



US009237914B2

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

(10) **Patent No.:** **US 9,237,914 B2**
(45) **Date of Patent:** **Jan. 19, 2016**

(54) **BONE FIXATION SYSTEM**

(71) Applicant: **DePuy Synthes Products, Inc.**,
Raynham, MA (US)

(72) Inventors: **Reto Nardini**, Grenchen (CH); **Robert Frigg**, Bettlach (CH)

(73) Assignee: **DePuy Synthes Products, Inc.**,
Raynham, MA (US)

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

(21) Appl. No.: **14/694,075**

(22) Filed: **Apr. 23, 2015**

(65) **Prior Publication Data**

US 2015/0223855 A1 Aug. 13, 2015

Related U.S. Application Data

(62) Division of application No. 13/078,188, filed on Apr. 1, 2011, now Pat. No. 9,039,683.

(60) Provisional application No. 61/417,614, filed on Nov. 29, 2010, provisional application No. 61/320,883, filed on Apr. 5, 2010.

(51) **Int. Cl.**
A61B 17/84 (2006.01)
A61B 17/70 (2006.01)

(Continued)

(52) **U.S. Cl.**
CPC **A61B 17/84** (2013.01); **A61B 17/16** (2013.01); **A61B 17/1624** (2013.01); **A61B 17/7059** (2013.01); **A61B 17/864** (2013.01); **A61B 17/866** (2013.01); **A61B 17/8863** (2013.01); **A61B 17/8872** (2013.01); **A61B 18/04** (2013.01); **A61B 18/20** (2013.01); **A61B 17/1617** (2013.01); **A61B 17/1626** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC **A61B 18/18**; **A61B 17/04**; **A61F 2/02**;
A61F 2/28; **A61F 2/30**; **B32B 7/04**; **A61C**
8/00

USPC **606/13**, **232**; **623/16**, **11**, **18**; **428/343**;
433/173

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,784,135 A 11/1988 Blum et al.
4,911,712 A 3/1990 Harrington

(Continued)

FOREIGN PATENT DOCUMENTS

CA 1238690 6/1988
CA 2055526 5/1992

(Continued)

OTHER PUBLICATIONS

Cherrick et al., "Indocyanine Green: Observations on it's Physical Properties, Plasma Decay and Hepatic Extraction", Thorndike Memorial Laboratory and the Second and Fourth (Harvard) Medical Services, Boston City Hospital and the Department of Medicine, Harvard Medical School, Boston MA., Dec. 4, 1959.

Primary Examiner — William Thomson

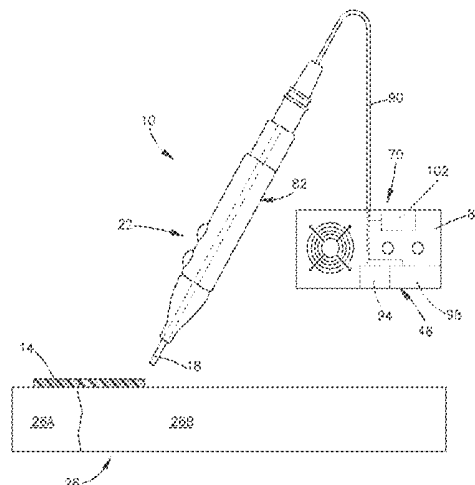
Assistant Examiner — Victor Shapiro

(74) *Attorney, Agent, or Firm* — Baker & Hostetler LLP

(57) **ABSTRACT**

A bone fixation system is provided. The bone fixation system may include a plate, one or more fasteners configured to attach the plate to a target anatomical location such as bone, and a surgical device that facilitates the attachment of the plate and the fasteners.

21 Claims, 8 Drawing Sheets



(51) **Int. Cl.**

A61B 17/86 (2006.01)
A61B 17/88 (2006.01)
A61B 18/20 (2006.01)
A61B 18/04 (2006.01)
A61B 17/16 (2006.01)
A61B 18/22 (2006.01)
A61B 18/28 (2006.01)
A61B 17/00 (2006.01)
A61B 18/00 (2006.01)

5,796,903 A 8/1998 Tran
 6,343,174 B1 1/2002 Neuberger
 6,802,838 B2 10/2004 Loeb et al.
 7,335,205 B2 2/2008 Aeschlimann et al.
 7,461,982 B2 12/2008 Boutousov et al.
 2003/0139735 A1 7/2003 Neuberger
 2004/0166309 A1 8/2004 Gong et al.
 2006/0282068 A1 12/2006 Griffin et al.
 2007/0270833 A1 11/2007 Bonutti et al.
 2007/0299449 A1 12/2007 Allinnemi et al.
 2008/0039845 A1 2/2008 Bonutti et al.
 2008/0047107 A1 2/2008 Clinch et al.
 2008/0219629 A1 9/2008 Rizioi et al.
 2008/0275500 A1 11/2008 Aeschlimann et al.
 2009/0024161 A1 1/2009 Bonutti et al.
 2010/0241229 A1 9/2010 Bachre et al.
 2012/0129131 A1 5/2012 Bachre et al.

(52) **U.S. Cl.**

CPC *A61B17/1628* (2013.01); *A61B 17/1633*
 (2013.01); *A61B 17/8685* (2013.01); *A61B*
18/22 (2013.01); *A61B 18/28* (2013.01); *A61B*
2017/00004 (2013.01); *A61B 2017/00039*
 (2013.01); *A61B 2017/00106* (2013.01); *A61B*
2017/00371 (2013.01); *A61B 2017/00389*
 (2013.01); *A61B 2017/1651* (2013.01); *A61B*
2018/00029 (2013.01); *A61B 2018/00178*
 (2013.01); *A61B 2018/00565* (2013.01); *A61B*
2018/00601 (2013.01); *A61B 2018/00994*
 (2013.01); *A61B 2217/005* (2013.01); *A61B*
2217/007 (2013.01); *A61B 2218/002* (2013.01)

FOREIGN PATENT DOCUMENTS

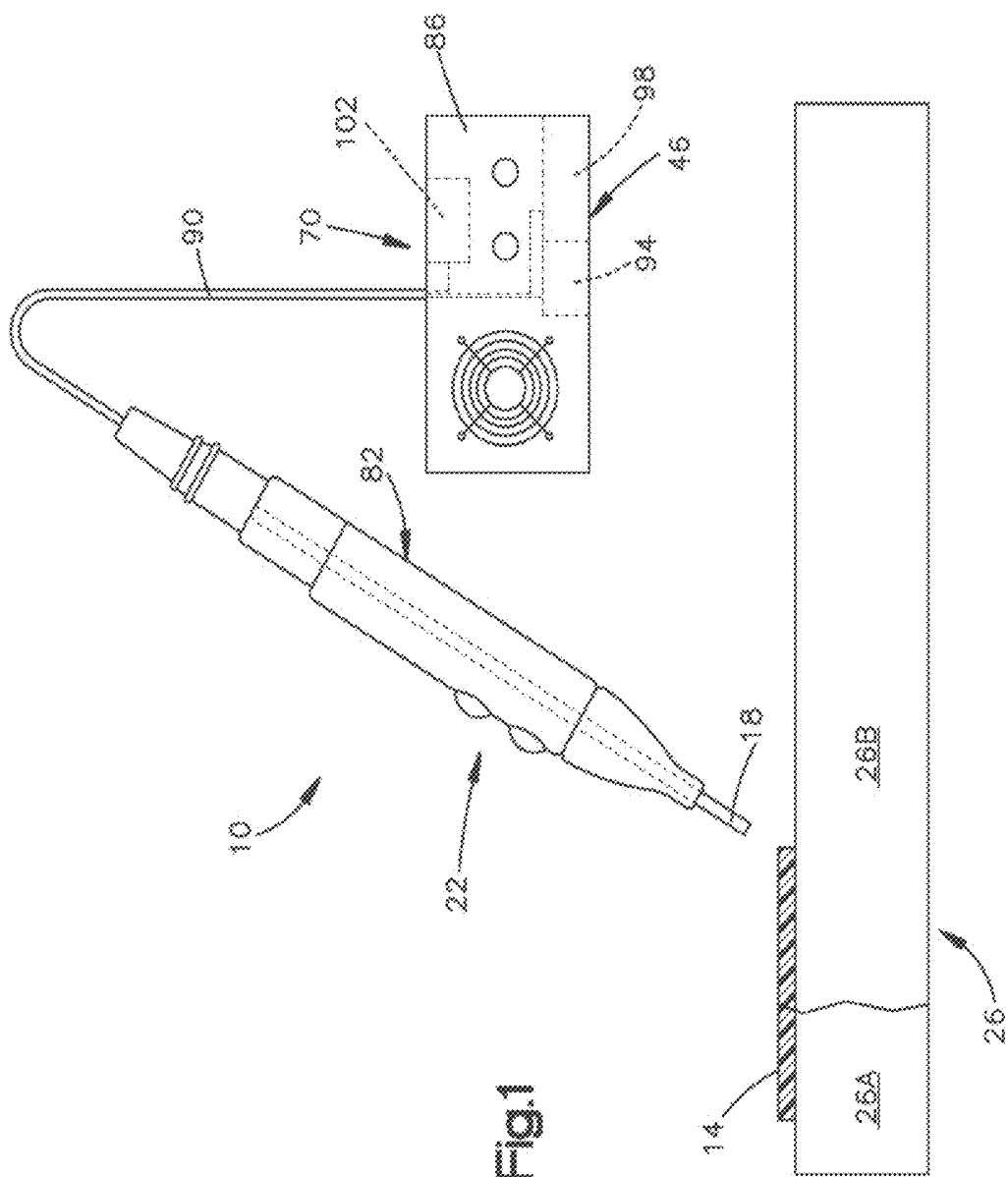
CN 201126922 10/2008
 DE 102007007915 8/2008
 EP 0392951 10/1990
 EP 2065017 6/2009
 WO WO 97/07928 3/1997
 WO WO 0044294 8/2000
 WO WO 2005/070129 8/2005
 WO WO 2008/034276 3/2008
 WO WO 2008/095327 8/2008
 WO WO 2008/101090 8/2008
 WO WO 2008/102428 8/2008
 WO WO 2008/116203 9/2008
 WO WO 2008/128588 10/2008
 WO WO 2009/003294 1/2009
 WO WO 2009/029908 3/2009
 WO WO 2009/036576 3/2009
 WO WO 2009/117837 10/2009
 WO WO 2009/132472 11/2009

