and 132 in the path of cement expelled by the lumen 32. Rotation of the dispensing end 34 through 90° passes the two loops 64 and 66 through the cement bolus 62, severing the cement bolus 62 from the cement mass residing in the dispensing end 34, in the manner shown in FIG. 5.

[0066] As FIG. 6 shows, the dispensing end 34 of the injection tube 30 shown in FIGS. 4 to 6 can, if desired, be preformed with a normal deflection, as previously described, to offset the dispensing end 34 with respect to the axis 46 of the injection tube 30. The tube 30 can also carry steering wires 50 and 52, as shown in FIG. 3, to steer the dispensing end 34.

[0067] Alternatively, the steering and cement cutting elements can be combined. For example, in the embodiment shown in FIG. 7, the nozzle assembly 10 includes a length of wire 134, which is threaded through side lumens 136A and 136B, which extend through the tube 30 (in the manner shown in FIG. 3). The wire 134 forms an exterior loop 58 at the tip of the dispensing end 34. In the illustrated and preferred embodiment, the side lumens 136A and 136B are generally diametrically spaced with respect to the center lumen 32, so that the exterior loop 58 extends across the center lumen 32, generally bisecting it. The exterior loop 58 serves as a cement cutting tool, as previously described.

[0068] In FIG. 7, the wire 134 is fixed to the tip of the dispensing end 34, so that pulling on either leg of the wire 134 will bend the dispensing end 34. The legs of the threaded wire 134 thereby serve as the first and second steering wires 50 and 52, which deflect the dispensing end 34 in the manner previously described and shown in FIG. 3.

[0069] FIG. 8 shows another alternative embodiment, in which two lengths of wires 138 and 140 are threaded through multiple pairs of side lumens 142A, 142B, 144A, and 144B, which extend through the tube 30. The wires 138 and 140 forming circumferentially spaced, multiple steering wires 50, 51, 52, and 53. The wires 138 and 140 also cross over the center lumen 32, forming two loops 64 and 66 across the dispensing end 34. The wires 138 and 140 are fixed by adhesive or other suitable manner to the tip of the dispensing end, forming multiple steering wire legs 50, 51, 52, 53. The fixed legs 50, 51, 52, and 53 provide multi-planar steering. The two loops 64 and 66 also serve as cement cutters.

[0070] FIGS. 9 to 11 show an alternative embodiment of a nozzle assembly 10, which includes a bent stylet 200 to cut loose an expelled cement bolus 62. The stylet 200 is slidably carried by an interior lumen 202 in the injection tube 30. As FIG. 11 best shows, a locating tab 206 on the stylet 200 mates with a groove or keyway 208 in the lumen 202, to prevent rotation of the stylet 200 in the lumen 202. A suitable push-pull mechanism (not shown) is accessible at the proximal end of the injection tube 30 to affect advancement and retraction of the stylet 200 in the lumen 202.

[0071] As FIG. 10 shows, the distal end 204 of the stylet 200 is preformed with an angle bend. When located in the lumen 202 (as FIG. 9 shows), the distal end 204 is retained in a straightened condition. When advanced free of the lumen 202, the distal end 204 assumes the preformed, bent configuration. The locating tab 206 and mating keyway 208 orient the stylet 200, so that, when moved free of the lumen 202, the distal end 204 bends toward and over the central opening 32

of the tube 32, as FIG. 10 shows. The distal end 204 preferably extends at least half way or more across the central opening 32 of the tube 30.

[0072] In use, while the distal stylet end 204 is withdrawn in the lumen 202, the cement bolus 62 is expressed from the central opening 32 of the dispensing end 34 (as FIG. 9 shows). When cement injection is completed, the physician slides the distal stylet end 204 forward from the lumen 202. The stylet end 204, freed from the lumen 202, bends over the central opening 32 into the cement bolus 62. Rotation of the dispensing end 34 through 360° (arrow 209 in FIG. 10) passes the distal stylet end 204 through the cement bolus 62, severing the bolus 62 from the cement mass in the dispensing end 34. The physician pulls on the stylet 200 to return the distal stylet end 204 to the lumen 202.

#### ii. Side Injection Port

[0073] FIGS. 12 and 13 show another alternative embodiment of a nozzle assembly 10 which, upon rotation, cuts loose an expelled cement bolus 62.

