UNITED STATES DISTRICT COURT
FOR THE
WESTERN DISTRICT OF TEXAS

BIOMEDICAL ENTERPRISES, INC. Plaintiff, v. SOLANA SURGICAL, LLC, WRIGHT MEDICAL GROUP, INC., and WRIGHT MEDICAL TECHNOLOGY, INC. Defendants.	)	Civil Action No. 1:14-cv-00095-LY JURY TRIAL DEMANDED

PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff Biomedical Enterprises, Inc., in its amended complaint against defendants Solana Surgical, LLC, Wright Medical Group, Inc., and Wright Medical Technology, Inc. ("Defendants"), respectfully alleges as follows:

THE PARTIES

1. Plaintiff BioMedical Enterprises, Inc. ("BME") is a corporation organized and existing under the laws of the State of Texas with a principal place of business within the Western District of Texas at 14785 Omicron Drive, Suite 205, San Antonio, Texas 78245.

2. BioMedical Enterprises is a reconstructive bone fusion product company and the worldwide leader in the understanding of memory metal and its orthopedic applications. BME was the first company to introduce above body temperature shape changing memory metal staples to the U.S., the first to develop and patent a method of controlling their compressive forces and the only U.S.-based memory metal small bone implant manufacturer. The BME implants are fabricated from Nitinol, a nickel-titanium alloy, and change shape when exposed to predetermined temperatures to provide fixation of bone or soft tissue to bone. The implants are

provided in sterile ready-to-use packaging for various procedures, including hammertoe and other foot conditions, wrist and hand arthritis, and high tibial osteotomy.

3. On information and belief, defendant Solana Surgical, LLC ("Solana") is a California corporation with its principal place of business located at 6363 Poplar Avenue, Suite 312, Memphis TN 38119.

4. On information and belief, defendant Wright Medical Group, Inc. is a Delaware corporation with is principal place of business at 1023 Cherry Road, Memphis, TN 38117.

5. On January 30, 2014, defendant Wright Medical Group, Inc. announced that it had acquired Solana.

6. On information and belief, defendant Wright Medical Group, Inc. operates through its subsidiary, defendant Wright Medical Technology, Inc.

7. On information and belief, defendant Wright Medical Technology, Inc. is a Delaware corporation with is principal place of business at 1023 Cherry Road, Memphis, TN 38117.

JURISDICTION AND VENUE

8. This action for patent infringement arises under the patent laws of the United States, Title 35 of the United States Code.

9. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 (jurisdiction over federal questions) and 28 U.S.C. § 1338(a) (jurisdiction over civil actions arising under any Act of Congress relating to patents).

10. This Court has personal jurisdiction over Defendants. On information and belief, Defendants are subject to this Court's specific and general personal jurisdiction pursuant to due process and/or the Texas Long Arm Statute, due at least to Defendants' substantial business in

this forum, including: (i) at least a portion of the infringements alleged herein; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided to individuals in Texas and in this district. Upon information and belief, Defendants are selling and offering to sell, and have within a reasonable period prior to the filing of this action, sold and offered to sell its products, including one or more of the infringing products, such as the FuseFORCE Fixation System, to customers in this state and in this district, either directly or indirectly.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and 1400(b).

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,584,853

12. BME repeats and re-alleges the allegations of paragraphs 1 through 11 as if fully set forth herein.

13. On November 19, 2013, United States Patent No. 8,584,853 ("the '853 Patent") entitled "METHOD AND APPARATUS FOR AN ORTHOPEDIC FIXATION SYSTEM" was duly and properly issued by the United States Patent and Trademark Office. A true and correct copy of the '853 Patent is attached to this Complaint as Exhibit A.

14. Plaintiff BME is the assignee and owner of the right, title, and interest in and to the '853 Patent.

15. On information and belief, Defendants have infringed and continue to infringe one or more claims of the '853 Patent in violation of 35 U.S.C. § 271(a) in the United States by making, using, offering to sell, or selling products that infringe one or more claims of the '853 Patent, including, without limitation, claim 15. Defendants' infringing products include, but are not limited to, the FuseFORCE Fixation System.

16. On information and belief, Defendants either knew of the '853 Patent or were

willfully blind in order not to become aware of the '853 Patent. Defendants also have knowledge of the '853 Patent and the infringement of it as of the filing of this Amended Complaint.

17. On information and belief, Defendants also have infringed and continue to infringe one or more of the claims of the '853 Patent in violation of 35 U.S.C. § 271(b) and/or (c) in this judicial district and elsewhere in the United States by actively inducing others to infringe and/or contributing to the infringement by selling the system to doctors located within this judicial district and elsewhere, and actively encouraging the doctors to use the system.

18. On information and belief, Defendants have acted in concert with users of its infringing products, such as doctors located within this judicial district and elsewhere, to infringe the '853 Patent. Defendants continue to knowingly induce infringement and possesses specific intent to encourage their users' infringement.

19. BME has suffered irreparable harm as a result of Defendants' infringement of '853 Patent and will continue to suffer irreparable harm unless Defendants are enjoined from infringing the '853 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court:

a. To enter a judgment in favor of BME that Defendants have infringed the '853 Patent in violation of 35 U.S.C. § 271(a), (b), and/or (c);

b. To enter orders enjoining Defendants and their officers, agents, employees, and all persons in active concert or participation with any of the foregoing, from further infringement in violation of 35 U.S.C. § 271(a), (b), and/or (c);

c. To award BME its damages in amounts sufficient to compensate it for Defendants' infringement, together with pre-judgment and post-judgment

interest and costs, pursuant to 35 U.S.C. § 284;

d. To find Defendants' infringement willful and award treble the amount of damages and losses sustained by BME as a result of Defendants' infringement under 35 U.S.C. § 284;

e. To declare this case to be exceptional under 35 U.S.C. § 285 and to award BME its attorneys' fees, expenses, and costs incurred in this action; and

f. To award BME any and all other relief which this Court deems just and proper.

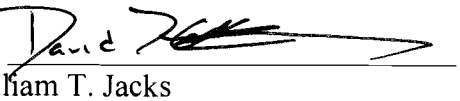
DEMAND FOR JURY TRIAL

BME has previously requested a trial by jury of any and all issues on which a trial by jury is available under applicable law.

Dated: February 27, 2015

Respectfully submitted,

FISH & RICHARDSON P.C.

By: 

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COUNSEL FOR BIOMEDICAL ENTERPRISES, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document was filed traditionally in compliance with Local Rule CV-5(a)(2) on February 27, 2015, and was served on counsel of record below via electronic mail and Certified Mail / Return Receipt Requested on February 27, 2015.

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EXHIBIT A

US008584853B2

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

(10) **Patent No.: US 8,584,853 B2**
(45) **Date of Patent: Nov. 19, 2013**

(54) **METHOD AND APPARATUS FOR AN ORTHOPEDIC FIXATION SYSTEM**

(75) Inventors: **Adam T. Knight**, San Antonio, TX (US); **Daniel F. Cheney**, San Antonio, TX (US); **Eric A. Marcano**, San Antonio, TX (US); **David J. Pancratz**, Helotes, TX (US)

(73) Assignee: **BioMedical Enterprises, Inc.**

(*) 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.: **13/385,387**

(22) Filed: **Feb. 16, 2012**

(65) **Prior Publication Data**

US 2013/0213843 A1 Aug. 22, 2013

(51) **Int. Cl.**

A61B 19/02	(2006.01)
A61B 17/08	(2006.01)
B65D 83/10	(2006.01)
B65D 85/24	(2006.01)

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

USPC **206/439**; 206/339; 206/363; 206/370; 206/570; 606/104; 606/219

(58) **Field of Classification Search**

USPC 206/63.3, 363, 368 370, 438, 439, 206/570–572, 210, 339; 606/102–105, 606/213–220

See application file for complete search history.