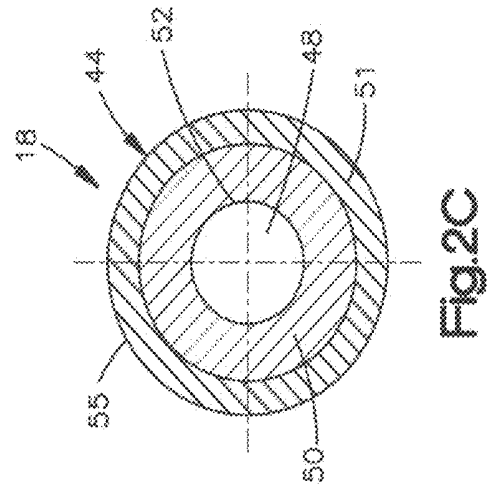
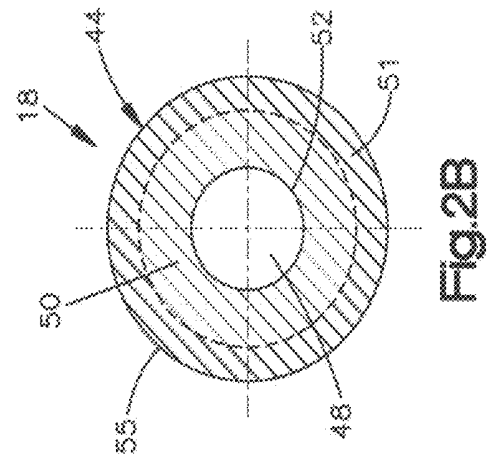
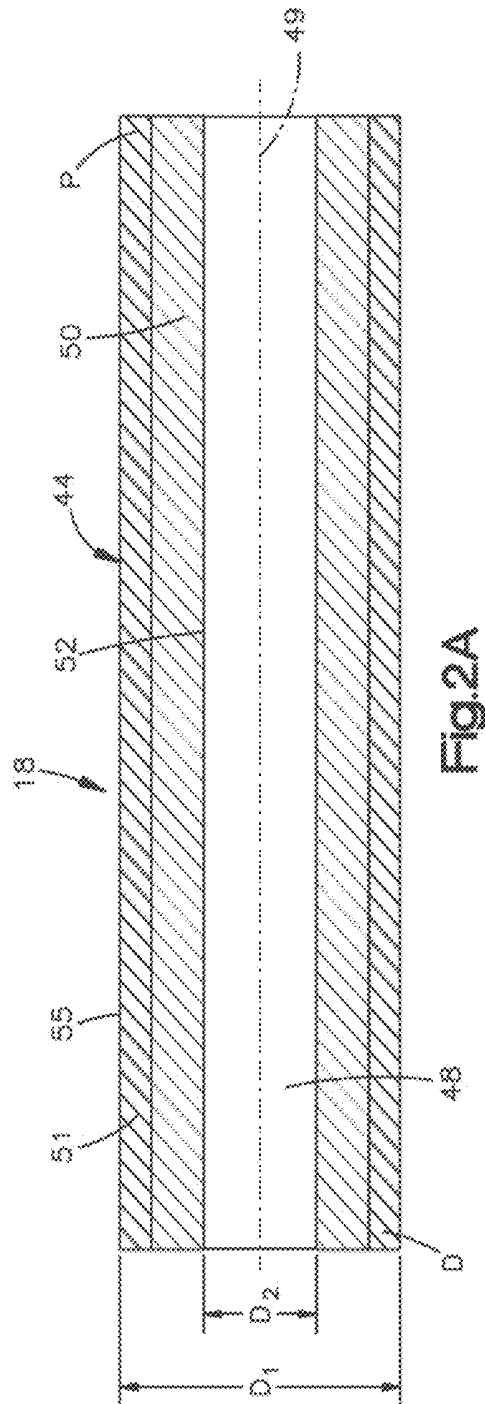
(56)

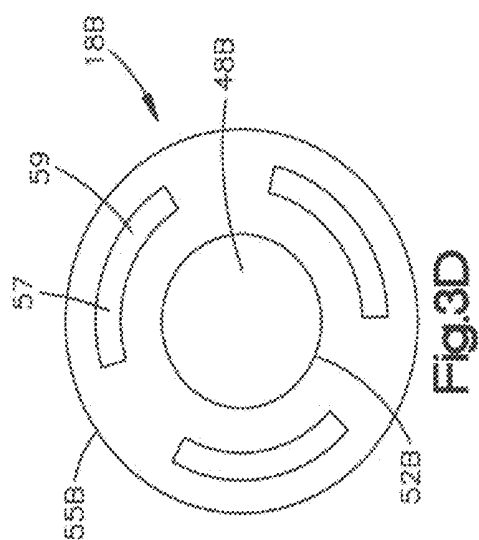
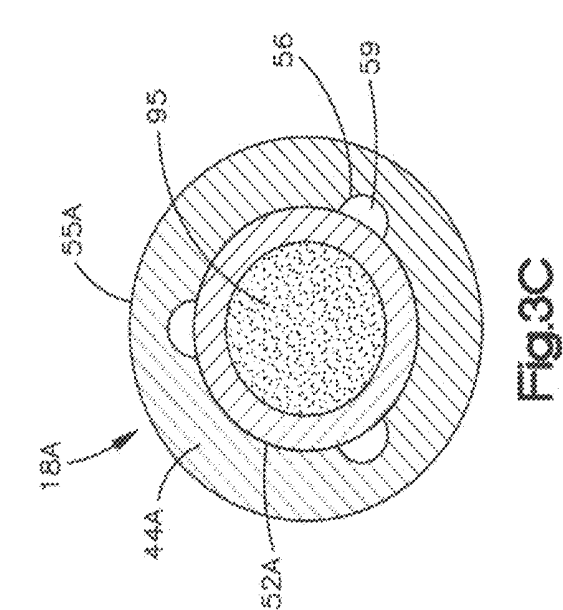
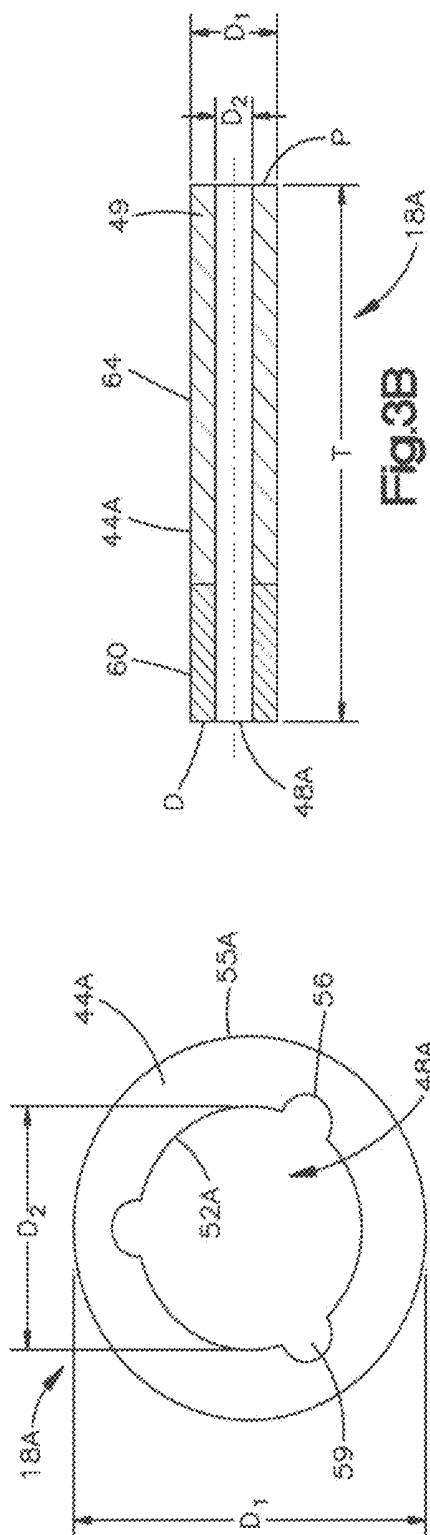
References Cited

