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02-16-2000

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MR2577-2

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1. Name of conveying party(ies):
John M. Mathis; Stephen M. Belkoff; Charles J. Phillips, Marshall D. Welch, III; Steven M. Kmiec

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2. Name and address of receiving party(ies)

Name: INTERNATIONAL MEDICAL SYSTEMS, INC.

Address: P.O. Box 4936,

Annapolis, MD 21403

City: Annapolis, MD Country: U.S.A.

Additional name(s) & address(es) attached? ☐ Yes ☒ No

3. Nature of conveyance:

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Execution Date: 1/5/00; 1/14/00; 1/12/00; & 1/6/00

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A. Patent Application No.(s)

09/324,106

B. Patent No.(s)

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5. Name and address of party to whom correspondence concerning document should be mailed:

Name: MORTON J. ROSENBERG, ESQ.

Internal Address: ROSENBERG, KLEIN & LEE

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SUITE 105

City: ELLICOTT CITY State: MD ZIP: 21043

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JOINT ASSIGNMENT

THIS JOINT ASSIGNMENT (this "Assignment") is entered into this 14th day of January, 2000, by and among John M. Mathis, Stephen M. Belkoff, Charles J. Phillips, Marshall D. Welch, III and Steven M. Kmiec (the "Assignors"), residing at 6270 Mt. Chestnut Road, Roanoke, VA 24018; 7449 Bradshaw Road, Kingsville, MD 21087; 1203 Cherry Tree Lane, Annapolis, MD 21403; 01116 Arapahoe Road, Lafayette, CO 80026; and 163 Ashbrook Drive, Coventry, CT 06238 respectively and for the benefit of International Medical Systems, Inc., a corporation duly organized under and pursuant to the laws of Maryland and having its business address at P.O. Box 4936, Annapolis, MD 21403 (the "Assignee").

W I T N E S S E T H

WHEREAS, said Assignors have invented certain new and useful improvements in a **BONE SCREW SYSTEM**, set forth in an application for Letters Patent of the United States attached hereto as Attachment A, having an oath or declaration executed on June 1, 1999;

WHEREAS, the Assignee is desirous of acquiring the entire right, title and interest in and to said inventions and said application for Letters Patent of the United States, and in and to any Letters Patent or Patents, United States or foreign, to be obtained therefor and thereon; and

WHEREAS, pursuant to an assignment of certain new and useful improvements in a **UNIVERSAL BIOPSY SYSTEM** set forth in an application for Letters Patent of the United States attached hereto as Attachment B dated May 7, 1999, and recorded with the Commissioner of Patents on July 26, 1999, said Assignors sold, assigned, transferred and set over to Assignee any and all the entire right, title and interest in the **UNIVERSAL BIOPSY SYSTEM**, application for Letters Patent, and any and all Letters Patent or Patents in the United States of America and all foreign countries which may be granted therefor and thereon, and in and to any and all divisions, continuations and continuations-in-part of said application, or reissues or extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property.

NOW, THEREFORE, in consideration of One Dollar ($1.00), a payment to John M. Mathis of (i) ten percent (10%) of the gross profits received from the sale, transfer or assignment of the above-mentioned inventions and (ii) ten percent (10%) of any royalties or any other fees received by Assignee based on the sales of a third party regarding the above-mentioned inventions, a payment to Stephen M. Belkoff of (i) five percent (5%) of the gross profits received from the sale, transfer or assignment of the above-mentioned inventions and (ii) five percent (5%) of any royalties or any other fees received by Assignee based on any sales regarding the above-mentioned inventions and other good and sufficient consideration, the receipt of which is hereby acknowledged, the Assignors have sold, assigned, transferred and set over, and by these presents do sell, assign, transfer and set over, unto said Assignee, its successors, legal representatives and assigns, the entire right, title and interest in and to the above-mentioned inventions, application for Letters Patent, and any and all Letters Patent or Patents in the United States of America and all foreign countries which may be granted therefor and thereon, and in and to any and all divisions, continuations and continuations-in-part of said application, or reissues or extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property, which application for Letters Patent is attached hereto as Attachment A, the same to be held and enjoyed by said Assignee, for

its own use and the use of its successors, legal representatives and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted, as fully and entirely as the same would have been held and enjoyed by the Assignors, had this sale and assignment not been made.

AND for the same consideration, said Assignors hereby covenant and agree to and with the Assignee, its successors, legal representatives and assigns, that, at the time of execution and delivery of these presents, said Assignors are the sole and lawful owners of the entire right, title and interest in and to said inventions and the application for Letters Patent above-mentioned, and that the same are unencumbered and that said Assignors have good and full right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, said Assignors hereby covenant and agree to and with Assignee, its successors, legal representatives and assigns, that said Assignors will, whenever counsel of Assignee, or the counsel of its successors, legal representatives and assigns, shall advise that any proceeding in connection with said inventions, or said application for Letters Patent, or any proceeding in connection with Letters Patent for said inventions in any country, including interference proceedings, is lawful and desirable, or that any division, continuation or continuation-in-part of any application for Letters Patent or any reissue or extension of any Letters Patent, to be obtained thereon, is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent for said inventions, without charge to said Assignors, their successors, legal representatives and assigns, but at the cost and expense of the Assignee, its successors, legal representatives and assigns.

AND said Assignors hereby request the Commissioner of Patents to issue said Letters Patent of the United States to said Assignee as the Assignee of said inventions and the Letters Patent to be issued thereon for the sole use of Assignee, its successors, legal representatives and assigns.

John M. Mathis MD
JOHN M. MATHIS

SUBSCRIBED AND EXECUTED AT:

Place Salem, VA

Date: 1/5/2000

SUBSCRIBED AND EXECUTED before me this 5th day of Jan, 2000.