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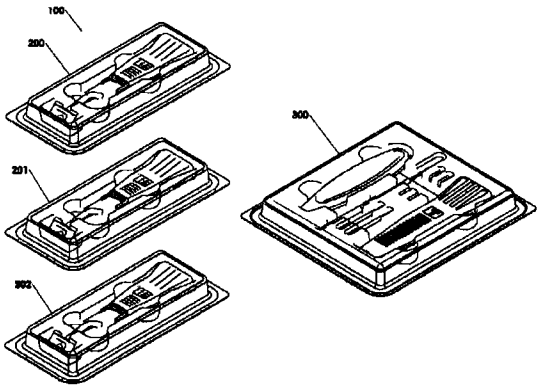
* cited by examiner

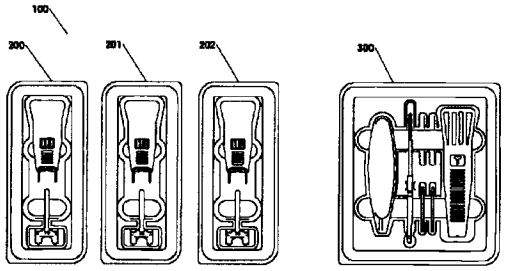
Primary Examiner — Bryon Gehman
(74) *Attorney, Agent, or Firm* — Christopher L. Makay

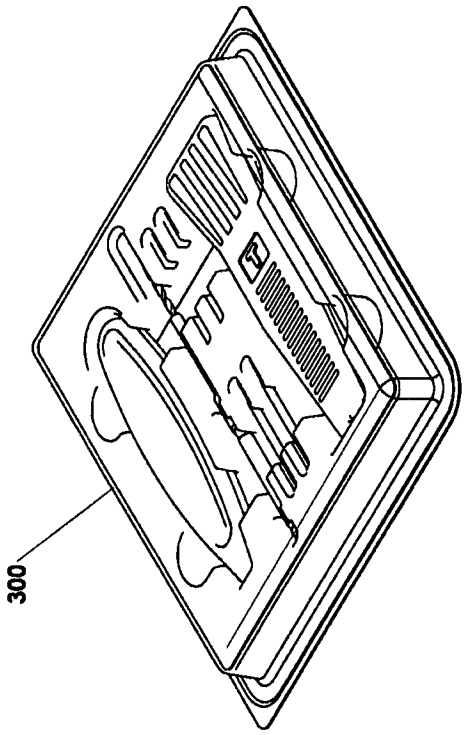
(57) **ABSTRACT**

An orthopedic fixation system includes a sterile packaged implant kit and a sterile packaged instrument kit. The sterile packaged implant kit includes at least one surgical implant, an insertion device, and an implant package adapted to receive the at least one surgical implant and the insertion device therein. The implant package maintains the at least one surgical implant and the insertion device sterile after sterilization of the sterile packaged implant kit. The sterile packaged instrument kit includes one or more instruments necessary to use the sterile packaged implant kit and an instrument package adapted to receive the one or more instruments therein. The instrument package maintains the one or more instruments sterile after sterilization of the sterile packaged instrument kit.

24 Claims, 18 Drawing Sheets







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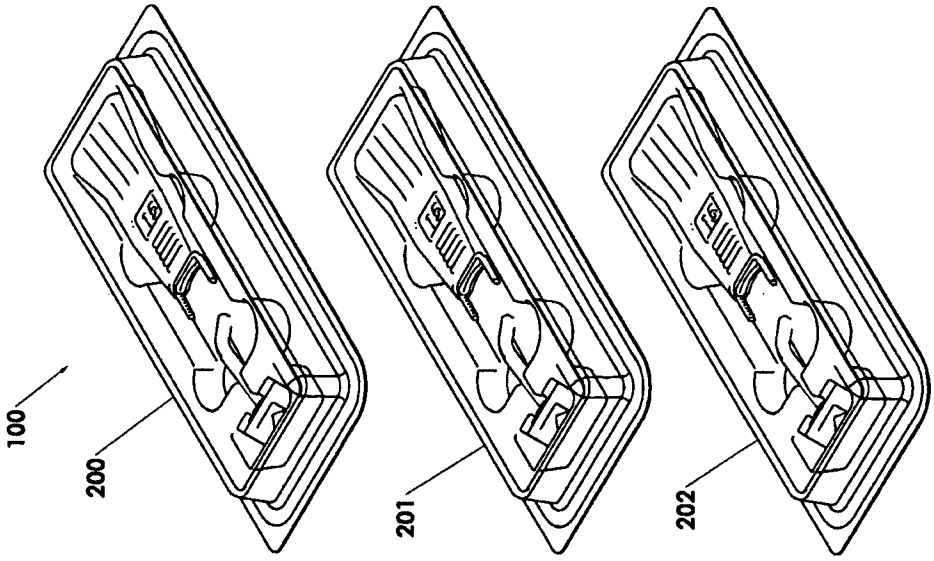

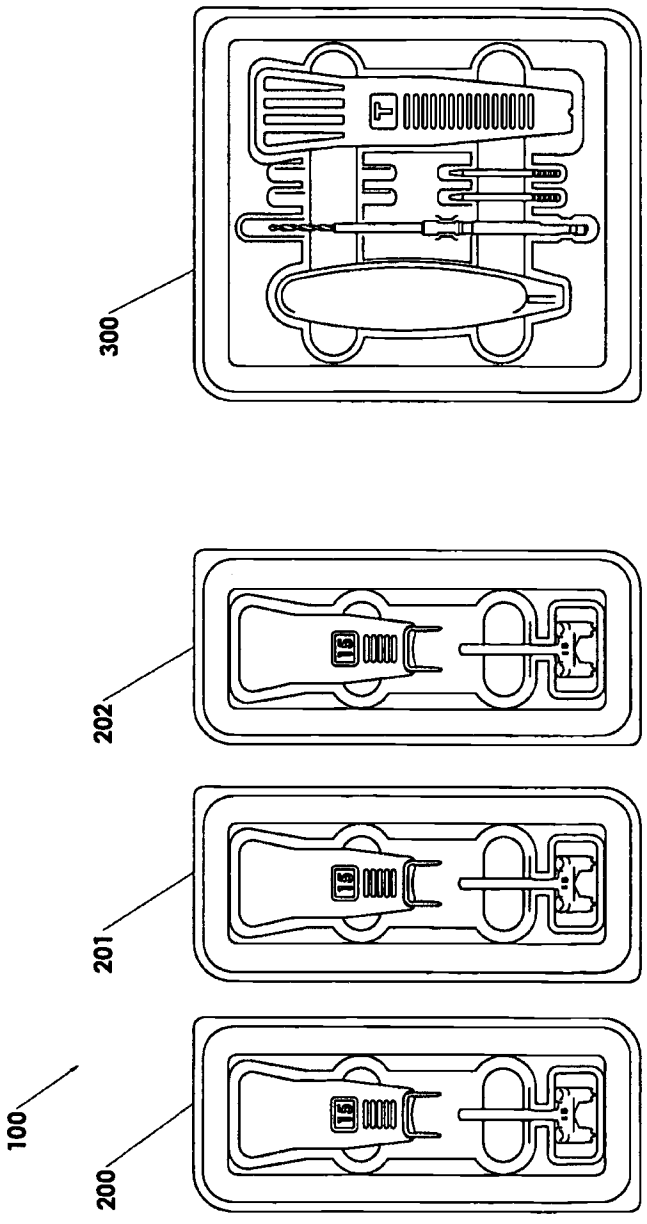

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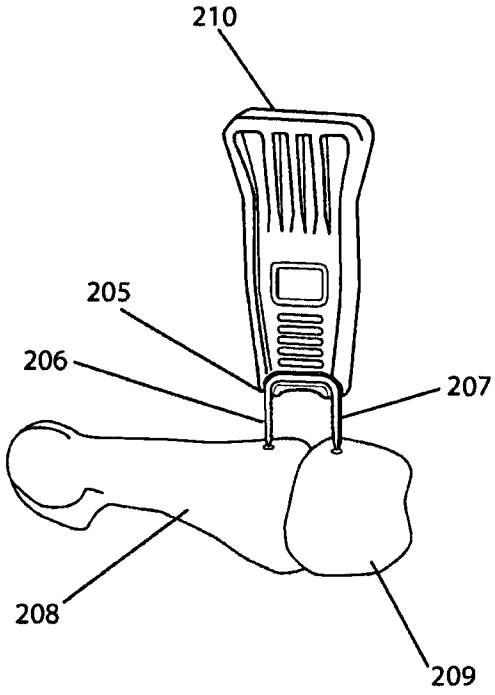