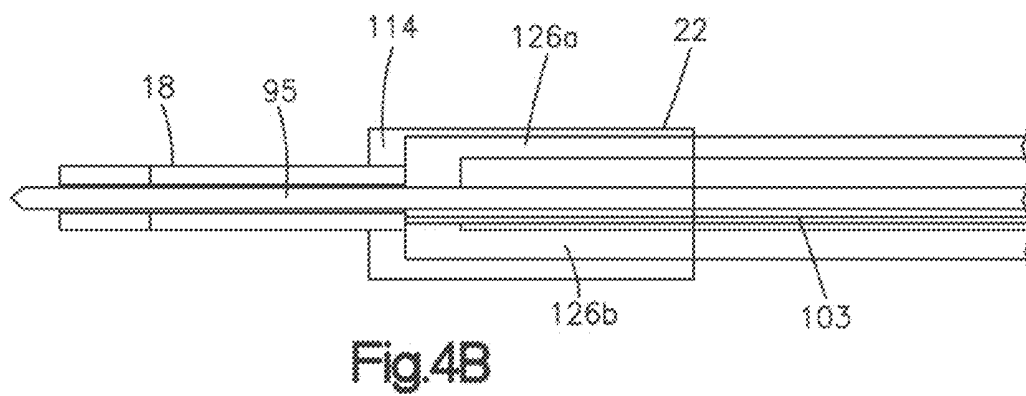
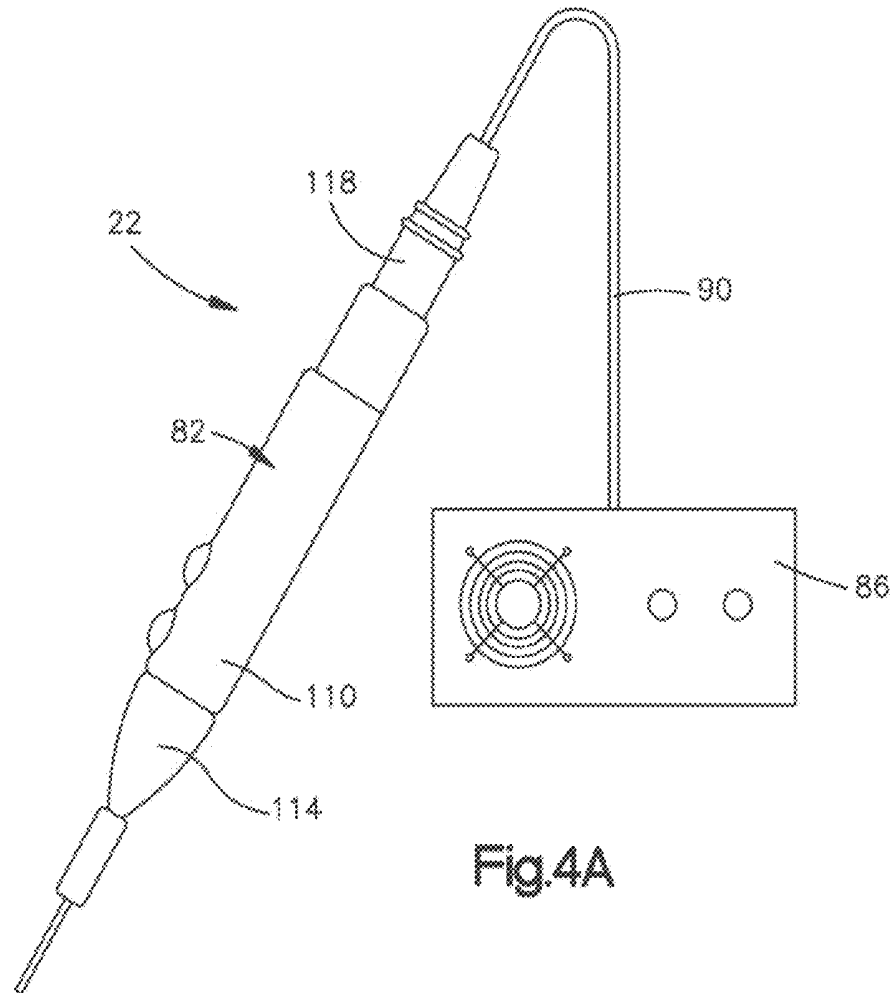
U.S. PATENT DOCUMENTS

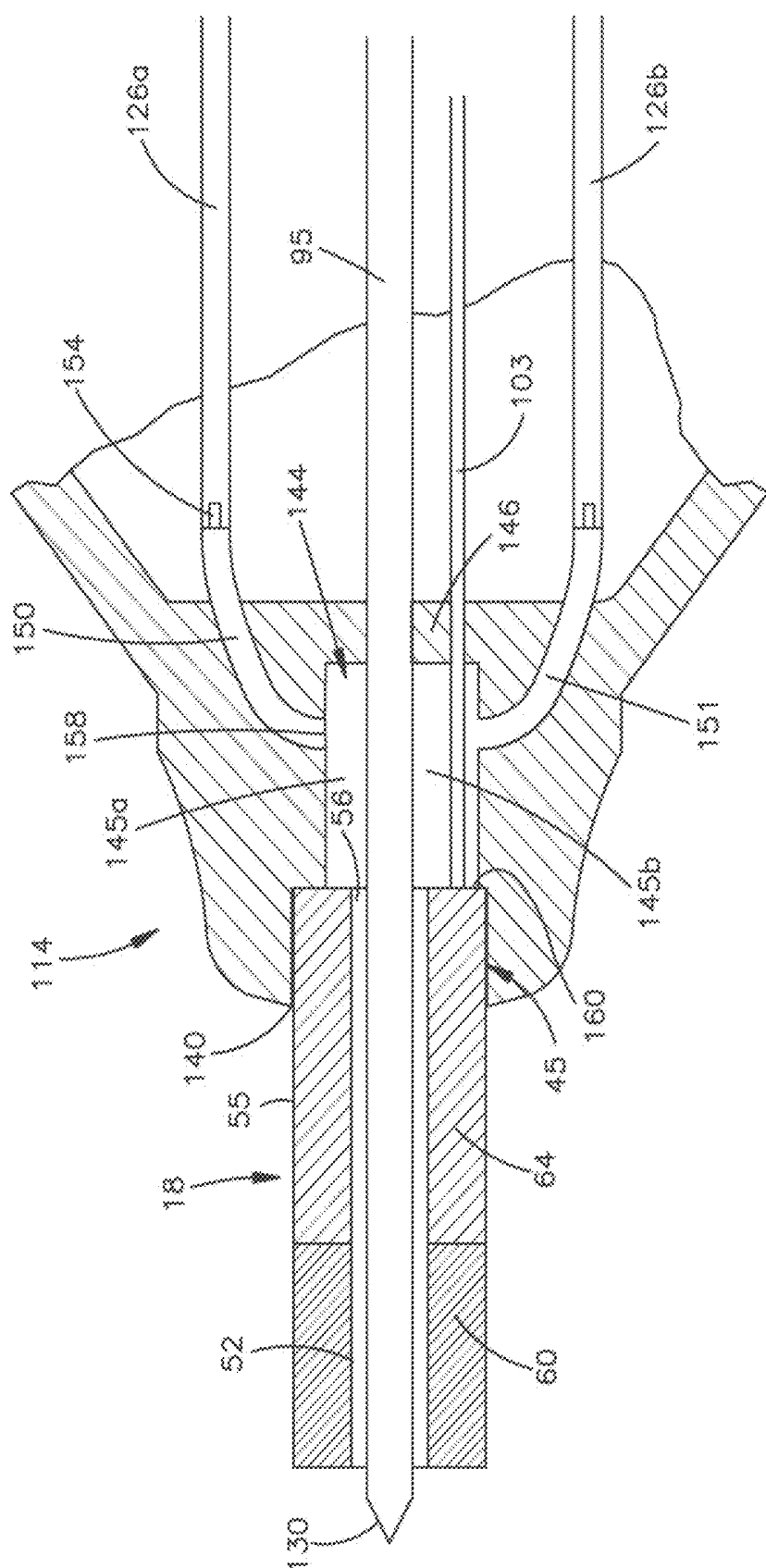
5,118,293 A 6/1992 Levy
 5,171,150 A 12/1992 Levy
 5,192,279 A 3/1993 Samuels et al.
 5,249,964 A 10/1993 Levy
 5,397,365 A 3/1995 Trentacosta