[0074] In this embodiment, the nozzle assembly 10 includes an injection tube 30 like that shown in FIG. 2. The tube 30 includes a threaded connector 36, which screws onto the connector 37 of the cement gun cartridge 26. The tube 30 includes a center lumen 32 to transport cement from the cartridge 26 to a distal dispensing end 34.

[0075] Unlike the embodiment shown in FIG. 2, the center lumen 32 does not extend axially through the tip of the distal dispensing end 34. Instead, in FIGS. 12 and 13, the tip of the dispensing end 34 is closed and includes at least one dispensing port 180 extending at an angle from the center lumen 32. The port 180 opens on a side of the dispensing end 34.

[0076] As FIG. 13 shows, the cement bolus 62 is expressed through the side dispensing port 180, and not through the distal tip of the dispensing end 34. As FIG. 13 shows, rotation of the dispensing end 34 (indicated by arrow 182) moves the dispensing port 180 along an arc transversely of and away from the cement bolus 62. The transverse movement of the side dispensing port 180 away from the bolus 62 severs the bolus 62 from the cement mass residing in the center lumen 32.

[0077] As FIG. 12 shows, the dispensing end 34 of the injection tube 30 can, if desired, be preformed with a normal deflection, as previously described, to offset the dispensing end 34 with respect to the axis 46 of the injection tube 30. The tube 30 can also carry steering wires 50 and 52, as shown in FIG. 3, to steer the dispensing end 34.

#### iii. Rotating Fitting

[0078] As FIG. 14 shows, the threaded connector 36, which releasably couples the injection tube 30 to the screw connector 37 on the front end of the cartridge 26 of the cement gun 22, can include a fitting 104 that permits rotation of the injection tube 30 relative to the connector 36 and the gun 22.

[0079] Various constructions for the rotating fitting 104 are possible. In the illustrated embodiment, the rotating fitting 104 includes an adaptor 108 carried for rotation within the connector 36. The proximal end 110 of the injector tube 30 is secured to the adaptor 108 for common rotation. A retaining ring 112 outside the connector 36 surrounds tube 30, allowing its rotation but otherwise restraining rearward axial move-

ment. An o-ring **114** is contained between the adaptor **108** and the end wall of the connector **36**. The o-ring **114** restrains forward axial movement of the tube **30**, while also preventing leakage of cement.

[0080] The rotating fitting **104** permits the physician to rotate the injection tube **30** with one hand, and thereby rotate the nozzle **34** (as arrows **106** show in FIG. **14**), while holding the gun **22** stationary in another hand. As FIG. **14** shows, the injection tube **30** can carry a hub or grip **115** to facilitate rotation.

[0081] The rotating fitting **104** simplifies handling and manipulation of the cement injection tool **14** during rotation of the injection tube **30**. The physician is able to rotate the injection tube **30**, causing the one or more cement cutting loops carried by the rotating dispensing end **34** to cut loose an expelled cement bolus **62** (as shown in FIGS. **4** and **5**, **9** and **10**, and **12** and **13**), without rotating the gun **22** itself. When combined with a deflected dispensing end **34**, rotation of the tube **30** further helps locate the dispensing end **34** in the desired position, again without the need to rotate the gun **22**.

[0082] As FIG. **15** shows, the rotating fitting **104** can include indicia to gauge orientation or rotation of the injection tube **30**. In the illustrated embodiment, the indicia includes an index mark **210** scribed on the connector **36**, which aligns with an index mark **212** scribed on the proximal end of the injection tube **30**. Alignment of the marks **210** and **212** places the dispensing end **34** in a particular, pre-established orientation.

[0083] For example, when the dispensing end **34** is normally biased in a deflected condition, as FIG. **15** shows, alignment of the marks **210** and **212** can designate that the deflection is to the right of the main axis **46**. The index mark **210** can also include a visual or tactile identifier (for example, a raised letter "R" in FIG. **15**) to further aid the physician in ascertaining the orientation.

[0084] The fitting **104** can also include additional auxiliary index marks (two of which **214** and **216** are shown in FIG. **15**) and associated visual or tactile identifiers (respectively, "U" and "D"). Alignment of the mark **212** with auxiliary mark **214** indicates that the deflection orients the dispensing end **34** upward. Likewise, alignment of the mark **212** with auxiliary mark **216** indicates that the deflection orients the dispensing end **34** downward. Another auxiliary mark and associated identifier (not shown), located diametrically opposite to the mark **210**, can also indicate a left orientation of the deflected dispensing end **34**.