Beth Hitchcock
NOTARY PUBLIC

My Commission Expires:

3/31/00

STEPHEN M. BELKOFF

SUBSCRIBED AND EXECUTED AT:

BALTIMORE, MD

Place

Date: 1/14/00

SUBSCRIBED AND EXECUTED before me this 14th day of January, 2000.

NOTARY PUBLIC

My Commission Expires: 7/21/02

CHARLES PHILLIPS

SUBSCRIBED AND EXECUTED AT:

DULUTH, GA

Place

Date: 1/12/00

SUBSCRIBED AND EXECUTED before me this 12 day of January, 2000.

NOTARY PUBLIC

Notary Public, Gwinnett County, Georgia
My Commission Expires September 8, 2003

My Commission Expires:

dn-50635

MARSHALL D. WELCH, III

SUBSCRIBED AND EXECUTED AT:

Ashburn, Virginia
Place

Date: January 6, 2000

SUBSCRIBED AND EXECUTED before me this 6th day of January, 2000.

NOTARY PUBLIC

Embossed Hereon Is My
Commonwealth of Virginia Notary Public Seal
My Commission Expires May 31, 2003
MELISSA E. KEARNEY

My Commission Expires:

dn-50635

STEVEN M. KMIEC

SUBSCRIBED AND EXECUTED AT:

New Haven, CT
Place

Date: 1/06/2000

SUBSCRIBED AND EXECUTED before me this 6th day of January, 2000.

Nancy C. Smith
NOTARY PUBLIC

My Commission Expires: _____

dn-50635

ATTACHMENT A

Application for Letters Patent for Bone Screw Device

dn-50635

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BONE SCREW SYSTEM

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The present invention relates in general to threaded fasteners utilized in the medical arts for engagement with bony tissue. More in particular, the present invention is directed to a cannulated bone screw adapted for dispensing a purchase enhancing composition to the threaded portion thereof. Further, the screw of the present invention is cannulated with a closed end bore to prevent the dispensing of a purchase enhancing composition through the distal end of the screw. Still further, the present invention includes an adapter releasably lockingly engageable with the head of the screw on one end thereof and adapted for coupling to a dispenser on the opposing end, wherein the purchase improving composition can be dispensed through the adapter into the screw.

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PRIOR ART

Cannulated fastening devices that function in cooperation with the dispensing of an adhesive are well known in the art. Prior art known to the Applicants include U.S. Patents #5,143,498; #5,483,781; #5,788,702; #5,725,581; #5,249,899; #4,065,817; #4,653,487; #4,860,513; #5,145,301; #4,712,957; #5,253,965; #4,760,844; and, #5,129,901.

While cannulated bone screws are known in the art, such typically have a passage formed longitudinally therethrough, to thereby allow placement of the screw over a guide wire. Where such screws are utilized with an adhesive composition, in an attempt to increase the purchase of the screw threads, the injection of the adhesive forms a pool at the distal end of the screw, which does little to enhance the purchase of the threads. If the adhesive is injected prior to the setting of the screw in its final position, the screw must move through the pool of adhesive, displacing the adhesive and bone tissue as the screw is tightened, thereby requiring greater torque to be applied to the screw. The requirement for greater torque is disadvantageous where small or fragile bones are being engaged.

In other fasteners, such as that embodied in U.S. Patents #5,249,899, #5,143,498, #4,653,487, and, #4,065,817, dispensing apertures are formed in diametrically opposed positions along the shank of the fastener. The arrangement of diametrically opposed apertures reduces the cross-sectional area of the shank wall, substantially weakening the fastening device. While a broken screw can be tolerated in many applications, such is not acceptable for a bone screw.

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SUMMARY OF THE INVENTION

A bone screw system is provided that includes a bone screw having a head adapted to be driven by a tool and a shank portion extending longitudinally from the head. The shank portion has threads formed on at least a portion thereof and a bore extending longitudinally to a closed distal end. The threaded portion has a plurality of apertures formed therein in open communication with the bore. The head has an opening formed therein and in open communication with the bore. The bone screw system further includes an adapter releasably lockingly coupled to the head of the bone screw and sealingly engaged with the bore for injection of a composition therein to pass through the plurality of apertures and thereby aid in fixation of the threads in a patient's bone.

Looking at the invention of the subject Patent Application from another aspect, a bone screw system is provided that includes an adapter having a passage formed longitudinally therethrough and a bone screw having a head adapted to be driven by a tool. The bone screw has a shank portion extending longitudinally from the head and has threads formed on at least a portion thereof and a bore extending longitudinally to a closed distal end. The threaded portion has a plurality of apertures formed therein in open communication with the bore. The head has an opening formed therein and in open communication with the bore for receiving a distal end of the adapter therein. The adapter passage is disposed in aligned relationship with the bore. The bone screw system further includes structures for releasably lockingly coupling the distal end of the adapter to the head of the screw.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the screw of the present invention;

FIG. 1A is a cross-sectional view of the adapter of the present invention;

FIG. 2 is an exploded view, partially sectioned, of the bone screw system of the present invention;

FIG. 3 is a proximal end view of the screw of the present invention; and,

FIG. 4 is a cross-sectional view of the screw of the present invention taken along the section line 4—4 of FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1-4, there is shown, bone screw system 100 for providing fixation in medical applications. In particular, the bone screw system 100 includes a bone screw 110 and an adapter 140 that may be releasably lockingly coupled to the bone screw 110. The adapter provides an interface for injection of a composition intended to improve the purchase of bone screw 110. Bone screw 110 is cannulated by a closed end bore 124 with a plurality of apertures 122 formed through the root portion 120 of the threaded area 116 for dispensing the injected composition therethrough. The composition dispensed through the apertures 122 may be a resin or other adhesive composition that is biocompatible. One such well known biocompatible adhesive resin is methylmethacrelate.

