



- (51) International Patent Classification:
A61B 17/86 (2006.01)
- (21) International Application Number:
PCT/US2014/020678
- (22) International Filing Date:
5 March 2014 (05.03.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/801,804 15 March 2013 (15.03.2013) US
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Federal Street, 15th Floor, Boston, MA 02110 (US).
- (81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,

KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM,
ZW.

- (84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

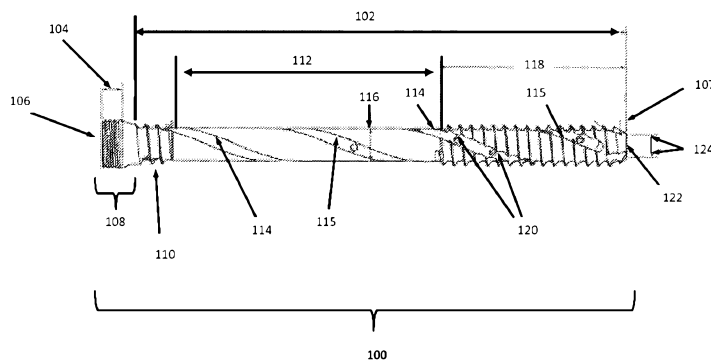
- as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))

(54) Title: BONE SCREWS AND METHODS OF USE THEREOF

Fig. 1



(57) Abstract: The invention features improved bone screws, a delivery manifold for delivering a flowable medium to a bone screw, and washers for use with the bone screw to provide compressive fixation. The invention also features methods of treatment using the bone screws, washers, and/or delivery manifold, and kits that include the same.

WO 2014/149746 A1

BONE SCREWS AND METHODS OF USE THEREOF

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FIELD OF THE INVENTION

The invention relates to devices, in particular, bone screws, washers and bone screw manifolds and methods of use thereof for the treatment of bone defects.

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BACKGROUND OF THE INVENTION

Fixation tools and devices, which are available in a wide variety of different shapes and sizes, have long been used in the repair of bone defects, such as bone fractures. A physician typically sets the bone to be repaired in the proper position and then uses the fixation tools and devices to secure the bone in that position during the healing process.

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A fixation device, such as a bone plate or rod, can be secured to the bone by a fixation tool, such as a bone screw. Alternatively, a bone screw can be used by itself to repair a bone defect. One drawback associated with prior art bone screws is the potential for the bone screw to back out after implantation. To inhibit back out, bone screws have been modified with various thread designs and locking features, with some success.

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When installing a bone anchor or screw, a surgeon will typically tap a hole, remove the tap and then install the screw into the hole while maintaining the alignment of the bone with another bone or prosthesis. The bone screw can be secured in the bony bed by filling the hole before installation of the screw with a bone cement, such as polymethylmethacrylate or other fillable and flowable materials.

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The use of a solid screw with a bone cement or other fillable material may increase the initial stiffness and strength of the repair, but may not significantly decrease loosening of the screw at the repair site. The substitution of solid screws with cannulated screws that can extrude a bone cement or other fillable material may improve the strength of the repair while at the same time reducing the likelihood that the screw will loosen and pull out, but distribution of the bone cement or fillable material through the screw and throughout the repair site remains a problem. In particular, self-hardening bone cements change viscosity after formulation and the even distribution along the length of the bone screw is challenging for such materials. Another challenge is providing adequate distribution of a bone cement or fillable material while maintaining sufficient screw mechanical strength. Often increasing the number of delivery channels or ports in the screw body can weaken the bone screw. Thus, there remains a need for a cannulated bone screw for use with a bone cement or fillable material that is capable of securing bone at a repair site while also preventing loosening and pull-out of the bone screw following the repair.

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SUMMARY OF THE INVENTION

In general, the invention features bone screws, delivery manifolds, kits, and methods of use thereof for the treatment of bone defects.

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Accordingly, in a first aspect, the invention features a bone screw (e.g., the bone screw is, or contains, stainless steel alloy, titanium alloy, commercially pure titanium, cobalt chrome, or polyetheretherketone, or combinations thereof) having a length from about 60 millimeters (mm) to 200 mm (e.g., 60 to 130 mm) and including: a cylindrical screw body includes a shaft that defines a

longitudinal axis, a screw head at the proximal end of the screw body, and a tip at the distal end of the screw body. The bone screw also includes: an interior channel extending longitudinally through the screw head and through at least a portion of the shaft of the screw body, in which the interior channel has a diameter of about 3 to 5 mm; a first threaded portion on the exterior of the screw head extending from about the proximal end of the screw head along at least a portion of the screw head; a second threaded portion on the exterior of the screw body adjacent to the screw head that extends in a direction along the screw body away from the screw head and having one or more delivery channels; a third threaded portion on the exterior of the screw body adjacent to the tip that extends along a distal portion of the screw body and having one or more delivery channels; a non-threaded portion between the second and third threaded portions on the exterior of the screw body and having one or more delivery channels; and at least first and second helical grooves extending along the exterior of the screw body, in which: the first helical groove is substantially anti-parallel to the second helical groove and the helical grooves extend continuously through the second threaded portion, the non-threaded portion, and at least a portion of the third threaded portion, the delivery channels are coincident with the helical grooves, each of the delivery channels within the helical grooves of the non-threaded portion is separated by a distance of about 18 to 24 mm along the helical groove, and each of the delivery channels of the third threaded portion is separated by a distance of about 5 to 7 mm along the helical groove.

In several embodiments, the bone screw contains one or more, or all, of the following characteristics: each of the delivery channels have a diameter of about 0.5 to 2 mm; the screw head has a length of about 4 to 7 mm and the first threaded portion has a length of about 2 to 4 mm and an exterior diameter of about 6 to 10 mm; the second threaded portion contains about 2 to 4 thread revolutions, 1 to 4 delivery channels and a length of about 5 to 8 mm; the third threaded portion contains about 10 to 20 thread revolutions, 8 to 12 delivery channels and a length of about 25 to 40 mm; the non-threaded portion has a length of about 16 to 86 mm; and/ or the ratio of the delivery channels in the third threaded portion to the non-threaded portion is at least 1.25:1.

In still other embodiments, the bone screw contains one or more, or all, of the following characteristics: the interior channel has a diameter of about 3.9 mm; the screw head has a length of about 5.3 mm and the first threaded portion has a length of about 3.2 mm and an exterior diameter of 8.3mm; the second threaded portion contains about 3 thread revolutions, about 2 delivery channels and a length of about 6.5 mm; the third threaded portion contains about 16 thread revolutions, about 10 delivery channels and a length of about 32 mm and each of the delivery channels of the third threaded portion is separated by a distance of about 6 mm along the helical grooves; the non-threaded portion has a length of about 16 mm to 86 mm and contains at least one to about 24 delivery channels and each of the delivery channels of the non-threaded portion is separated by a distance of about 21 mm along the helical grooves; and/or each of the delivery channels have a diameter of about 1.2 mm.

In several embodiments, the first threaded portion contains about 1 to 5 thread revolutions, the delivery channels are not within about 5 mm of the proximal end and distal end of the bone screw, and the delivery channels are distributed along the helical grooves to provide substantially equal distribution of a flowable medium (e.g., a bone void filler, a cement (e.g., a self-hardening calcium phosphate composition), or a pharmaceutical agent) extruded through each of the delivery channels following introduction of the flowable medium through the screw head into the interior channel. In yet other embodiments, each of the delivery channels is tapered along at least a portion of its radial axis or is

substantially cylindrical. In another embodiment, at least one edge of the helical groove(s) contains a self-cutting edge. In still another embodiment, the bone screw has a mean bending stiffness of at least 90-160 N/mm (e.g., 136 N/mm) in a 4-point bend test.

A second aspect of the invention features a bone screw manifold (e.g., which is or contains a polymeric material, such as polypropylene, polyethylene, polystyrene, polytetrafluoroethylene or polyetheretherketone, or combinations thereof) for delivering a fluid to a cannulated and fenestrated bone screw that includes a sheath and a sheath adapter, in which:

a) the sheath contains a cylindrical sheath body that defines a longitudinal axis, a first attachment portion (e.g., the first attachment portion that is sized and shaped to be threadingly engaged with the bone screw head of the bone screw of the first aspect of the invention) at the distal end of the sheath body, a second attachment portion (e.g., the second attachment portion is sized and shaped to be threadingly engaged with a device (e.g., a syringe) for injecting a flowable medium (e.g., a flowable medium that is or contains a bone void filler, a cement, or a pharmaceutical agent)) at the proximal end of the sheath body, and an internal channel having a diameter of at least about 5 mm that extends continuously through the sheath body and through the first and second attachment portions to provide fluid communication through the manifold and in which:

- i) the sheath body has a length of about 60 to 90 mm;
- ii) the first attachment portion contains a threaded region within the internal channel; and
- iii) the second attachment portion contains a threaded region within the internal channel, and contains a first handling portion on the exterior of at least a portion of the second attachment portion; and

b) the sheath adapter contains a cylindrical sheath adapter body that defines a longitudinal axis, a third attachment portion at the proximal end of the sheath adapter body, a second handling portion adjacent to the third attachment portion, a fourth attachment portion adjacent to the second handling portion, a tapered portion at the distal end of the sheath adapter body, and an internal channel having a diameter of at least about 2 mm that extends continuously through the sheath adapter body, the third attachment portion, the second handling portion, the fourth attachment portion, and the tapered portion to provide fluid communication through the sheath adapter, in which:

- i) the sheath adapter body has a length of about 50 to 80 mm and an external diameter that is less than the diameter of the internal channel of the sheath;
- ii) the third attachment portion contains a threaded region on an exterior portion thereof;
- iii) the second handling portion contains raised ridges on an exterior portion thereof; and
- iv) the fourth attachment portion contains a threaded region on an exterior portion thereof; and

in which the sheath adapter body is sized and shaped for insertion into the internal channel of the sheath, the threaded region of the third attachment portion of the sheath adapter is sized and shaped to be threadingly engaged with the threaded

region of the second attachment portion of the sheath, thereby reversibly joining the sheath and the sheath adapter when engaged, and, when the sheath and the sheath adapter are joined, the tapered portion of the sheath adapter extends into the first attachment portion of the sheath, and

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in which the manifold is capable of delivering a self-hardening calcium phosphate bone cement to the distal tip of a cannulated and fenestrated bone screw having a length of at least about 130 mm using manual pressure.

10 In several embodiments of the second aspect of the invention, the bone screw manifold contains one or more, or all, of the following characteristics:

- 15 a. the sheath body has an external diameter of at least 8 mm;
- b. the first attachment portion has a length of about 5 to 8 mm, the threaded region of the first attachment portion has a length of about 2 to 4 mm and at least 3 thread revolutions, and the internal channel of the first attachment portion has an internal diameter of about
- 20 c. the second attachment portion has a length of about 16 to 24 mm, and in which the threaded region of the second attachment portion has a length of about 4 to 7 mm and at least 2 thread revolutions, and the internal channel of the second attachment portion has an internal diameter of about 5 to 8 mm;
- d. the first handling portion includes at least five raised ridges that extend in a direction substantially parallel to the longitudinal axis of the sheath body;
- e. the third attachment portion has a length of about 6 to 10 mm and the threaded region of the third attachment portion has a length of about 4 to 7 mm and at least 2 thread revolutions;
- 25 f. the second handling portion has a length of about 10 to 15 mm and contains at least four raised ridges on an exterior portion thereof that extend in a direction substantially parallel to the longitudinal axis of the sheath adapter body;
- g. the fourth attachment portion has a length of about 6 to 9 mm and the threaded region of the fourth attachment portion has a length of about 3 to 5 mm and at least 2 thread revolutions; and/or
- 30 h. the tapered portion has a length of about 5 to 7 mm and an exterior diameter of about 2.5 to 7 mm, and the tapered portion has a chamfer at the distal end.

In still other embodiments of the second aspect of the invention, the bone screw manifold contains one or more, or all, of the following characteristics:

- 35 a) the sheath body has a length of about 76.2 mm and the internal channel of the sheath has a diameter of 5.8 mm;
- b) the first attachment portion has a length of about 6.4 mm and the threaded region of the first attachment portion has a length of about 3.2 mm, about 3 thread revolutions, and has an internal diameter of about 7.8 mm;
- 40 c) the second attachment portion has a length of about 20.4 mm and the threaded region of the second attachment portion has a length of about 5.6 mm, about 2 thread revolutions, and has an internal diameter of about 6.7 mm and contains eight raised ridges;

- d) the sheath adapter body has a length of about 67.1 mm and an external diameter of about 5.3 mm and the internal channel of the sheath adapter has a diameter of 2.5 mm;
- e) the third attachment portion has a length of about 8.5 mm and the threaded region of the third attachment portion has a length of about 5 mm and about 2 thread revolutions;
- 5 f) the second handling portion has a length of about 12.5 mm and contains six raised ridges;
- g) the fourth attachment portion has a length of about 7.5 mm and the threaded region has a length of about 4.3 mm and about 2 thread revolutions; and/or
- 10 h) the tapered portion has a length of about 6.1 mm and an exterior diameter of about 3 mm.

In other embodiments of the second aspect of the invention, the threaded region of the second attachment portion has about 2 to 4 thread revolutions, the threaded region of the third attachment portion has about 2 to 4 thread revolutions, and the threaded region of the fourth attachment portion has about 2 to 4 thread revolutions.

15 A third aspect of the invention features a bone screw washer, which includes i) a cylindrical body includes a shaft that defines a longitudinal axis, in which the body has a length of about 5 to 8 mm and a diameter of 7 to 10.5 mm; ii) a bone engaging portion at the proximal end of the body includes a circumferential lip with a thickness of 1 to 2 mm and a radial diameter of 10 to 15 mm; and iii) a screw head engaging portion at the distal end of the body having a diameter of 6 to 9 mm, in which the diameter
20 of the screw head engaging portion is less than the diameter of the body; and in which the washer is sized and shaped to accept the screw head of the bone screw of the first aspect of the invention and to engage a bone surface. In several embodiments, the washer contains one or more, or all, of the following characteristics:

- a) the body has a length of about 6.3 mm and a diameter of 8.6 mm,
- 25 b) the circumferential lip of the bone engaging portion has a thickness of 1.6 mm and a radial diameter of 12.7 mm, and/or
- c) the screw head engaging portion has a diameter of 7.5 mm.

In still other embodiments, the washer further contains one or more fenestrations for suture attachment.

30 A fourth aspect of the invention features a method of treating a patient having a bone defect (e.g., a bone defect that is or that contains a fracture (e.g., a subarticular fracture or a compression fracture), or is a defect of the radius, ulna, fibula, clavicle, humerus, pelvis, femur, patella, tibia, talus, Calcaneus, navicular, cuneiforms, metatarsals, metacarpals, phalanges, scapula, ankle or vertebra), which includes one or more of the following steps of i) positioning the bone screw of the first aspect of the invention in
35 proximity to the bone defect; ii) attaching the sheath of the bone screw manifold of the second aspect of the invention; iii) attaching the sheath adapter of the second aspect of the invention to the sheath; iv) attaching a manual pressure injection device to the fourth attachment portion of the sheath adapter; and v) introducing a flowable medium into the interior channel of the bone screw, whereby the flowable material is extruded through the delivery channels and, upon upon hardening of the flowable medium, the
40 bone screw is fixed in place, thereby treating the bone defect in the patient.

In several embodiments, the flowable medium is a bone void filler, a cement (e.g., a self-hardening calcium phosphate composition), or a pharmaceutical agent.

In other embodiments, the method further includes, prior to step a), joining the washer of the third aspect of the invention to the screw head, whereby tightening or screwing the bone screw into bone of the patient at or near the fracture provides a compression union that stabilizes the fracture.

5 A fifth aspect of the invention features a kit, which includes any one or more, or all, of the following: i) the bone screw of the first aspect of the invention; ii) the manifold of the second aspect of the invention; and iii) the washer of the third aspect of the invention. The kit may optionally contain one or more of an injection device, a self-hardening bone cement powder, and instructions for using the kit.

10 Definitions

As used herein, the term "about" means $\pm 10\%$ of the recited value.

By "biocompatible" is meant that the material does not elicit a substantial detrimental response (e.g., an immune response) in the host. It should be appreciated that a foreign object introduced into a living body may induce an immune reaction that will have negative effects on the host. As used herein,
15 the term "biocompatible" is intended to include those materials that may cause some inflammation but does not rise to the level of pathogenesis.

The term "bioresorbable" is meant the ability of a material to be resorbed by the body *in vivo*. The resorption process involves elimination of the original bioresorbable implant materials through the action of body fluids, enzymes, or cells. "Strongly bioresorbable" means that at least 80% of the total mass of material implanted *in vivo* is resorbed within one year.
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By "bone defect" is meant any bone deficient region, such as a void, gap, recess, or other discontinuity in a bone. A bone defect can be artificially or naturally established, and can occur, for example, due to disease or trauma. Thus, a bone defect can occur as a consequence of pathologic or inflammatory diseases, formation and/or removal of a bone tumor, a surgical intervention, a congenital defect, or a bone fracture, and the like. For example, in the case of certain diseases, such as bone tumors, the bone defect may be artificially established due to removal of the tumor tissue. The bone screws of the invention can be applied, for example, in the repair of periodontal defects, in craniofacial or maxillofacial surgery or reconstruction, in hand surgery, in joint reconstruction, in fracture repair, in orthopedic surgical procedures, and in spinal fusion. The term "bony defect" is also intended to include
25 anatomical sites where augmentation to a bony feature is desired by the patient in the absence of disease or trauma, such as in elective cosmetic surgery. Thus, the "defect" can be one that is subjectively perceived by the patient, and where augmentation of the bone deficient region is desired.

By "bone fill material" or "infill material" is meant any material for infilling a bone that includes an *in-situ* hardenable material, including, e.g., a flowable medium. The fill material also can include other
35 "fillers," such as filaments, microspheres, powders, granular elements, flakes, chips, tubules and the like, autograft or allograft materials, as well as other chemicals, pharmacological agents, or other bioactive agents.

By "flowable medium" is meant, generally, a formulation of a resorbable or non-resorbable biocompatible agent, e.g., a polymer, such as a thermoset polymer or a thermoplastic polymer, e.g.,
40 PMMA (polymethylmethacrylate), a bone void filler material, a cement, or a pharmaceutical agent. In particular, the flowable medium may be a resorbable calcium phosphate or calcium sulphate cement, which is typically self-hardening and, once hardened, may allow for the gradual replacement of the

cement with bone. Both resorbable and non-resorbable biocompatible agents, such as bone cements, have been used successfully in the treatment of bone defects.