04.09.11

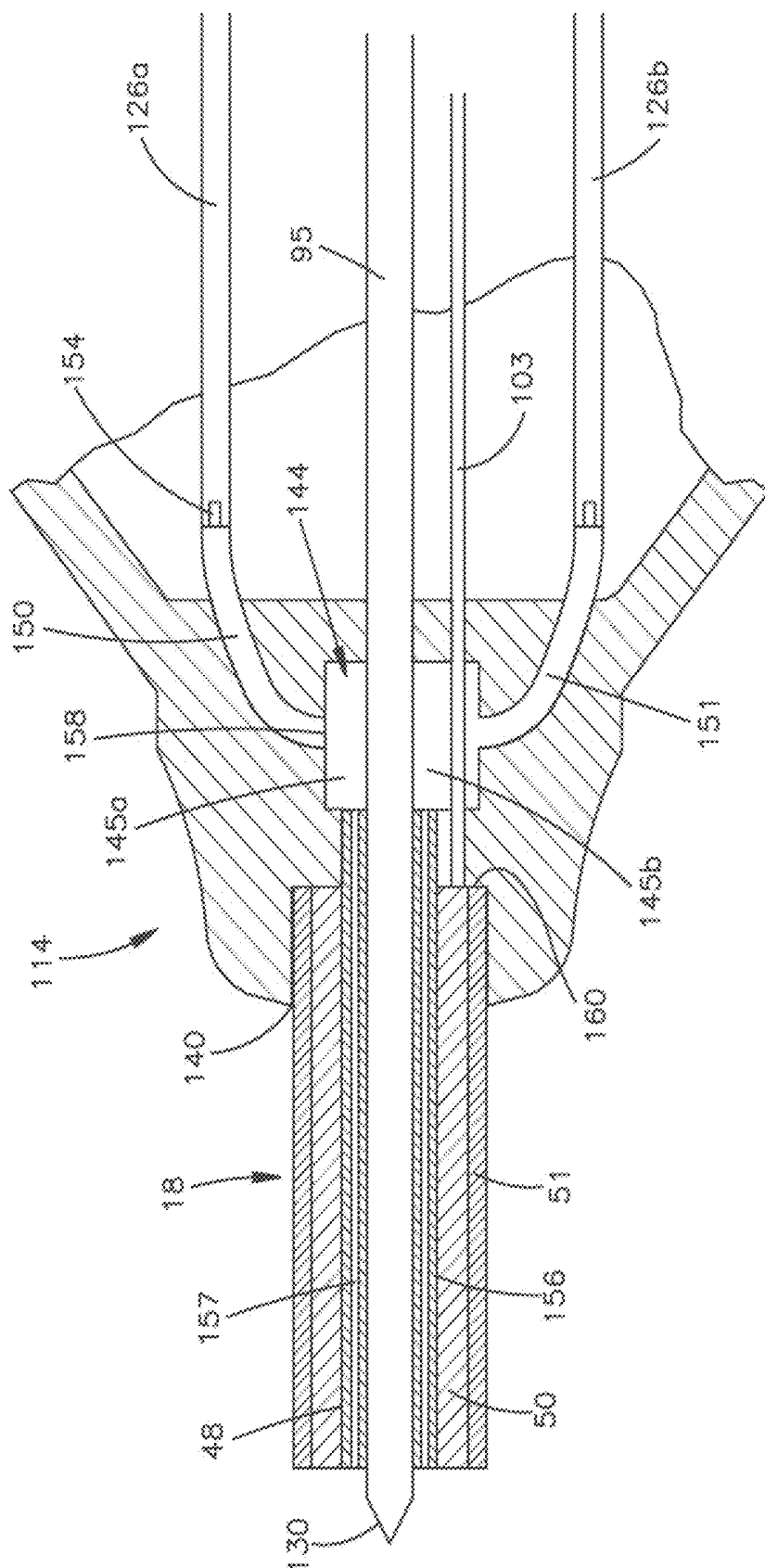
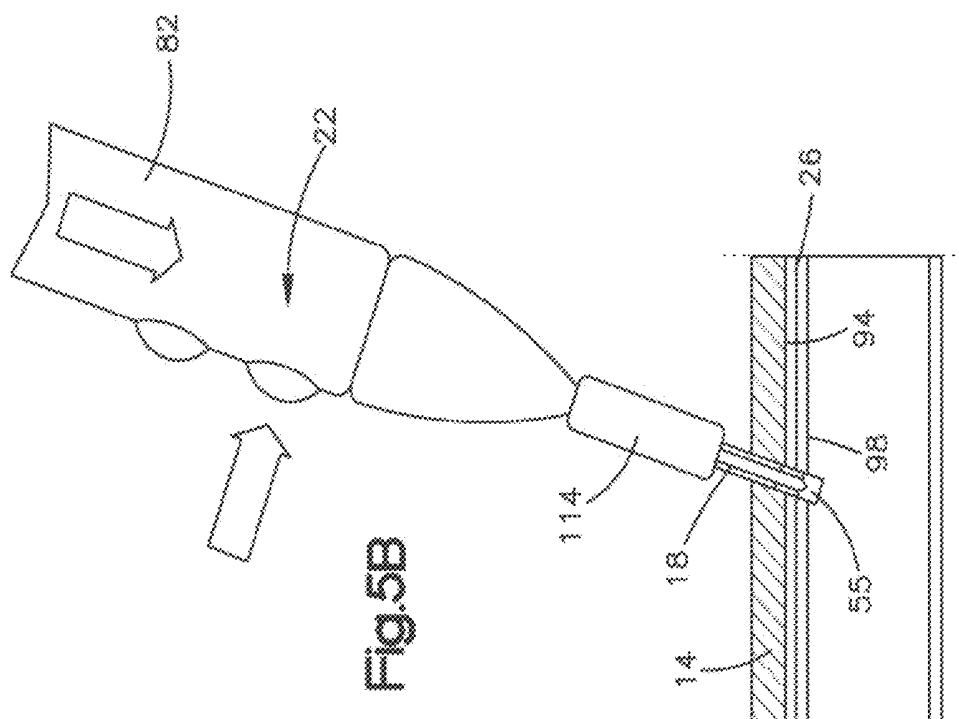
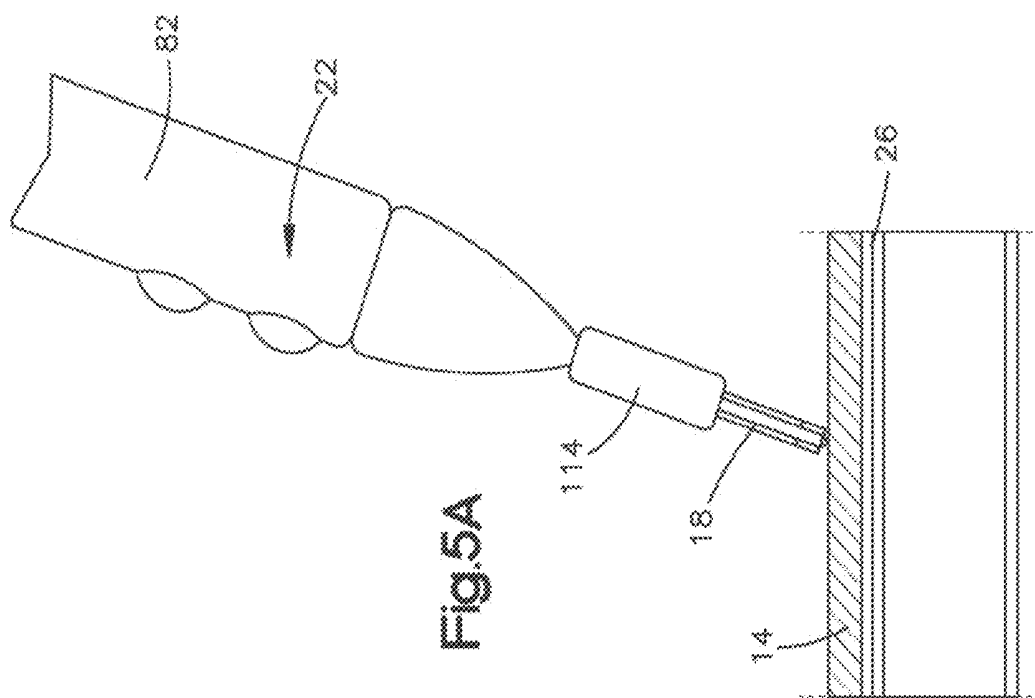


Fig. 4D



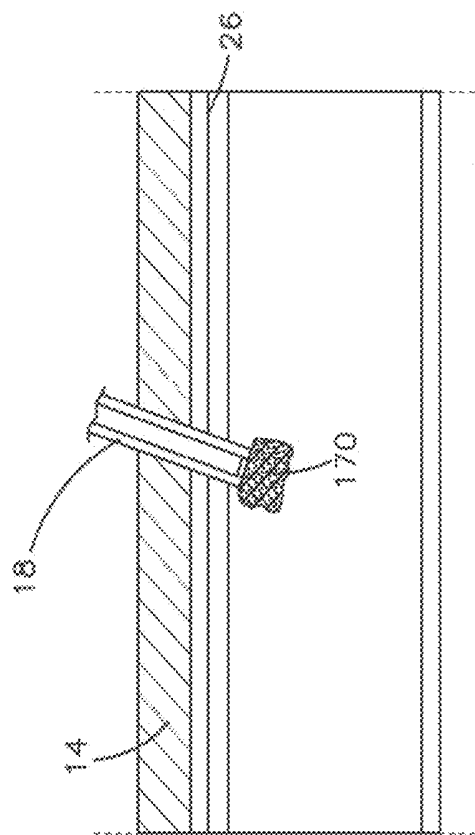
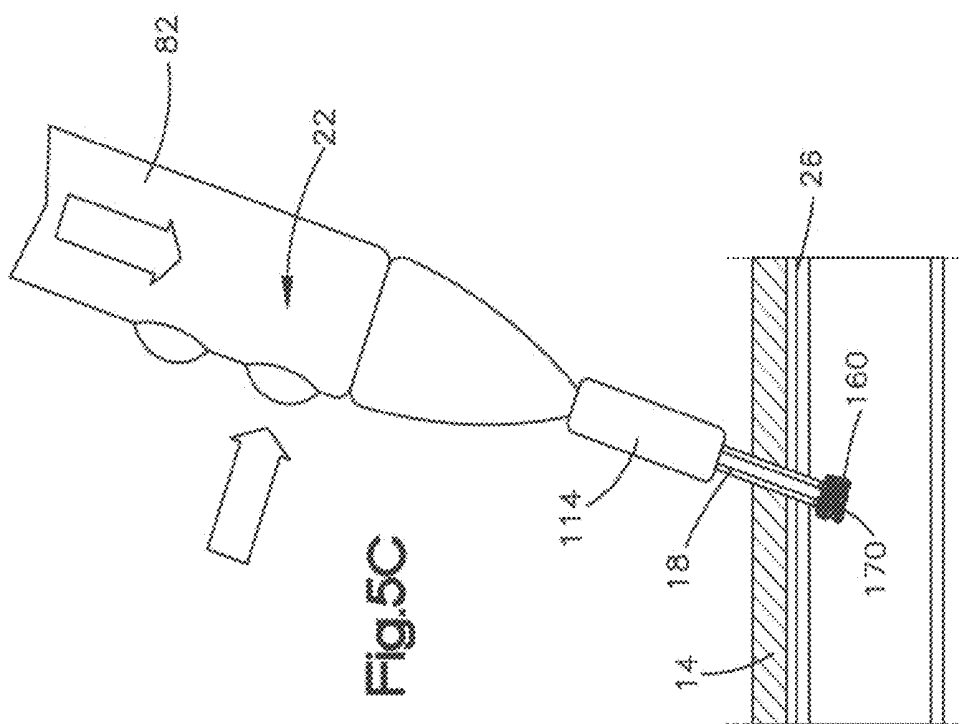


Fig. 5D

BONE FIXATION SYSTEM**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a divisional of U.S. patent application Ser. No. 13/078,188, entitled "A Bone Fixation System," filed Apr. 1, 2011, which claims the benefit of U.S. Provisional Patent Application Ser. No. 61/417,614 filed Nov. 29, 2010, and further claims the benefit of U.S. Provisional Patent Application Ser. No. 61/320,883 filed Apr. 5, 2010, the disclosure of each of which is hereby incorporated by reference as if set forth in its entirety herein.