Bone screw 110 includes a head 112 adapted to be driven by a tool. As shown, head 112 includes an hexagonally shaped opening 126 for receiving an Allen type wrench therein. Obviously, other shaped openings may be utilized for rotative coupling to a tool having a complementary contour, or the outer contours of the head may be shaped to receive a driving tool thereon. Extending distally from the head 112, there is a shank portion 114 having at least a threaded portion 116 formed thereon. Threaded portion 116 is formed with thread crests 118 helically disposed on the shank 114, with the root portion of the threads being helically disposed between adjacent thread crests 118. As shown, threaded portion 116 occupies a distal end portion of the shank 114. The extent of shank 114 having threads is a function of the application for which the screw 110 is being used and may occupy a 10% - 100% portion of the shank 114.

Extending through the shank portion 114 is a bore 124, the bore extending longitudinally to a closed distal end 125. The opening 126 of head 112 is disposed in open communication with the bore 124, so that the composition that is injected can pass into the bore 124. A plurality of apertures 122 are formed in the root portion of the

threads, and are formed in open communication with the bore 124. Therefore, when the composition is injected into the bore 124, such flows out through the apertures 122.

The apertures 122 extend radially outward from the central bore 124, and are spaced one from another by an angle , while being longitudinally displaced, one from another, as a function of the slope of the helical path of the root portion 120 of the thread. It has been found that an optimal combination of dispersion of the injected composition and wall cross-sectional area occurs when there are three apertures per screw revolution, 360 angular degrees. Where the apertures 122 are uniformly spaced, the apertures are located at 120° intervals. The apertures 122 may be spaced at other angles, as long as they are not located in a diametrically opposing location. The apertures 122 are displaced longitudinally one from another, following the helical contour of the thread root 120. By that arrangement, none of the apertures 122 are diametrically opposed from another aperture 122. With the apertures 122 not being diametrically opposed, there is a minimal reduction in cross-sectional area of any particular longitudinal location of the threaded portion 116, which is a critically important characteristic.

Injection of the purchase enhancing composition requires the dispensing of the composition under pressure into the bore 124 of bone screw 110. In order to accomplish the pressurized injection of the composition into bore 124, adapter 140 is provided. Adapter 140 is provided with a distal end 150 which is insertable into the opening 126 of the bone screw head 112. The opposing proximal end of adapter 140 has a fitting for fluid connection formed thereon. Where the purchase enhancing composition is to be dispensed from hypodermic-type syringes, the fitting 142 formed on the proximal end of adapter 140 is a luer-type connection, having a conically tapered portion 164 formed therein. Further, the fitting 142 may include a pair of opposing lugs 144 for releasable coupling with a mating luer-lock type fitting.

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The distal end 150 of adapter 140 includes a conically shaped external surface 146 which sealingly mates with a respective conically shaped internal surface 130 formed at the distal end of opening 126, adjacent the bore 124. A portion 148 of distal end 150, adjacent to the conically-shaped surfaced 146, is formed with a pair of opposing locking lugs 152 extending therefrom. Locking lugs 152 provide for releasable coupling within respective recesses 132 formed in opposing interior wall surfaces of the opening 126. More specifically, the recesses 132 are formed in the proximal portion 128 of opening 126. Each of the recesses 132 includes a longitudinally directed section 134 for guiding displacement of the locking lugs 152 responsive to insert of the adapter distal end 150 into the opening 126 in the bone screw head 112. At the distal end of the longitudinally directed section 134, there is formed an angularly directed section 136, the section 136 being angled toward the distal end of the screw 110. As the locking lugs 152 are disposed on an incline to mate with the angularly directed section 136 of recess 132, rotation of the adapter 140 longitudinally displaces the adapter 140. The conically shaped portion 146 of the adapter distal end 150 is thereby tightly engaged with the conically shaped internal surface 130 of opening 126, providing a seal therebetween. By that arrangement, the passage 162 of adapter 140 is placed in open communication with the bore 124 of screw 110. Thus, with adapter 140 coupled to screw 110, fluid communication is established between a dispensing device coupled to fitting 142 and the plurality of apertures 122.

Adapter 140 is formed with a grip portion 154 disposed intermediate the opposing ends thereof. Grip portion 154 is formed with a plurality of annular ridges disposed in longitudinally spaced relationship. Each of the annular ridges 156 are separated by a respective groove 158, to thereby increase the grippable surface area of the adapter grip portion 154. The plurality of annular ridges 156 need not be of the same diameter. In order to further enhance the gripping contact area, the plurality of annular ridges 156 are dimensioned to collectively define an arcuate longitudinal cross-sectional contour, as

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indicated by the contour line 160 shown in FIG. 1A, providing a depression in the adapter's surface for receiving the user's fingers therein. That arrangement of the gripping portion 154 allows a physician to easily engage and disengage the adapter from the screw 110.

Bone screw system 100 includes a bone screw 110 and an adapter 140 having a distal end 150 that is releasably lockingly coupled to the head 112 of bone screw 110 for dispensing a purchase improving composition supplied to the proximal end of the adapter 140. The conically shaped external surface 146 formed on the distal end 150 of adapter 140 is forced into sealing engagement with the corresponding conically shaped internal surface 130 of the opening 126. The sealing engagement is established by the insertion and rotation of the distal end 150 of adapter 140 within the opening 126. The locking lugs 152 pass through the longitudinally directed section 134 of respective recesses 132 as the distal end 150 is inserted into the opening 126, and respectively follow the angularly directed section as the adapter 140 is rotated.