[0085] The alignment of the index mark **212** with the index marks **210**, **214**, and **216** allows the physician to remotely orient the deflected end **34** in a desired way, without reliance upon x-ray or other internal visualization technique. Tracking the rotation of the index mark **212** relative to one or more of the index marks **210**, **214**, or **216** also allows the physician to gauge the rotation of the injection tube **30**, to achieve the degree of rotation necessary to cut the cement bolus **62** loose.

[0086] When the dispensing end **34** is steerable (as shown in FIG. **3**), alignment of the marks **210** and **212** can designate that the steering wires **50** and **52** extend in a particular vertical or horizontal plane. With this orientation known, the physician can operate the steering mechanism **56** to achieve the desired bending action, without reliance upon x-ray or other form of internal visualization. Relative movement of the

index marks also allows the physician to monitor the extent of rotation of the injection tube **30** when cutting the cement bolus **62** loose.

[0087] When the dispensing end **34** includes a side dispensing port **180** (as shown in FIGS. **12** and **13**), alignment of the marks **210** and **212** can designate the orientation of the dispensing port **180**, either left, right, up, or down. Relative movement of the index marks also allows the physician to monitor the extent of rotation of the injection tube **30** when cutting the cement bolus **62** loose.

#### [0088] C. Radiological Monitoring

[0089] In all the embodiments shown in FIGS. **2** to **15**, the nozzle assembly **10** includes one or more radiological markers **68**. The markers **68** are made from known radiopaque materials, like platinum, gold, calcium, tantalum, and other heavy metals. At least one marker **68** is placed at or near the dispensing end **34**, to allow radiologic visualization of the dispensing end **34** within the targeted bone area.

[0090] Other forms of markers can be used to allow the physician to visualize the location of the dispensing end **34** within the targeted treatment area.

#### II. Deployment of Nozzle Assembly in a Vertebral Body

[0091] Use of the nozzle assembly **10** will now be described when deployed in a human vertebra **150**, which FIG. **16** shows in coronal (top) view. It should be appreciated, however, the nozzle assembly **10** is not limited in its application to vertebrae. The system **10** can be deployed equally as well in long bones and other bone types.

[0092] The vertebra **150** includes a vertebral body **152**, which extends on the anterior (i.e., front or chest) side of the vertebra **150**. The vertebral body **152** includes an exterior formed from compact cortical bone **158**. The cortical bone **158** encloses an interior volume of reticulated cancellous, or spongy, bone **160** (also called medullary bone or trabecular bone).

[0093] The vertebral body **152** is in the shape of an oval disk, which is generally symmetric about an anterior-posterior axis **154** and a mid-lateral axis **156**. The axes **154** and **156** intersect in the middle region or geometric center of the body **152**, which is designated MR in the drawings.

[0094] As FIG. **16** shows, access to the interior volume of the vertebral body **152** can be achieved. e.g., by drilling an access portal **162** through a side of the vertebral body **152**, which is called a postero-lateral approach. The portal **162** for the postero-lateral approach enters at a posterior side of the body **152** and extends at angle forwardly toward the anterior of the body **152**. The portal **162** can be performed either with a closed, minimally invasive procedure or with an open procedure.

[0095] As FIG. **16** shows, a guide sheath **166** is located in the access portal **162**. Under radiologic, CT, or MRI monitoring, the tool **12** is introduced through the guide sheath **166**, with the expandable body **20** collapsed. When deployed in the cancellous bone **160**, the physician conveys a pressurized fluid into the body **20** to expand it. The fluid is preferably radio-opaque to facilitate visualization. For example, Renografin™ contrast media can be used for this purpose.

[0096] Expansion of the body **20** within the interior volume compresses cancellous bone **160** to form a cavity **164**. The

compaction of cancellous bone also exerts interior force upon cortical bone **158**, making it possible to elevate or push broken and compressed bone back to or near its original prefracture position.