BACKGROUND

Fractured bones are a common injury seen in trauma centers. Surgeons in trauma centers frequently encounter many different types of fractures with a variety of different bones. For stabilizing a bone fracture, a metal fixation plate with suitable holes is fixed to bone fragments on opposing sides of the fracture using metal screws or pins. Typically the screws are self-cutting and are rotated into threadless openings in the bone, or they are screwed into pre-drilled threaded openings. Fracture fixation using such plates and screws may include several procedural steps and several instruments. For example, a first instrument may be used to cut the holes in the bone, and then a second instrument may be used to place the screws or pins. Therefore, the complexity and duration of the surgery may be unnecessarily lengthy and complex.

SUMMARY

Disclosed is a surgical fastener may include a body that includes a first portion and a second portion. The body may define a bore that extends through at least the first portion along a longitudinal axis of the body. The bore may be configured to receive a cutting mechanism. The first portion of the body may be transmissive to electromagnetic radiation and the second portion of the body may be absorptive to electromagnetic radiation such that upon absorbing electromagnetic radiation the second portion of the body softens and is capable of deforming. In one embodiment, the body defines a proximal end and a distal end spaced from the proximal end along the longitudinal axis, the proximal end is configured to attach to a surgical device that emits an energy source, and the first portion is disposed proximally with respect to the second portion. In another embodiment, the first portion may be an inner core portion and the second portion may be an outer peripheral portion.

The surgical fastener may be part of a kit that includes both a bone plate and at least one polymer based fastener. The bone plate may be comprised of a thermoplastic material. The fastener may include a body that defines a first portion, and a second portion. The second portion may have laser absorbing properties. The fastener may also include a bore that extends through at least the first portion of the body. The bore may be configured to receive a cutting mechanism.

Also disclosed is a surgical device configured to implant a surgical fastener into a target anatomical location. The surgical device may include a hand piece having a body that is configured to support a fastener that has a body and a bore that extends through the body. The surgical device may also include a cutting mechanism and an energy source. The cutting mechanism may be configured to extend through the bore

of the fastener and cut into a target anatomical location. The energy source may be configured to heat and soften a portion of the fastener.

Also disclosed is a method of fixation of a surgical fastener to a target anatomical location. According to the method a hole may be cut into the target anatomical location by using a cutting mechanism of a surgical device. A fastener that is attached to a tip of the surgical device may be advanced into the hole of the boney structure as the cutting mechanism is cutting the hole. An energy source of the surgical device may then be activated to thereby heat the fastener so as to soften at least a portion of the fastener. Once finished the surgical device may be removed while the fastener remains attached to the boney structure.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of preferred embodiments of the application, will be better understood when read in conjunction with the appended drawings. For the purposes of illustrating the surgical fasteners and devices of the present application, there is shown in the drawings preferred embodiments. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown. In the drawings:

FIG. 1 is a schematic view showing a surgical device fixing a bone plate to bone with a surgical fastener;

FIG. 2A is a longitudinal cross-sectional view of a surgical fastener according to one embodiment, the surgical fastener having a core portion and a peripheral portion capable of deforming;

FIG. 2B is a transverse cross-sectional view of the surgical fastener shown in FIG. 2A, the core portion and the peripheral portion are joined such that the surgical fastener is configured as a one-piece fastener;

FIG. 2C is a transverse cross-sectional view of the surgical fastener shown in FIG. 2A, the peripheral portion being a coating disposed on the core portion;

FIG. 3A is a front elevational view of a surgical fastener in accordance with another embodiment, the surgical fastener having a distal portion capable of deforming;

FIG. 3B is a longitudinal cross-sectional view of the surgical fastener shown in FIG. 3A;

FIG. 3C is a transverse cross-sectional view of the surgical fastener shown in FIG. 3A, including an optical waveguide extending through the bore of the fastener;

FIG. 3D is a front elevational view of a surgical fastener in accordance with another embodiment, the surgical fastener including closed irrigation channels;

FIG. 4A is a side elevational elevation view of a surgical device configured to affix a bone plate to bone using a surgical fastener;

FIG. 4B is a schematic view showing a first laser, a second laser and an irrigation supply of the device shown in FIG. 4A;

FIG. 4C is a detailed side view illustrating the tip of the device shown in FIG. 4A holding a surgical fastener for affixing a bone plate to bone;

FIG. 4D is a detailed side view illustrating the tip of the device shown in FIG. 4A holding another embodiment of the surgical fastener for affixing a bone plate to bone;

FIG. 5A is a schematic view of a surgical device being positioned to affix a bone plate to bone;

FIG. 5B is a schematic view of the surgical device shown in FIG. 5A activating a first laser to drill through the bone plate and bone, and simultaneously advancing a surgical fastener;

FIG. 5C is a schematic view of the surgical device shown in FIG. 5B activating a second laser to soften at least a portion of the surgical fastener; and

FIG. 5D is a schematic view showing the surgical fastener affixing the bone plate to bone after the surgical device is removed.

DETAILED DESCRIPTION

Referring to FIG. 1, a bone fixation system 10 includes a plate 14, one or more fasteners 18 configured to attach the plate 14 to a target anatomical location such as bone 26, and a surgical device 22 that facilitates the attachment of the plate 14 and the fasteners 18. It should be appreciated that the bone 26 can include two or more fractured bone segments, such as bone segments 26A and 26B, or can include any other deformity amenable to treatment using bone fixation. Moreover, the target anatomical location may be structure other than bone, such as ligaments, and other soft or hard tissue structures. As shown, the plate 14 is placed over or onto the bone 26, and the surgical device 22 may be positioned over the plate 14 to cut a hole in either the plate 14, the bone 26, or both, so as to affix the plate 14 to the bone 26 using the fastener 18. The fixation of the plate 14 using one or more fasteners 18 and the surgical device 22 may be performed using a single device. For instance, only a single device 22 can be used to cut a hole, place the fastener 18, and affix the plate 14 to the bone 26 with the one or more fasteners 18. It should be understood that the entire fixation system 10 may be sold as a kit or alternatively, the plate 14, and the one or more fasteners 18 may be sold as a kit themselves. For instance, a plurality of fasteners 18 having different sizes and/or shapes can be provided as a kit.

Alternatively or additionally, a plurality of plates 14 having different sizes and/or shapes can be provided as a kit. Alternatively or additionally still, a combination of fasteners 18 and plates 14 having the same or different sizes and/or shapes can be provided as a kit, either alone or in combination with the surgical device 22. Furthermore, while the fasteners 18 are illustrated as pins, they can alternatively be provided as screws having threaded surfaces, nails having smooth or toothed surfaces, bolts, or any alternative fixation device configured to fix the bone plate 14 to the underlying bone 26.

As shown in FIG. 1, the surgical device 22 includes a hand piece 82, and a control unit 86 that is connected to the hand piece 82 by a cord 90. The control unit supplies a cutting mechanism 46 that is configured to cut the holes into the plate 14 and the bone 26, and an energy source 70 that is configured to heat and soften the fasteners 18 to thereby attach the plate 14 to the bone 26. The cutting mechanism 46 may include a first laser 94 and an irrigation system 98, and the energy source 70 may include a second laser 102. The first laser 94, the irrigation system 98 and the second laser 102 are arranged in the control unit 86 and delivered to the hand piece 82 of the surgical device 22 through the cord 90.

The plate 14 provides a load bearing structure that can be connected to bone fragments. The plate 14 is preferably made from a polymer material. For example the plate 14 may be made from poly-alpha-hydroxyester, polyorthoester, polyanhydride, polyphosphazenes, poly(propylenefumarate), polyesteramide, polyethylenefumarate, polylactide, polyglycolide, polycaprolacton, trimethylenecarbonate, polydioxanone, polyhydrobutyrate, as well as their copolymers and mixtures. The plate 14 may also include electromagnetic radiation absorption properties. For example, the plate 14 may include an additive, such as chlorophyll, carbon black, iron oxide, graphite, fluorescein, methylene blue,

indocyanine green, eosine; eosine Y (514 nm), ethyleosine (532 nm), acridine, acridine orange, copper phthalocyanine, chrome-cobalt-aluminum oxide, ferrous ammonium citrate, pyrogallol, logwood extract, chlorophyll-copper complex, D&C blue No. 9, D&C green No. 5, [phthalocyaninate(2-)] copper, D&C blue no. 2, D&C blue no. 6, D&C green no. 6, D&C violet no. 2, and D&C yellow No. 10, which allows the plate 14 to absorb energy such as heat from the second laser 102. In operation, the portion of the plate 14 that has the electromagnetic radiation absorption properties, absorbs the laser beam and deforms, thereby contributing to the fixation of the plate 14 to the bone 26. In another embodiment, the electromagnetic radiation absorbing component may include magnetic nano-particles, and the second laser 102 may be replaced by an electromagnetic transmitter that emits an electromagnetic signal in the range of 20 kHz to 10 GHz. Alternatively, ultrasonic vibrations, a conventionally heated metal bolt or heated air flow might be used for melting the fastener/plate.

Further, the plate 14 may be provided without predrilled holes and thus may define a continuous surface between opposing edges along a length that defines a target location for the insertion of one or more of the fasteners 18. During installation, the cutting mechanism of the surgical device 22 may be used to produce holes in the plate 14. It should be understood, however, that the plate 14 is not limited to plates defining continuous surfaces, and may be provided with pre-drilled holes. Furthermore, it should be understood by one of skill in the art, that the plate 14 and the holes may be provided in a variety of shapes and sizes.

As shown in FIGS. 2A-2C each surgical fastener 18 includes a body 44 that is elongate in a longitudinal direction L and defines a distal end D and a proximal end P. Each surgical fastener 18 further includes a bore 48 that extends through the body 44 in the longitudinal direction L and along a longitudinal axis 49 that may define a central axis of the fastener 18. In this way, the body 44 is tubular having an outer diameter D1 that defines an external surface 55 of the body 44, and an inner diameter D2 that defines an internal surface 52 of the body 44. As shown, the body 44 may be separated into a first or core portion 50 adjoining the internal surface 52, and a second or peripheral portion 51 adjoining the external surface 55.