Preferred calcium phosphate bone cements that can be used with the bone screws of the invention are described in, e.g., U.S. Patent No. 5,783,217, U.S. Patent No. 6,027,742, U.S. Patent No. 6,214,368, U.S. Patent No. 6,287,341, U.S. Patent No. 6,331,312, U.S. Patent No. 6,541,037, U.S. Patent No. 6,953,594, U.S. Patent No. 6,972,130, U.S. Patent No. 7,150,879, U.S. Patent No. 7,318,841, and U.S. Patent No. 7,517,539, each of which is incorporated herein by reference, and includes commercially available cements such as BETA-BSM™ injectable paste and CARRIGEN® porous bone substitute material (Etex Corporation, Cambridge, MA).

By "major diameter" of a bone screw is meant the longest diameter of the screw body, in a threaded portion, including its threads.

By "minor diameter" of a bone screw is meant the shortest diameter of the screw body, in a threaded portion, including its threads.

By "osteoplasty" is meant any procedure in which bone fill material and/or a flowable medium is delivered into the interior of a bone.

By "self-cutting edge" is meant an edge, flute or angle of a groove or thread of a bone screw that allows the screw to be removed from bone after hardening of the flowable medium that has been extruded from one or more delivery channels (e.g., fenestrations) of the bone screw. Removal of a bone screw having a self-cutting edge may occur without significant torque, e.g. less than 2,500 Newton millimeters (Nmm). A self-cutting edge is active when rotating in the direction where the self-cutting edge is the trailing edge and can scrap material into the groove.

By "treating" or "treatment" is meant the medical management of a patient with the intent that an amelioration, repair, or prevention of an injury or disease, pathological condition, or disorder associated with a bone defect will result. This term includes active treatment, that is, treatment directed specifically toward improvement of the injury or disease, pathological condition, or disorder, and also includes causal treatment, that is, treatment directed toward removal of the cause of the injury or disease, pathological condition, or disorder. In addition, this term includes palliative treatment, that is, treatment designed for the relief of symptoms rather than the curing of the injury or disease, pathological condition, or disorder; preventive treatment, that is, treatment directed to prevention of the injury or disease, pathological condition, or disorder; and supportive treatment, that is, treatment employed to supplement another specific therapy directed toward the improvement of the injury or disease, pathological condition, or disorder.

"Vertebroplasty" includes its ordinary meaning and means any procedure in which fill material is delivered into the interior of a vertebra, e.g., in conjunction with, or using a bone screw of the invention.

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of a schematic representation of an embodiment of a bone screw of the invention having first, second, and third threaded portions, a non-threaded portion, and substantially helical exterior grooves that are coincident with a plurality of delivery channels.

Figs. 2A-2C are views of a bone screw of the invention. Fig. 2A is side of the bone screw of Fig. 1, which has been rotated $\sim 180^\circ$ along the longitudinal axis. Fig. 2B is a cross-sectional view of the bone screw of Fig. 2a, as viewed along line A—A in Fig. 2A. Fig. 2C is a cross-sectional view of the bone screw of Fig. 2A, as viewed along line B—B in Fig. 2A.

5 Fig. 3 is a cross-sectional view of a bone screw of the invention, as viewed along line A—A of Fig. 3.

Figs. 4A and 4B are views of a bone screw of the invention. Fig. 4A is a transparent side view of a bone screw of the invention. Helical grooves on the exterior of the far side of the screw are shown in broken line, while helical grooves on the exterior of the near side of the screw are shown in solid line.

10 Fig. 4B is a cross-sectional view of the bone screw of Fig. 4A, as viewed along line A—A of Fig. 4A.

Figs. 5A and 5B are views of a bone screw of the invention. Fig. 5A is a transparent side view of a bone screw of the invention. Helical grooves on the exterior of the far side of the screw are shown in broken line, while helical grooves on the exterior of the near side of the screw are shown in solid line. Fig. 5B is a cross-sectional view of the bone screw of Fig. 5A, as viewed along line A—A of Fig. 5A.

15 Figs. 6A-6E are views of a sheath portion of a bone screw manifold of the invention. Fig. 6A is a side view of the sheath. Fig. 6B is a cross-sectional view of the sheath of Fig. 6A, as viewed along line A—A in Fig. 6A. Fig. 6C is an expanded view of region A of Fig. 6B showing the internal threads on the distal end of the sheath. Fig. 6D is an expanded view of region B showing the internal threads of the proximal end of the sheath. Fig. 6E is a cross-sectional view of the sheath of Fig. 6A, as viewed along
20 line B—B in Fig. 6A and showing the raised ridges of the handling portion.

Figs. 7A-7D are views of a sheath adapter portion of a bone screw manifold of the invention. Fig. 7A is a side view of the sheath adapter. Fig. 7B is a second side view of the sheath adapter. Fig. 7C is a cross-sectional view of the sheath adapter of Fig. 7B, as viewed along line B—B in Fig. 7B and showing the raised ridges of the handling portion.

25 Figs 8A-8C are views of a bone screw washer of the invention. Fig. 8A is a frontal view of the washer. Fig. 8B is a side view of the washer. Fig. 8C is a cross-sectional view of the washer, as viewed along line A—A in Fig. 8A.

Figs. 9A and 9B are schematics showing testing of a bone screw of the invention using a bone void model (with dimensions shown). Fig. 9A is a depiction of a basic design of the bone void model, in which a syringe is directly attached to a bone screw of the invention. The bone void model does not include a "fracture." The dark area depicts the "bone" into which the screw is inserted. Fig. 9B is a depiction of the bone void model in which a cannula is used as a control. In Fig. 9B, the bone void model has a "fracture" (fracture line shown). A bone screw of the invention is shown for comparison.

Figs. 10A and 10B are schematics showing testing of a bone screw of the invention attached to a bone screw manifold of the invention in the bone void model (with dimensions shown). Fig. 10A show the bone void model without a "fracture," while Fig. 10B shows the bone void model with a "fracture."

Figs. 11A-11D are fluoroscopy images showing the results of the testing of the bone screw of the invention using a bone void model. Fig. 11A shows the results of injection of BETA-BSMTM using a bone screw of the invention. Fig. 11B shows the results of injection of BETA-BSMTM using a cannula (control). Fig. 11C shows the results of injection of CARRIGENTM using a bone screw of the invention. Fig. 11D shows the results of injection of CARRIGENTM using a cannula (control). The results show that injection
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of these flowable media through the bone screw produces no signs of voids (light areas), which demonstrates that the bone screws are capable of filling voids in bone.

Fig. 12 is a photograph showing attachment of the sheath portion of a manifold of the invention to a bone screw of the invention.

5 Fig. 13 is a photograph showing attachment of an injection device (a syringe) to the sheath adapter portion of a manifold of the invention.

Fig. 14 is a photograph showing insertion of the sheath adapter of Fig. 13 into the sheath of Fig. 12.

10 Fig. 15 is a photograph showing complete assembly of the manifold (sheath + sheath adapter) and the bone screw.

Fig. 16 is a side view of a bone screw of the invention engaged with a washer of the invention (covering the screw head). The washer also includes two fenestrations that permit suture attachment from the washer to adjacent tissues (e.g., bone or soft tissues).

15 Fig. 17 is a side view of the bone screw and washer of Fig. 16 engaged with a delivery manifold (sheath + sheath adapter) of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The invention features bone screws, manifolds, bone screw washers, kits, and methods of treating patients using these devices.

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Bone Screws

In particular, bone screws of the invention allow passage of a flowable medium (e.g., a bone cement, such as a resorbable calcium phosphate-based bone cement) through an interior channel of the screws (i.e., a cannula) and extrusion of the flowable medium through a plurality of delivery channels (i.e., 25 fenestrations) that connect the internal channel to the exterior of the screws. Extrusion of the flowable medium to a position around the exterior of bone screws of the invention promotes anchorage of the bone screws in bone after implantation of the screws and upon hardening of the flowable medium. The screws are designed in particular, for fixation of bone fractures using compression. One advantage of bone screws of the invention is that injection of a flowable medium (e.g., a self-hardening calcium phosphate based bone cement) can be achieved using manual pressure (i.e., injection by hand, e.g., using a force of 30 < 20 Kgf, such as less than 10 Kgf).

The bone screws are designed to achieve a substantially uniform rate of flow of the flowable medium through substantially all (or at least a plurality of) the delivery channels along the body of the screws with the use of manual pressure and to achieve a substantially uniform distribution of the flowable 35 medium around the exterior surface of the bone screw, thereby anchoring it in the bone. A substantially uniform flow rate of a flowable medium through the delivery channels of the bone screw is achieved by, e.g., varying the number and location of delivery channels along helical exterior grooves (e.g., at least two helical grooves). In particular, the bone screw may have fewer delivery channels at the proximal end than at the distal end. The helical grooves also aid in the distribution of flowable medium to the exterior of the 40 screw, thereby allowing for the medium to flow both axial and radially along the screw in the groove.

Bone screws of the invention have more delivery channels along the exterior groove (e.g., helical groove) in the distal end relative to the proximal end which provides several advantages with respect to

the delivery of a flowable medium through and around the cannulated and fenestrated screws. For example, during injection of the flowable material, the material flows from the proximal end of the screw towards the distal end. Extrusion of the flowable medium preferentially out of the proximal most delivery channels, as opposed to equally through the proximal and distal delivery channels, results in voids of bone cement around the bone screw. The bone screw of the invention achieves substantially uniform distribution of the flowable medium along the entire longitudinal axis by reducing the number of and increasing the spacing of the delivery channels at the proximal end of the screw shaft, thereby promoting delivery of the flowable material along the the entire length of the screw, including to the distal end of the screw. Increasing the number of delivery channels at the distal end, relative to the proximal end of the bone screw shaft also results in a reduction of the resistance of the flow of a flowable medium along the entire length of the bone screws, including the distal end. The inventive screw solves this problem by having a larger number of delivery channels at the distal end, thus reducing the resistance to flow.

The reduction in flow resistance at the distal end of the screw provides another important benefit; the flowable medium can be injected into the screw of the invention using manual pressure. In this context, manual pressure includes any method of injecting a flowable medium (e.g., an injectable self-hardening calcium phosphate bone paste) by hand (i.e., without the aid of a mechanical, electrical, or motorized pump or hydraulic) into the bone screw of the invention. This improves the ease of use of the bone screw and minimizes the risk of any potential over-pressurization of the flowable medium during screw installation. The manifold of the invention provides an effective and stable way to provide a flowable medium to the bone screw interior channel. The use of manual pressure is greatly simplified by the use of a sheath and sheath adapter, which combine to produce the manifold and create a reliable and efficient system for transferring the flowable material into the bone screw.

The bone screws of the invention also exhibit improved mechanical properties and help avoid a loss of mechanical integrity of the screw, which can result in a number of medical complications. For example, the length of the bone screw is increased by varying the length of the non-threaded portion of the screw. This portion of the screw has fewer delivery channels, which provides additional strength to the screw.

The bone screws of the invention also include two anti-parallel helical grooves that, in combination with an asymmetric distribution of delivery channels along the screw body, provide a mechanically strong, highly efficient bone screw for use with flowable medium at manual pressures.

The bone screws of the invention can be used even with bones of reduced quality (e.g., osteoporotic bone) or in revision surgeries (e.g., they can be used to replaced previously inserted bone screws).

The bone screws of the invention can be used, for example, in osteosynthesis to internally stabilize and/or join bones, e.g., fractured (broken) bones, either in conjunction with other mechanical devices, such as metal plates, pins, rods, or wires, or individually. Without limitation, the bone screws of the invention can be used as, e.g., small fragment screws, cortex screws, cancellous screws, dynamic hip screws, lag screws, non-self-tapping and self-tapping screws, and malleolar screws. The size and function of the bone screw of the invention may vary depending on its intended use (e.g., depending on the length necessary to provide fixation in the cortex of a long bone above and below a fracture). The head of the bone screw may be modified in order to operate with any of a number of appropriate drivers and drills known in the art (e.g., Robertson driver, a slotted driver, a Phillips driver, a Torx driver, a triple

square driver, a polydrive driver, a one-way clutch driver, a spline drive driver, a double hex driver, or a Bristol driver).

Structure

5 Referring to Figs. 1 to 5, bone screw **100** includes threaded screw body **102** and screw head **108** attached to one end of screw body **102**, and tip **122**. Bone screw **100** includes proximal end **106**, which defines the end of the bone screw accessible during installation of the screw, and distal end **107** is defines the end of the bone screw that enters the bone first during installation. Bone screw **100** further includes interior channel **124** extending longitudinally through screw head **108** and through screw body
10 **102**. Bone screw **100** includes three threaded portions. First threaded portion **104** is located on the exterior of the screw head **108**. Second threaded portion **110** is located adjacent to the screw head **108**. Third threaded portion **118** is located adjacent to distal tip **122**. Second and third threaded portions are separated by non-threaded portion **112**. Bone screw **100** also includes two helical grooves **114, 115**, which extend continuously through portions of **110, 112**, and **118**. Helical grooves **114, 115** are
15 substantially anti-parallel and have a periodicity such that the two helical grooves do not overlap with each other. Other configurations may be employed for the exterior grooves (e.g., semi-parallel, parallel, oscillating, overlapping). Coincident with helical grooves **114, 115** are a plurality of delivery channels **120** (two representative delivery channels are identified by the arrows in Fig. 1).

Bone screw **100** may have a length in the range of about 60 mm to 200 mm, e.g., about 60 mm,
20 65 mm, 70 mm, 75 mm, 80 mm, 85 mm, 90 mm, 95 mm, 100 mm, 105 mm, 110 mm, 115 mm, 120 mm, 125 mm, 130 mm, 140 mm, 150 mm, 160 mm, 170 mm, 180 mm, 190 mm, or 200 mm, or a value in a range spanning any of the preceding values. A preferred bone screw of the invention may have length of about 60 mm to 130 mm. Bone screw **100** has exterior diameter **116** of about 4 mm to 7 mm, e.g., about 4 mm, 4.5 mm, 5 mm, 5.5mm, 6 mm, 6.5 mm, or 7mm or a value in a range spanning any of the
25 preceding values, and preferably 5.7 mm (see Figs. 1 and 4B).

Screw head **108** may have a length of about 4 mm to 7 mm, e.g., about 4 mm, 5 mm, 6 mm, and 7 mm, or a value in a range spanning any of the preceding values. In a preferred embodiment bone screw **100** has a screw head length of about 5.3 mm. Screw head **108** may have an external diameter in a range of about 6.5 mm to 9.5 mm, e.g., about 6.5 mm, 7 mm, 7.5 mm, 8 mm, 8.5mm, 9 mm, and 9.5
30 mm, or a value in a range spanning any of the preceding values. In a preferred embodiment the screw head length is about 8.3 mm. The screw head has hexagonal opening **128** (see Fig. 2B) with a width in the range of about 4 mm to 6 mm, e.g., about 4 mm, 4.5 mm, 5 mm, 5.5 mm or 6 mm, or a value in a range spanning any of the preceding values, and preferably about 4.76 mm.

Tip **122** of bone screw **100** may have internal diameter **132** in a range of about 3mm to 3.8 mm,
35 e.g., about 3.0, 3.2, 3.4, 3.6, or 3.8 mm, or a value in a range spanning any of the preceding values, and preferably about 3.4 mm (see Fig. 1C).

Interior channel **124** has a diameter in the range of about 3 mm to 5 mm, e.g., about 3 mm, 3.5 mm, 4 mm, 4.5 mm, and 5 mm, or a value in a range spanning any of the preceding values (Fig. 1). In a preferred embodiment, interior channel **124** has a length of about 3.9 mm.

40 First threaded portion **104** has a length in the range of about 2 mm to 5 mm, e.g., about 2 mm, 2.5 mm, 3 mm, 3.5 mm, 4 mm, 4.5 mm, 5 mm, or a value in a range spanning any of the preceding values, and preferably about 3.5 mm. First threaded portion **104** may have 1, 2, 3, or 4 thread

revolutions, most preferably about 3 thread revolutions. Screw threads of first threaded portion **104** may have a major diameter **136** in the range of about 7.9 mm to 8.7 mm, e.g., about 7.9, 8.1, 7.0, 8.5, or 8.7 mm, or a value in a range spanning any of the preceding values, and preferably 8.3 mm (see Fig. 3). Screw threads of first threaded portion **104** may have a minor diameter **134** in the range of about 7.3 mm to 7.9 mm, e.g., about 7.3, 7.5, 7.7, 7.9, or 8.1 mm, or a value in a range spanning any of the preceding values, and preferably about 7.7 mm. Screw threads of first threaded portion **104** may have a thread thickness **138** in the range of about 0.1 mm to 0.5 mm, e.g., about 0.1, 0.2, 0.3, 0.4, or 0.5 mm, or a value in a range spanning any of the preceding values, and preferably about 0.3 mm. Screw threads of first threaded portion **104** may have a thread spacing **140** in a range of about 0.5 mm to 1.1 mm, e.g., about 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, or 1.1 mm, or a value in a range spanning any of the preceding values, and preferably about 0.8 mm.

Second threaded portion **110** may have a length in a range of about 3 mm to 9 mm, e.g., about 3 mm, 4 mm, 5.6 mm, 7 mm or 9 mm, or a value in a range spanning any of the preceding values. In a preferred embodiment, the has a screw head length of about 5.6 mm. Screw threads of second threaded portion **110** may have a major diameter in a range of about 6.0 mm to 8.0 mm, e.g., about 6.0, 6.5, 7, 7.5, or 8 mm, or a value in a range spanning any of the preceding values, and preferably about 7 mm. Screw threads of second threaded portion **110** may have a minor diameter in the range of about 5.4 mm to 6.5 mm, e.g., about 5.4.5, 5.0, 5.5, 6.0, or 6.5 mm, or a value in a range spanning any of the preceding values, and preferably about 5.4 mm. Screw threads of second threaded portion **110** may have a thread thickness in a range of about 0.05 mm to 0.35 mm, e.g., about 0.05, 0.1, 0.15, 0.2, 0.25, 0.3, or 0.35 mm, or a value in a range spanning any of the preceding values, and preferably about 0.2 mm. Screw threads of the second threaded portion **110** may have a thread spacing in a range of about 1.6 mm to 2.2 mm, e.g., about 1.6, 1.7, 1.8, 1.9, 2.0, 2.1, or 2.2 mm, or a value in a range spanning any of the preceding values, and preferably about 1.9 mm. The second threaded portion may have 1, 2, 3, or 4 thread revolutions, and preferably about 2 thread revolutions.