[0097] The body **20** is preferably left inflated for an appropriate waiting period, for example, three to five minutes, to allow coagulation inside the vertebral body **152**. After the appropriate waiting period, the physician collapses the body **20** and removes it. As FIG. **17** shows, the formed cavity **164** remains in the interior volume of the vertebral body **152**.

[0098] As FIG. **17** shows, the second tool **14** is now readied for deployment. With the cartridge **26** filled with cement **38**, the physician directs the injection tube **30** through the guide sheath **166** into the formed cavity **164**.

[0099] If the dispensing end **34** is normally biased into a bent condition (as exemplified in FIG. **2**), passage through the guide sheath **166** overcomes the bias and straightens out the dispensing end **34**. Once free of the guide sheath **166**, the dispensing end **34** returns to its normally biased condition.

[0100] As shown in FIGS. **19A**, **19B**, and **19C**, the tube **30** can include prepositioned markers **218** (0) to **218** (2) along its length. The markers **218** (0) to **218** (2) are positioned to successively align with the proximal edge **220** of the guide sheath **166** at intervals that mark the extent to which the dispensing end **34** extends beyond the distal edge **222** of the guide sheath **166**.

[0101] As FIG. **19A** shows, when marker **218** (0) and the proximal edge **220** align, the distal edge **222** of the guide sheath **166** and the dispensing end **34** are coincident (i.e., the tip of the dispensing end **34** coterminous with the distal edge **222** of the sheath **166**).

[0102] As FIG. **19B** shows, subsequent movement of the tube **30** in the sheath **166** brings the marker **218** (1) into alignment with the proximal edge **220**. This alignment indicates that the tip of the dispensing end **34** projects beyond the distal edge **222** by a first, predetermined distance D1.

[0103] As FIG. **19C** shows, subsequent movement of the tube **30** to further advance the dispensing end **34** brings the marker **218** (2) into alignment with the proximal edge **220**. This alignment indicates that the dispensing end **34** projects beyond the distal edge **222** by a second, predetermined distance D2.

[0104] Of course, the number and spacing of the markers **218** can vary. The markers **218** allow the physician to gauge when and to what extent the dispensing end **34** projects into the targeted site, without need for direct visualization.

[0105] Under radiologic visualization provided by the markers **68**, the physician may rotate the injection tube **30**. Rotation of the injection tube **30** orients the dispensing end **34** within the cavity **164** before or during the injection of cement **38**. In the embodiment shown in FIG. **14**, the rotation may be accomplished without rotating the gun **22**. In the embodiment shown in FIG. **15**, the extent of rotation and the orientation of the dispensing end **34** can be observed using the markers **212/210**, **214**, and **216** on the fitting **104** (see FIG. **15**), without active internal visualization.

[0106] Alternatively, if the tube **30** carries one or more steering wires **50** and **52** (as exemplified in FIG. **3**), the physician may selectively bend the dispensing end **34** under

radiological visualization provided by the markers **68**. In this way, the physician can steer the dispensing end **34** into the desired position or positions within the cavity **164** before or during injection of cement **38**. In the embodiment shown in FIG. **15**, the markers **212/210**, **214**, and **216** on the fitting **104** aid the steering process (see FIG. **15**), without active internal visualization.

[0107] As shown in FIG. **17**, the postero-lateral access portal **162** does not align the injection tube **30** with the geometric axes **154** and **156** of the vertebral body **152**. Nevertheless, deflection of the dispensing end **34** aligns the end **34** in the middle region MR of the body **152** along the mid-lateral axis **156**.

[0108] As FIG. **17** shows, the gun **22** urges the cement **38**, or other filling material, into the cavity **164**. While injecting the material **38**, the physician preferably begins with the dispensing end **34** positioned in the lateral region opposite to the access portal **162**. As the material **38** flows into the cavity **164**, the physician progressively moves the dispensing end **34** along the mid-lateral axis **156** through the middle region MR and toward the access portal **162**. The deflection of the dispensing end **34** (by virtue of either the preformed bias or by active steering) allows the physician to maintain the desired alignment with the mid-lateral axis **156**. The deflection of the dispensing end **34** (by virtue of either the preformed bias or by active steering) also allows the physician to keep the dispensing end **34** continuously submerged in the filling material **38**, to thereby avoid the formation of air or fluid pockets.

[0109] The physician observes the progress of the injection radiologically using the markers **68**, positioning the dispensing end **34** by rotation or steering, or both, as just described.