The body 44 of the fastener 18 is made from a thermoplastic material, for example poly-alpha-hydroxyester, polyorthoester, polyanhydride, polyphosphazenes, poly(propylenefumarate), polyesteramide, polyethylenefumarate, polylactide, polyglycolide, polycaprolacton, trimethylenecarbonate, polydioxanone, polyhydrobutyrate, as well as their copolymers and mixtures. The peripheral portion 51 of the body 44 adjoining the external surface 55 is colored sufficiently to include electromagnetic radiation absorption properties while the core portion 50 of the body 44 adjoining the internal surface 52 is transmissive to the electromagnetic radiation provided by the energy source. For example, the colored peripheral portion 51 may include an additive, such as chlorophyll, carbon black, iron oxide, graphite, fluorescein, methylene blue, indocyanine green, eosine; eosine Y (514 nm), ethyleosine (532 nm), acridine, acridine orange, copper phthalocyanine, chrome-cobalt-aluminum oxide, ferrous ammonium citrate, pyrogallol, logwood extract, chlorophyll-copper complex, D&C blue No. 9, D&C green No. 5, [phthalocyaninate(2-)] copper, D&C blue no. 2, D&C blue no. 6, D&C green no. 6, D&C violet no. 2, and D&C yellow No. 10, which allows absorption of electromagnetic radiation provided by the second laser 102.

By absorbing the energy of the second laser **102**, the thermoplastic material of the peripheral portion **51** heats up and softens. That is, the softening of the fastener **18** occurs by the heat generated by the absorption of radiation from the second laser **102**, to the point that allows the fastener **18** to be deformed. In particular, the additive, and in some cases some of the thermoplastic itself absorbs the laser and heats up to thereby cause the thermoplastic to soften. The softened thermoplastic material is capable of deforming and expanding into the hollow spaces of the bone tissue thereby affixing the fastener **18** and the plate **14** to the bone **26**. The peripheral portion **51** may absorb at least twice as much irradiated energy as the core portion **50**. Typically, however, a factor of 5-1000 times more energy is absorbed in the peripheral portion **51** with respect to the core portion **50**. In other words, the peripheral portion **51** may absorb 50-100% of the energy, while the core portion **50** absorbs 0-10%. The thickness of the peripheral portion **51** is preferably over 0.1 mm and/or between 1 to 20% of the outer diameter D1. It should be understood that the peripheral portion **51** is not limited to thermoplastic materials capable of absorbing the second laser **102** and that other materials may be used. For example, the peripheral portion **51** may include magnetic nano-particles, and the laser can be replaced by an electromagnetic transmitter that emits an electromagnetic signal in the range of 1 kHz to 1 MHz or 100 KHz to 100 GHz.

The core portion **50** of the fastener **18** which is transmissive to the electromagnetic radiation may be configured so as not to warm-up at all or only partially, and to maintain its mechanical strength. At the same time, the core portion **50** can serve as an optical element and transmit the energy onward into the bone plate **14**. The fastener **18** can then be pushed into a previously produced hole which may be undersized, and the warmed-up, softened polymer is then pressed into the inter-spaces of the bone. After turning off the energy source, the polymer (thermoplastic material) cools off and quickly hardens (<1-2 minutes), and the mechanical interdigitation between the fastener **18** and the bone and/or the bone plate **14** is established.

The core portion **50** and the peripheral portion **51** may be separate discrete components that are coupled together with the peripheral portion **51** e.g. being a coating that includes the electromagnetic radiation absorbing properties as shown in FIG. 2C, or they may be integral and thus one component, with the peripheral portion **51** comprising a chromophore (i.e. color or pigment) as shown in FIG. 2B. Further, in some embodiments, the peripheral portion **51** may be a zone with a variable absorption coefficient "a". In any case, the peripheral portion **51** includes the electromagnetic radiation absorbing properties sufficient to cause the peripheral portion **51** to deform in response to exposure to the first laser **94**, while the region of thermoplastic material of the core portion **50** has a transparency to the second laser **102** that is greater than that of the peripheral portion **51**. Therefore, the inner uncolored core portion **50** substantially maintains its structural integrity when exposed to the first laser **94** that deforms the peripheral portion **51**.

As shown in FIGS. 3A-3D, in another embodiment, a fastener **18A** includes a body **44A** having first and second portions that are aligned with respect to a direction that extends substantially parallel to the longitudinal axis **49**. As shown in FIG. 3B, the body **44A** of the fastener **18A** may include a first axial portion **64** and a second axial portion **60** disposed distally with respect to the first portion **64**. The first portion **64** may be transmissive to electromagnetic radiation, while the second portion **60** may be configured to absorb electromagnetic radiation.

As with the fastener **18**, fastener **18A** may be made from a thermoplastic material. For example each fastener **18A** may be made from poly-alpha-hydroxyester, polyorthoester, poly-anhydride, polyphosphazenes, poly(propylenefumarate), polyesteramide, polyethylenefumarate, polylactide, polyglycolide, polycaprolacton, trimethylenecarbonate, polydioxanone, polyhydrobutyrate, as well as their copolymers and mixtures. The second axial portion **60** can be colored throughout its complete volume, and includes electromagnetic radiation absorption properties that allow the second portion to absorb energy provided by for example the laser **102**, and the first axial portion **64** is transmissive to the energy provided by the laser **102**. For example, the colored second portion **60** may include an additive, such as chlorophyll, carbon black, iron oxide, graphite, fluorescein, methylene blue, indocyanine green, eosine; eosine Y (514 nm), ethyl-eosine (532 nm), acridine, acridine orange, copper phthalocyanine, chrome-cobalt-aluminum oxide, ferrous ammonium citrate, pyrogallol, logwood extract, chlorophyll-copper complex, D&C blue No. 9, D&C green No. 5, [phtalocyaninate (2-)] copper, D&C blue no. 2, D&C blue no. 6, D&C green no. 6, D&C violet no. 2, and D&C yellow No. 10, which allows absorption of electromagnetic radiation provided by the second laser **102**. In operation, the thermoplastic material in the complete volume of the second axial portion **60** of the fastener **18A** absorbs the laser beam and deforms, thereby affixing the plate **14** to the bone **26**. In another embodiment the second axial portion **60** may include magnetic nano-particles, and the first laser may be replaced by an electromagnetic transmitter that emits an electromagnetic signal in the range of 20 kHz to 10 GHz.

The first axial portion **64** and the second axial portion **60** may be separate discrete components that are coupled together, or they may be integral and thus one component, with the second axial portion **60** having a coating that includes the electromagnetic radiation absorbing properties. In either case, the second axial portion **60** includes the electromagnetic radiation absorbing properties sufficient to cause the second axial portion **60** to deform in response to exposure to an energy source such as the laser beam **102**, while the thermoplastic material of the first axial portion **64** has a transparency to the laser beam **102** that is greater than that of the second axial portion **60**, such that the uncolored first axial portion **64** substantially maintains its structural integrity when exposed to the laser beam **102** that deforms the second axial portion **60**. The second axial portion **60** is shown in FIG. 3B as being disposed at the distal end "D" of the body **44**, and the first axial portion **64** is illustrated as being disposed proximal with respect to the second axial portion **60**. The colored second axial portion **60** may be from 10 to 80% of the overall length of the fastener **18A** along the longitudinal direction.

As shown in FIGS. 3A-3D, the fasteners may be provided with irrigation channels **59** configured as recesses **56** or closed passages **57** as illustrated in FIGS. 3A and 3D. As shown in FIGS. 3A and 3B, a fastener **18A** includes a hollow-cylindrical body **44A** that is elongate along a longitudinal axis **49**. The body **44A** includes an external surface **55A** that defines an outer diameter D1. As shown, each fastener **18A** includes a bore **48A** that extends through the body **44A** in the direction of the longitudinal axis **49**. As shown, the bore **48A** has an inner diameter D2 that defines an internal surface **52A** of the body **44A**. The body **44A** further defines a plurality of irrigation channels **59** configured as recesses **56** that extend into the internal surface **52A** along the entire length of the bore **48A** from the proximal end P to the distal end D. While the body **44A** is illustrated as defining three circumferentially equidistantly spaced recesses **56** (i.e. disposed at 120° when

viewed in cross-section), the body 44A can include any number of recesses 56 as desired spaced circumferentially about the body 44A as desired. As shown in FIG. 3A, in cross-section, each recess 56 may be in the shape of a half circle and may be configured to receive and carry an irrigation fluid. Each recess 56 may have a radius of about 0.1 mm to about 0.5. The recesses 56 may be radially spaced apart from each other to provide a number of irrigations channels 59 that allow an irrigation fluid to be injected through e.g. two of the three irrigation channels 59 and to be sucked off through e.g. one of the three irrigation channels 59. It should be understood, however, that the recesses 56 are not limited to being half circles and may be any shape capable of receiving an irrigation liquid.

In another embodiment and as illustrated in FIG. 3D the fasteners may include irrigation channels 59 that are closed passages 57. As shown, a fastener 18B includes a tubular body 44B, a bore 48B that extends through the body 44B, and three circumferentially equidistantly spaced closed passages 57 that extend through the body 44B between an internal surface 52B and an external surface 55B of the body 44B, such that no communication to the bore 48B exists. While the body 44B is illustrated as defining three circumferentially equidistantly spaced passages 57, the body 44B can include any number of passages 57 as desired spaced circumferentially about the body 44B as desired.

The fasteners 18, 18A, and 18B may be provided in a variety of sizes. For example, the outer diameter D1 of each fastener may be between 1.5 and 5 mm and the bores of the fasteners may have a diameter D2 of about 0.4 mm to 3 mm. Furthermore, the fasteners may have a length T extending along the longitudinal axis 49 that is between about 3 mm and about 20 mm long. The dimensions provided are for illustrative purposes only, and it should be understood that the fasteners may include any dimension capable of affixing the plate 14 to the underlying bone 26.