Third threaded portion **118** may have a length in the range of about 26 mm to 38 mm, e.g., about 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm, or 38 mm, and preferably about 32 mm. Third threaded portion **118** may have thread revolutions in a range of about 10 to 22, e.g., about 10, 12, 14, 16, 18, 20, or 22 thread revolutions, or a value in a range spanning any of the preceding values, and preferably about 16 thread revolutions. Third threaded portion **118** may have delivery channels in a range of about 8 to 12 delivery channels, e.g., about 8, 9, 10, 11, or 12 delivery channels, and preferably 10 delivery channels each of which is preferably coincident with an exterior helical groove. Screw threads of third threaded portion **118** may have a major diameter **148** in a range of about 6 mm to 8 mm, e.g., about 6.0, 6.5, 7, 7.5, or 8 mm, or a value in a range spanning any of the preceding values, and preferably about 7 mm. Screw threads of third threaded portion **118** may have a minor diameter **146** in a range of about 5.4 mm to 6.5 mm, e.g., about 5.4.5, 5.0, 5.5, 6.0, or 6.5 mm, or a value in a range spanning any of the preceding values, and preferably about 5.4 mm (Fig. 3). Screw threads of third threaded portion **118** may have a thread thickness **142** in a range of about 0.05 mm to 0.35 mm, e.g., about 0.05, 0.1, 0.15, 0.2, 0.25, 0.3, or 0.35 mm, or a value in a range spanning any of the preceding values, and preferably about 0.2 mm. Screw threads of third threaded portion **118** may have thread spacing **144** in a range of about 1.6 mm to 1.9 mm, e.g., about 1.6, 1.7, 1.8, 1.9, 2.0, 2.1, or 2.2 mm, or a value in a range spanning any of the preceding values, and preferably about 1.9 mm (Fig. 3).

Bone screw **100** has non-threaded portion **112** that may have a length in the range of about 16 mm to 86 mm, e.g., 16 mm, 32mm, 48 mm, 64 mm, 80mm, and 86 mm, or a value in a range spanning any of the preceding values. Non-threaded portion **112** may have about 2 delivery channels for about every 21 mm length of helical groove **114, 115**.

5 Delivery channels **120** may have a diameter of about 0.5 to 2 mm, preferably about 1.2 mm. The delivery channels are coincident with the anti-parallel substantially helical grooves **114, 115**. Delivery channel **120** may have a spacing along the helical groove(s) of between 5 to 7 mm within third threaded portion **118** and may have a spacing within non-threaded portion **112** of between 18 to 24 mm. Preferably, delivery channels **120** in third threaded portion **118** have a separation of about 6 mm along
10 the helical grooves **114, 115**. Preferably, delivery channels **120** in non-threaded portion **112** have a separation of about 21 mm along the helical grooves **114, 115**.

The bone screw tip **122** can provide a self-tapping configuration (see Fig. 2C).

Functional design

15 The length of a bone screw of the invention may varied by increasing the length of non-threaded portion **112** (see Fig. 1), while the lengths of second and third threaded portions, **110** and **118**, may remain constant (see, Fig. 1).

Bone screw **100** contains screw head **108** with first threaded portion **104**, second threaded portion **110**, non-threaded portion **112**, third threaded portion **118**, interior channel **124** and tip **122** (see
20 Fig. 1). Screw body **102** of bone screw **100** also contains two substantially, anti-parallel helical exterior grooves **114** connecting delivery channels **120** to the exterior of the screw body.

Screw head **108** is circular and includes screw head threads **104** on its exterior (Fig. 1), to which, e.g., sheath **200** of a delivery manifold of the invention may be attached. In particular, first attachment portion **202** of sheath **200** is sized and shaped to engage screw head threads **104** of bone screw **100** (Fig
25 6). Screw head **108** additionally contains hexagonal opening **128** internal to screw head **108**, viewed in Fig. 2B from proximal end **106**, in which a rotational driver may be inserted. Opening **128** for coupling a driver can have other shapes, such as a hexagonal shape, square shape, pentagonal shape, diamond shape, etc., that allow mating of a driver or other instrument to screw head **108**. Screw head **108** can provide a self-tapping configuration (see Figs. 2A and 2B).

30 For example, screw head **108** may be shaped for engagement with, and driven by, a variety of drivers, such as a Robertson driver, a slotted driver, a Phillips driver, a Torx driver, a triple square driver, a polydrive driver, a one-way clutch driver, a spline drive driver, a double hex driver, or a Bristol driver. Rotational drivers may turn clockwise or counter-clockwise (depending on the thread direction) to tighten a bone screw into final or near-final position.

35 Interior channel **124** (Fig. 1) may have a diameter that facilitates the transfer and delivery of a flowable medium, such as a bone void filler, cement, or pharmaceutical agent substantially throughout the length of a bone screw and through tip **122** when bone screw **100** is fully cannulated.

First threaded portion **108** allows for the attachment of a manifold or other threaded device to proximal end of the bone screw **106** of the bone screw **100** (Fig. 1). Second threaded portion **110** allows
40 for anchoring of the proximal end bone screw **100** into bone. A portion of at least one exterior groove (e.g., exterior helical groove **114, 115**) may extend into second threaded portion **110**. Also, second threaded portion **110** may have one or more delivery channels coincident with the exterior groove(s). In

one embodiment, second threaded portion **110** has a length of 8.5 mm, about three thread revolutions and at least 1 delivery channels coincident with a first exterior helical groove **114** and at least 1 delivery channel coincident with a second helical groove **115**.

Third threaded portion **118** is adjacent to tip **122** at distal end **107** of bone screw **100**. Third threaded portion **118** contains a portion of at least one, and preferably at least two, exterior grooves (e.g., at least a portion of substantially anti-parallel exterior grooves **114** and **115**). Third threaded portion may have one or more delivery channels **120** coincident with the exterior groove(s). Third threaded portion has more delivery channels, e.g., a ratio of at least about 1.25:1, than the two more proximal portions: the non-threaded and second threaded portions.

The length of bone screw **100** may be increased or decreased by increasing or decreasing, e.g., the length of non-threaded portion **112**. Non-threaded portion **112** is designed with fewer delivery channels relative to the third threaded portion **118** in order to facilitate the flow of a flowable medium to the distal end of bone screw **100** and to promote a substantially uniform delivery of the flowable medium around the exterior of the bone screw. The ratio of the delivery channels in non-threaded portion **112** to the third threaded portion **118** depends on the length of both portions. For example, if third threaded portion **118** has a length of 32 mm and a spacing of delivery channels about every 6 mm, then the ratio of delivery channels in third threaded portion **118** to non-threaded portion **112** ranges from about 6.7:1 to 1.25:1 for screws up to about 130 mm in length.

Exterior grooves **114**, **115** are substantially helical and anti-parallel. Exterior grooves **114**, **115** are coincident with delivery channels **120**. Exterior grooves **114**, **115** provide a path for a flowable medium to move around the exterior of bone screw **100**. Exterior grooves **114**, **115** may have a periodicity of about 50.8 mm. In some embodiments, bone screw **100** may have one **114** or two **114**, **115** external grooves or more (e.g., more than three external grooves). Also exterior grooves of bone screw **100** may be parallel, anti-parallel, semi-parallel, oscillating, or overlapping.

Delivery channels **120** allow for a flowable medium to be distributed to the exterior of bone screw **100**. Delivery channels **120** are coincident with exterior grooves **114**, **115**. Third threaded region **118** has more delivery channels **120** than non-threaded portion **112** and second threaded portion **110**. In general, the ratio of delivery channels in third threaded portion **118** to non-threaded portion **112** is at least 1.25:1 (e.g., at least 2:1). In one embodiment, third threaded portion **118** has ten delivery channels (5 in each helical groove in the third threaded portion **118**), second threaded portion **110** has 2 delivery channels (1 in each helical groove), and non-threaded portion **112** has a length of about 86 mm (for a full screw body length of 130 mm) and 8 delivery channels (4 delivery channels in each groove). This configuration achieves a substantially uniform flow rate of a flowable medium through delivery channels **120**. In this configuration, the distance **150** from proximal end **106** of bone screw **100** to the first delivery channel in second threaded portion **110** is about 8 mm. The distance from proximal end **106** of bone screw **100** and the first delivery channel in non-threaded portion **112** is about 16.5 mm.

Bone screw tip **122** can provide a self-tapping configuration (see Fig. 2C). A self-tapping configuration allows for easier entry into the bone and more efficient installation.

Bone Screw Manifolds

The invention also features a manifold which, in combination with the bone screw, provides efficient and effective transfer of a flowable medium into the bone screw. The bone screw manifold of the

invention is formed of two parts: a sheath and a sheath adapter. Sheaths of the invention are cylindrical bodies with attachment portions on both the distal and proximal ends (i.e., first and second attachment portions, respectively). The first attachment portion of the sheath attaches to the bone screw head, while the second attachment portion attaches to the sheath adapter. Sheath adapters of the invention are cylindrical bodies with two attachment portions: a third attachment portion that connects the sheath adapter to the sheath and a fourth attachment portion that attaches the sheath adapter to an injection device.

Manifolds of the invention have several advantages. The sheath portion of the manifold provides a guiding cylindrical body for accessing the screw head of the bone screw. The sheath can act like a guidewire during bone repair surgical procedures by assisting the surgeon to locate the screw head (e.g., for contact with a rotational driver or other instrument, as well as with the sheath adapter). The sheath also provides a stable anchoring point for the sheath adapter, thereby making the process of injecting the flowable medium more efficient. Sheath adapters of the invention provide a reduced manifold volume for injection because the internal channel of the sheath adapter can be smaller than a single manifold design in which the sheath internal diameter is similar to the screw head diameter. Sheath adapters of the invention also provide a seal for injecting the flowable medium within the bone screw head, thereby isolating the flowable medium from the sheath and preventing the sheath from filling with the flowable medium, which can make accessing the screw head more difficult.

Structure

Referring to Figs. 6 and 7, sheath **200** (Fig. 6) and sheath adapter **300** (Fig. 7) are used in combination to form a delivery manifold of the invention, which facilitates introduction of a flowable medium into a cannulated and fenestrated bone screw (e.g., a bone screw of the invention, such as bone screw **100** of Figs. 1-5). Attachment of sheath **200** to screw head **108** of bone screw **100** provides a channel for insertion and stabilization of the sheath adapter **300**. Sheath **200** has a cylindrical body **204** and distal end **250** containing first attachment portion **202** for attachment to bone screw **100** (Fig. 6A). Sheath **200** has second attachment portion **210** at proximal end **252** of cylindrical body **204** for attachment to sheath adapter **300** (Fig. 6A). A series of raised ridges **218** (Fig. 6E) comprising first handling portion **254** (Fig. 6A) can be located on the outside of second attachment portion **210** (side view in Fig. 6A, view down longitudinal axis in Fig. 6E).

Sheath adapter **300** has cylindrical body **344**, (Fig. 7B), and tapered portion **304** (Fig. 7A) and fluid communication channel **356** (internal channel; Fig. &C), for conveying a flowable medium into bone screw **100**. Tapered portion **304** is adjacent distal end **346**. Sheath adapter **300** has third attachment portion **326** (Fig. 7B) that is shaped and sized to be reversibly, threadingly engaged with second attachment portion **232** of sheath **200**. Second handling portion **352** is adjacent to third attachment portion **326** and includes at least 4 raised ridges that facilitate handling and tightening to sheath **200** during installation of bone screw **100**. Adjacent to second handling portion **352** is fourth attachment portion **318** (Fig. &A) adjacent to proximal end **348**.

Sheath cylindrical body **204** defines a longitudinal axis and has a length of about 60 mm to 90 mm, exterior diameter **208** of at least about 8 mm, and interior channel **256** with a diameter **230** of 5.7 mm (see, Figs. 6A and 6B).

Sheath first attachment portion **202** is (Fig. 6A) located at the distal end of sheath body **204** and has a length of about 5 mm to 8 mm, and internal threaded region **222** (Fig. 6B) with an interior diameter of about 6 mm to 9 mm. Threaded region **222** of first attachment portion **202** may have thread thickness **240** of about 0.3 mm and thread spacing **242** of about 0.8 mm (see Fig. 6C).

5 Second attachment portion **210** (Fig. 6A) may have a length of about 16 to 24 mm, preferably about 20.4 mm. Threaded region **234** (Fig. 6B) may have a length of about 5.6 mm, about 2 thread revolutions, and a thread thickness **246** of about 0.7 mm and a thread spacing **244** of about 1.5 mm to 2.5 mm (see Fig. 6D). Threaded region **234** of second attachment portion **210** is within internal channel **256** (Fig. 6B) and may have a diameter of about 6.7 mm. Sheath first handling portion **254** is on the exterior of the second attachment portion **210**.

10 First handling portion **254** (Fig. 6A) has about 8 raised ridges **218** (Fig. 6E) which are substantially parallel to cylindrical body **204** of sheath **200**. First handling portion **254** may have a length of about 16 mm to 24 mm, preferably about 20.4 mm.

15 Sheath adapter cylindrical body **344** (Fig. 7B) defines a longitudinal axis and may have a length of about 50 to 80 mm. Cylindrical body **344** of sheath adapter **300** may have an exterior diameter of about 4 to 7 mm. Internal channel **356** (Fig. 7C) may have a diameter of about 1 mm to 3 mm. Cylindrical body **344** may have a length of about 50 mm to 80 mm, or a value in a range spanning any of the preceding values, preferably about 67.1 mm.

20 Sheath adapter third attachment portion **326** (Fig. 7B) at proximal end **350** of sheath adapter cylindrical body, may have a length of about 6 mm to 10 mm and contains exterior threaded portion **354** with a length of about 4 mm to 7 mm and at least 2 thread revolutions.

Sheath adapter second handling portion **352** is adjacent to the third attachment portion **326**. Second handling region **352** has a length of about 10 mm to 15 mm and has at least four (e.g., 4, 5, or 6) raised ridges on an exterior portion thereof.

25 Sheath adapter fourth attachment portion **318** (Fig. 7A) is adjacent to second handling portion **352** and is located at the proximal end of sheath adapter **300**. Fourth attachment portion **318** may have a length of about 3 mm to 5 mm and has an exterior threaded portion **328** (Fig. 7B) that may have at least 2 thread revolutions.

30 Sheath adapter tapered portion **304** (Fig. 7A) is located at the end of the distal end of the sheath adapter body. Tapered portion **304** may have a length of about 5 mm to 7 mm and an exterior diameter of about 2.5 mm to 7 mm. Tapered portion may have a chamfer at the distal end.

Functional design

35 First attachment portion **202** of sheath **200** is sized and shaped to be threadingly engaged to bone screw **100** (see Fig. 6). Sheath **200** provides a conduit for, and stabilizes, sheath adapter **300** and provides a stable manifold for sealing tapered portion **304** of sheath adapter **300** with interior channel **124** of bone screw **100**.

40 Second attachment portion **210** of sheath **200** is located at proximal end **252** and provides a threaded region **234** (Fig. 6B) for threadingly engaging with third attachment portion **326** of the sheath adapter **300**, thereby reversibly lockingly coupling sheath **200** to sheath adapter **300** (see Figs. 6-7). Once the sheath adapter has been secured to the sheath, the tapered portion of the sheath adapter is sealed into the interior channel of bone screw **100**.

First handling portion **254** has a plurality of raised ridges **218** (Fig. 6E) that are substantially parallel to cylindrical body **204** of sheath **200**. First handling portion **250** facilitates the attachment of the sheath **200** onto bone screw head **108** by making cylindrical body **204** easier to grip and turn.

Cylindrical body **302** has distal **346** and proximal **348** ends: distal end **346** has tapered end **304** that seals into bone screw interior channel **124** when sheath **200** and sheath adapter **300** are engaged, which allows for transfer of a flowable medium from an injection device into bone screw **100**.

Third attachment portion **326** of sheath adapter **300** is at proximal end **350** of the sheath adapter cylindrical body. The third attachment portion threadingly engages the second attachment portion **210** of the sheath **200** to form a reversible union between the sheath and the sheath adapter.

Second handling portion **352** of sheath adapter **300** assists in the coupling of third attachment portion **326** to second attachment portion **210**, thus easing the joining the sheath and sheath adapter by hand. Second handling portion allows for easy installation or removal of the sheath adapter, thereby improving the efficiency of bone defect repair.

Fourth attachment portion **318** of sheath adapter **300** is adjacent to second handling portion **352** and located at proximal end **348** of sheath adapter **300**. Fourth attachment portion **318** has threads **328** sized and shaped to engage an injection device, such as a syringe. Threads **328** can be in the form of, e.g., a Luer lock. Fourth attachment portion **318** may have threads **328** to facilitate coupling to other injection devices.

Sheath adapter tapered portion **304** is located at distal end **346** of sheath adapter **300**. Tapered portion **304** may have a tapered diameter and a chamfered end to allow the joining and sealing of sheath adapter **300** into screw head **108** producing a continuous interior channel by the combination of interior channels of the bone screw **124** and internal channel **356** of sheath adapter **300**.

Bone Screw Washers

The invention also includes a washer for use with the bone screw of the invention. The combination of a mechanically strong fenestrated screw with a washer allows for compression applications in the treatment and repair of a large range of bone defects and fractures, e.g., fractures that require compression. The bone screw washers have a proximal end with a circumferential lip, a cylindrical body, and a distal end with a diameter restriction.

Structure

Referring to Fig. 8, bone screw washer **400** has cylindrical body **430** that defines a longitudinal axis or shaft having outer diameter **418** of about 7 to 12 mm (Fig. 8c), a length of about 5 to 8 mm and internal diameter **404** of about 7 to 10.5 mm. Washer **400** has proximal end **422** and distal end **424** (Fig. 8C). Distal end **424** has radial constriction **406** that facilitates engagement of washer **400** with bone screw **100**. Radial constriction **406** has an internal diameter of about 6 to 9 mm. Washer **400** has circumferential lip **412** that engages the exterior surface of bone when used with a bone screw, e.g., bone screw **100** (see Figs. 8A, 8C). Circumferential lip **412** extends radially outward from body **430** (Fig. 8C) to engage a bone surface and to facilitate compression when used in fracture fixation. Circumferential lip **412** has a diameter of about 10 to 15 mm and a thickness of about 1 to 2 mm. Proximal end **422** of washer **400** is sized and shaped to allow for insertion of, and engagement with, a bone screw (e.g., bone screw **100** of Figs. 1-5). Opening **402** of washer **400** has a diameter of about 7.5 to 12 mm. Bone screw

washer **400** may have fenestrations (e.g. on the circumferential lip **412**) that facilitate suture attachment for securing ligaments and tendons.

Functional design

5 Bone screw washer **400** (Fig. 8) is sized and shaped to accept bone screw head **108** of bone screw **100** by passing the distal end **107** of bone screw **100** through proximal end **422** and into shaft **404**. Bone screw **100** is conveyed through washer **400** until screw head **108** engages distal constriction **406** of bone screw washer **400** (see Figs. 16 and 17, showing assembly of bone screw and washer). Bone screw washer **400** contains proximal opening **402** that allows screw head **108** to fit inside washer **400**,
10 such that screw head **108** does not extend substantially above the surface of proximal opening **402** when used in compression fixation (see Fig. 16). During injection of a flowable medium into bone screw **100**, e.g., using a manifold of the invention, washer **400** can be moved towards the distal end of bone screw **100** to provide access to the threads of first attachment portion **108** by sheath **200** (see Fig. 17).