Further, the strength of the cannulated screw 110 is maintained by limiting the number of apertures 122 formed in the threaded portion 116, and forming such in both angular and longitudinal spaced relationship, in the helically directed root portion 120 of the thread. The apertures being both angularly and longitudinally displaced one from another, minimizes the reduction in cross-sectional area of the wall surrounding the centrally disposed bore 124, which is of critical importance. In particular, the dispensing of adhesive onto the threads of the screw and the minimization of cross-sectional area reduction is achieved with three apertures within any 360 angular degree section of the threaded portion 116. While an angular spacing of 120° has been illustrated, to provide equidistantly spaced apertures, it should be understood that other angular spacings may be utilized. Further, more than three apertures may be utilized in a 360 angular degree section, if the screw pitch is sufficient such that there are no

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apertures in diametrically opposed locations, minimizing any further reduction in the cross-sectional area of the annular wall of the shank 114.

The adapter 140 is formed with a grip portion 154 having an arcuate longitudinally directed arcuate outer surface contour defined by a mathematical arcuate envelope established by the plurality of annular ridges 156 spaced one from another by respective grooves 158. The arcuate envelope is formed by the combination of ridge apexes, where the respective diameters of the ridges 156 are not uniform. The respective diameters vary in order to collectively form a longitudinally directed arcuate outer surface contour.

The adapter 140 includes a passage 162 extending longitudinally therethrough. The proximal end of the passage 162 may include a conically tapered portion 164 for mating with a complementary conical surface of a connector or other device for dispensing a selected composition through adapter 140 into screw 110. Through the use of system 100, the bone screw 110 can be set and an adhesive dispensed from the threaded portion in a radial direction for improving the purchase of the screw threads, and thereby avoid the problems associated with dispensing adhesive from a distal end of a bone screw.

Although this invention has been described in connection with specific forms and embodiments thereof, it will be appreciated that various modifications other than those discussed above may be resorted to without departing from the spirit or scope of the invention. For example, equivalent elements may be substituted for those specifically shown and described, certain features may be used independently of other features, and in certain cases, particular locations of elements may be reversed or interposed, all without departing from the spirit or scope of the invention as defined in the appended Claims.

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WHAT IS BEING CLAIMED IS:

1. A bone screw system, comprising:

a bone screw having a head adapted to be driven by a tool and a shank portion extending longitudinally from said head, said shank portion having threads formed on at least a portion thereof and a bore extending longitudinally to a closed distal end, said threaded portion having a plurality of apertures formed therein in open communication with said bore, said head having an opening formed therein and in open communication with said bore; and,

an adapter releasably lockingly coupled to said head of said screw and sealingly engaged with said bore for injection of a composition therein to pass through said plurality of apertures and thereby aid in fixation of said threads in a patient's bone.

2. The bone screw system as recited in Claim 1 where said plurality of apertures are respectively formed in a root portion of said threads and spaced at increments of 120°.

3. The bone screw system as recited in Claim 1 where said adapter includes a pair of opposing locking lugs extending therefrom adjacent a distal end thereof.

4. The bone screw system as recited in Claim 3 where said opening in said head has a pair of recesses formed in opposing interior wall surfaces thereof and extending from a proximal end of said head for respectively receiving said locking lugs therein.

5. The bone screw system as recited in Claim 4 where each of said pair of recesses has a longitudinally directed section for guiding displacement of said locking lugs responsive to insert of said adapter distal end into said opening in said head, and an angularly directed section to provide releasable locking engagement with said locking lugs.

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6. The bone screw system as recited in Claim 1 where said opening in said head has a substantially conically shaped interior surface portion adjacent to said bore.

7. The bone screw system as recited in Claim 6 where said adapter has a substantially conically shaped external distal end surface corresponding to said conically shaped internal surface portion of said opening in said head to provide sealing engagement therebetween.

8. The bone screw system as recited in Claim 6 where said adapter includes a pair of opposing locking lugs extending therefrom adjacent said conically shaped external distal end surface thereof.

9. The bone screw system as recited in Claim 8 where said opening in said head has a pair of recesses extending from a proximal end of said opening and formed in opposing interior wall surfaces thereof adjacent said conically shaped internal surface portion for respectively receiving said locking lugs therein.

10. The bone screw system as recited in Claim 9 where each of said pair of recesses has a longitudinally directed section for guiding displacement of said locking lugs responsive to insert of said adapter distal end into said opening in said head, and an angularly directed section to provide releasable locking engagement with said locking lugs and provide said sealing engagement between said conically shaped surfaces.

11. The bone screw system as recited in Claim 10 where said adapter includes a luer-type coupling on a proximal end thereof.

12. The bone screw system as recited in Claim 11 where said adapter includes a grip section disposed intermediate said proximal and distal ends thereof.

13. The bone screw system as recited in Claim 12 where said grip section is formed with a plurality of annular ridges.

14. The bone screw system as recited in Claim 12 where said plurality of annular ridges collectively form a longitudinally directed arcuate outer surface contour.

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15. The bone screw system as recited in Claim 1 where said adapter includes a grip section disposed intermediate opposing ends thereof.

16. The bone screw system as recited in Claim 15 where said grip section is formed with a plurality of annular ridges.

17. The bone screw system as recited in Claim 16 where said plurality of annular ridges collectively form a longitudinally directed arcuate outer surface contour.

18. A bone screw system, comprising:

an adapter having a passage formed longitudinally therethrough;

a bone screw having a head adapted to be driven by a tool and a shank portion extending longitudinally from said head, said shank portion having threads formed on at least a portion thereof and a bore extending longitudinally to a closed distal end, said threaded portion having a plurality of apertures formed therein in open communication with said bore, said head having an opening formed therein and in open communication with said bore for receiving a distal end of said adapter therein, said adapter passage being disposed in aligned relationship with said bore; and,

means for releasably lockingly coupling said distal end of said adapter to said head of said screw.