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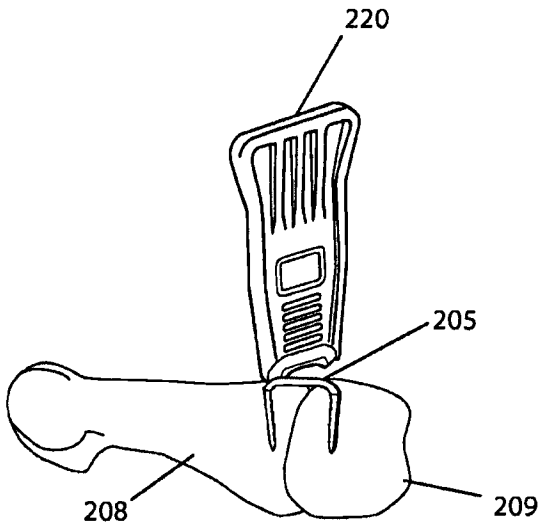


Figure 2B

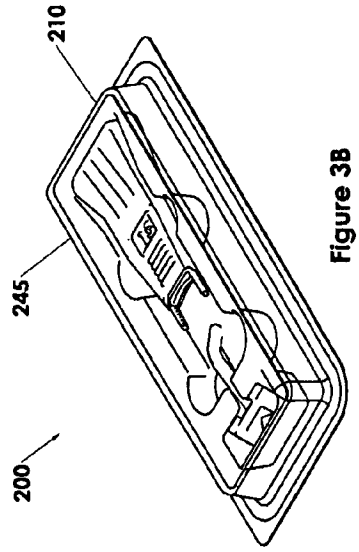


Figure 3B

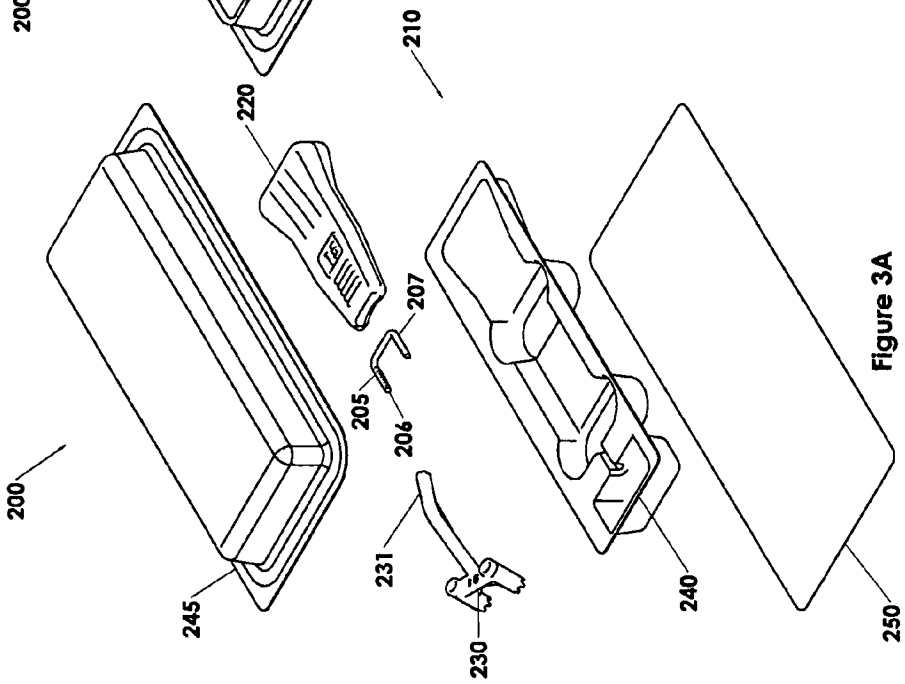
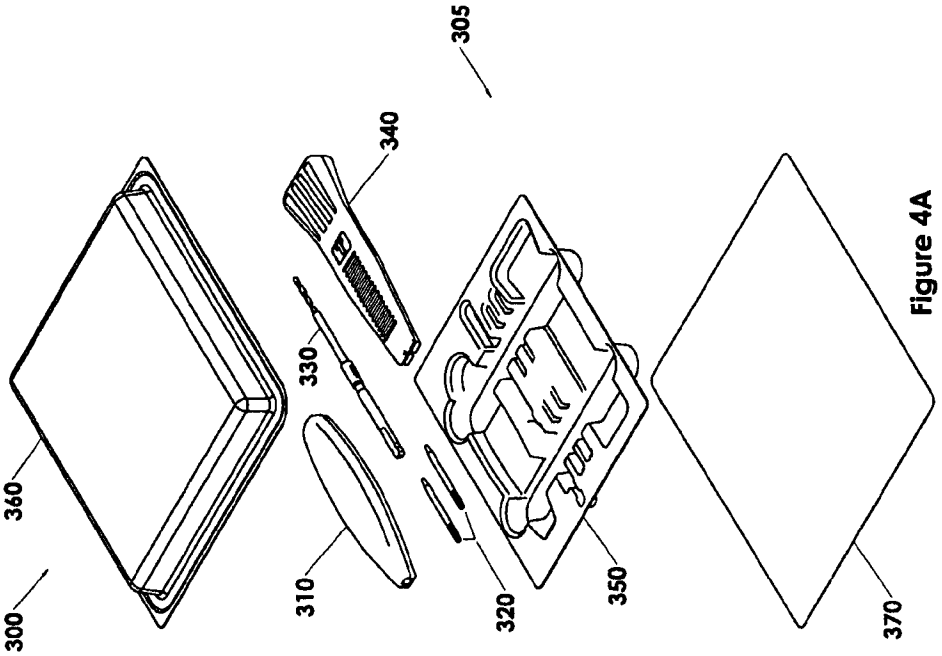


Figure 3A



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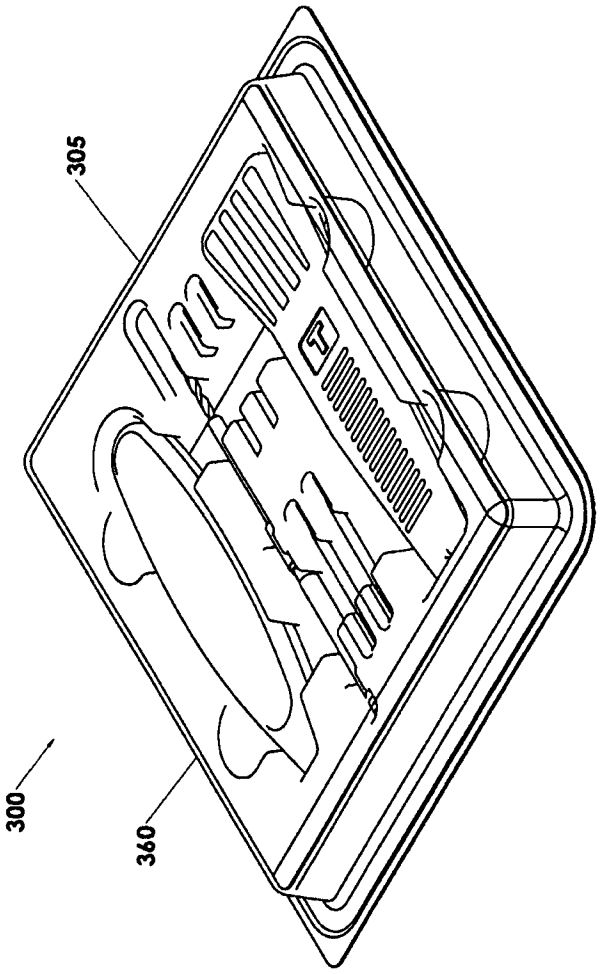