15 **Methods of Treatment Using a Bone Screw of the Invention**

The bone screws of the invention may be used to treat a bone defect in a patient in need thereof. In particular, the bone screws of the invention, when used with a bone screw washer, such as the washer of the invention, can be used to provide compressive fixation in a patient with a fracture requiring compression.

20 Particular bone defects that may be treated using the bone screws of the invention include, e.g., any bone deficient region, such as a void, gap, recess, or other discontinuity in a bone. The bone defect may be due to, for example, disease or trauma. The bone screws of the invention can be applied, for example, in the repair of periodontal defects, in craniofacial or maxillofacial surgery or reconstruction, in hand surgery, in joint reconstruction, in fracture repair, in orthopedic surgical procedures, and in spinal
25 fusion. The bone screws of the invention may also be used, for example, in osteosynthesis to internally stabilize and/or join bones, e.g., fractured (broken) bones, either in conjunction with other mechanical devices, such as washers (e.g., a washer of the invention), metal plates, pins, rods, or wires, or individually. For example, the bone screws of the invention can be used with a bone screw washer (e.g., a washer of the invention) to provide compressive fixation of bone defects and bone fractures. In
30 particular, the bone screws are useful for the treatment of defects or breaks in large bones. Non-limiting examples of bone fractures include, e.g., stable fractures, transverse fractures, oblique fractures, spiral fractures, comminuted fractures and open and displaced fractures. Exemplary large bones that may require fracture fixation include, e.g., the femur, tibia, fibula, humerus, ulna, radius, 7th and 8th ribs, innominate bone (hip bone) and sternum.

35 The method of treating a patient having a bone defect (e.g., subarticular fracture, a defect of the spine or vertebra, or a defect of the radius, ulna, fibula, clavicle, humerus, pelvis, femur, patella, tibia, talus, calcaneus, navicular, cuneiforms, metatarsals, metacarpals, phalanges, scapula, ankle, teeth, or mandible) includes the following: a) positioning the bone screw of the invention in proximity to the bone defect (e.g., positioning the bone screw so that it contacts the intraosseous space of a bone, and/or, in
40 the treatment of a fracture, spans the fracture line); b) introducing a flowable medium (e.g., a bone void filler material, a cement, or a pharmaceutical agent, such as by use of a manifold of the invention (see below)) into the interior channel of the bone screw; c) allowing the flowable medium to be extruded

through the delivery channels (e.g., the flowable medium is extruded through substantially all or a plurality of the delivery channels, e.g., in substantially equal volumes), and d) allowing the flowable medium to harden, thereby fixing the bone screw in place. The bone screw of the invention may be used, e.g., for maxillomandibular or craniofacial fixation, temporary fixation for repairing a bone defect in a staged reconstruction, glenoid or humeral fixation, patellar fixation, or spine fixation.

For vertebral fixation, the bone screw may be placed within a pedicle, used to anchor an interbody device, used to anchor spinal fusion plates and spacer replacement, used in an osteoporotic vertebra, or positioned in proximity to the spinous processes of adjacent vertebrae.

The method of treatment using a bone screw of the invention may also include the insertion of a rod, pin, nail, or bone plate in proximity to the bone defect. One or more of these devices may be used in conjunction with the bone screw or separate from the bone screw.

When the method is performed to provide compressive fixation, the method may include, prior to step a), i) positioning a washer (e.g., a washer of the invention) over the proximal end of the bone screw (near the screw head), ii) inserting the distal end of the bone screw into the bone so that it passes through the fracture line, and iii) tightening the bone screw such that the distal threads of the bone screw provide compressive force that pulls the bone screw head (and the washer) against the surface of the patient's bone (e.g., contact of the circumferential lip of the washer (see, e.g., Fig. 8) to the surface of the patient's bone holds the proximal end of the bone screw in place).

When the method is performed using a manifold of the invention, the method may, prior to step b) above, further include i) fluidically coupling the screw head to the sheath portion of a delivery manifold of the invention, ii) fluidically coupling an injection device, such as a syringe, that includes a flowable medium (e.g., a bone cement, such as a self-setting, injectable calcium phosphate-based bone cement (e.g., BETA-BSM™ and CARRIGEN™)) to the sheath adapter portion of a delivery manifold of the invention, iii) inserting the sheath adapter into the sheath, iv) threading the third attachment portion of the sheath adapter to the second attachment portion of the sheath to form a fluid tight seal, and v) injecting the flowable medium into the interior channel of the bone screw using, e.g., manual pressure, which results in extrusion of the bone cement through delivery channels in the bone screw. The flowable medium flows substantially evenly around the bone screw exterior (along the exterior grooves (e.g., helical grooves)) and into the bone defect. The flowable medium subsequently hardens to provide substantially fixation of the bone screw and the patient's bone. The manifold is removed from the bone screw and the surgical site is closed.

The method may also, optionally, include, prior to step d) above, i) inserting a rotational driver into the screw head (e.g., through the sheath of the manifold after removal of the sheath adapter); ii) engaging the screw head with the rotational driver; and iii) tightening the bone screw into final position by rotating the rotational driver.

Kits

The invention also features a kit that includes one or more of i) a bone screw of the invention, ii) a manifold of the invention (e.g., the sheath and sheath adapter portions), and iii) a washer of the invention. The kit may, optionally, include one or more of an injection device (e.g., a syringe), a powder of a flowable medium (e.g., a self-hardening bone cement powder), and a physiologically acceptable fluid for hydrating the bone cement powder. The flowable medium may be provided in the form of a powder

that may be hydrated with a pharmaceutically acceptable fluid (e.g., water, serum, or saline) prior to use, or in a ready to use form (e.g., a paste, putty, or slurry). The kit may further include instructions for use of the bone screw, manifold, and/or washer to treat a bone defect (e.g., subarticular fracture, a defect of the spine or vertebra, or a defect of the radius, ulna, fibula, clavicle, humerus, pelvis, femur, patella, tibia, talus, calcaneus, navicular, cuneiforms, metatarsals, metacarpals, phalanges, scapula, ankle, teeth, or mandible).

Operation

The operation of bone screw **100** in combination with sheath **200** and sheath adapter **300** portions of the bone screw manifold allows for several advantages. Bone screw **100** provides an even distribution of bone cement throughout the delivery channels and along screw body **102** upon injection of bone cement into bone screw **100**. Use of the manifold of the invention with the bone screw of the invention allows for the reliable injection of a flowable medium into bone screw **100** with manual pressure. Once the flowable medium has hardened, a self-cutting edge that is present along the edge of one or more of the exterior groove(s) (i.e., the edge is not radiused), as well as a self-cutting edge in the threads of the first attachment portion **110**, facilitates removal of bone screw **100** without substantial damage to the newly hardened material or the bone screw itself.

In one exemplary method, bone screw **100** is provided in proximity of the bone defect. Self-tapping tip configuration **132** facilitates installation of bone screw **100** into the bone defect, e.g., with a pilot hole or with a hole smaller than the diameter of bone screw **100**. A rotational driver can be used to move a bone screw into final or near-final position. The rotational driver can be disconnected and sheath **200** then attached to screw head **108** by turning first handling portion **210** manually. Sheath adapter **300** is then inserted into sheath **200** and manually tightened into place by engaging second attachment portion **210** of sheath **200** to third attachment portion **326** of sheath adapter **300**. An injection device, such as a syringe, filled with a flowable medium may be attached to fourth attachment portion **318** and the injection device manually tightened into place (attachment of the injection device may also precede insertion of sheath adapter **300** into sheath **200**). The stable assembly (see Figs. 12-15 for examples of assembly of bone screw **100**, sheath **200**, and sheath adapter **300**) of bone screw **100**, sheath **200**, sheath adapter **300**, and an injection device facilitates injection of a flowable medium, such as a bone cement, into, through, and to the exterior of, the bone screw body **102**, thereby repairing the bone defect or fracture. After injection, the injection device, sheath adapter and sheath may be disassembled to provide access to screw head **108** for further adjustment. Alternatively, the injection device and sheath adapter **300** may be disassembled and a rotational driver inserted into screw head **108** through sheath **200**. If necessary, after the flowable medium has been allowed to harden, bone screw **100** can be removed, aided by a self-cutting edge of helical groove(s) **114**, **115** and the self-cutting edge of the threads of first attachment portion **110**.

In another exemplary method, bone screw **100** is provided in proximity to a bone defect. Prior to insertion into the bone, bone screw **100** is inserted through internal diameter **404** of bone screw washer **400**. Bone screw washer **400** engages screw head **108**. Self-tapping tip configuration **132** facilitates entrance of bone screw **100** into the bone defect. Threads of third threaded portion **118** and washer lip **412** provide oppositional forces as the screw is tightened in place, thereby compressing the bone defect or fracture together. A rotational driver can be used to move the bone screw into final or near-final

position and achieve optimal compression of the bone defect. The injection of a flowable medium and disassembly of the bone screw **100**, sheath **200**, sheath adapter **300**, and injection device can occur as described above.

The bone screws of the present invention provide numerous advantages over other bone screws known in the art. For example, in some embodiments of the bone screws of the present invention, the diameter of the interior channel is smaller than in cannulated bone screws in the art, resulting in improved strength and the option of reduced overall screw size. In addition, by having a smaller interior channel diameter, bone screws of the present invention are optimized for use with state-of-the-art bone cements, e.g., fourth-generation self-hardening calcium phosphate-based bone cements, which have reduced viscosity, and thus require application of less pressure than older bone cements. In additional embodiments, the threaded screw head allows for airtight attachment of a removable delivery manifold, e.g., a plastic manifold, which, in turn, facilitates loading of flowable medium by allowing a surgeon or other user to apply manual pressure rather than hydraulic pressure. This reduces the likelihood of unwanted introduction of air embolisms into the bone cavity or other surgical site. In addition, unlike prior art screws that require connection of a delivery manifold inside the rotational driver, producing very small orifices and correspondingly high operating pressure, bone screws of the present invention have no restriction in the flow path of the flowable medium, reducing the necessary operating pressure.

It is also significantly easier to remove, or to adjust the position of, a bone screw of the present invention that has been placed in a surgical site, in comparison to bone screws of the prior art. Because the rotational driver is inserted inside the screw head, it is not necessary to grasp the external surface of the screw head in order to remove an implanted screw prior to hardening of the cement.

Upon hardening of the cement around a bone screw of the present invention, the bone screw is more stable and secure than a conventional screw because of the even distribution of cement that covers a large percentage of the surface area of the screw body and contacted bone. This increased stability reduces the likelihood of "backout" of a screw from the surgical site, which may occur with a conventional screw.

In additional embodiments, the presence of exterior grooves facilitates equalized distribution of flowable medium along the exterior surface of the screw. For example, if one exterior opening is blocked, flowable medium from an adjacent exterior opening may flow along an exterior groove to "back-fill" or compensate for the blocked opening. The presence of exterior grooves, in particular, straight exterior grooves, can also increase the strength characteristics of the screw body.

In additional embodiments, use of an adjustable interior plug allows for selective delivery of flowable medium to desired delivery channels while blocking off other delivery channels. Such a plug may be designed to be pushed in or screwed in and may be either permanent or removable. In addition, in some embodiments, the tip or distal end of the screw body, i.e., the end of the screw body distal to the screw head, may be manufactured to be open or closed; in open embodiments, a removable tip plug may be added as needed according to the surgical indication. The inclusion of such adjustable plugs significantly increases the flexibility of use of bone screws of the present invention.

40 **Examples**

The following examples are to illustrate the invention. They are not meant to limit the invention in any way.

Example 1: Use of a bone screw of the invention to repair a fracture or other bone defect.

A bone screw of the invention (e.g., a bone screw of Figs. 1-5) can be used to provide fracture support, e.g., for a subarticular fracture, in conjunction with conventional fixation. The site to be supported can be accessed using either a percutaneous or open technique. The extraction technique preferably ensures maximal bone conservation.

Example 2: Use of a bone screw of the invention for compression fixation.

A bone screw of the invention can be used for compression fixation in combination with a washer of the invention to repair a hip fracture. The fractured bone is aligned and held in the proper position by traction.

A bone screw of the invention is inserted into a washer of the invention. The surgical site is prepared (e.g., by reaming or drilling) to accept the bone screw and body of the washer. The bone screw tip is inserted into the bone such that the threaded portion at the distal end of the body of the bone screw passes beyond the fracture line and into the femoral head. Tightening of the bone screw forces the circumferential lip of the washer against the exterior surface of the bone, which compresses the bone above and below the fracture line, thereby providing compression fixation. A bone cement is injected into the head of the bone screw (e.g., using a manifold of the invention), and hardening of the bone cement fixes the bone screw in place.

Example 3: Use of a bone screw of the invention to repair a fracture or other bone defect with manual pressure.

A bone model system was used to experimentally determine the forces required to inject a flowable material into a bone screw of the inventive method.

The clinical objective of bone screws of the invention is to provide secure fixation across a fracture and to enable delivery of a Bone Void Filler (BVF) to the surrounding defect area. It is standard of care to reduce fractures with 4 mm diameter fixation screws. These screws are often used together with BVF material injected around the screw into the fracture site to fill voids.

We created bone void models (BVM) to simulate a 4.5 milliliter (mL) defect. We used a closed cell 12.5 PCF bone foam to represent typical metaphyseal cancellous bone. Foam blocks were split in half and a hole drilled into each side to form a 4.5 mL hollow cavity when assembled together (Fig. 9).

The distal end of the bone screw is typically embedded into the distal fragment by approximately 10 mm. Screws are placed through the center of the void such that the distal end of the screw was located approximately 10 mm past the void. Four smaller (1.5 mL) bone void models were constructed similarly to the 4.5 mL models. BVF was also tested in these models to verify the ability to fill smaller voids through the screw even if fewer holes are exposed to the void.

Static extraction torque testing was performed to demonstrate the bone screw can be removed without damaging the screw or the surrounding BVF. Testing was also performed using CARRIGEN™ to evaluate static extraction torque with this BVF.

Delivery of BVF through 11 gauge Cannula

A test set up was constructed as shown in Figs. 9 and 10 consisting of a 50 mm length by 4 mm diameter fixation screw, an injection needle, foam test block construct, insertion syringe, and BVF. This

test set up simulated the current standard of care method for delivery of BVF during a bone void filling procedure. Test blocks were constructed from foam mimicking cancellous bone (PCF 12.5 polyurethane). A 44 mm x 64 mm x 41 mm block was split in half and a 16mm diameter hole drilled into each side to total depth of 22 mm to form a 4.5 mL hollow cavity when assembled together. The two halves of the model were clamped together using 2" sheetrock screws, external to the void. The fixation screw was inserted through the center of the defect to a depth of approximately 10 mm fixation in the distal block.

The injection needle was then inserted into the specimen adjacent to the screw into the void. The BVF was prepared according to the manufacturer's Instructions for Use. The BVF was loaded into the syringes. To simulate worst case handling of the materials, each was left at room temperature in a mixed condition for the maximum allowed per the manufacturer's Instructions for Use (BETA-BSM™ – 2 minutes; CARRIGEN™ – 15 minutes). Each was then attached to the luer lock of the needle and injected under finger pressure into the needle/test block assembly. Injection pressure was measured according to the protocol according to Example 4. The stylet was inserted into the needle to expel residual BVF within the needle. The test samples were then placed in a 37° C incubator for two hours to allow the BVF to harden. Mass of the specimen was measured before and after BVF injection to determine amount of fill of the BVF into the specimen. The specimens were imaged using C-arm fluoroscopy.

The static torque extraction tests were performed by hand using calibrated torque wrench. The peak torque required to loosen each screw from the foam test blocks was recorded. The specimens were then sectioned to assess the fill of the void and any damage to the BVF after screw removal.

Delivery of BVF through the Bone Screw

A test set up was constructed as shown in Figs. 9 and 10 consisting of a 50 mm length N-force by 4mm diameter fixation screw, screw sheath, foam test block construct, insertion syringe, and BVF. This test set up simulated delivery of BVF during a bone void filling procedure through the bone screw. Test blocks were constructed from foam mimicking cancellous bone (PCF12.5 polyurethane). A 44 mm x 64 mm x 41 mm block was split in half and a 16 mm hole drilled into each side for a total depth of 22 mm to form a 4.5 mL hollow cavity when assembled together. The halves of the model were clamped together using 2" sheetrock screws, external to the void. The fixation screw was inserted through the center of the defect to a depth of approximately 10mm fixation in the distal block. The BVF was prepared according to the manufacturer's Instructions for Use. The BVF was loaded into the syringes. To simulate worst case handling of the materials, each was left at room temperature in a mixed condition for the maximum allowed per the manufacturer's Instructions for Use (BETA-BSM™ – 2 minutes; CARRIGEN™ – 15 minutes). Each was then attached to the luer lock of the sheath and injected under finger pressure into the screw/test block assembly. Delivery pressure was measured per the protocol described in Example 4. The hex driver was inserted through the sheath into the screw to expel residual BVF within the sheath. The test samples were then placed in a 37° C incubator for two hours to allow the BVF to harden.

Mass of the specimen was measured before and after BVF injection to determine amount of fill of the BVF into the specimen. The specimens were imaged using C-arm fluoroscopy. The static torque extraction tests were performed by hand using calibrated torque wrench. The peak torque required to loosen each screw from the foam test blocks was recorded. The specimens were then sectioned to

assess the fill of the void and any damage to the BVF after screw removal. The results are shown in Table 1 below.

Delivery force measurement procedure

5 The force required to deliver BVF throughout the length of a bone screw of the invention was compared to a simple cannula. Twelve kits containing the respective bone void fillers BETA-BSM™ and CARRIGEN™ were used to conduct the experiments. The simple cannula used was a 63.5 mm x 11 Gauge cannulae (Hamilton Corp, Part #: 7750-02).

The bone screws had were 4mm (internal diameter) x 50mm in length. The bone void models (BVM) were used as described in Example 3. Four smaller 1.5 mL simulated bone void models were constructed similarly to the 4.5 mL models but the 16 mm holes were drilled to a depth of 3.75 mm.

The bone void fillers, BETA-BSM™ and CARRIGEN™, were prepared using commercial kit components per the mixing instructions from the manufacturers. BETA-BSM™ was left in the 10 mL mixing/delivery syringe which is supplied with the kit. The resulting material from each CARRIGEN™ kit was transferred into five 1 mL syringes. The filled syringes were attached to bone screws or cannulae which had been placed in the bone models as shown in Fig. 9 and 10. Injectability testing was performed by placing the syringe with the BVM attached into a support frame. The syringe plunger was moved using the measurement end of a force measuring device. The Average and maximum injection force was measured using a uniaxial load frame. Delivered mass was measured by weighing the bone model before and after delivery. Delivered volume was calculated by dividing the delivered mass by the appropriate material density (1.8g/mL for CARRIGEN™, 1.6g/mL for BETA-BSM™). For each product (BETA-BSM™ and CARRIGEN™) five of the kits were delivered through a cannula and five delivered through a bone screw. Statistical analysis was performed on the resulting data using STATGRAPHICS Plus 4.1 for Windows. An additional 2 kits of each product were delivered through bone screws into the small defect models to verify the defect size did not impact the results .