[0110] The physician flows material **38** into the cavity **164**, until the material **38** reaches the interior end of the guide sheath **166**. If the dispensing end **34** carries one or more exterior loops (as exemplified in FIGS. **4** to **10**), or a side dispensing port **180** (as exemplified in FIGS. **12** and **13**), rotation of the dispensing end **34** will cleanly sever the injected cement bolus residing in the cavity **164** from the unexpelled cement residing within the dispensing end **34** (as FIGS. **4** and **5** and FIGS. **12** and **13** show). In this way, cement residing in the cavity **164** will not be inadvertently drawn out of the cavity **164** upon withdrawal of the dispensing end **34**. Rotation of the dispensing end **34** to sever the material bolus also avoids the formation of sharp pedicles in the material bolus, which could irritate surrounding tissue.

[0111] In the embodiment shown in FIG. **15**, the markers **212/210**, **214**, and **216** on the fitting **104** aid in monitoring the extent of rotation, without active internal visualization.

[0112] As FIG. **18** shows in a lateral view, access into the interior volume of a vertebral body **152** can also be accomplished by drilling an access portal **168** through either pedicle **170**. This is called a transpedicular approach. As FIG. **18** shows, the access portal **170** for a transpedicular approach enters at the top of the vertebral body **152**, where the pedicle **170** is relatively thin, and extends at an angle downward toward the bottom of the vertebral body **152** to enter the interior volume.

[0113] The tool **12** is deployed through a guide sheath **166** in the portal **168** to form a cavity **172**, in the same manner described above. The physician can manipulate the second tool **14** to steer the dispensing end **34** of the nozzle assembly

**10** into the cavity **172**. Although the transpedicular access portal aligns the tube **30** obliquely with respect to the axes **154** and **156**, the deflected dispensing end **34** can be rotated into general alignment with either the anterior-posterior axis **154** or the mid-lateral axis **156** while injecting cement.

[0114] The deflected dispensing end **34** allows the introduction of cement **38** into the middle region MR of the vertebral body **152**, using either postero-lateral access or a transpedicular access. The cement **28**, when hardened, provides support uniformly across the middle region MR. The capability of the vertebral body **152** to withstand loads is thereby enhanced.

[0115] The above-described procedure, carried out in a minimally invasive manner, can also be carried out using an open surgical procedure. Using open surgery, the physician can approach the bone to be treated as if the procedure is percutaneous, except that there is no skin and other tissues between the surgeon and the bone being treated. This keeps the cortical bone as intact as possible, and can provide more freedom in accessing the interior volume of the vertebral body **152**.

### III. Cooled Nozzle Assembly

[0116] After mixing and while curing, the cement **38** undergoes a chemical reaction that generates heat. When the cement temperature is below a given threshold value, the cement **38** maintains a flowing, viscous liquid state, which is suited for introduction through the nozzle assembly **10** into the targeted region. As the temperature increases beyond the threshold value, the cement **38** begins to harden, progressively losing its flow characteristic and becoming more resistant to passage through the nozzle assembly **10**. It is desirable to expel the loose cement bolus **62** before the threshold temperature is reached.

[0117] FIG. 20 shows a system **240** for cooling the nozzle assembly **10** during passage of the cement **38** through the dispensing end **34**. The system **240** includes the injection tube **30**, which is releasably coupled to the front end of the cartridge **26** by the threaded connector **36**, as previously described. The tube **30** includes the center lumen **30**, through which cement **38** conveyed from the cartridge **26** passes.

[0118] The system **240** further includes at least one paired set of side lumens, which extend through the tube **30** axially beside the center lumen **30**. In the illustrated embodiment (see FIG. 22), four paired lumen sets are shown, designated **242 A** and **B**, **244 A** and **B**, **246 A** and **B**, and **248 A** and **B**. As shown in FIGS. 21 and 22, each lumen set **242 A/B**; **244 A/B**; **246 A/B**; and **248 A/B** comprises a closed loop for carrying a cooling fluid from a source **250**, through the tube **30**, and to waste **252**.