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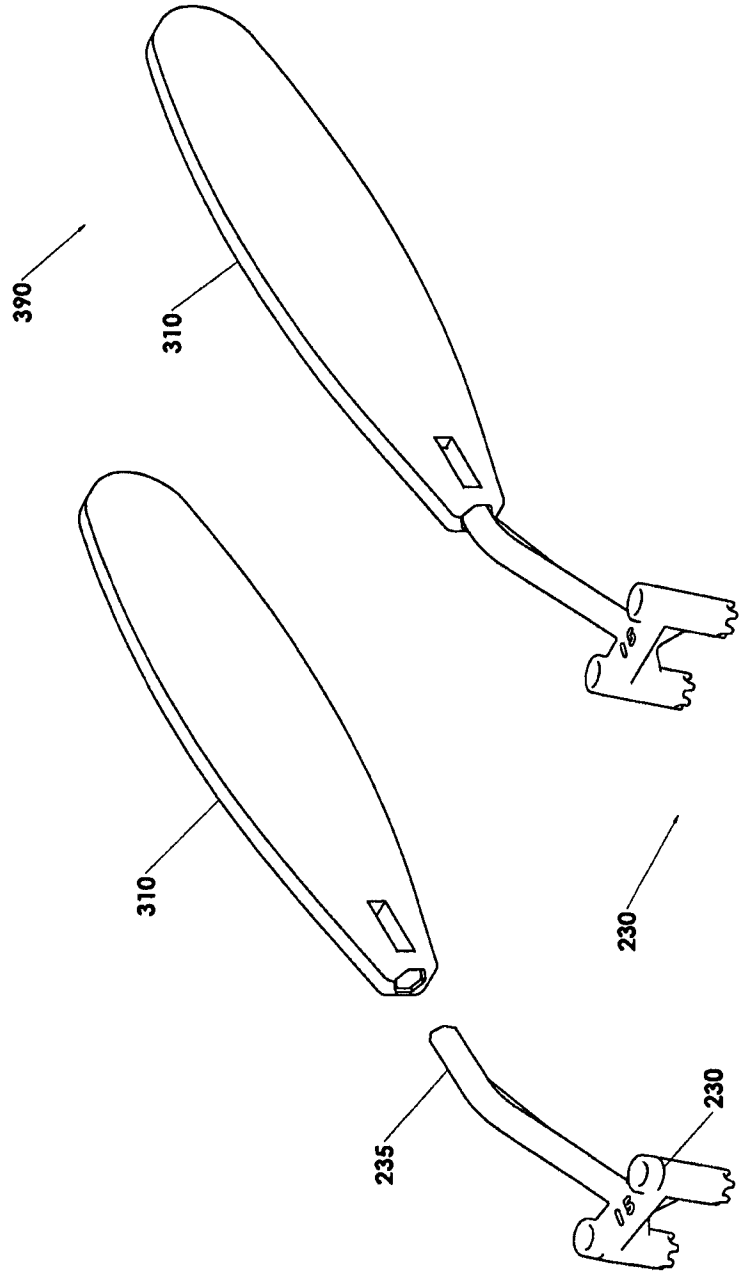
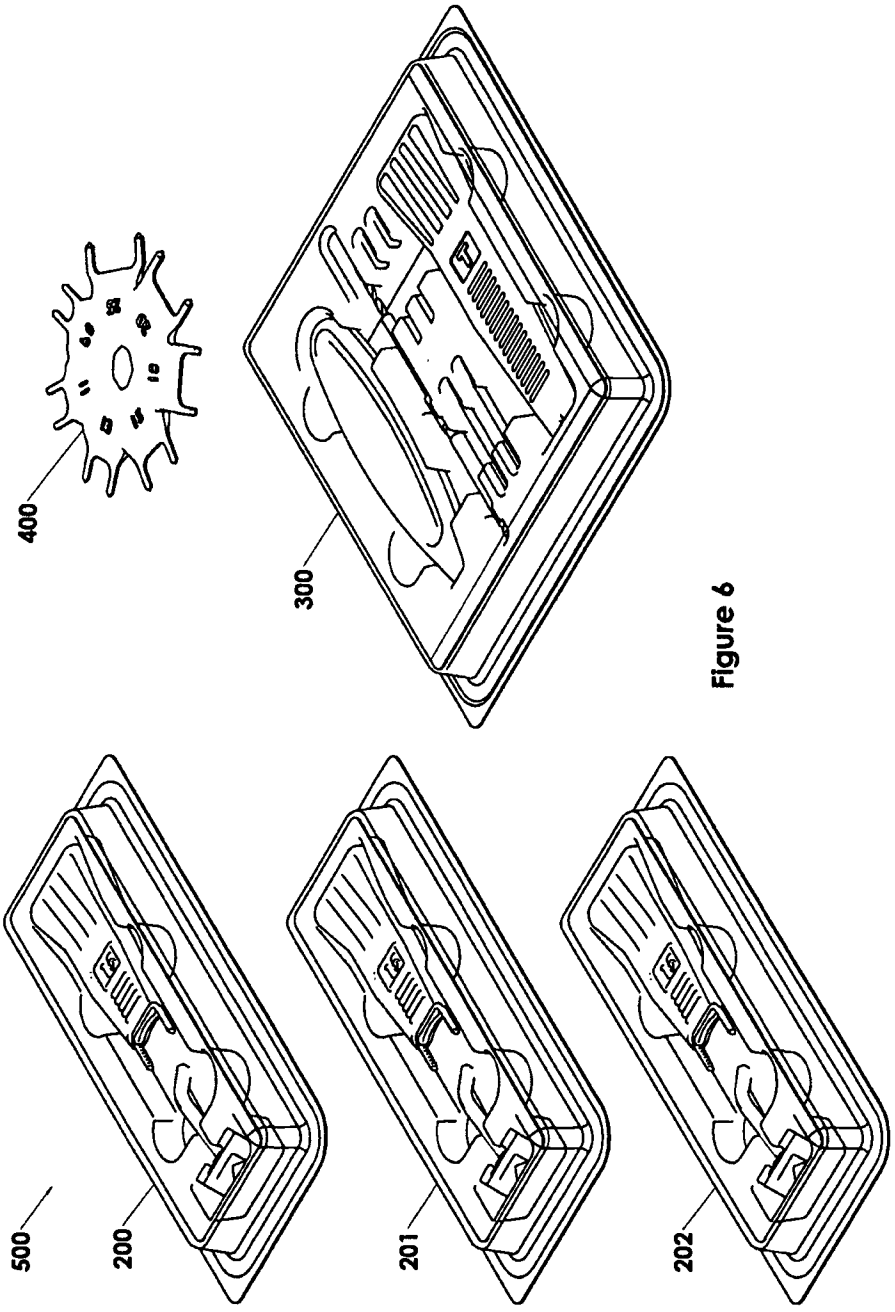


Figure 5B

Figure 5A



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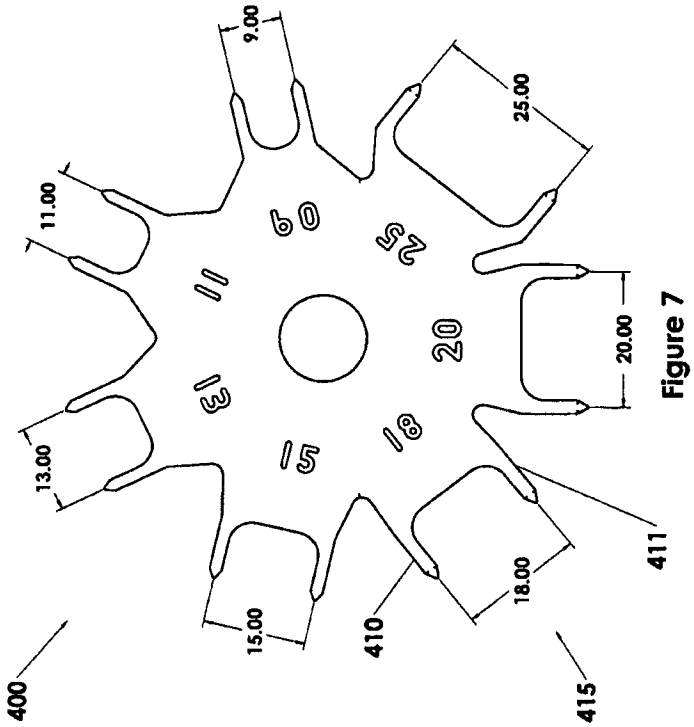