19. The bone screw system as recited in Claim 18 where said releasable locking means includes a pair of opposing locking lugs extending from an external surface of said adapter adjacent said distal end thereof, and a pair of recesses formed in opposing interior wall surfaces of said opening in said head for respectively receiving said locking lugs therein.

20. The bone screw system as recited in Claim 18 where said adapter includes a grip section disposed intermediate opposing ends thereof.

21. The bone screw system as recited in Claim 18 where said adapter includes a luer-type coupling on a proximal end thereof.

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22. The bone screw system as recited in Claim 1 where said opening in said head has a substantially conically shaped interior surface portion adjacent to said bore and said adapter has a substantially conically shaped external distal end surface corresponding to said conically shaped internal surface portion of said opening in said head to provide sealing engagement therebetween.

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BONE SCREW SYSTEM

ABSTRACT

A bone screw system (100) is provided that includes a cannulated bone screw (110) and an adapter (140) designed to be releasably coupled to the screw (110). The screw (110) has a head (112) with an opening (126) formed therein. A shank portion (114) of screw (110) extends from the head (112) and has a closed end bore (124) formed therein in open communication with the opening (126). The screw (110) has a threaded portion (116) in which a plurality of apertures (122) are formed in a root portion (120) of the thread. The adapter (140) has a distal end (150) adapted for releasable coupling with the head (112) and has a passage (162) extending longitudinally therethrough for open communication with the bore (124) of the screw (110). The adapter (140) further includes a grip portion (154) formed by a plurality of spaced annular ridges (156). The proximal end of adapter (140) has a fitting (142) formed thereon for coupling to a device for dispensing a purchase enhancing composition, through the adapter (140) and bore (124) to the apertures (122).

ATTACHMENT B

Application for Letters Patent for Universal Biopsy System

UNIVERSAL BIOPSY SYSTEM

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

This invention directs itself to biopsy devices utilized for percutaneous medical procedures. In particular, this invention directs itself to a biopsy system wherein a handle is releasably coupled to a cannula assembly, providing particular advantages for the performance of vertebroplasty procedures. More in particular, the handle of the present invention includes an opening formed in a lower side thereof wherein recesses are formed in opposing interior wall surfaces of the opening for receiving respective projections formed on the hub portion of the cannula. Still more in particular, this invention pertains to a biopsy system wherein the recesses formed in the opening of the handle have terminal portions in which lower and upper locking recesses are formed for rotatively and axially displacing the cannula assembly, either toward or away from patient, respectively.

PRIOR ART

Biopsy systems are well known in the art. The best prior art known to the Applicants include U.S. Patents #4,922,602; #5,331,972; #5,385,151; #5,807,275; #5,752,923; #5,538,009; #5,476,102; #5,257,632; #4,256,119; #4,793,363; #5,127,419; #5,634,473; #5,758,655; #5,186,197; #4,513,754; #5,036,860; #3,949,747; #5,807,277; #5,526,821; #5,429,138; #4,356,828; #4,266,555; and, #4,262,676.

In some prior art systems the proximal end of the cannula is accessible through an opening formed in an upper side of the handle, subsequent to removal or displacement of a cover therefor. Such systems, however, do not provide a clear field of view for the physician. Other prior art systems, such as that disclosed by U.S. Patent #3,949,747, have a removable handle for selective engagement with any one of a plurality of punches and probes. However, such handle is threadedly connected to the punches and probes, and therefore only capable of rotatively driving the punch or probe in a single direction, in the tightening direction of the handle, as rotation in the opposing direction will cause the handle to disengage from the selected tip.

In still other prior art systems, such as that disclosed by U.S. Patent #4,513,754, the cannula is releasably held within the jaws of a collet. As the cannula is a tube, the jaw pressure thereon is limited, in order not to crush the tube, thereby limiting the axial and rotational forces which may be transferred from the handle to the cannula.

Such deficiencies are overcome by the structure of the invention of the subject Patent Application, by virtue of the removable handle that is capable of rotating a cannula assembly in either a clockwise or a counterclockwise direction while an axial force, either toward or away from a patient is applied. The utility of the invention of the subject Patent Application is further enhanced by the formation of a grip portion on the cannula hub and the inclusion of a luer-type coupling system with the cannula hub.

SUMMARY OF THE INVENTION

A universal biopsy system is provided. The universal biopsy system includes a cannula having an open axially extended passage formed therein. The cannula has a distal end with a predetermined contour for penetrating a patient's tissue. The universal bi

opsy system further includes a cannula hub member having a distal end coupled to a proximal end of the cannula. The hub member has a through bore disposed in axially aligned relationship with the passage of the cannula. Still further, the universal biopsy system includes a handle having an opening formed in a lower side thereof for receiving the cannula hub member therein and releasably engagement therewith.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of the present invention;

FIG. 1A is a cross-sectional view of a portion of the present invention taken along the Section Line 1a — 1a of FIG. 1;

FIG. 2 is a partially sectioned exploded view of the present invention;

FIG. 3 is an exploded perspective view of another embodiment of the present invention; and,

FIG. 4 is an enlarged view of a distal end portion of the embodiment of the present invention shown in FIG. 3.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1, 1A and 2, there is shown universal biopsy system 100 for percutaneous medical procedures. As will be seen in following paragraphs, universal biopsy system 100 is specifically directed to the concept of providing a cannula assembly 101 removably coupled to a handle 132, wherein a physician is able to rotate the handle and cannula assembly as an insertion or withdrawing force is applied thereto. Although the universal biopsy system 100 is usable for performing biopsies of both soft tissue and bone, universal biopsy system 100 is particularly adapted for use in performing vertebroplasty and delivery of medicaments. Such applications are facilitated by the removability of the handle 132 from the cannula assembly 101, while still maintaining an ability to rotate the cannula assembly 101 while applying an axially directed force, either to advance the cannula tube 102 or withdraw it.