[0119] As best shown in FIG. 21, the lumen designated **A** in each set **242 A/B**; **244 A/B**; **246 A/B**; and **248 A/B** communicates at its proximal end with the cooling fluid source **250** via an in line pump **254**. The lumen designated **A** in each set **242 A/B**; **244 A/B**; **246 A/B**; and **248 A/B** therefore comprises an inlet path for the cooling fluid.

[0120] As FIG. 21 also shows, the inlet lumen **A** of each set **242 A/B**; **244 A/B**; **246 A/B**; and **248 A/B** communicates at its distal end with the distal end of the lumen designated **B** in its respective set **242 A/B**; **244 A/B**; **246 A/B**; or **248 A/B**.

[0121] As FIGS. 21 and 22 show, communication between the distal ends of the lumens **A** and **B** in each set **242 A/B**;

**244 A/B**; **246 A/B**; and **248 A/B** is established by removing material between the lumens **A** and **B** to form a channel **256** between them, and laying a sealing material **258** over the channel **256**. The proximal ends of the lumens **B** in each set **242 A/B**; **244 A/B**; **246 A/B**; and **248 A/B** communicate with waste **252**. The lumen **B** of each set **242 A/B**; **244 A/B**; **246 A/B**; and **248 A/B** thereby comprises a return path for the cooling fluid.

[0122] At the source **250**, the cooling fluid is at a desired temperature, which is cooler than the threshold temperature of the cement **38**. For example, the source fluid can comprise tap water at a temperature of about 68° F. (20° C.). While cement **38** is conveyed by the center lumen **32** for discharge, the pump **254** conveys cooling fluid from the source **250** through the inlet paths **242 A**, **244 A**, **246 B**, and **248 B**. The return paths **242 B**, **244 B**, **246 B**, and **248 B** carry the cooling fluid to waste **252**. The circulation of cooling fluid in the tube **30** along the center lumen **32** dissipates heat generated by the curing cement **38**, to mediate the temperature increase in the curing cement **38**. The circulation of cooling fluid thereby keeps the curing cement **38** in the center lumen **32** in a viscous flowing condition for a longer period of time.

[0123] In the illustrated embodiment (see FIGS. 20 and 21), the return paths **242 B**, **244 B**, **246 B**, and **248 B** convey cooling fluid to waste **252** downstream of proximal end of the center lumen **30**. This quickens the discharge of heated return fluid from the tube **30** to thereby further minimize the temperature increase within the center lumen **32**.

[0124] It should be appreciated that the system **250** can also include a cutting element to sever the cement flow in response to rotation of the tube **30**, as well as means for deflecting the dispensing end **34**, in any of the manners previously described.

### IV. Injector Nozzle Assembly with Variable Delivery Rates

[0125] FIGS. 23 to 25 show another embodiment of an injector nozzle assembly **300** for conveying a flowable material **302** into bone or another location, such as a cavity, in the body. Like the injector nozzle assemblies previously described, the assembly **300** shown in FIGS. 23 to 25 is capable of carrying diverse types of flowable materials, e.g., bone cement or a suspension of one or more therapeutic substances, or both at the same time. The assembly **300** shown in FIGS. 23 and 24 can likewise be used for diverse therapeutic purposes, as well, e.g., to treat a diseased bone, or to prevent or treat fracture or collapse of a bone, or both at the same time.

[0126] As shown in FIGS. 23 to 25, the assembly **300** comprises a syringe body **304** coupled to a syringe handle **306**. In use, a volume of flowable material **302** is loaded into the syringe body **304** (see FIGS. 26 and 27). As FIG. 24 best shows, a syringe plunger **308** is carried in a plunger chamber **310** formed in the interior of the syringe handle **306**. The syringe plunger **308** axially advances through the syringe body **304**, thereby expelling the flowable material **302** out the distal end of the syringe body **304** (as FIGS. 26 and 27 show).

[0127] The syringe handle **306** and syringe body **304** can comprise, e.g., formed plastic or metal parts. The syringe handle **306** can be formed to possess different shapes and sizes. It is desired that the handle **306** is sized to fit comfortably in the hand of an operator.

[0128] The syringe body 304 can comprise a component that can be easily coupled to the handle 306 at time of use and then decoupled from the handle 306 and discarded after use. An o-ring 334 (see FIG. 25) desirably seals the periphery of the releasable junction between the body 304 and the handle 306. Syringe bodies 304 possessing different lengths and/or different interior volumes can also be provided, to meet the particular delivery objectives of the targeted site. The syringe plunger 308 desirably comprises a material, e.g., polyisoprene rubber, that makes moving sealing engagement against the interior wall of the syringe body 304, to exert an expelling force upon the material 302.