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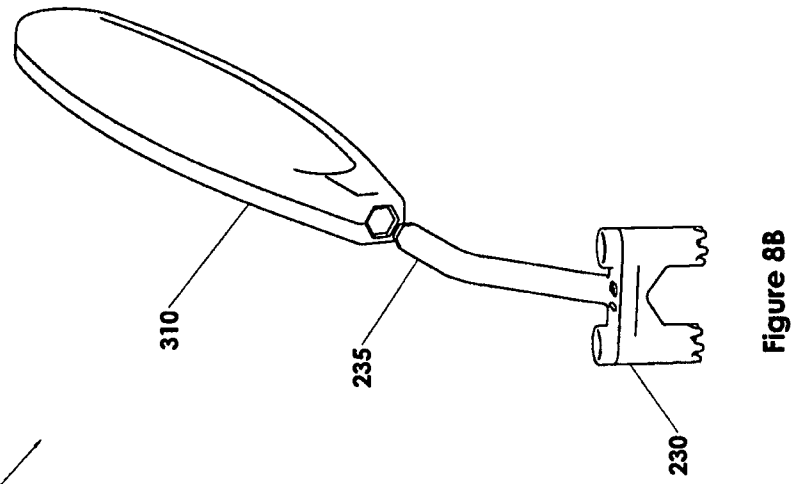

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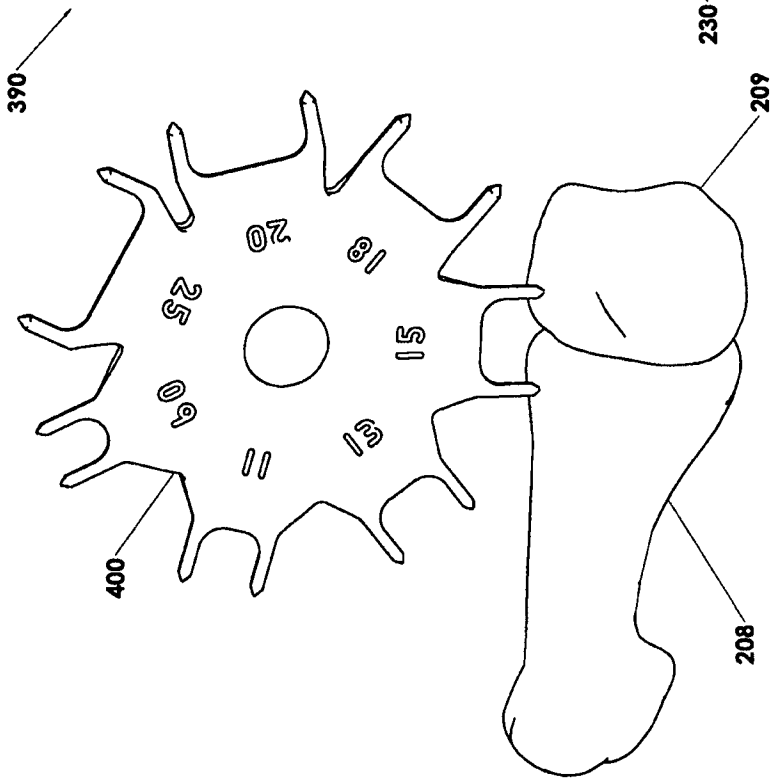

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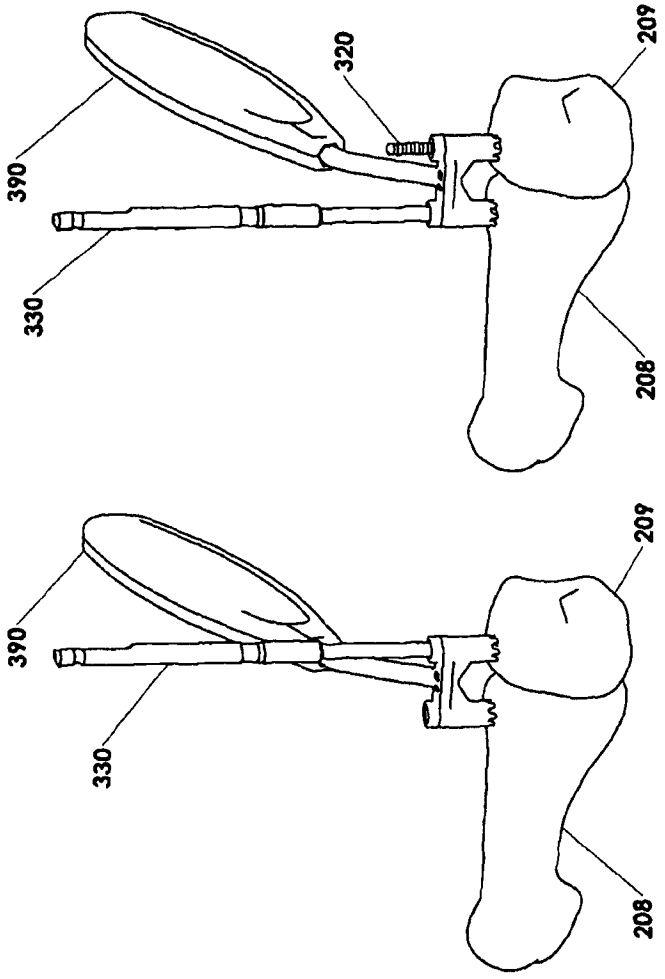