The color material or particles may be worked into the polymer of the fasteners using a variety of methods. For example, color-containing polymer layers or implant elements can be produced in a so-called two-component injection molding process. In this case, the uncolored portion of the fastener is injected in a first phase, and after modifying the cavity in the injection mold, the color containing portion is injected in a second phase.

The layers of color-containing polymer may also be achieved by applying and drying the color and polymer containing solutions. It is in this case possible to achieve layers of color containing polymer by depositing and drying the color and polymer containing solutions, similar to a candle-drawing process (dip-coating process) or by spraying. The use of the first-mentioned depositing process allows achieving layers of a very thin (micrometer-thin) up to a very thick (sub-and millimeter range) size.

The color layer(s) may also be achieved by applying and drying color-particles containing suspension or solution. In this case, the coating occurs by first warming-up the color-containing particles. The heated particles may then be jetted onto the surface of the uncolored part of the fastener, so that the particles fuse with the polymer of the uncolored portion of the fastener and are fixated on the surface.

Ceramic or other non-thermally sensitive particles may also be applied to the surface by jetting them onto the polymer surface in a heated condition, where they can locally fuse with the polymer and be fixated in the surface. An example for this is given by the plasma spraying process by which hip joint prostheses are for instance coated with calcium phosphate particles. The use of processes such as Chemical Vapor Depo-

sition (CVD) or Physical Vapor Deposition (PVD) is also conceivable in the presence of suitable substrates.

Each fastener may be positioned and affixed to the plate 14 and the bone 26 using the surgical device 22 shown in FIGS. 4A-4C. As shown, the surgical device 22 includes a hand piece 82, a control unit 86, and a cord 90 connecting the hand piece 82 to the control unit 86. The surgical device 22 is a processing apparatus configured to provide both the cutting mechanism 46 and the energy source 70. In the embodiment shown, the cutting mechanism includes a first laser 94 and an irrigation supply 98 that is connected to a first optical waveguide 95, while the energy source 70 includes a second laser 102 that is connected to a second optical waveguide 103. The first laser 94 and irrigation supply 98 may be configured to cut through the plate 14, the bone 26, or both, and the second laser 102 may be configured to heat and deform the second axial portion 60 or the tubular peripheral portion 51 of the fasteners 18, 18A, and/or 18B. The irrigation supply 98 is configured to supply a coolant liquid and to remove the debris from the cutting site. The optical waveguides 95, 103 may be flexible or rigid optical light-transmitting structures, such as for instance glass fiber cables or reflecting hoses (e.g. also nano-tubes) used to transmit electromagnetic radiation from the source to the fastener. On the other hand, the fastener itself may serve as an optical fiber and light diffuser. After entering the fastener, the light is transmitted through the first portion of the fastener until it arrives at the point where the softening of the polymer, mostly at its surface, is to take place. In order to transmit the light through the optical fiber to the fastener up to the desired point, the fastener may on one hand actually transmit the light, meaning for instance to the tip of a pin and then distribute it there, so as to reach the surface of the fastener, for instance by diffusion.

In one embodiment, the first laser 94 is a 3 μ m infrared laser, the irrigation supply 98 uses a liquid such as water, and the second laser 102 is an 800 nm infrared laser. It should be understood, however, that the device 22 is not limited to a cutting mechanism 46 comprising the 3 μ m infrared laser, and water supply, nor is it limited to an energy source 70 comprising the 800 nm infrared laser. For example, the cutting mechanism 46 may also be a 10 μ m CO₂ laser combined with an irrigation supply, or a 2.8 μ m Erbium YAG laser combined with an irrigation supply. Similarly, the second laser 102 may be a laser having a wave length in the range of 400 nm to 1800 nm or it may be replaced by an electromagnetic transmitter in the range of 20 kHz to 10 GHz, or both infrared lasers may be replaced by an ultrasonic source capable of both: (i) cutting through the plate 14, and the boney structure 26, and (ii) heating and thereby softening the fastener 18.

The control unit 86 includes each of the first laser 94, the irrigation supply 98, and the second laser 102. The control unit 86 can include settings that are controlled by a user to determine the operation of the bone fixation system. For example, a user may at first set the control unit 86 to simultaneously supply the first laser 94, and the irrigation supply 98, to cut through the plate 14 and the bone 26, and then mid-procedure, change the control unit 86 to supply the second laser 102 to deform the fastener 18.

As shown in FIGS. 1, and 4A-4C, the hand piece 82 includes an elongated body 110 having a tip 114 at its distal end and a connecting portion 118 at its proximal end for connecting the body 110 to the cord 90. The elongated body 110 is generally a tube-like structure that is constructed to contain said first and second waveguides 95, 103 and/or irrigation tubes 126a, 126b, as shown in FIG. 4C. The first and second optical waveguides 95, 103 may be optical fibers, which are configured to transmit the beams of the first and

second laser **94** and **102** from the control unit **86** through the body **110** and to the tip **114**. Similarly, the irrigation tubes **126** are configured to transport the irrigation liquid from the control unit **86** through the body **110** and to the tip **114** and to suck the irrigation fluid off in the reverse direction, and can thus also be referred to as irrigation tubes. A fiber tip end **130** proximate to the distal end of the fastener disperses the beam of the first laser **94** as desired so as to allow the hole that is cut into the plate **14** and bone **26** to have a diameter that allows the fastener to pass through. The fiber tip end **130** can give way several mm back into the device **22**, to enable compression of the second axial portion **60** of the fastener inside the boney structure **26**. For example, as the fastener is compressed down by a user, the fiber tip end **130** may be retracted proximally either by translating proximally with respect to the handle, or by compressing, as a portion of such as the axial portion **60** of the fastener **18A** compresses or otherwise deforms.

Referring also to FIG. 3C, the first optical waveguide **95** is configured to extend through the bore **48** of the body **44** of the fastener **18**. In particular, the first optical waveguide **95** defines a diameter that is substantially equal to the diameter of the bore **48**. Thus, the bore **48** of the fastener **18** is sized to receive the first optical waveguide **95** that guides the beam of the first laser **94** such that there is little clearance between the first optical waveguide **95** and the internal surface **52** of the bore **48**. As a result, the first optical waveguide **95** substantially closes the inner radial ends of each of the recesses **56** so as to define a plurality of irrigation channels **59**, which extend along the length of the fastener **18**.

FIG. 4C illustrates a tip **114** configured to be used with a fastener such as fastener **18**, as shown in FIG. 2A, and fasteners **18A**, and **18B** including irrigation channels **59** as shown in FIGS. 3A and 3D. The tip **114** is configured to grip and hold or otherwise support the fasteners. The proximal end P of the fastener **18** can comprise an attachment portion **45** that can be e.g. configured as a cylindrical portion dimensioned for a press fit with a corresponding bore **140** in the tip **114**. As shown, the tip **114** includes a channel **144** extending from a wall **146** and toward the distal end of the tip **114**, and a bore **140** that extends proximally from the distal end of the tip **114** in alignment with the channel **144**. The bore **140** defines a diameter greater than that of the channel **144**, such that the tip **114** provides a seat **148** at the interface between the bore **140** and the channel **144**. The interface abuts and supports the fastener **18** at the distal end of the channel **144** when the fastener **18** is fully inserted or otherwise disposed in the bore **140**. The channel **144** is separated into an injection segment **145a** for injecting an irrigation liquid and a suction segment **145b** allowing to suck off the irrigation liquid together with the debris. The hand piece body **110** further includes a first and a second port **150**, **151** extending into the tip **114**. Each of the first and second ports **150**, **151** has a coupling **154** at its proximal end for coupling an irrigation tube **126a**, **126b** thereto and an opening **158** at its distal end. The openings **158** of the first and second port **150**, **151** extend into the channel **144** so as to place the channel **144** in fluid communication with the couplings **154** of the first and second port **150**, **151**.

The bore **140** is sized to receive and hold a fastener such as fasteners **18A** or **18B** as described above, and the channel **144** is configured to guide the irrigation liquid of the irrigation supply **98** from the port opening **158** to two irrigation channels **59** of the fastener which can be recesses **56** or closed passages **57** and to suck the irrigation fluid and the debris off through the third irrigation channel **59** of the fastener **18**.

A first irrigation tube **126a** is connected to the coupling **154** of the first port **150**, and the irrigation liquid of the irrigation

supply **98** travels through the first irrigation tube **126a**, into the injection segment **145a** of the channel **144** via the first port **150** and through two irrigation channels **59** of the fastener. A second irrigation tube **126b** is connected to the coupling **154** of the second port **151**, and the irrigation fluid with the debris can be sucked off through the third irrigation channel **59** of the fastener **18** defined by the third irrigation channel **59** into the suction segment **145b** of the channel **144** and via the second port **151** into the second irrigation tube **126b**.

The beam of the first laser **94** and the irrigation liquid of the irrigation supply **98** may simultaneously travel longitudinally through the fastener **18A** and out the distal end D of the fastener **18A** to thereby cut the hole into the plate **14** and/or the bone **26**. As shown, the beam of the second laser **102** may be guided to a front or proximal wall **160** of the fastener **18A**. When the second laser **102** is activated, the light travels through the transparent first axial portion **64** of the fastener **18A**, and is absorbed by the laser absorbing second axial portion **60**. Alternatively, when using a fastener **18** according to FIGS. 2A to 2C the light travels through the thermoplastic material in the core portion **50** and is absorbed by the laser absorbing colored thermoplastic material of the peripheral portion **51** adjoining the external surface **55** of the fastener **18**, and by the adjacent portion of the plate **14**.

The tip **114** may be a sterile single use part that may consist of a fastener, such as anyone of fasteners **18**, **18A**, or **18B** and the fiber tip end **130** that is configured to adequately cut through the bone **26** (note that the fiber tip end may be shaped in a way to disperse the laser beam, so that it is actually possible to drill a hole that is large enough to fit the fastener—which is larger than the fiber tip. The single use part may be configured to be selectively attached to or detached from a distal end of the body **110**. The single use part may also be made from a material that is capable of being placed in an autoclave.