[0129] A plunger advancement mechanism 312 is carried by the syringe handle 306, as FIGS. 23 and 24 best show. The mechanism 312 is coupled to the syringe plunger 308. As FIGS. 26 and 27 show, force applied to the plunger advancement mechanism 312 causes the syringe plunger 308 to move axially through the plunger chamber 310 and the syringe body 304, thereby expelling the flowable material from the body 304.

[0130] Desirably, the plunger advancement mechanism 312 is configured to accommodate different delivery objectives. For example, in a first delivery mode, the advancement mechanism 312 causes the syringe plunger 308 to advance or retract a set distance per rotation of a first actuator 314. In a second delivery mode, the advancement mechanism 312 causes the syringe plunger 308 to advance or retract at a different set distance per rotation of a second actuator 316.

[0131] In the illustrated embodiment, the first axial displacement is greater than the second axial displacement. The operator is thereby able to expel material 302 from the syringe body 304 in the first delivery mode more quickly per rotation of the actuator than in the second delivery mode. The operator can thereby easily switch from a relatively rapid, high volume discharge of flowable material, when so desired, to relatively slower, more metered, lower volume discharge of flowable material, when so desired. The operator is also able, in the first, high volume delivery mode, to rapidly retract the syringe plunger 308, to withdraw the pressure force of the syringe plunger 308 against the material 302, to thereby quickly terminate the flow of material from the syringe body 304. The ability to start and stop both large volume flow and metered, smaller volume flow makes it possible to rapidly respond to in situ flow conditions, to thereby prevent or minimize the flow of material 302 under pressure through cracks, openings, or voids in cortical bone, in a process called "extravasation." The operation of the plunger advancement mechanism 312 to achieve a variable rate of delivery can be implemented in various ways. In the illustrated embodiment, the plunger advancement mechanism 312 responds to the application of rotational force to advance the syringe plunger 308. In this arrangement, rotatable first and second actuators or control knobs 314 and 316 are carried at the proximal end of the syringe handle 306. In use, the operator holds the syringe handle 306 in one hand, while applying force with the other hand to rotate either the first or second control knob 314 and 316. As FIG. 26 shows, rotation of the first control knob 314 advances the syringe plunger 308 at a first axial displacement per rotation, to discharge a given volume of material 302 per amount of rotation. As FIG. 27 shows, rotation of the second control knob 316 advances the syringe plunger 308 at a slower, second axial displacement per rotation, discharging a lesser volume of material 302 per amount of rotation.

[0132] In the illustrated embodiment (see FIG. 25), the syringe plunger 308 is attached to the distal end of a threaded slow advancement screw 318. In the illustrated embodiment, a snap fit clip 332 is provided on the distal end of the slow advancement screw to couple the plunger 308 to the screw 318. The second rotatable control knob 316 is attached to the opposite end of the slow advancement screw 318, to rotate the slow advancement screw 318 about its axis.

[0133] The threaded slow advancement screw 318 is itself carried within the bore 322 of an externally threaded fast advancement screw 320. The exterior threads 324 of the slow advancement screw 318 engage interior threads 326 in the bore 322 of the fast advancement screw 320 (see FIG. 25). Rotation of the slow advancement screw 318 about its axis causes the slow advancement screw 318 to move relative to the fast advancement screw 320, either fore or aft, depending upon the direction of rotation. The syringe plunger 308 carried at the end of the screw 318 is thereby also caused to move.