The cannula assembly 101 includes a cannula tube 102 that is coupled on a proximal end 106 thereof to a cannula hub 108. The cannula tube 102 is formed with an axially extended passageway 114 through which other devices or materials can be passed from a location external to a patient's body to a particular internal site. The distal end 104 of the cannula tube 102 is sharpened to penetrate a patient's bodily structures. The precise configuration of the sharpened end 104 will depend on the particular procedure for which it is to be utilized, and may be configured for coring or cutting when rotated in a particular direction, i.e. clockwise or counterclockwise.

The cannula hub 108 has a grip portion 110 disposed adjacent the distal end of the cannula hub 108. The grip portion 110 has a polygonal contour so that it may be digitally grasped by the physician or engaged with a tool, for supporting the cannula assembly as the handle is removed or installed, and for adjusting the position of the cannula tube 102 subsequent to removal of the handle 132. As particularly shown in the cross-sectional view of FIG. 1A, the grip portion 110 has a substantially square cross-

sectional contour having sides 110a-110d. Although a square cross-sectional contour is shown in the drawings, it should be understood by those skilled in the art that other configurations would provide similar functionality, i.e. oval, triangular, pentagonal, hexagonal, octagonal, etc. With appropriate surface treatment, even a circular cross-sectional contour could function to permit the physician to easily displace the cannula tube 102 by displacement of the grip portion 110 of cannula hub 108. Each side 110a-110d of the grip portion 110 has a plurality of ridges formed thereon for enhancing engagement with the physician's fingers. As shown, the ridges 112 extend horizontally and are disposed in axially displaced parallel relationship. Obviously, other configurations of ridges, such as axially extended ridges which are spaced longitudinally one from another or angularly directed ridges would function similarly. Besides the use of ridges, other methods of enhancing the friction which can be achieved between the surface of the grip portion 110 and the user's fingers may be utilized, such as various forms of knurling or cross-cutting.

The proximal end of the cannula hub 108 includes a luer-type coupling system for coupling to other medical devices, such as an aspiration system, a hypodermic syringe, or other medical fluid or semi-fluid delivery systems.

The handle 132 has a bottom or lower surface 133 in which an opening 134 is formed. The opening 134 is dimensioned to receive a proximal portion of the cannula hub 108 therein, and is particularly adapted for releasable coupling therewith. Handle 132 includes a pair of recesses 138 formed in opposing interior wall surfaces of the opening 134 for respectively receiving projections 118, 120 formed on opposing sides of the cannula hub 108. Each of the recesses 138 includes an axially directed section 140 extending from an end thereof disposed at a distal end of the opening 134, and a circumferential section 142 extending from a second end of the axially directed section to a terminal portion 145 thereof. The terminal portion 145 of each recess 138 extends

axially to an upper locking recess 144 and a lower locking recess 146, disposed in axially aligned relationship.

Thus, when the proximal portion of the cannula hub 108 is inserted into the opening 134 the projections 118, 120 slide into a respective recess 138. Each projection 118, 120 is displaced axially through a respective axially directed section 140 of recess 138 until the circumferential section 142 is reached. The physician, utilizing the grip portion 110 of cannula hub 108 then rotates the cannula hub relative to the handle 132, or vice versa, to displace the respective projections 118, 120 along a respective circumferential section 142 of recess 138, as indicated by the directional arrow 150, shown in FIG. 2. If the physician is inserting the cannula tube 102 into a patient's body, the axially directed force applied to the handle 132 would be in a downward direction, toward the distal sharpened end 104 of the cannula tube 102. In that situation, the projections 118, 120 will be received within a respective upper locking recess 144, allowing the physician to rotate the handle in either a clockwise or counterclockwise direction, which rotation is transferred to the cannula assembly 101, while applying a downward force.

If the physician is applying an axial force to the handle for displacing the cannula tube 102 in a direction to at least partially withdraw the cannula tube 102 from the patient, the projections 118, 120 are then received in a respective lower locking recess 146 of the terminal portion 145 of a respective recess 138. With the projections 118, 120 received within a respective lower locking recess 146, the physician is able to rotate the cannula assembly 101 by rotation of the handle 132, while applying an axially directed force in a direction away from the patient.

Proper positioning of the cannula tube 102 may require axial displacement of the cannula tube 102 in a direction toward the patient followed by at least a partial withdrawal, displacing the cannula tube 102 in an opposing direction. Once the cannula assembly 101 has been properly positioned, the handle 132 can be rotated relative to the

cannula assembly 101 to position the projections 118, 120 at the end of the axially directed section 140 of a respective recess 138. The handle 132 is then displaced axially with respect to the cannula assembly 101 in order to separate the handle 132 from cannula assembly 101. With the handle removed, the luer-type coupling 116 may then be engaged, or other instruments may be inserted through the through bore 124 of the cannula hub 108 and through the cannula passage 114. Free and clear access to the luer-type coupling 116 and a less obtrusive field of view are of particular importance to the use of biopsy system 100 in providing percutaneous access for other devices and delivering medications or other compositions, such as those compositions utilized in vertebroplasty bone augmentation procedures. Such access and improved field of view are achieved by the removability of handle 132 from the cannula assembly 101.