Results

Acceptance criteria for delivery pressure (digital pressure) was set at 10 kgf based on previous design criteria for BETA-BSM™ and product release. Delivery force values for all samples were well below this limit as seen in the Table 1. All samples exhibited 100% injection and were delivered into the void by digital pressure (<10 Kgf) through both the 11 gauge cannula and the bone screws.

The bone fillers, BETA-BSM™ and CARRIGEN™, both filled the 4.5 mL BVM regardless of whether delivered through an 11gauge Cannula or the bone screw. Table 1 shows that both delivery methods delivered at least 4.5 mL of BVF to the bone void model. All samples exhibited delivered volumes greater than 4.5 mL, the volume of the defect. In addition to the void fill measurement, visual inspection was made of the samples through fluoroscopy images and digital images after sectioning. The fluoroscopy images, in Fig. 11, showed that BETA-BSM™ and CARRIGEN™ achieved proper fill of the 4.5 mL defect regardless of delivery through an 11 gauge cannula or through the bone screw. Visual inspection of the sectioned samples also showed the voids were filled with BETA-BSM™ or CARRIGEN™ regardless of delivery through an 11 gauge cannula or the bone screw.

Screw removal testing (Table 1) showed that the bone screws could be removed from hardened BETA-BSM™ and hardened CARRIGEN™ at clinically acceptable torques (mean peak removal torque)

regardless of delivery through an 11 gauge cannula or the bone screw. All of the removal torques were well below the mean torque to failure (screw fracture) of the screw of 2,960±27 Nmm. Visual inspection showed that screw removal did no damage to the hardened BVF. The thread forms were still visible after screw removal.

5 Results from sampling (n=2) small void models (1.5 mL) showed that both BVF's were able to fill a small void through the N-Force screws even with fewer fenestrations contacting the void. Also, delivery pressures and screw removal torques were well within limits described in Table 1.

No difference was seen in the performance of BETA-BSM™ and CARRIGEN™ BVF's delivered via the bone screws with respect to their ability deliver with digital pressure and to fill a bone void relative to delivery through an 11 gauge cannula. Screws of this invention could be removed from defects filled with hardened BETA-BSM™ and CARRIGEN™ BVF without damaging the screws or BVF.

Table 1. Summary of Results

Parameter	BVF: BETA-BSM™		BVF: CARRIGEN™	
	Inventive Bone Screw	Cannula	Inventive Bone Screw	Cannula
Average Delivery Force (kgf)	1.25±0.18	0.91±0.19	1.57±0.14	1.31±0.08
Maximum Delivery Force (kgf)	2.05±0.23	2.09±0.53	2.17±0.34	1.74±0.10
Delivered Mass (g)	7.42±0.14	7.58±0.10	8.32±0.29	8.86±0.07
Calculated Delivered Volume (mL)	4.64±0.09	4.74±0.06	4.62±0.16	4.92±0.04
Screw Removal Mean Peak Torque (Nmm)	1,360±153	1,300±68	1,710±204	1,520±102

15

Example 4: Strength of Inventive Bone Screw

Mechanical Testing Methodology

Bone screws of the invention were tested to confirm the retention of mechanical properties after being fenestrated. Five screws with the dimensions 7 mm x 130 mm were tested in accordance with ASTM method ASTM F1264-03(2012). Specifically, the static 4-point bend tests were completed as outlined in ASTM F1264-03(2012). They were performed in stroke control at a rate of 6 mm per minute starting at zero load and continuing until failure. Force vs. displacement data were recorded throughout test duration. The support span was 114 mm, the span between loading points was 38 mm, the load to support span was 38 mm, and the roller diameter was 12.6 mm.

25

Results

The results show that the bone screws exhibit a mean bending stiffness of 172 N/mm, a mean bending yield force of 886 N, a mean bending yield moment of 16.8 Nm, a mean bending structural stiffness of 3.93 Nm², a mean bending ultimate force of 1,173 N and a mean bending ultimate moment of

22.3 Nm. Failure mode was the screw yielding. The mechanical results show that bone screws of the invention are compatible for use in the repair of bone defects, such as in fracture fixation.

Other Embodiments

5 All publications, patents, and patent applications mentioned in the above specification are hereby incorporated by reference, including U.S. Application Publication No. 2011/0060373. Various modifications and variations of the described method and system of the invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific embodiments, it should be understood that the invention
10 as claimed should not be unduly limited to such specific embodiments. Indeed, various modifications of the described modes for carrying out the invention that are obvious to those skilled in the art are intended to be within the scope of the invention.

Other embodiments are in the claims.

15

CLAIMS

1. A bone screw having a length from about 60 millimeters (mm) to 200 mm and comprising: i) a cylindrical screw body comprising a shaft that defines a longitudinal axis, ii) a screw head at the proximal end of said screw body, and iii) a tip at the distal end of said screw body, said bone screw further comprising:
 - a. an interior channel extending longitudinally through said screw head and through at least a portion of the shaft of said screw body, wherein said interior channel has a diameter of about 3 to 5 mm;
 - b. a first threaded portion on the exterior of said screw head extending from about the proximal end of said screw head along at least a portion of the screw head;
 - c. a second threaded portion on the exterior of said screw body adjacent to the screw head that extends in a direction along the screw body away from said screw head and having one or more delivery channels;
 - d. a third threaded portion on the exterior of said screw body adjacent to the tip that extends along a distal portion of the screw body and having one or more delivery channels;
 - e. a non-threaded portion between the second and third threaded portions on the exterior of said screw body and having one or more delivery channels; and
 - f. at least first and second helical grooves extending along the exterior of said screw body, wherein:
 - i. said first helical groove is substantially anti-parallel to said second helical groove and said helical grooves extend continuously through said second threaded portion, said non-threaded portion, and at least a portion of said third threaded portion,
 - ii. said delivery channels are coincident with said helical grooves,
 - iii. each of said delivery channels within the helical grooves of said non-threaded portion is separated by a distance of about 18 to 24 mm along said helical groove, and
 - iv. each of said delivery channels of said third threaded portion is separated by a distance of about 5 to 7 mm along said helical groove.
2. The bone screw of claim 1, wherein said bone screw comprises one or more, or all, of the following characteristics:
 - a. each of said delivery channels have a diameter of about 0.5 to 2 mm;
 - b. said screw head has a length of about 4 to 7 mm and said first threaded portion has a length of about 2 to 4 mm and an exterior diameter of about 6 to 10 mm;
 - c. said second threaded portion comprises about 2 to 4 thread revolutions, 1 to 4 delivery channels and a length of about 5 to 8 mm;
 - d. said third threaded portion comprises about 10 to 20 thread revolutions, 8 to 12 delivery channels and a length of about 25 to 40 mm;
 - e. said non-threaded portion has a length of about 16 to 86 mm; and/or

- f. the ratio of said delivery channels in said third threaded portion to said non-threaded portion is at least 1.25:1.
3. The bone screw of claims 1 or 2, wherein said bone screw comprises one or more, or all, of the following characteristics:
 - a. said interior channel has a diameter of about 3.9 mm;
 - b. said screw head has a length of about 5.3 mm and said first threaded portion has a length of about 3.2 mm and an exterior diameter of 8.3mm;
 - c. said second threaded portion comprises about 3 thread revolutions, about 2 delivery channels and a length of about 6.5 mm;
 - d. said third threaded portion comprises about 16 thread revolutions, about 10 delivery channels and a length of about 32 mm and each of said delivery channels of said third threaded portion is separated by a distance of about 6 mm along said helical grooves;
 - e. said non-threaded portion has a length of about 16 mm to 86 mm and comprises at least one to about 24 delivery channels and each of said delivery channels of said non-threaded portion is separated by a distance of about 21 mm along said helical grooves; and/or
 - f. each of said delivery channels have a diameter of about 1.2 mm.
4. The bone screw of claim 3, comprising each of the characteristics a) through f).
5. The bone screw of any one of claims 1 to 4, wherein said bone screw has a length of about 60 to 130 mm.
6. The bone screw of any one of claims 1 to 5, wherein said first threaded portion comprises about 1 to 5 thread revolutions.
7. The bone screw of any one of claims 1 to 6, wherein said delivery channels are not within about 5 mm of the proximal end and distal end of said bone screw.
8. The bone screw of any one of claims 1 to 7, wherein said delivery channels are distributed along said helical grooves to provide substantially equal distribution of a flowable medium extruded through each of said delivery channels following introduction of said flowable medium through said screw head into said interior channel.
9. The bone screw of claim 8, wherein the flowable medium comprises a bone void filler, a cement, or a pharmaceutical agent.
10. The bone screw of claim 9, wherein the cement is a self-hardening calcium phosphate composition.

11. The bone screw of any one of claims 1 to 10, wherein said bone screw is, or comprises, stainless steel alloy, titanium alloy, commercially pure titanium, cobalt chrome, or polyetheretherketone, or combinations thereof.
12. The bone screw of any one of claims 1 to 11, wherein each of said delivery channels is tapered along at least a portion of its radial axis or is substantially cylindrical.
13. The bone screw of any one of claims 1 to 12, wherein at least one edge of said helical grooves comprises a self-cutting edge.
14. The bone screw of any one of claims 1 to 13, wherein said bone screw has a mean bending stiffness of at least 136 N/mm in a 4-point bend test.
15. A bone screw manifold for delivering a fluid to a cannulated and fenestrated bone screw comprising a sheath and a sheath adapter, wherein:
 - a) said sheath comprises a cylindrical sheath body that defines a longitudinal axis, a first attachment portion at the distal end of said sheath body, a second attachment portion at the proximal end of said sheath body, and an internal channel having a diameter of at least about 5 mm that extends continuously through said sheath body and through said first and second attachment portions to provide fluid communication through said manifold, wherein:
 - i) said sheath body has a length of about 60 to 90 mm;
 - ii) said first attachment portion comprises a threaded region within said internal channel; and
 - iii) said second attachment portion comprises a threaded region within said internal channel, and comprises a first handling portion on the exterior of at least a portion of said second attachment portion; and
 - b) said sheath adapter comprises a cylindrical sheath adapter body that defines a longitudinal axis, a third attachment portion at the proximal end of said sheath adapter body, a second handling portion adjacent to said third attachment portion, a fourth attachment portion adjacent to said second handling portion, a tapered portion at the distal end of said sheath adapter body, and an internal channel having a diameter of at least about 2 mm that extends continuously through said sheath adapter body, said third attachment portion, said second handling portion, said fourth attachment portion, and said tapered portion to provide fluid communication through said sheath adapter, wherein:
 - i) said sheath adapter body has a length of about 50 to 80 mm and an external diameter that is less than the diameter of the internal channel of said sheath;
 - ii) said third attachment portion comprises a threaded region on an exterior portion thereof;

- iii) said second handling portion comprises raised ridges on an exterior portion thereof; and
- iv) said fourth attachment portion comprises a threaded region on an exterior portion thereof; and

wherein the sheath adapter body is sized and shaped for insertion into the internal channel of said sheath, the threaded region of said third attachment portion of said sheath adapter is sized and shaped to be threadingly engaged with the threaded region of said second attachment portion of said sheath, thereby reversibly joining said sheath and said sheath adapter when engaged, and, when said sheath and said sheath adapter are joined, said tapered portion of said sheath adapter extends into said first attachment portion of said sheath, and

wherein said manifold is capable of delivering a self-hardening calcium phosphate bone cement to the distal tip of a cannulated and fenestrated bone screw having a length of at least about 130 mm using manual pressure.

- 16. The sheath of claim 15, wherein said first attachment portion is sized and shaped to be threadingly engaged with the bone screw head of the bone screw of any one of claims 1 to 14.
- 17. The sheath adapter of claim 15 or 16, wherein said second attachment portion is sized and shaped to be threadingly engaged with a device for injecting a flowable medium, wherein said flowable medium comprises said bone void filler, said cement, or said pharmaceutical agent.
- 18. The sheath adapter of claim 17, wherein said device is a syringe.
- 19. The bone screw manifold of any one of claims 15 to 18, wherein said bone screw manifold comprises one or more, or all, of the following characteristics:
 - a. said sheath body has an external diameter of at least 8 mm;
 - b. said first attachment portion has a length of about 5 to 8 mm, said threaded region of said first attachment portion has a length of about 2 to 4 mm and at least 3 thread revolutions, and said internal channel of said first attachment portion has an internal diameter of about 6 to 9 mm;
 - c. said second attachment portion has a length of about 16 to 24 mm, and wherein said threaded region of said second attachment portion has a length of about 4 to 7 mm and at least 2 thread revolutions, and said internal channel of said second attachment portion has an internal diameter of about 5 to 8 mm;
 - d. said first handling portion comprising at least five raised ridges that extend in a direction substantially parallel to the longitudinal axis of said sheath body;
 - e. said third attachment portion has a length of about 6 to 10 mm and said threaded region of said third attachment portion has a length of about 4 to 7 mm and at least 2 thread revolutions;

- f. said second handling portion has a length of about 10 to 15 mm and comprises at least four raised ridges on an exterior portion thereof that extend in a direction substantially parallel to the longitudinal axis of said sheath adapter body;
 - g. said fourth attachment portion has a length of about 6 to 9 mm and said threaded region of said fourth attachment portion has a length of about 3 to 5 mm and at least 2 thread revolutions; and/or
 - h. said tapered portion has a length of about 5 to 7 mm and an exterior diameter of about 2.5 to 7 mm, and said tapered portion has a chamfer at the distal end.
20. The bone screw manifold of any one of claims 15 to 19, wherein said bone screw manifold comprises one or more, or all, of the following characteristics:
- a. said sheath body has a length of about 76.2 mm and said internal channel of said sheath has a diameter of 5.8 mm;
 - b. said first attachment portion has a length of about 6.4 mm and said threaded region of said first attachment portion has a length of about 3.2 mm, about 3 thread revolutions, and has an internal diameter of about 7.8 mm;
 - c. said second attachment portion has a length of about 20.4 mm and said threaded region of said second attachment portion has a length of about 5.6 mm, about 2 thread revolutions, and has an internal diameter of about 6.7 mm and comprises eight raised ridges;
 - d. said sheath adapter body has a length of about 67.1 mm and an external diameter of about 5.3 mm and said internal channel of said sheath adapter has a diameter of 2.5 mm;
 - e. said third attachment portion has a length of about 8.5 mm and said threaded region of said third attachment portion has a length of about 5 mm and about 2 thread revolutions;
 - f. said second handling portion has a length of about 12.5 mm and comprises six raised ridges;
 - g. said fourth attachment portion has a length of about 7.5 mm and said threaded region has a length of about 4.3 mm and about 2 thread revolutions; and/or
 - h. said tapered portion has a length of about 6.1 mm and an exterior diameter of about 3 mm.
21. The bone screw manifold of claim 20, comprising each of the characteristics a) through h).
22. The bone screw manifold of any one of claims 15 to 21, wherein:
- a. said threaded region of said second attachment portion has about 2 to 4 thread revolutions,
 - b. said threaded region of said third attachment portion has about 2 to 4 thread revolutions, and
 - c. said threaded region of said fourth attachment portion has about 2 to 4 thread revolutions.

23. The bone screw manifold of any one of claims 15 to 22, wherein said manifold is, or comprises, a polymeric material.

24. The bone screw manifold of claim 23, wherein said polymeric material is, or comprises, polypropylene, polyethylene, polystyrene, polytetrafluoroethylene or polyetheretherketone, or combinations thereof.

25. A bone screw washer comprising:

- a. a cylindrical body comprising a shaft that defines a longitudinal axis, wherein said body has a length of about 5 to 8 mm and a diameter of 7 to 10.5 mm;
- b. a bone engaging portion at the proximal end of the body comprising a circumferential lip with a thickness of 1 to 2 mm and a radial diameter of 10 to 15 mm; and
- c. a screw head engaging portion at the distal end of the body having a diameter of 6 to 9 mm, wherein the diameter of the screw head engaging portion is less than the diameter of the body; and

wherein said washer is sized and shaped to accept the screw head of the bone screw of any one of claims 1 to 14 and to engage a bone surface.

26. The washer of claim 25, wherein said washer comprises one or more, or all, of the following characteristics:

- a. said body has a length of about 6.3 mm and a diameter of 8.6 mm,
- b. said circumferential lip of the bone engaging portion has a thickness of 1.6 mm and a radial diameter of 12.7 mm, and/or
- c. said screw head engaging portion has a diameter of 7.5 mm.

27. The washer of claim 25 or 26 further comprises one or more fenestrations for suture attachment.

28. A method of treating a patient having a bone defect, said method comprising the steps of:

- a. positioning the bone screw of any one of claims 1 to 14 in proximity to said bone defect;
- b. attaching said sheath of said bone screw manifold;
- c. attaching said sheath adapter to said sheath;
- d. attaching a manual pressure injection device to said fourth attachment portion of said sheath adapter; and
- e. introducing a flowable medium into said interior channel of said bone screw, whereby said flowable material is extruded through said delivery channels;

wherein hardening of the flowable medium fixes said bone screw in place, thereby treating said bone defect in said patient.

29. The method of claim 28, wherein the flowable medium is a bone void filler, a cement, or a pharmaceutical agent.

30. The method of claim 29, wherein the cement is a self-hardening calcium phosphate composition.
31. The method of any one of claims 28 to 30, wherein the bone defect comprises a subarticular fracture or a defect of the radius, ulna, fibula, clavicle, humerus, pelvis, femur, patella, tibia, talus, Calcaneus, navicular, cuneiforms, metatarsals, metacarpals, phalanges, scapula, ankle or vertebra.
32. The method of any one of claims 28 to 31, wherein said bone defect is a compression fracture.
33. The method of claim 32 further comprising, prior to step a), joining the washer of any one of claims 25 to 27 to said screw head, whereby tightening or screwing said bone screw into bone of said patient at or near said fracture provides a compression union that stabilizes said fracture.
34. A kit comprising any one or more, or all, of the following:
- a. the bone screw of any one of claims 1 to 14;
 - b. the manifold of any one of claims 15 to 24; and/or
 - c. the washer of any one of claims 25 to 27;
- wherein said kit optionally comprises one or more of an injection device, a self-hardening bone cement powder, and instructions for using said kit.
35. The kit of claim 34, wherein said kit comprises the bone screw of any one of claims 1 to 14, the manifold of any one of claims 15 to 24, and the washer of any one of claim 25 to 27.