FIG. 4D illustrates another embodiment of the tip **114** configured to be used with a fastener **18** as illustrated in FIGS. 2A to 2C. The embodiment of the tip **114** according to FIG. 4D differs from the embodiment of FIG. 4C only therein that the tip **114** comprises a sleeve **156** affixed to the tip **114** and comprising two or more bore holes **157** in fluid communication with the channel **144**. The sleeve **156** can be inserted into the bore **48** of the fastener **18** and surrounds the first optical waveguide **95**. The two or more bore holes **157** are arranged circumferentially equally spaced and suitable to guide the irrigation liquid of the irrigation supply **98** from the channel **144** to the tip **130**. The channel **144** is separated into an injection segment **145a** for injecting the irrigation liquid and a suction segment **145b** allowing to suck off the irrigation liquid together with the debris. The injection segment **145a** is configured to guide the irrigation liquid of the irrigation supply **98** from the port opening **158** through two or more bore holes **157** in the sleeve **156** that is inserted in the bore **48** of the fastener **18** and the suction segment **145b** is configured to suck the irrigation fluid and the debris off through one or more of the bore holes **157** in the sleeve **156**.

In operation and in reference to FIGS. 5A-5D the surgical device **22** may affix the plate **14** and the fastener **18** (or **18A** or **18B**) in a simple and efficient manner. As shown in FIG. 5A, the fastener **18** is placed into the tip **114** of the hand piece **82** such that the fastener **18** partially extends distally of the tip **114**, and the plate **14** is positioned on the bone **26** over the fractured area. The hand piece **82** along with the fastener **18** may then be positioned on the surface of the plate **14** and at an angle of 90° with respect to the plate **14**, or offset with respect to the 90° angle if desired. Once the hand piece **82** is positioned, the control unit **86** may be activated to cause the beam

11

of the first laser **94** and the irrigation supply **98** to cut or drill a hole **55** through the plate **14** and into the bone **26** if desired. As shown in FIG. **5B**, the first laser **94** and the irrigation liquid of the irrigation supply **98** travel through the bore **48** of the fastener **18** and out a distal end of the fastener **18**. As the hole **55** is being cut, the hand piece **82** and thus the fastener **18** may be gently pushed into the hole as it is created over time.

Once the desired depth of the hole is reached and the fastener **18** is properly positioned within the hole, the control unit **86** may be switched to deactivate the first laser **94** and the irrigation supply **98**, and activate the second laser **102** to thereby deform a portion of the fastener **18**. As shown in FIG. **5C**, the beam of the second laser **102** may soften and deform the fastener **18** and the interface between the plate **14** and the fastener **18**. A gentle push of the device **22** in the direction of said longitudinal axis **49** into the hole **55** causes a portion of the fastener **18** to deform and define an outer dimension that is greater than that of the hole **55**. Thus, the fastener **18** transforms into a rivet **170** that couples the plate **14** to the bone **26**.

The bone fixation procedure described above can be performed to fix the bone plate **14** to one or more bone segments of the bone **26** that are separated by a fracture. For instance, the bone plate **14** is positioned over the fracture site or fracture sites, and one or more fasteners can couple the plate **14** to each bone segment in the manner described above.

As shown in FIG. **5D**, the device **22** may be removed, while the plate **14** and fastener **18** remain behind. The plate **14** and fastener **18** may be made from a resorbable material.

The foregoing description is provided for the purpose of explanation and is not to be construed as limiting the invention. While various embodiments have been described with reference to preferred embodiments or preferred methods, it is understood that the words which have been used herein are words of description and illustration, rather than words of limitation. Furthermore, although the embodiments have been described herein with reference to particular structure, methods, and embodiments, the invention is not intended to be limited to the particulars disclosed herein. Moreover, any of the embodiments described above can incorporate any structures or features of any of the other embodiments described above, as desired. Those skilled in the relevant art, having the benefit of the teachings of this specification, may effect numerous modifications to the invention as described herein, and changes may be made without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A surgical system comprising:

a surgical fastener having a fastener body that defines a proximal end and a distal end that is spaced from the proximal end along a longitudinal axis, the body having a bore that extends into the body along the longitudinal axis; and

a surgical device configured to implant the surgical fastener into a target anatomical location, the surgical device including:

a hand piece having a hand piece body that is configured to support the surgical fastener,

a cutting mechanism that is configured to extend through the bore of the fastener when the fastener is supported by the hand piece body, the cutting mechanism configured to cut into the target anatomical location, and an energy source that is coupled to the hand piece body and configured to heat and soften a portion of the fastener body;

12

wherein the fastener body is absorptive to energy emitted from the energy source, such that when the fastener is supported by the hand piece body and energy is applied by the energy source to the fastener body, the fastener body softens and deforms.

2. The surgical system of claim **1**, wherein the hand piece of the surgical device further comprises a tip that extends from the hand piece body and supports the fastener.

3. The surgical system of claim **1**, wherein the surgical device further comprises a control unit that is configured to supply the cutting mechanism and the energy source.

4. The surgical system of claim **3**, wherein the control unit is tethered to the handpiece.

5. The surgical system of claim **1**, wherein the cutting mechanism of the surgical device comprises a first laser.

6. The surgical system of claim **5**, wherein the first laser is a 3 μ m infrared laser, a 10 μ m CO₂ laser, or a 2.8 μ m Erbium YAG laser.

7. The surgical system of claim **5**, wherein the cutting mechanism further comprises an irrigation supply.

8. The surgical system of claim **7**, wherein the bore of the surgical fastener extends completely through the fastener body.

9. The surgical system of claim **1**, wherein the energy source of the surgical device comprises a 800 nm laser.

10. The surgical system of claim **1**, wherein the energy source of the surgical device is an ultrasonic source.

11. The surgical system of claim **1**, wherein the surgical fastener comprises a thermoplastic material.

12. A surgical system of comprising:

a surgical fastener having a generally cylindrical fastener body that is elongate from a distal end to a proximal end along a longitudinal axis, the fastener body defining a central bore that longitudinally extends through the fastener body from the distal end to the proximal end, the fastener body being absorptive to the application of energy by an energy source; and

a surgical device configured to implant the surgical fastener into a target anatomical location, the surgical device including:

a hand piece including an elongated hand piece body having a tip sized and dimensioned to detachably engage and retain the surgical fastener, the hand piece including a first waveguide and a second waveguide, a control unit capable of selectively and individually transmitting 1) a first energy source through the first waveguide and into the central bore of the surgical fastener when the fastener is disposed in the tip, and 2) a second energy source through the second waveguide,

wherein application of the first energy source causes the surgical device to cut into the target anatomical location, and application of the second energy source causes the fastener body to soften and deform.

13. The surgical system of claim **12**, wherein at least one of the first and second waveguides of the surgical device are optical waveguides.

14. The surgical system of claim **12**, wherein the control unit of the surgical device further includes an irrigation supply configured to supply a coolant liquid to the tip near the tip end to remove debris created by application of the first energy source.

15. The surgical system of claim **14**, wherein the coolant liquid and the first energy source are transmitted by the control unit at the same time.

16. The surgical system of claim **12**, wherein the first energy source of the surgical device comprises a first laser.

17. The surgical system of claim 16, wherein the first laser is a 3 μm infrared laser, a 10 μm CO₂ laser, or a 2.8 μm Erbium YAG laser.

18. The surgical system of claim 12, wherein the second energy source of the surgical device comprises a 800 nm laser. 5

19. The surgical system of claim 12, wherein the second energy source of the surgical device is an ultrasonic source.

20. The surgical system of claim 12, wherein the portion of the surgical fastener is a thermoplastic material.

21. The surgical system of claim 12, wherein the first 10 waveguide of the surgical device further includes a tip end that is configured to extend through the central bore of the surgical fastener when the fastener is disposed in the tip.

* * * * *

专利名称(译)	骨固定系统		
公开(公告)号	US9237914	公开(公告)日	2016-01-19
申请号	US14/694075	申请日	2015-04-23
[标]申请(专利权)人(译)	DePuy公司SYNTHES产品，INC.		
申请(专利权)人(译)	DePuy公司SYNTHES PRODUCTS，INC.		
当前申请(专利权)人(译)	DePuy公司SYNTHES PRODUCTS，INC.		
[标]发明人	NARDINI RETO FRIGG ROBERT		
发明人	NARDINI, RETO FRIGG, ROBERT		
IPC分类号	A61B17/84 A61B17/88 A61B17/86 A61B17/70 A61B18/20 A61B18/04 A61B17/16 A61B18/22 A61B18/28 A61B17/00 A61B18/00		
CPC分类号	A61B17/84 A61B17/16 A61B17/1624 A61B17/7059 A61B17/864 A61B17/866 A61B17/8863 A61B17/8872 A61B18/04 A61B18/20 A61B17/1617 A61B17/1626 A61B17/1628 A61B17/1633 A61B17/8685 A61B18/22 A61B18/28 A61B2017/00004 A61B2017/00039 A61B2017/00106 A61B2017/00371 A61B2017/00389 A61B2017/1651 A61B2018/00029 A61B2018/00178 A61B2018/00565 A61B2018/00601 A61B2018/00994 A61B2217/005 A61B2217/007 A61B2218/002 A61B18/18 A61B17/68 A61B17/80 A61B17/844 A61B2018/207 A61B2018/2285 Y10T428/28		
审查员(译)	THOMSON，WILLIAM		
助理审查员(译)	夏皮罗VICTOR		
优先权	61/417614 2010-11-29 US 61/320883 2010-04-05 US		
其他公开文献	US20150223855A1		
外部链接	Espacenet USPTO		

摘要(译)

提供了一种骨固定系统。骨固定系统可包括板，一个或多个紧固件，其构造成将板附接到目标解剖位置（例如骨），以及外科手术装置，其有助于板和紧固件的附接。