The luer-type coupling 116 includes a cylindrical body 125 having a diameter less than the diameter of the remaining portion of cannula hub 108. The proximal end 126 of the through bore 124 extending axially through cannula hub 108 has a conically shaped contour, typical of known luer-type couplings, to provide sealing engagement with mating medical couplings and syringes. The proximal end of the cylindrical body 125 has a pair of opposing tabs 128 extending therefrom for engagement with a releasable locking structure of the mating luer-type coupling or syringes. The dimension between the outer extent of the two opposed tabs 128 is no greater than the largest diameter portion of the portion of cannula hub 108 that is received within the opening 134 of handle 132, so that the coupling 116 can be received into the opening 134.

Formed within each lower locking recess 146 there is a latching tab 148 extending therein. Further, each of the projections 118, 120 has a latching groove 122 formed therein for engagement by a respective latching tab 148. Thus, when the handle 132 is pulled relative to the cannula assembly 101 and the projections 118, 120 are received within respective lower locking recesses 146, the handle 132 is maintained in that

distended position by the detent action of the latching tabs 148 releasably engaging the grooves 122. The latching tabs respectively engage the latching grooves 122 so that the handle 132 will not be axially displaced relative to the cannula assembly 101 by its own weight. By preventing the handle from "falling" from its uppermost position to its lowermost position, any displacement of the cannula tube 102 which could result from the impact of such a displacement, is avoided. Although latching tabs 148 have been discussed with respect to the lower locking recesses 146, it should be understood that latching tabs may also be formed in the upper locking recesses 144.

Handle 132 has an upper surface 135 having an aperture 136 formed therein. The aperture 136 has a funnel shape and is in open communication with the opening 134 and thereby in open communication with the cannula passage 114. The funnel-shaped aperture 136 provides an access for a guide wire to be passed through the handle 132 and cannula assembly 101. The guide wire is inserted into a patient and the biopsy system 100 is then displaced along the guide wire to accurately locate the cannula tube 102 at a predetermined site within the patient's body.

Cannula hub 108 includes a recess 130 formed in an annular flange 129 disposed adjacent a lower end of the cylindrical luer-type coupling body 125. Recess 130 is provided to receive a projection extending from a medical device, such as a stylette, that is inserted into the cannula passage 114, to prevent relative rotation therebetween.

Referring to FIGS. 3 and 4, there is shown universal biopsy system 100_ which incorporates the handle 132, as previously described, and a cannula assembly 101_. The cannula assembly 101_ includes a cannula tube 102 coupled to a cannula hub 108, as previously described, and a stylette 160 having a rod-shaped body 162 which is inserted into the passage 114 of cannula tube 102 through the bore 124 of the cannula hub 108. The distal end 168 of the rod-shaped body 162 is shaped for cooperation with the sharpened distal end 104 of cannula tube 102. The shapes of the distal ends 104 and 168 of the cannula tube 102 and rod-shaped body 162, respectively, vary as a function

of the procedure for which they are intended to be used. In some cases, the distal end 168 of the stylette rod-shaped body 162 will extend beyond the distal end 104 of the cannula tube 102, and in other cases, the distal ends 104, 168 will be substantially co-located. Further, in some cases, the angles of the sharpened distal ends 104 and 168 will be identical, while in other cases they will differ in order to perform a particular cutting operation.

The proximal end of the rod-shaped body 162 is coupled to a stylette hub 164, the stylette hub 164 being designed to overlay the cylindrical body 125 of the luer-type coupling system 116. The outside diameter of the stylette hub 164 is no greater than the portion of the cannula hub 108 which is inserted into the opening 134 of handle 132. By that arrangement, a stylette 160 can be assembled to the cannula hub 108 and that combination received within the opening of handle 132. Stylette hub 164 includes a projection 166 extending downwardly therefrom for receipt within the recess 130 formed in an annular flange 129 of cannula hub 108, thereby preventing relative rotational displacement of the rod-shaped body 162 relative to the cannula tube 102. The opening 134 in handle 132 is dimensioned to receive a portion of cannula hub 108 with the stylette hub 164 overlying the proximal end, the luer-type coupling 116, and thereby preventing axial displacement of the stylette 160. Thus, when engaged with the handle 132, both the cannula tube 102 and the rod-shaped stylette body 162 are rotated and axially displaced in unison by respective displacement of handle 132, or by respective displacement of the grip portion 110.

The cannula assembly 101_, including the stylette 160 is releasably coupled to the handle 132 by means of a pair of projections 118 and 120 that are respectively received within a pair of recesses 138 formed in the handle 132, as previously described. Therefore, subsequent to percutaneous placement, the handle 132 can be removed in order to have access to the stylette 160. For certain procedures, the stylette 160 will be removed and the remaining portion of the cannula assembly 101_ utilized for such

functions as aspiration, the introduction of medications, the introduction of resinous materials or the introduction of other medical devices.

Although this invention has been described in connection with specific forms and embodiments thereof, it will be appreciated that various modifications other than those discussed above may be resorted to without departing from the spirit or scope of the invention. For example, equivalent elements may be substituted for those specifically shown and described, certain features may be used independently of other features, and in certain cases, particular locations of elements may be reversed or interposed, all without departing from the spirit or scope of the invention as defined in the appended Claims.

WHAT IS BEING CLAIMED IS:

1. A universal biopsy system, comprising:

a cannula having an open axially extended passage formed therein, said cannula having a distal end with a predetermined contour for penetrating a patient's tissue;

a cannula hub member having a distal end coupled to a proximal end of said cannula, said hub member having a through bore disposed in axially aligned relationship with said passage of said cannula; and,

a handle having an opening formed in a lower side thereof for receiving said cannula hub member therein and releasable engagement therewith.