[0134] The fast advancement screw 320 is itself coupled to the first control knob 314, which is rotatably coupled to the syringe handle 306. The first control handle 314 includes an annular, internally threaded aperture 328 (see FIG. 25). The threaded aperture 328 engages the external threads 330 of the fast advancement screw 320. As FIG. 23 shows, when the fast advancement screw 320 is threadably engaged in the first control knob 314, the slow advancement screw 318, which is itself threaded in the fast advancement screw 320, extends into the handle 306. The syringe plunger 308, carried at the distal end of the slow advancement screw 318, extends into the plunger chamber 310. Rotation of the first control knob 314 about the fast advancement screw 320 moves the fast advancement screw 320 fore or aft, depending upon the direction of rotation. The slow advancement screw 318 moves in tandem with the fast advancement screw 320, causing the syringe plunger 308 to also move in the plunger chamber 310 and syringe body 304 in response to rotation of the first control knob 314. As before explained, rotation of the second control knob 316 will likewise independently cause movement of the slow advancement screw 318 within the fast advancement screw 320, likewise moving the syringe plunger 308 within the plunger chamber 310 and syringe body 304. The distance and direction that the syringe plunger 308 travels in one rotation of either the slow advancement screw 318 or the fast advancement screw 320 is controlled by the configuration of the mating threads.

[0135] In a representative embodiment, the exterior threads 324 of the slow advancement screw 318 comprise 10-degree modified right handed square threads (class 2G, single start), with sixteen threads to the inch. In this arrangement (see FIG. 27), clockwise rotation of the slow advancement screw 318 advances the syringe plunger 308 toward the distal end of the syringe body 304, and counter-clockwise rotation of the slow advancement screw 318 retracts the syringe plunger 308 away from the distal end of the syringe body 304. One revolution of the second control knob 316 moves the syringe plunger 308 about one-sixteenth ( $\frac{1}{16}$ th) of an inch.

[0136] Likewise, in a representative embodiment, the exterior threads 326 of the fast advancement screw 320 comprise 10-degree modified left handed square threads (class 2G, three start), with six threads to the inch. In this arrangement (see FIG. 26), counter-clockwise rotation of the fast advancement screw 320 retracts the syringe plunger 308 away from



the distal end of the syringe body **304**, and clockwise rotation of the fast advancement screw **320** advances the syringe plunger **308** toward the distal end of the syringe body **304**. One revolution of the first control knob **314** moves the syringe plunger **308** about one-half ( $\frac{1}{2}$ ) inch. Thus, a single rotation of the first control knob **314** moves the syringe plunger **308** farther than a single rotation of the second control knob **316**, expelling a greater volume of material **302** per rotation of the actuator.

[0137] As described, the plunger advancement mechanism **312** is operated manually. It should be appreciated that the plunger advancement mechanism can be operated by means of an electric motor or the like.

[0138] The assembly **300** shown in FIGS. **23** to **27** can be used to convey material **310** into a cavity created in cancellous bone by an expandable structure, as earlier described and as shown in FIGS. **16** and **17**. The assembly **300** may also be used in association with a vertebroplasty procedure, which injects cement under pressure into a vertebral body, without prior formation of a cavity.

[0139] In a representative embodiment, the syringe handle **306** (which can be made of polycarbonate) measures about 3.9 inches in length and 2.6 inches in width. The syringe body **304** (which also can be made of polycarbonate) measures about 5.1 inches in overall length, with an interior lumen having an inside diameter of about 0.5 inch.

[0140] In this representative embodiment, the first control knob **314** (which can be made from Celcon™ plastic material) is shaped round and has a diameter of about 2.5 inches. The fast advancement screw **320** (which can also be made from Celcon™ plastic material) has a length of about 4.5

inches and an outside thread diameter of about 0.75 inch. The internal threads extend for a distance of about 0.75 inch.

[0141] In this representative embodiment, the slow advancement screw **318** (which can also be made from Celcon™ plastic material) extends from the second control knob **316** for a length of about 9.35 inches and has an outside thread diameter of about  $\frac{3}{8}$  inch. The second control knob **316** is elliptical in shape, measuring about 2.0 inches along its major axis, about 0.625 inch along its minor axis, and about 1.5 inches in height.

[0142] The features and advantages of the invention are set forth in the following claims.

We claim:

1. An assembly for injecting flowable material into bone comprising
  - a tubular body including an interior bore to carry a material flow, the tubular body having a longitudinal axis and including a dispensing end,
  - an opening in the dispensing end communicating with the bore to dispense the material flow,
  - a plunger located at least partially within the tubular body, the plunger adapted to be displaced along the longitudinal axis of the tubular body,
  - an advancement mechanism attached to the plunger, whereby the advancement mechanism displaces the plunger a first longitudinal displacement in response to a first delivery impulse, and a second longitudinal displacement in response to a second delivery impulse.

\* \* \* \* \*