Figure 8D

Figure 8C

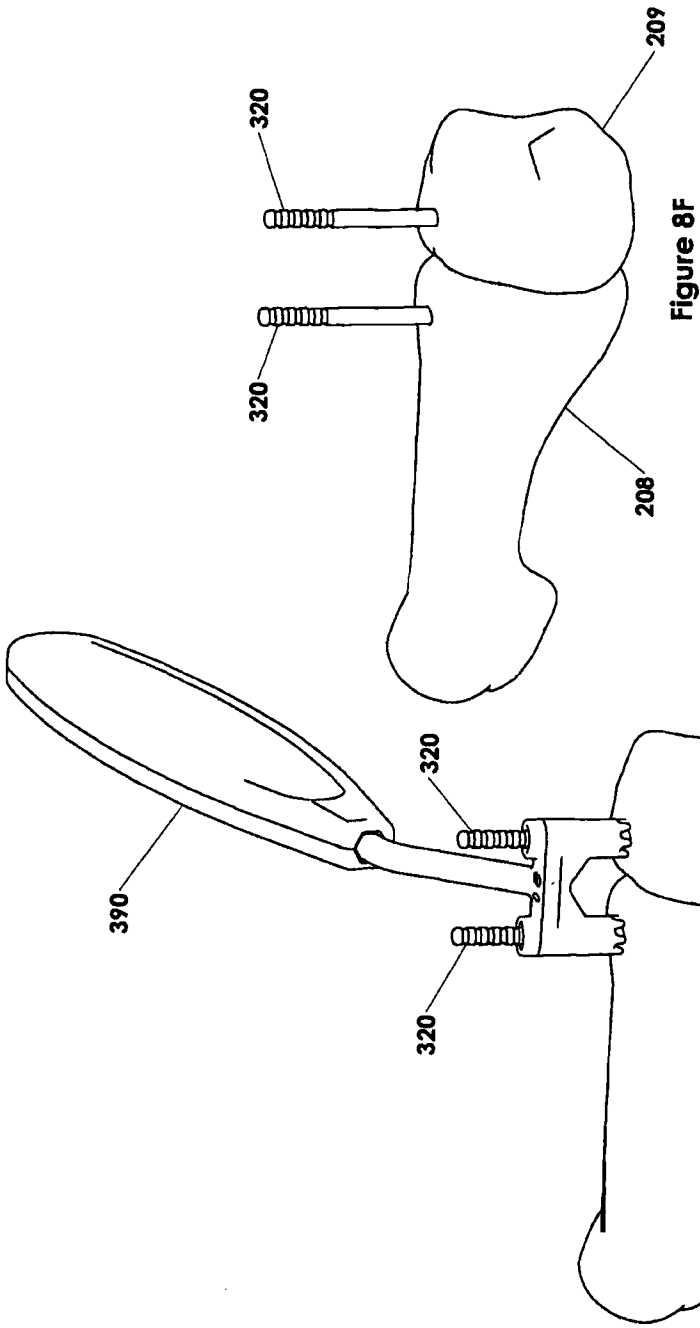


Figure 8F

Figure 8E

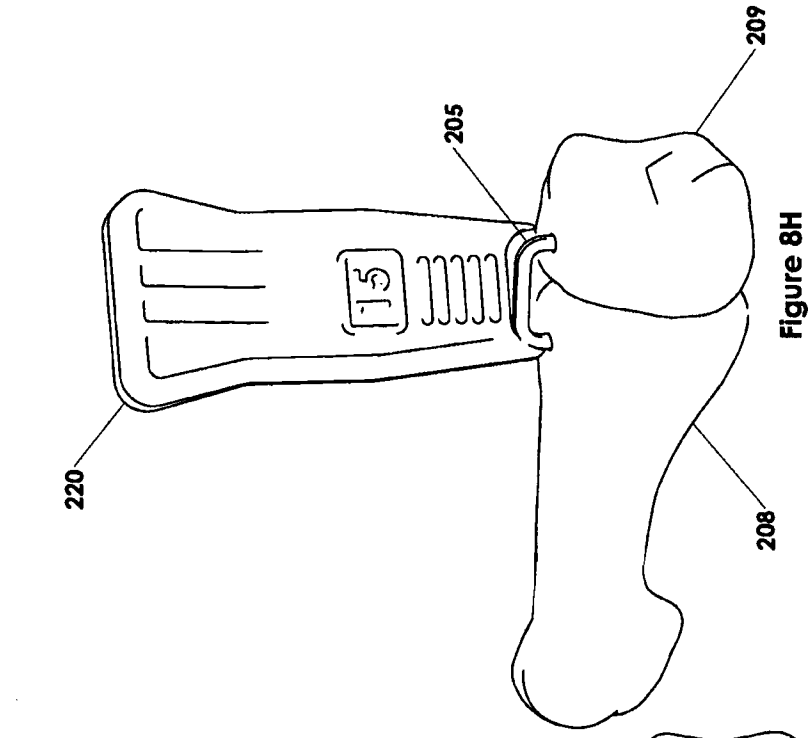


Figure 8H

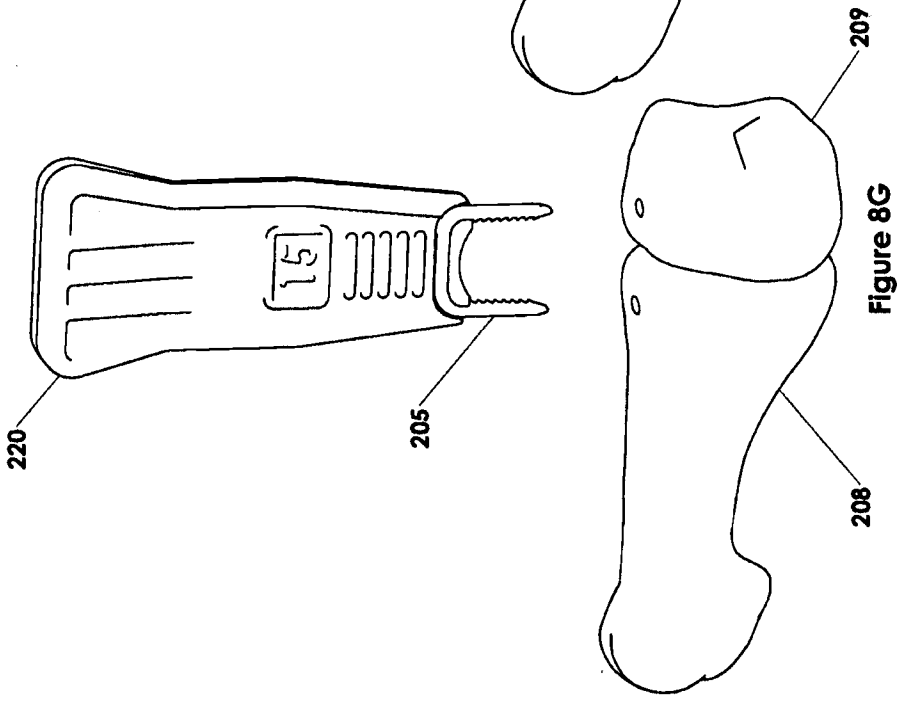
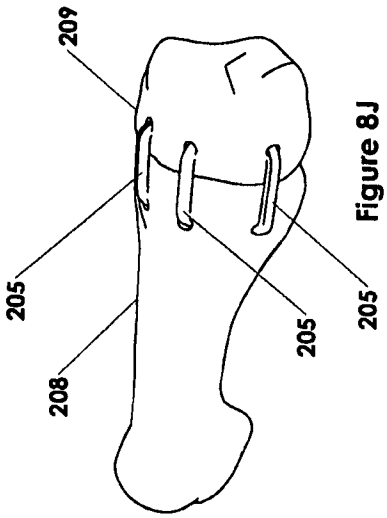


Figure 8G



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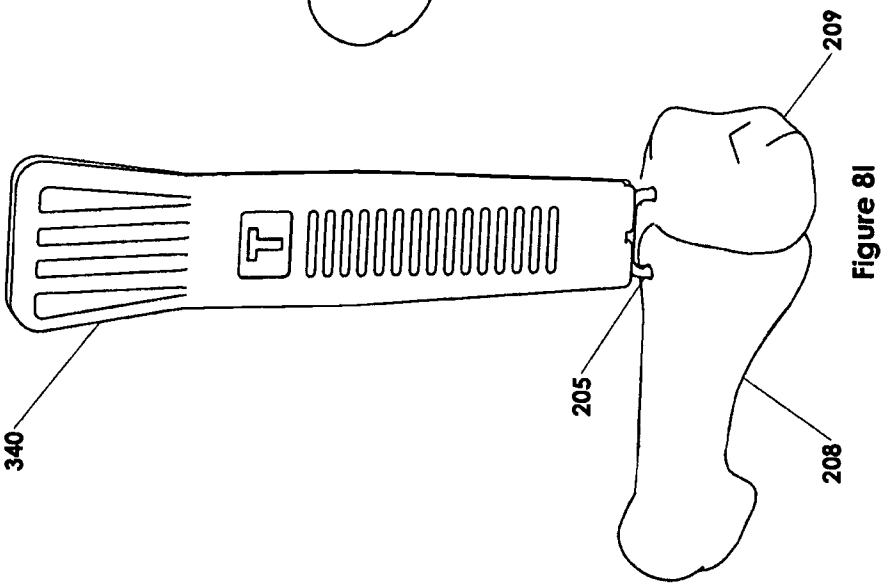