Fig. 1

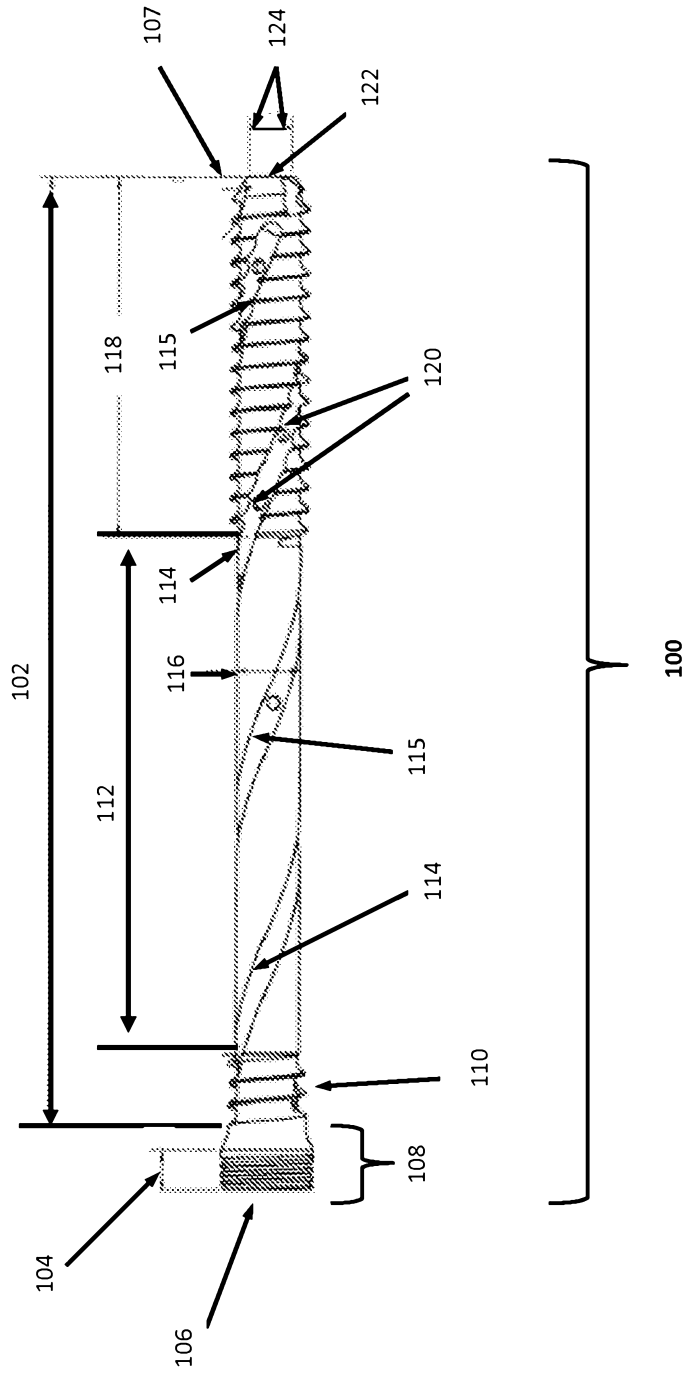


Fig. 2

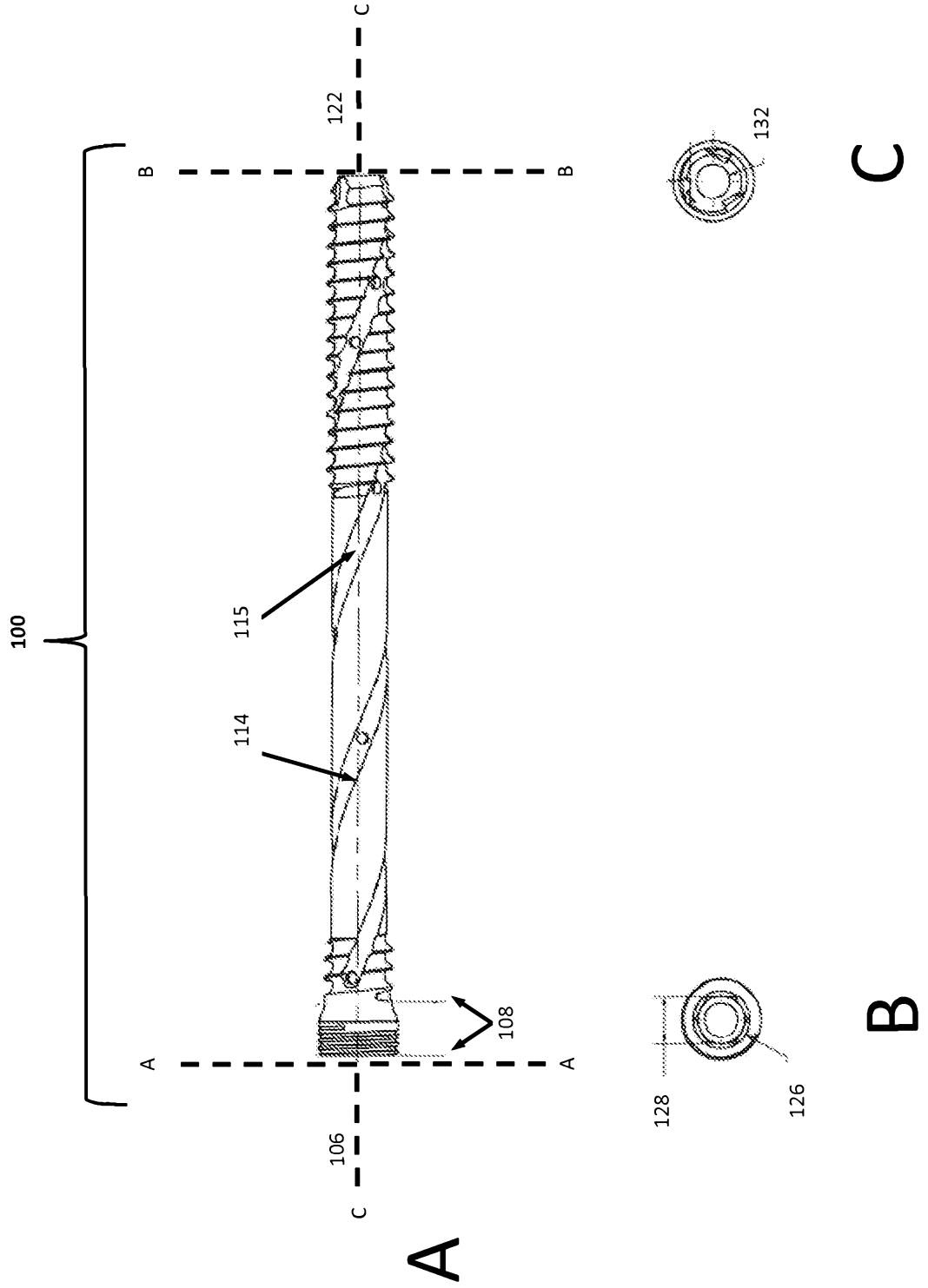


Fig. 3

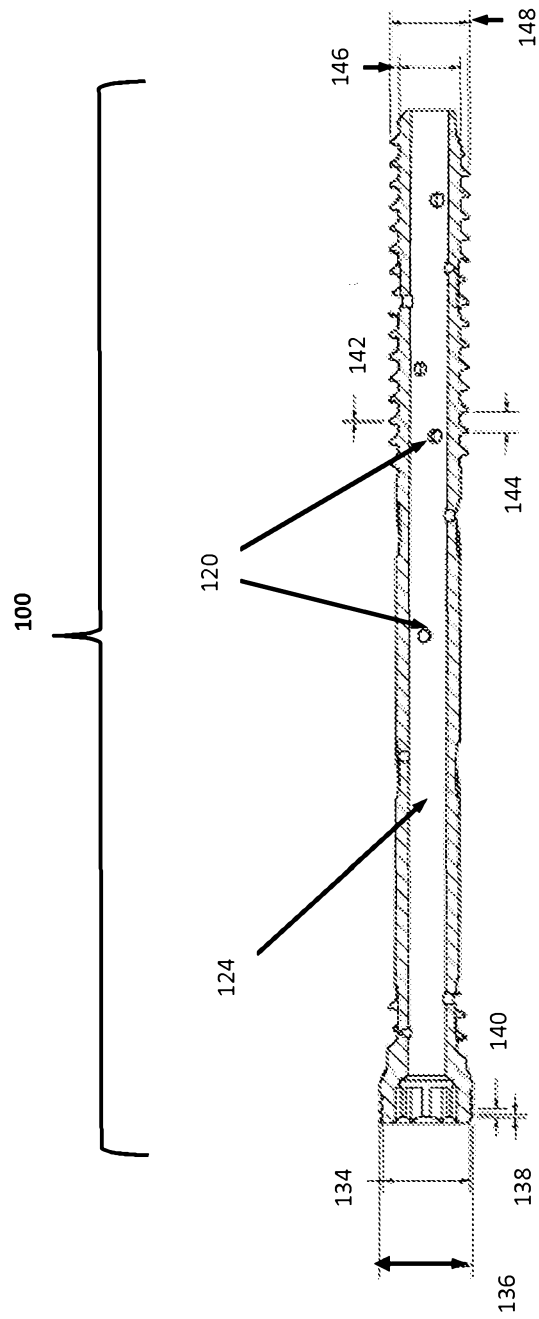


Fig. 4

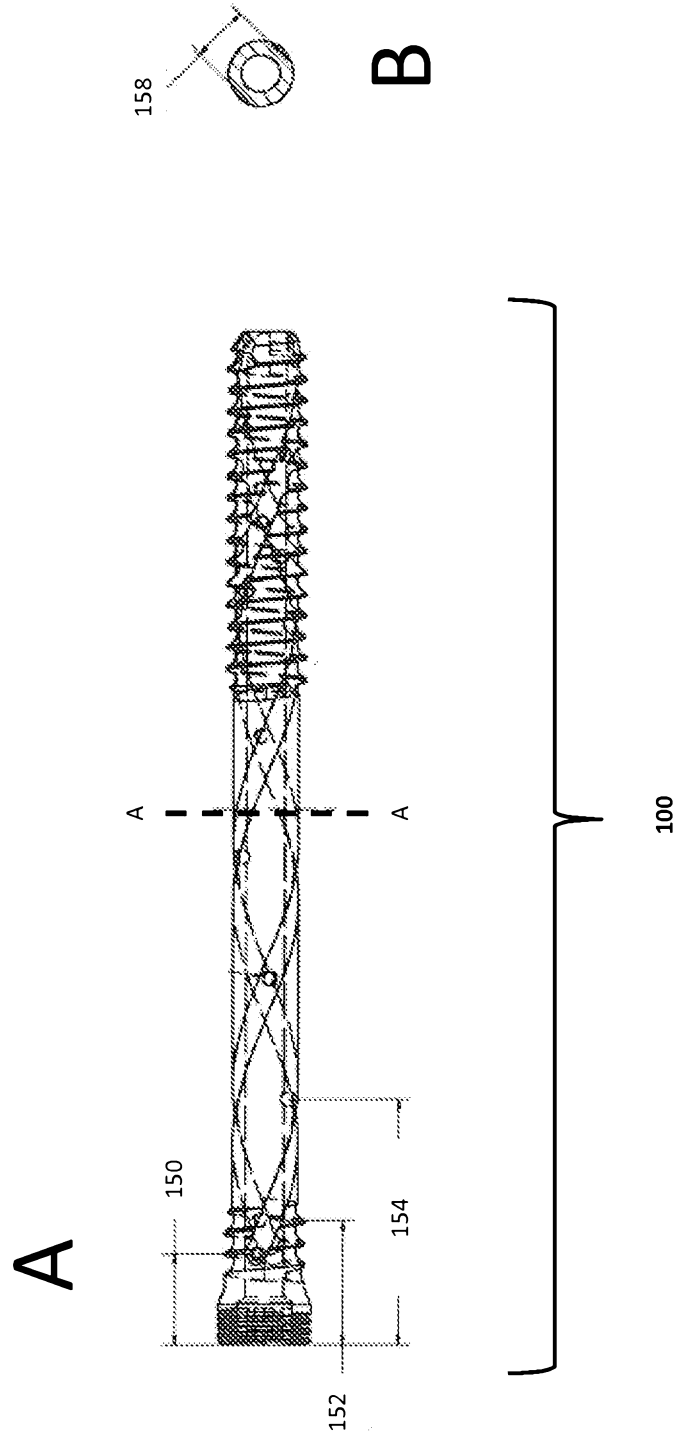


Fig. 5

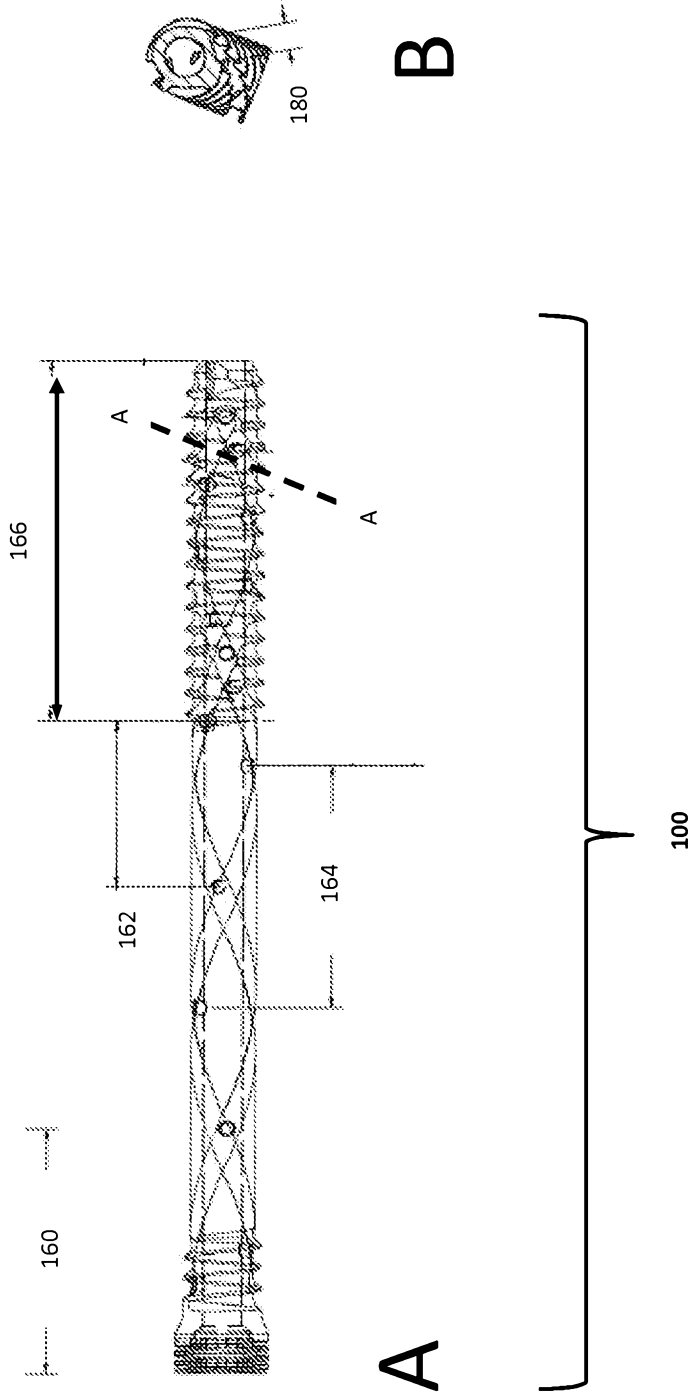


Fig. 6

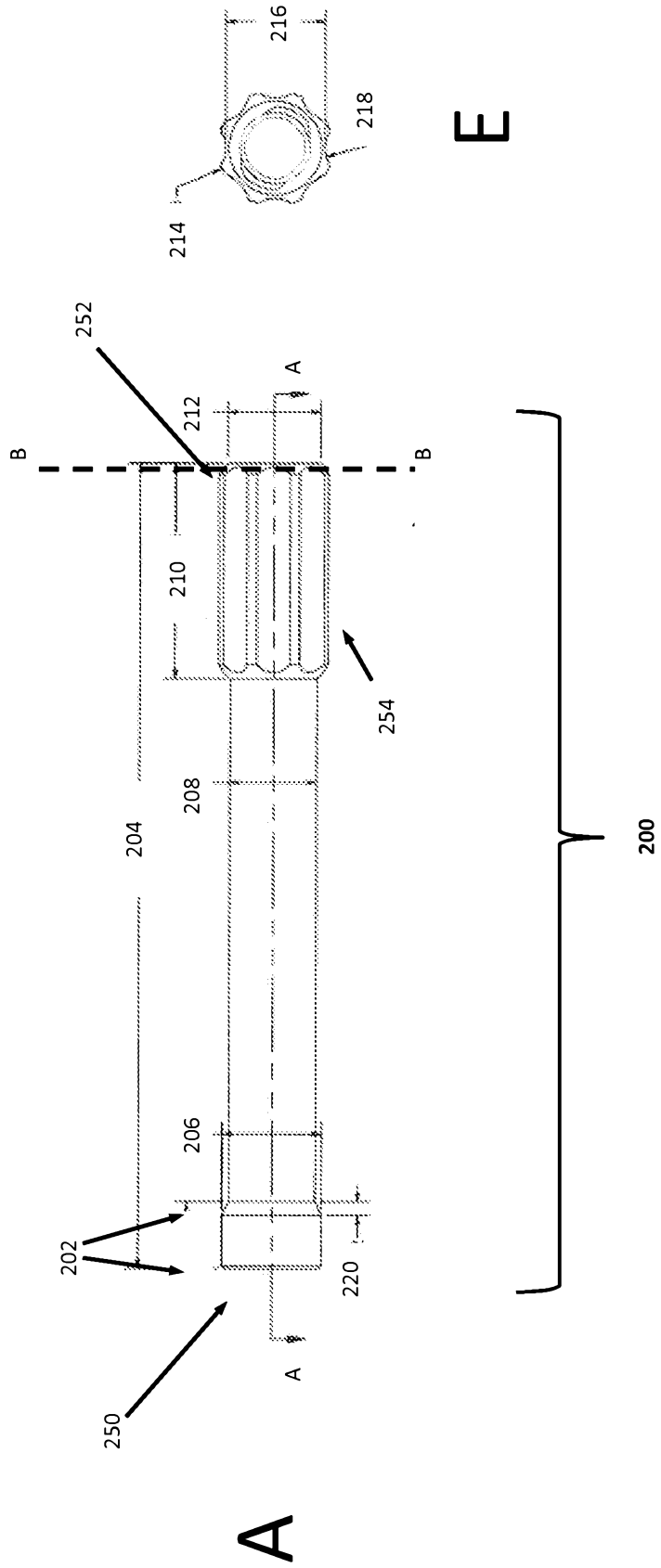


Fig. 6 (Con't)