2. The universal biopsy system as recited in Claim 1 where said handle has an aperture formed through an upper surface thereof in open communication with said opening and in axially aligned relationship with said through bore of said cannula hub member.

3. The universal biopsy system as recited in Claim 1 where said cannula hub member includes a pair of projections extending from opposing sides of said cannula hub member for engagement with said handle and transmitting rotational and axially directed forces from said handle to said cannula hub member and cannula.

4. The universal biopsy system as recited in Claim 3 where said handle includes a pair of recesses formed in opposing interior wall surfaces of said opening for respectively receiving said projections therein.

5. The universal biopsy system as recited in Claim 4 where each of said pair of recesses includes an axially directed section extending from a first end disposed at a distal end of said opening and a circumferential section extending from a second end of said axially directed section to a terminal portion thereof.

6. The universal biopsy system as recited in Claim 5 where said terminal portion of each said circumferential section includes an upper locking recess and an

opposing lower locking recess for selectively respectively receiving said pair of projections therein to rotationally couple said handle to said cannula hub member responsive an axial displacement of said handle relative to said cannula hub member.

7. The universal biopsy system as recited in Claim 6 where each of said pair of projections has a latching groove formed therein.

8. The universal biopsy system as recited in Claim 7 where each of at least one of said upper and lower locking recesses has a latching tab formed therein for releasable engagement with said latching groove of a respective one of said pair of projections to releasably secure said handle in an axial position relative to said cannula hub member.

9. The universal biopsy system as recited in Claim 1 where a proximal end of said cannula hub member is formed with a pair of tabs respectively extending from opposing sides of said cannula hub member and a proximal portion of said through bore being tapered to form a mating connection for a luer-type coupling system.

10. The universal biopsy system as recited in Claim 1 where said cannula hub member has a grip portion defined by a distal portion of said cannula hub member having a polygonal outer surface contour.

11. The universal biopsy system as recited in Claim 10 where said grip portion has a substantially square cross-sectional contour.

12. The universal biopsy system as recited in Claim 10 where said grip portion has non-planar surfaces formed thereon to enhance a user's ability to grip said grip portion.

13. The universal biopsy system as recited in Claim 1 further comprising a stylette slidably disposed in said through bore of said cannula hub member and said passage of said cannula.

14. The universal biopsy system as recited in Claim 13 where said stylette has a stylette hub formed on a proximal end thereof, said stylette hub being releasably

coupled to a proximal end of said cannula hub member to substantially prevent rotation of said stylette relative to said cannula, said stylette hub being receivable within said opening of said handle.

15. A universal biopsy system, comprising:

a cannula having an open axially extended passage formed therein, said cannula having a sharpened distal end;

a cannula hub member having a distal end coupled to a proximal end of said cannula, said cannula hub member having a through bore disposed in axially aligned relationship with said passage of said cannula;

a stylette slidably disposed in said through bore of said cannula hub member and said passage of said cannula and having sharpened distal end corresponding to said sharpened distal end of said cannula; and,

a handle releasably coupled to said cannula hub member for applying rotational and axially directed forces to said cannula hub member and cannula.

16. The universal biopsy system as recited in Claim 15 where said stylette has a stylette hub formed on a proximal end thereof, said stylette hub being releasably coupled to a proximal end of said cannula hub member to substantially prevent rotation of said stylette relative to said cannula, said stylette hub being receivable within said opening of said handle.

17. The universal biopsy system as recited in Claim 15 where said cannula hub member has a grip portion defined by a distal portion of said cannula hub member having a polygonal outer surface contour.

18. The universal biopsy system as recited in Claim 17 where said grip portion has non-planar surfaces formed thereon to enhance a user's ability to grip said grip portion.

19. The universal biopsy system as recited in Claim 15 where said handle has a funnel-shaped aperture formed through an upper surface thereof in open communication

with said opening and in axially aligned relationship with said through bore of said cannula hub member for passage of a guide wire therethrough.

20. The universal biopsy system as recited in Claim 15 where said cannula hub member includes a pair of projections extending from opposing sides of said cannula hub member for engagement with said handle and transmitting rotational and axially directed forces from said handle to said cannula hub member and cannula.

21. The universal biopsy system as recited in Claim 20 where said handle includes a pair of recesses formed in opposing interior wall surfaces of said opening for respectively receiving said projections therein.

22. The universal biopsy system as recited in Claim 21 where each of said pair of recesses includes an axially directed section extending from a first end disposed at a distal end of said opening and a circumferential section extending from a second end of said axially directed section to a terminal portion thereof.

23. The universal biopsy system as recited in Claim 22 where said terminal portion of each said circumferential section includes an upper locking recess and an opposing lower locking recess for selectively respectively receiving said pair of projections therein to rotationally couple said handle to said cannula hub member responsive an axial displacement of said handle relative to said cannula hub member.

24. The universal biopsy system as recited in Claim 23 where each of said pair of projections has a latching groove formed therein.

25. The universal biopsy system as recited in Claim 24 where each of at least one of said upper and lower locking recesses has a latching tab formed therein for releasable engagement with said latching groove of a respective one of said pair of projections to releasably secure said handle in an axial position relative to said cannula hub member.

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UNIVERSAL BIOPSY SYSTEM

ABSTRACT OF THE DISCLOSURE

A universal biopsy system (100, 100_) is provided for performing percutaneous medical procedures. The biopsy system (100, 100_) includes a cannula assembly (101, 101_) removably coupled to a handle (132). The releasable coupling structures of handle (132) and cannula assembly (101, 101_) allows for rotational displacement of the cannula assembly (101, 101_) using the handle (132), as well as the application of an axially directed force, either toward or away from the patient.