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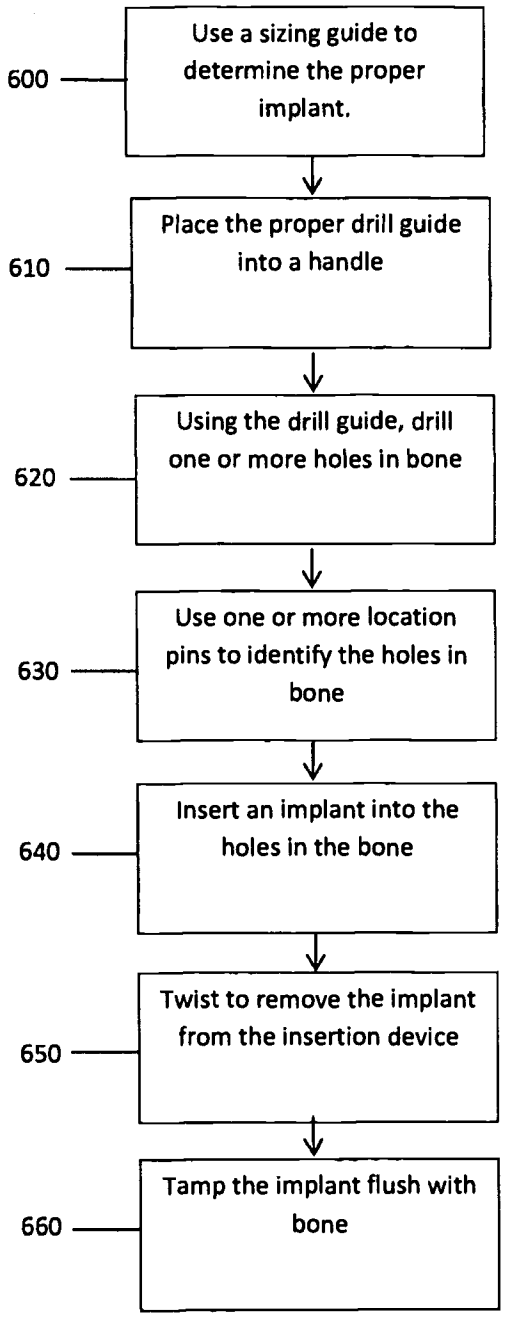
600
Use a sizing guide to determine the proper implant.
610
Place the proper drill guide into a handle
620
Using the drill guide, drill one or more holes in bone
630
Use one or more location pins to identify the holes in bone
640
Insert an implant into the holes in the bone
650
Twist to remove the implant from the insertion device
660
Tamp the implant flush with bone

Figure 9

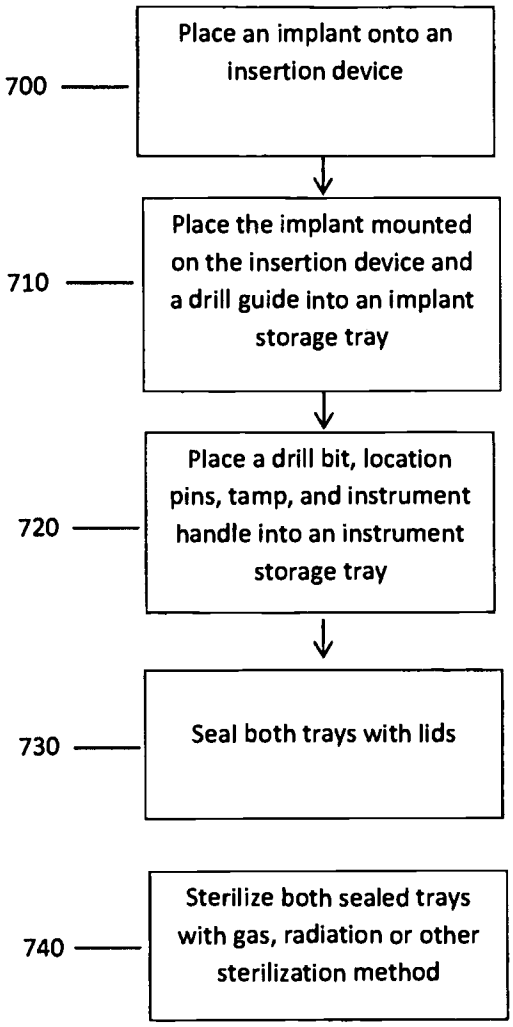
700
Place an implant onto an insertion device
710
Place the implant mounted on the insertion device and a drill guide into an implant storage tray
720
Place a drill bit, location pins, tamp, and instrument handle into an instrument storage tray
730
Seal both trays with lids
740
Sterilize both sealed trays with gas, radiation or other sterilization method

Figure 10

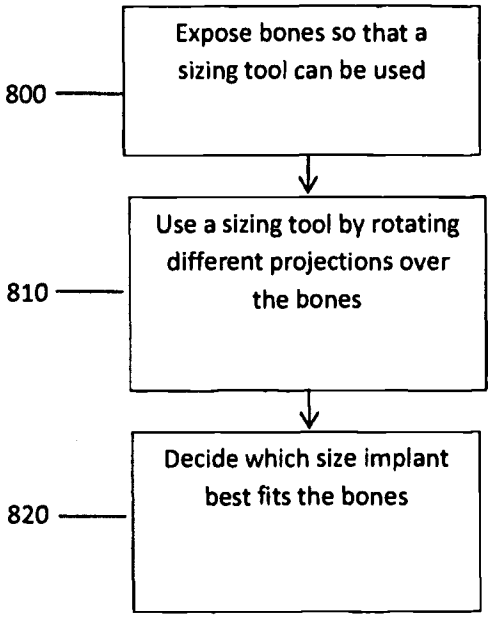
Expose bones so that a sizing tool can be used
800
Use a sizing tool by rotating different projections over the bones
810
Decide which size implant best fits the bones
820

Figure 11

METHOD AND APPARATUS FOR AN ORTHOPEDIC FIXATION SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an orthopedic fixation system consisting of a sterile packaged implant kit and a sterile packaged instrument kit.

2. Description of the Related Art

Bone fusion and healing in orthopedics often involves metallic implants being attached to bones in some way to fixate them together during the healing process. There are many forms of bone fixation devices including intramedullary devices, pins, screws, plates, and staples. Implants made from shape memory materials, such as nitinol, are a popular material for fixation because their shape memory and superelastic properties allow the device to create compression that can augment healing.

Many orthopedic implants are delivered to hospitals in a non-sterile form, and sterilized prior to surgery at the hospital. This is easier for the medical device manufacturer, since the implant requires less preparation than one that is sterile-packaged, however it places an onus on the hospital to insure sterility at the time of surgery. Frequently these implants are delivered in caddies, and the implants that are not used in surgery have to be re-sterilized before any subsequent surgical procedure.

Many other orthopedic implants are delivered to hospitals in a sterile packaged form. While this is more difficult and expensive for the medical device manufacturer, it is easier for the hospital to simply provide the implant at the time of surgery.

Finally, orthopedic instruments are generally provided as part of an instrument tray. The tray needs to be sterilized prior to surgical use. Furthermore, after surgery the tray needs to be properly cleaned, and then subsequently re-sterilized prior to the next use.

While there are numerous combinations of sterile and non-sterile orthopedic implants on the market, they all use an instrument tray that requires cleaning and sterilization.

The process of cleaning and sterilization at hospitals is known in the literature to periodically result in a phenomenon known as Hospital Acquired Infection. In this situation, patients are exposed to an infectious agent due to improperly cleaned or improperly sterilized equipment. Preventing and treating these infections is costly to hospitals.

Accordingly, a system is described herein for providing a sterile packaged implant kit mounted on an insertion device, and a complementary sterile packaged instrument kit. Methods of packaging the system, and delivering and using the system, are also presented.

SUMMARY OF THE INVENTION

The invention herein consists of a sterile packaged implant kit and a complementary sterile packaged instrument kit and methods for use and packaging thereof.

The sterile packaged implant kit includes an implant mounted on an insertion device and a drill guide. The sterile packaged implant kit further includes an implant tray shaped to hold the at least one surgical implant, the insertion device, and the drill guide therein, an implant outer cover insertable over the implant tray, and an implant seal securable over the implant outer cover. The implant seal encloses the implant outer cover such that the implant, the insertion device, and the drill guide remain sterile within the implant tray and implant outer cover after sterilization of the sterile packaged implant kit.