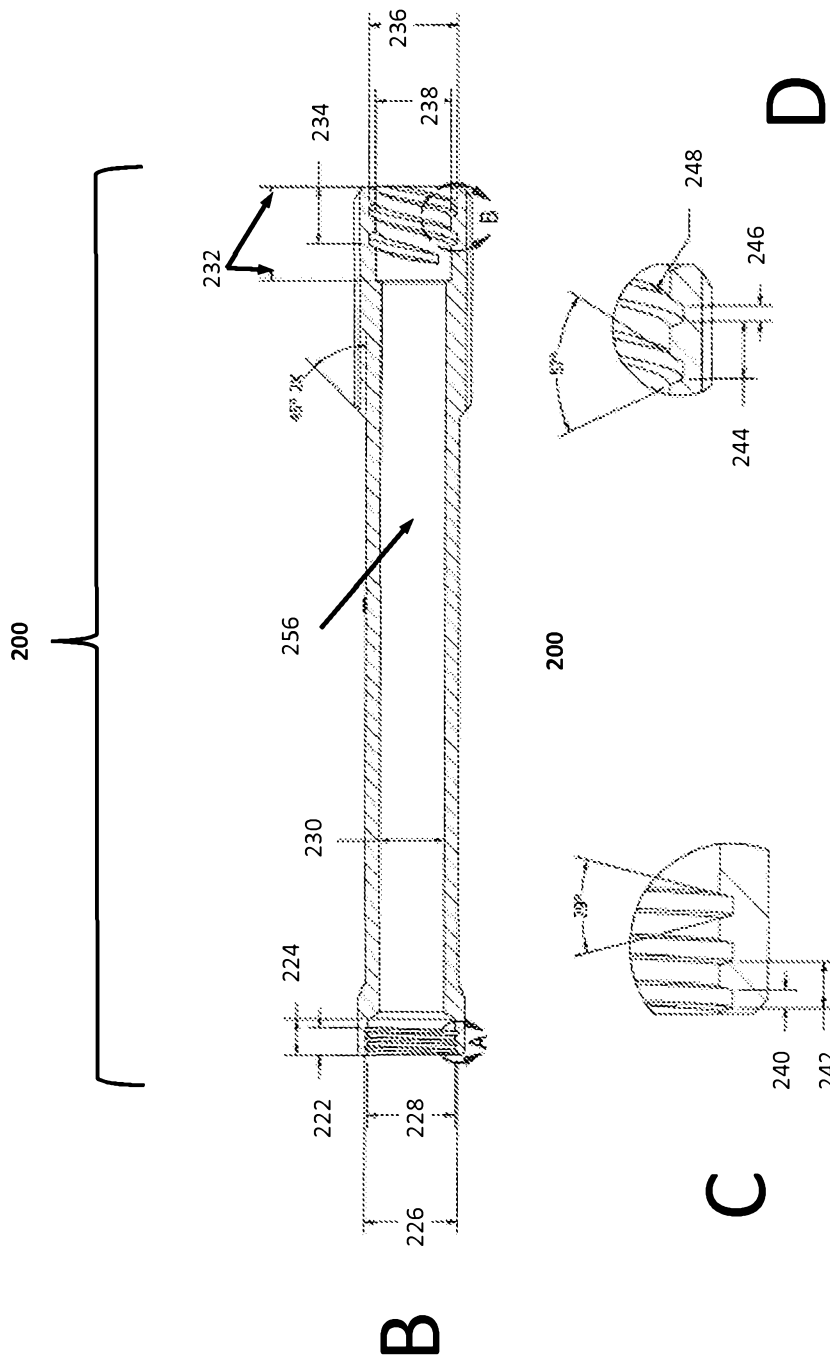


Fig. 7

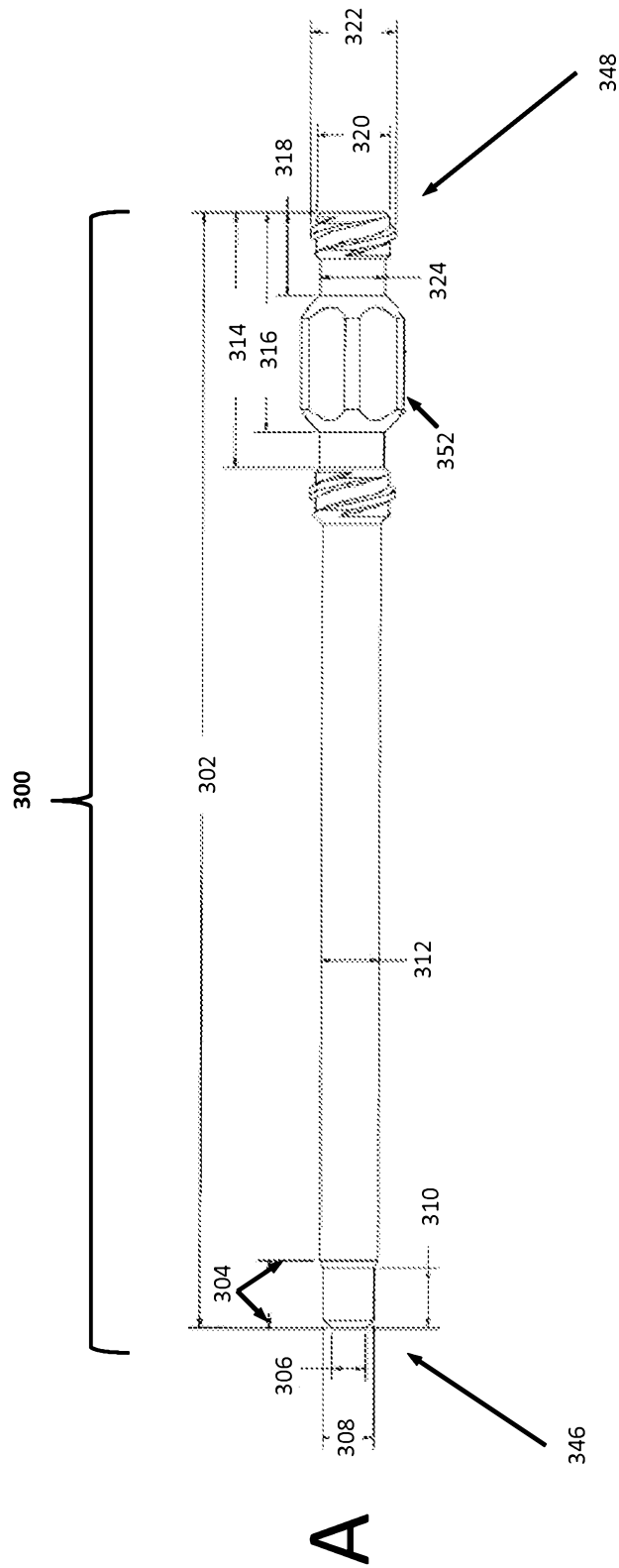


Fig. 7 (Con't)

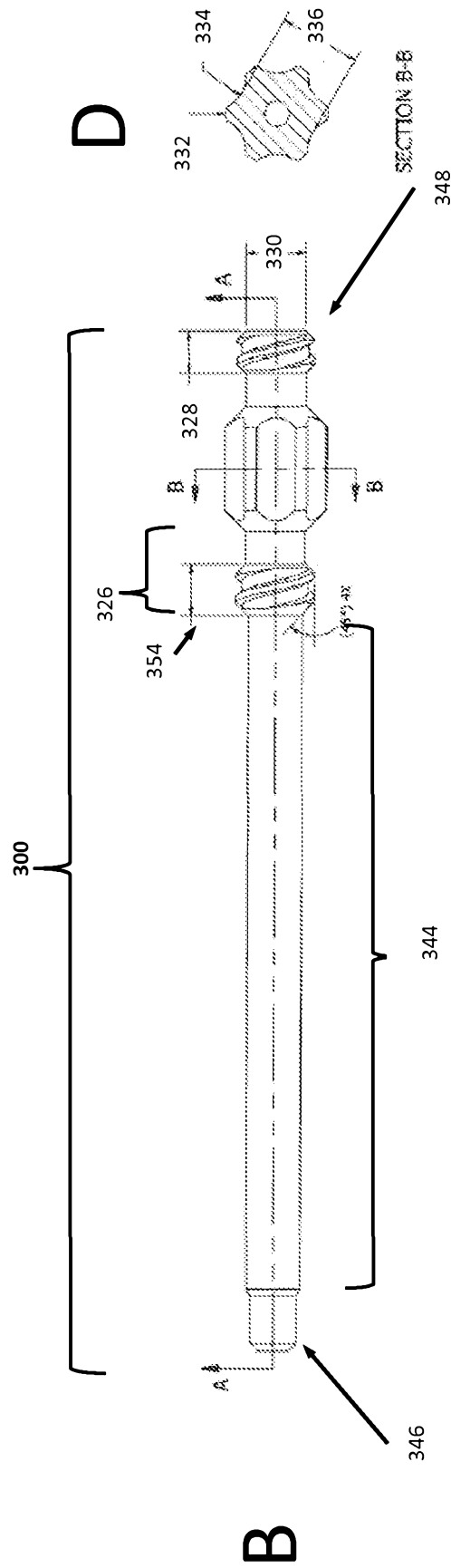
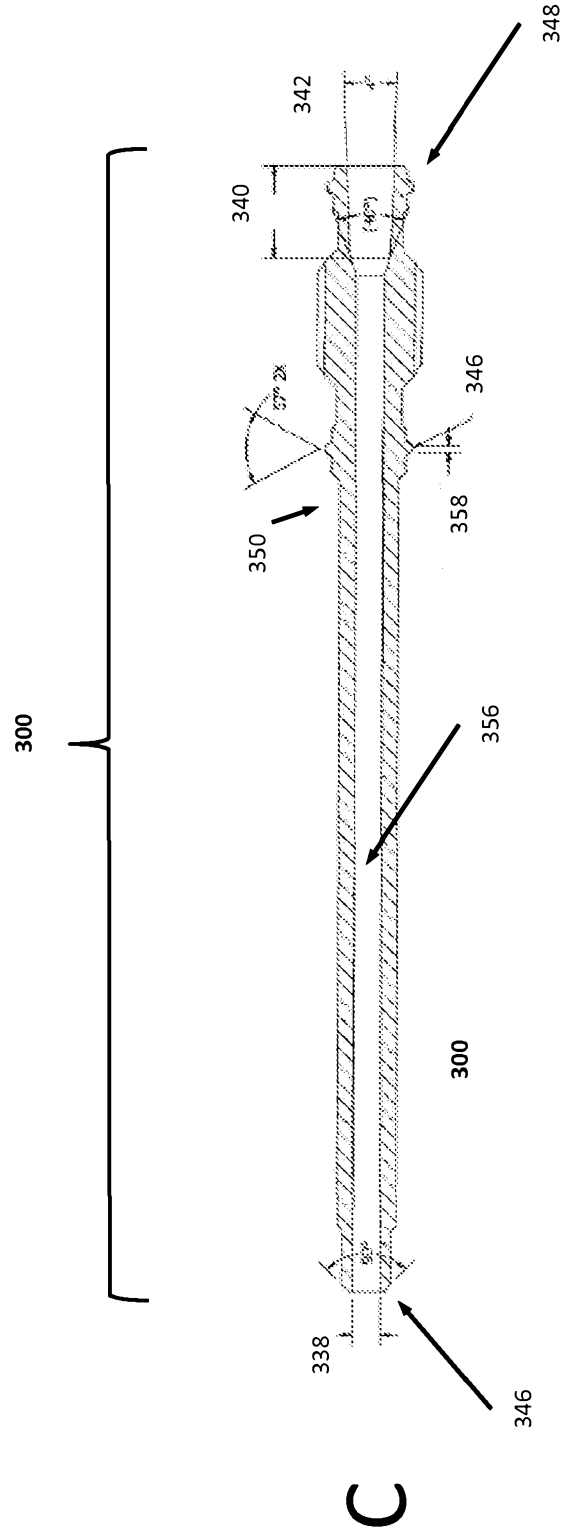


Fig. 7 (Con't)



Scale 3:1

Fig. 8

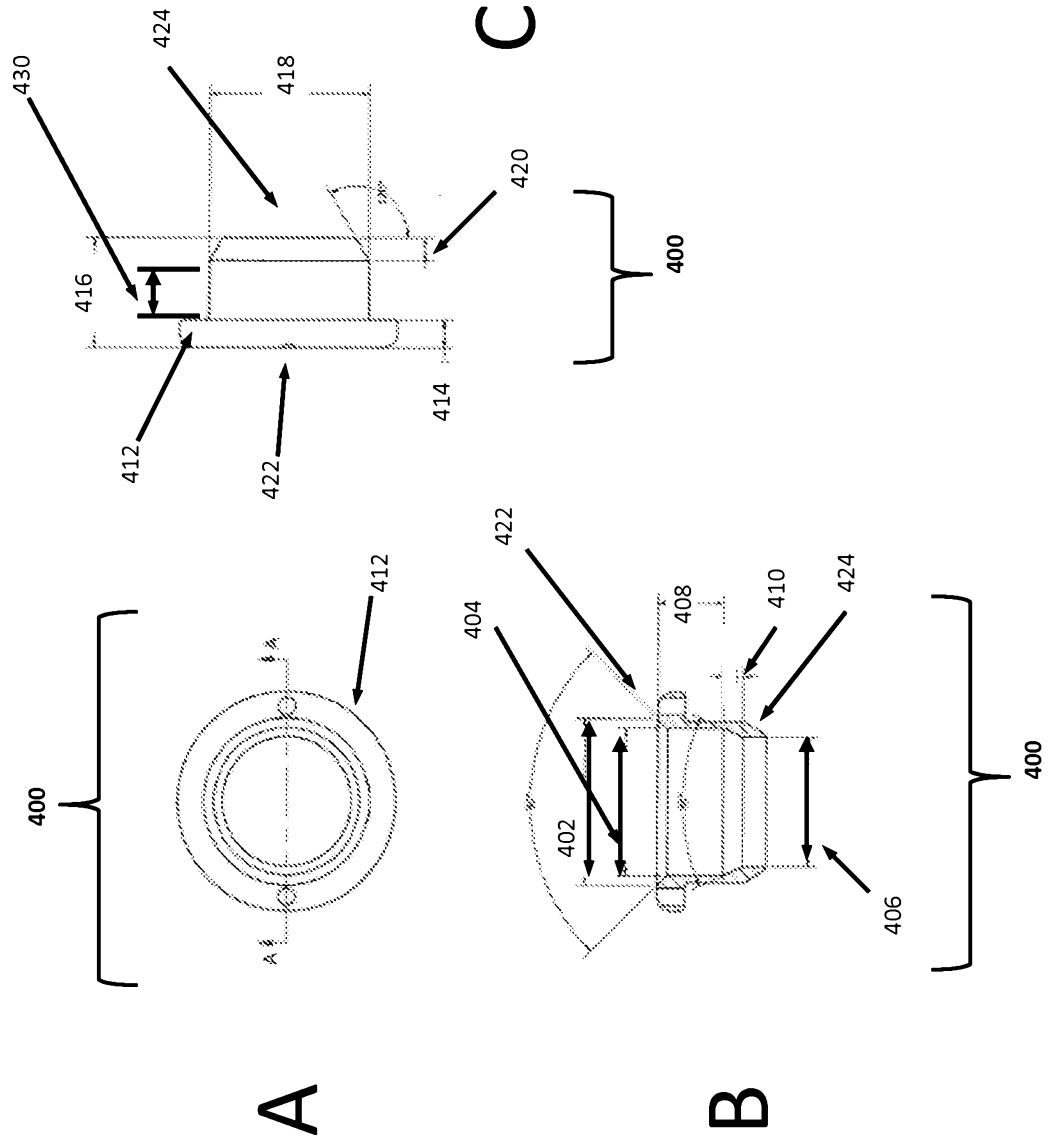


Fig. 9

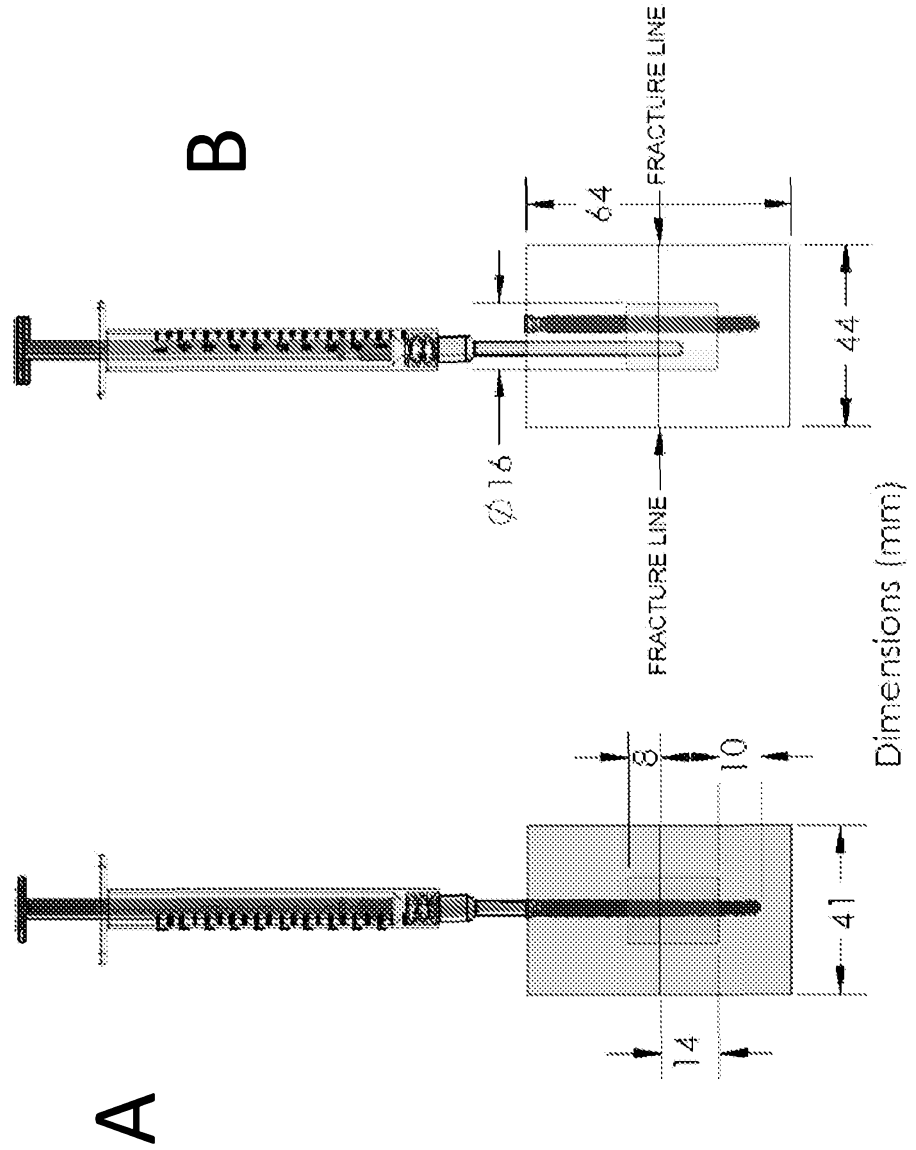


Fig. 10

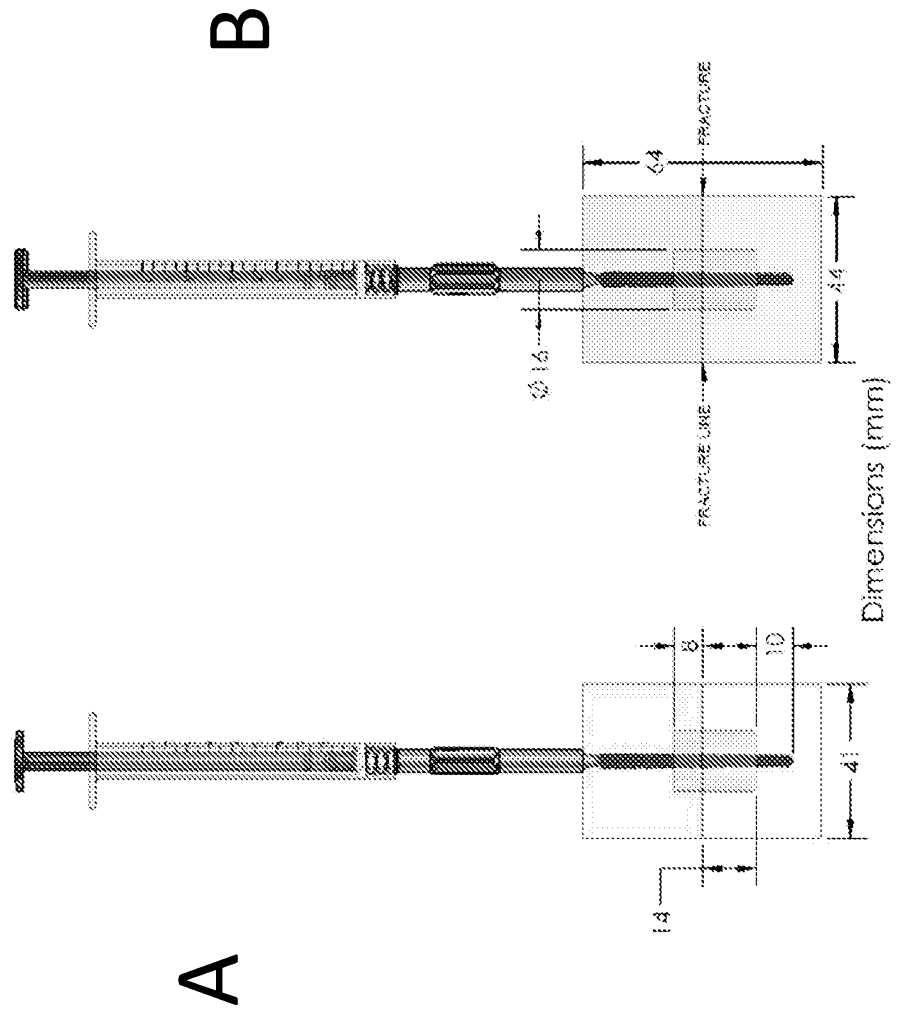


Fig. 11

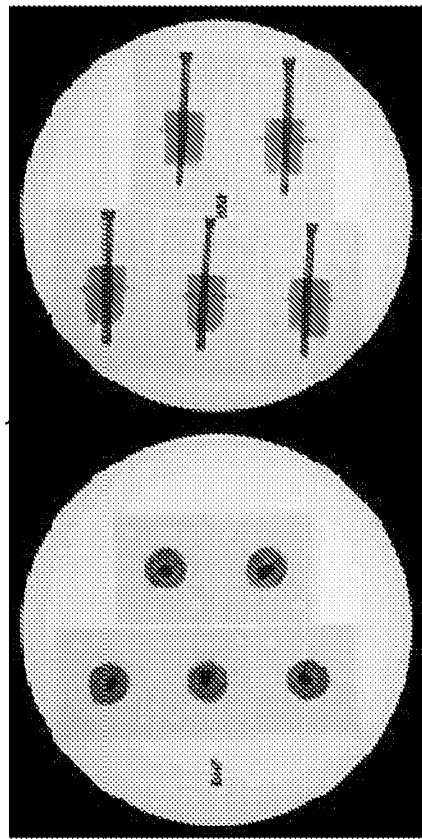
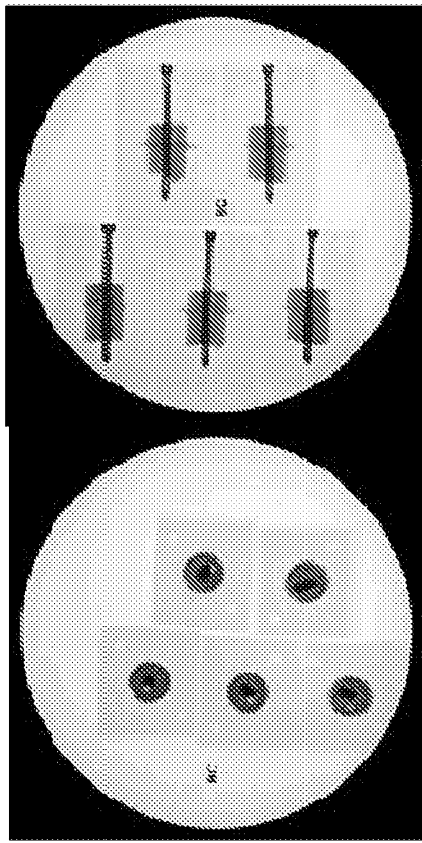


Fig. 12

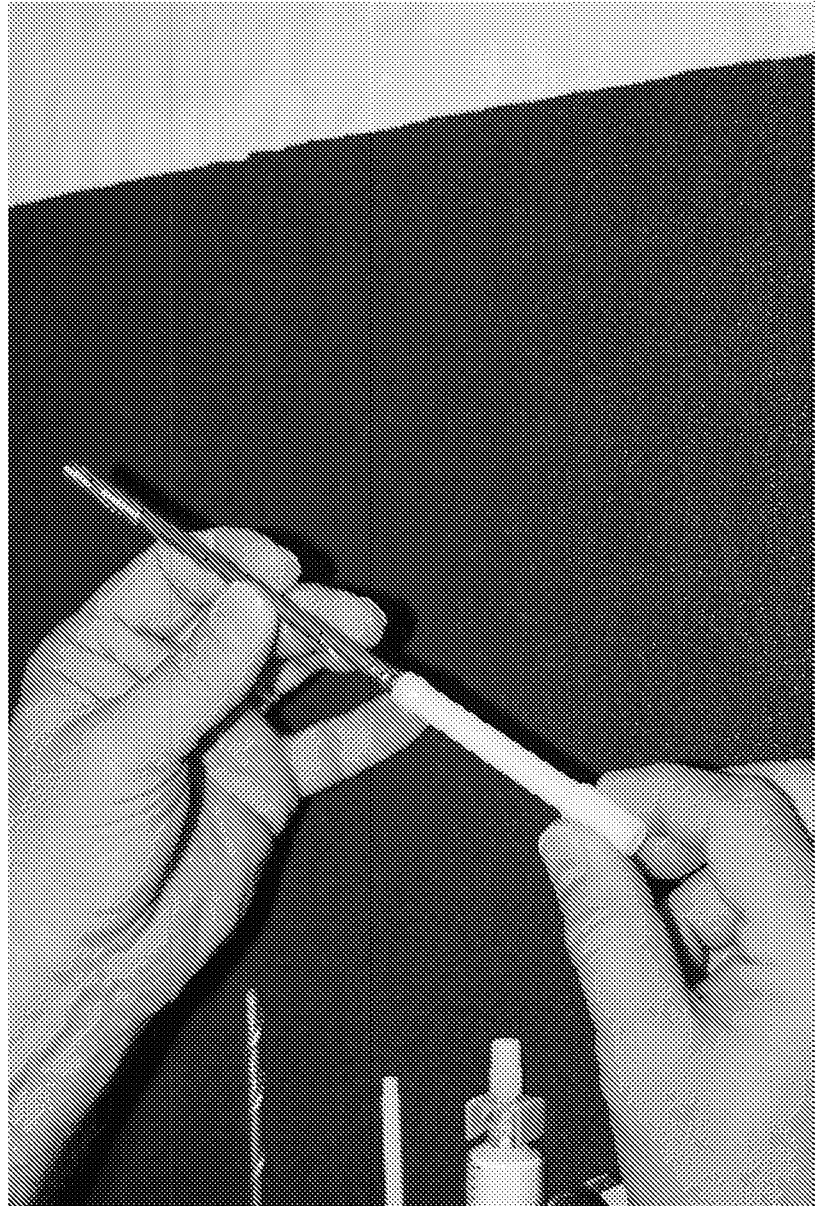


Fig. 13

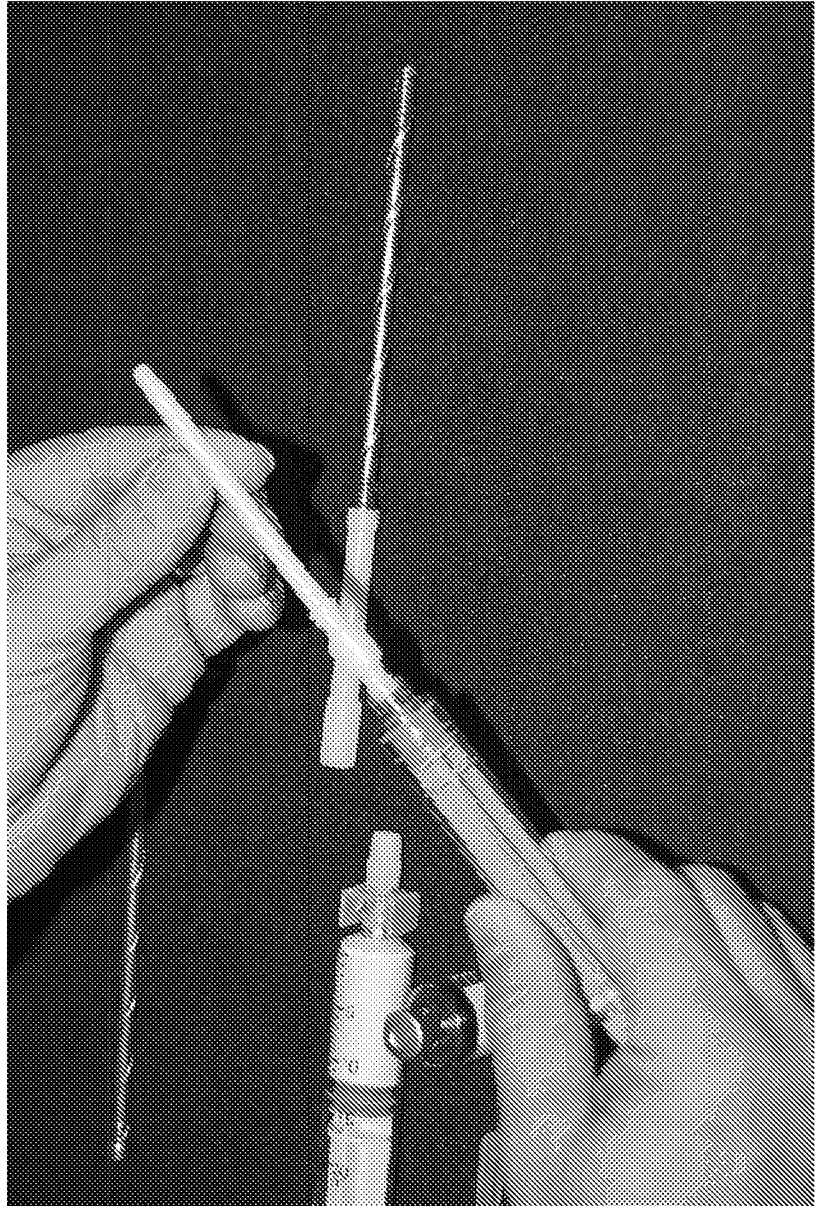


Fig. 14

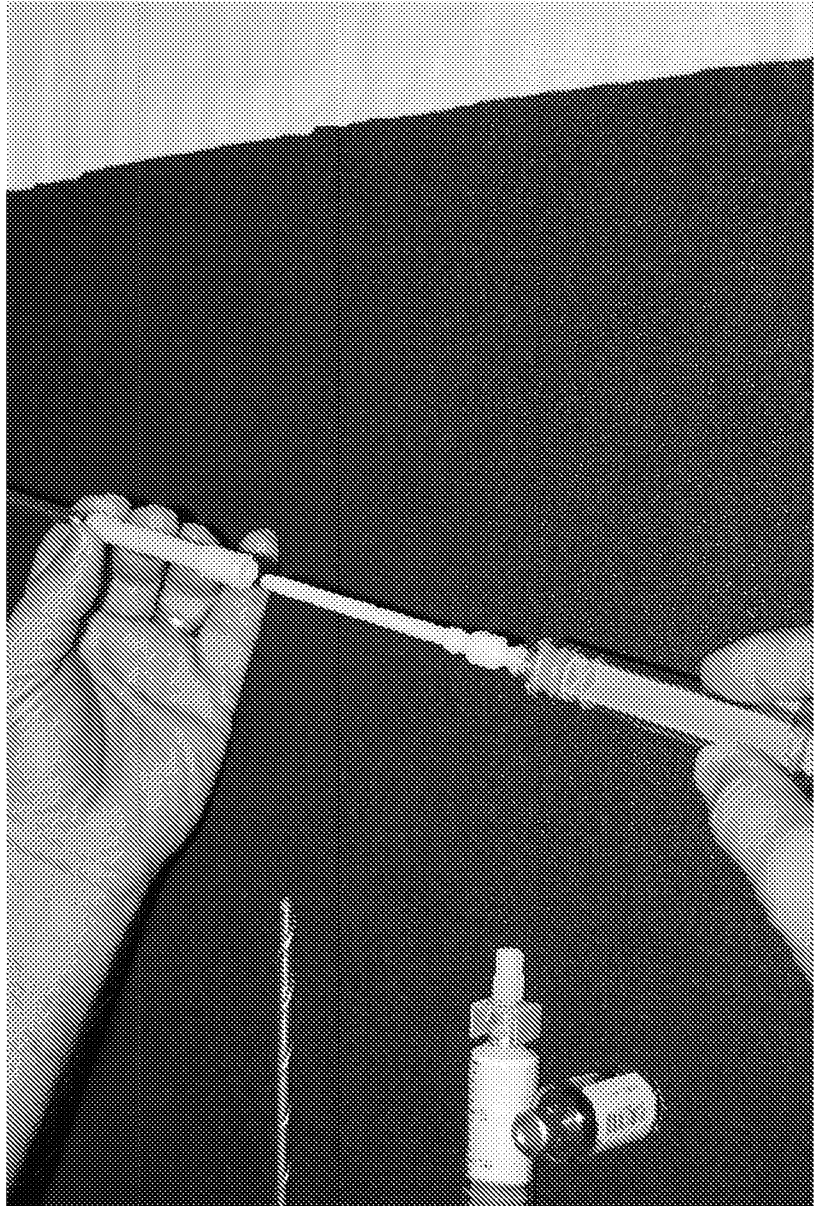


Fig. 15

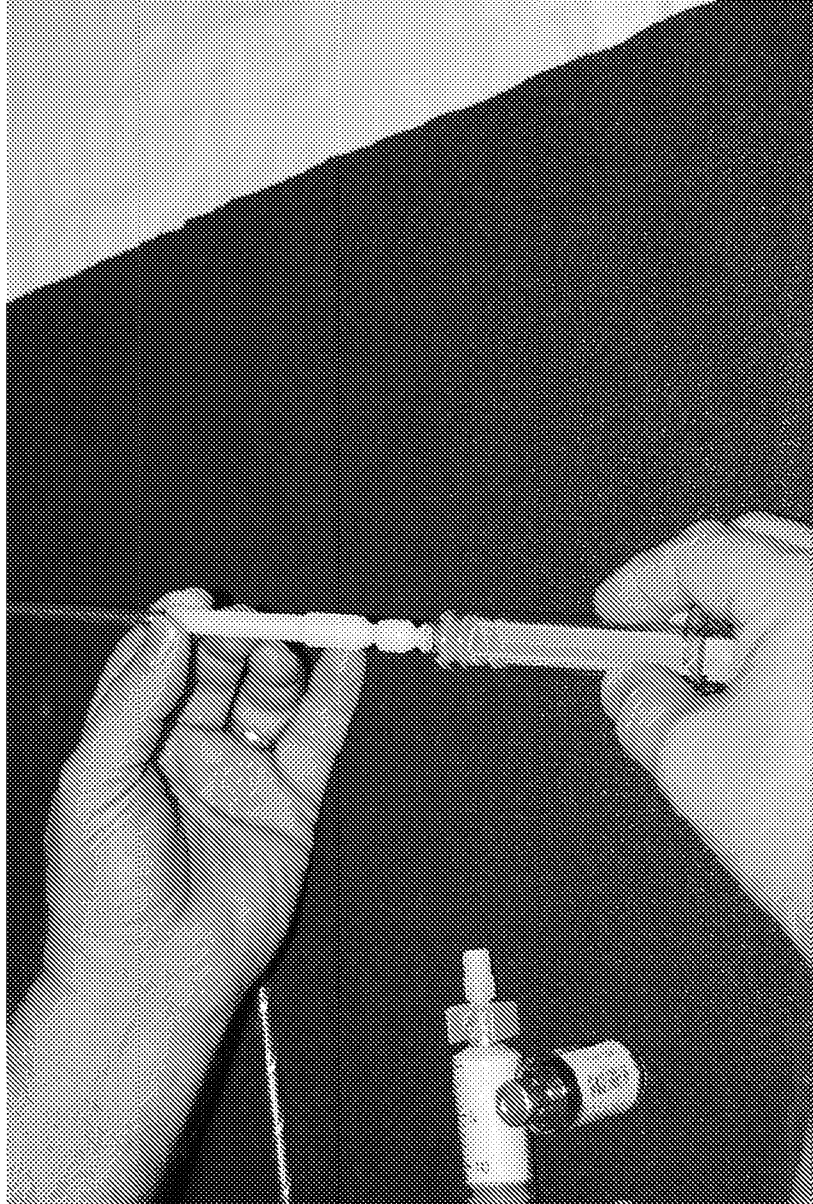


Fig. 16



Fig. 17