The sterile packaged instrument kit includes a drill bit, locating pins, an instrument handle, and an implant tamp. The sterile packaged instrument kit includes an instrument tray shaped to hold the drill bit, locating pins, instrument handle, and implant tamp therein, an instrument outer cover insertable over the instrument tray, and an instrument seal securable over the instrument outer cover. The instrument seal encloses the instrument outer cover such that the drill bit, locating pins, instrument handle, and implant tamp remain sterile within the instrument tray and instrument outer cover after sterilization of the sterile packaged instrument kit.

A method of using an orthopedic fixation system is as follows. A sterile packaged implant kit is opened to access an implant, insertion device, and drill guide. A sterile packaged instrument kit is opened to access a drill bit and tamp. The drill guide and the drill bit are used to drill holes in bone. The insertion device is used to insert the implant. The insertion device is also used to release and activate the implant. The tamp is used to push the implant flush with bone. The foregoing method may also include the use of a sizing wheel to determine the proper implant selection.

A method of packaging an orthopedic fixation system is as follows. An implant is inserted into an insertion device, and the insertion device is inserted into an implant tray. A drill guide is inserted into the implant tray. The implant tray is enclosed by inserting an implant outer cover over the implant tray and securing an implant seal over the implant outer cover. A drill bit is inserted into an instrument tray. An implant tamp is inserted into the instrument tray. One or more locating pins are inserted into the instrument tray. An instrument handle is inserted into the instrument tray. The instrument tray is enclosed by inserting an instrument outer cover over the instrument tray and securing an instrument seal over the instrument outer cover. The enclosed implant tray and the implant, the insertion device, and the drill guide therein are sterilized. The enclosed instrument tray and the drill bit, the implant tamp, the one or more locating pins, and the instrument handle therein are sterilized.

It is an object of the present invention to present the surgeon with an implant ready for implantation, pre-mounted on an insertion device.

It is a further object of the present invention to provide the implant and insertion in a sterile packaged format.

It is still further an object of the present invention to provide all the instruments needed for use with this implant in sterile packaged format.

Still other objects, features, and advantages of the present invention will become evident to those of ordinary skill in the art in light of the following. Also, it should be understood that the scope of this invention is intended to be broad, and any combination of any subset of the features, elements, or steps described herein is part of the intended scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A provides an isometric view of an orthopedic fixation system.

FIG. **1**B provides a plan view of an orthopedic fixation system.

FIG. **2**A provides an isometric view of an insertion device being used to insert an implant into bones.

FIG. **2**B provides an isometric view of an implant being released from an insertion stick into bones.

FIG. **3**A provides an exploded isometric view of a sterile-packaged implant kit.

FIG. **3**B provides an assembled isometric view of a sterile-packaged implant kit.

FIG. **4**A provides an exploded isometric view of a sterile-packaged instrument kit.

FIG. **4**B provides an assembled isometric view of a sterile-packaged instrument kit.

FIG. **5**A provides an exploded view of a drill guide and an instrument handle.

FIG. **5**B provides an assembled isometric view of a drill guide system.

FIG. **6** provides an alternative embodiment of an orthopedic fixation system that includes a sizing guide.

FIG. **7** provides a plan view of a sizing guide.

FIGS. **8**A-**8**J provide a sequence of images showing the use of an orthopedic fixation system.

FIG. **9** provides a method for using a sterile orthopedic fixation system.

FIG. **10** provides a method for packaging a sterile orthopedic fixation system.

FIG. **11** provides a method for using an orthopedic sizing guide to select the proper implant.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. It is further to be understood that the figures are not necessarily to scale, and some features may be exaggerated to show details of particular components or steps.

In this invention, a method and system for a sterile packaged implant and complementary sterile packaged instrument kit are described. As shown in FIGS. **1**A and **1**B, an orthopedic fixation system **100** consists of one or more sterile packaged implant kits **200**, **201**, and **202**, and a sterile packaged instrument kit **300**. Implant kits **200**, **201**, and **202** are identical, except that the implants maybe sized differently as required by the physician.

The orthopedic fixation implant is shown in FIG. **2**A. The fixation implant **205** consists of an implant made from a shape-memory or superelastic material such as nitinol. Implant **205** has two legs, **206** and **207**, that are designed to swing inward. Implant **205** is mounted on disposable insertion device **220**. The insertion device **220** holds the implant **205** such that implants legs **206** and **207** are held mechanically in a parallel position for easier insertion into bone. FIG. **2**A shows the implant **205** being inserted into two bones **208** and **209**. Insertion device **220** can be twisted off implant **205**, as shown in FIG. **2**B, releasing the implant to squeeze bones **208** and **209**.

The representative sterile packaged implant kit **200** is shown in more detail in exploded view FIG. **3**A and assembly FIG. **3**B. Implant kit **200** includes the aforementioned implant **205** and insertion device **220**. Implant kit **200** also includes a drill guide **230**. The purpose of drill guide **230** is to allow a surgeon to drill parallel holes into bone with the proper separation distance to match implant **205** and parallel legs **206** and **207**. Drill guide **230** has a universal mating shaft **231** that can be used to attach to a handle. The entire assembly, consisting of implant **205** mounted to insertion device **220** and matching drill guide **230** are placed into an implant package **210** suitable to house implant **205**, insertion device **220**, and matching drill guide **230** and maintain implant **205**, insertion device **220**, and matching drill guide **230** sterile. In particular, implant **205**, insertion device **220**, and matching drill guide **230** are placed into an implant tray **240**. Implant tray **240** could be made from thermoformed plastic or a similar material, and is shaped to hold and secure insertion device **220** and drill guide **230**. While implant tray **240** in the preferred embodiment is shaped to hold insertion device **220** with implant **205** mounted, one of ordinary skill in the art will recognize that implant tray **240** could hold insertion device **220** and implant **205** separately. Implant tray **240** fits into implant outer cover **245**, which protects all of the contents. Both implant tray **240** and implant outer cover **245** can be made from transparent plastic so that implant **205** is visible from outside. An implant seal **250** secures over and encloses implant outer cover **245** using any suitable means such as a heat and pressure activated adhesive. Implant seal **250** is made from a suitable material for insuring sterility while still allowing air passage. After sealing the system with implant seal **250**, implant kit **200** can be sterilized by any common sterilization method such as gas, radiation, or another type. All of the components of implant kit **200** can be made from disposable materials such as injection molded plastic, metal, or other suitable materials, with the exception of implant **205** which is made from a superelastic or shape-memory material. It is an objective of implant kit **200** to be packaged and then sterilized to simplify the surgical implantation of implant **205**, and then allow all of the other components to be discarded after surgery.

Instrument kit **300** is displayed in exploded view FIG. **4**A and assembly FIG. **4**B. Instrument kit **300** is sterile-packaged and designed to work in conjunction with one or more implant kits **200**, **201**, or **202**, or any combination of implant kits. In this embodiment, the instrument kit **300** includes multiple instruments needed by the surgeon for the implant kit. Instrument kit **300** consists of a handle **310** that mates with previously mentioned drill guide **230**. Instrument kit **300** also consists of one or more locating pins **320**, drill bit **330**, and tamp **340**. Locating pins **320** are used to fit inside drill guide **230**. Drill bit **330** also fits inside drill guide **230** and can drill a hole in bone. Tamp **340** is used to press down on implant **205** to push it flush to bone. The handle **310**, one or more locating pins **320**, drill bit **330**, and tamp **340** all fit into instrument package **305** suitable to house handle **310**, one or more locating pins **320**, drill bit **330**, and tamp **340** and maintain handle **310**, one or more locating pins **320**, drill bit **330**, and tamp **340** sterile. In particular, the handle **310**, one or more locating pins **320**, drill bit **330**, and tamp **340** all fit into instrument tray **350**. Instrument tray **350** is made from a thermoformed plastic or similar material that is shaped to conform and hold each instrument; namely, handle **310**, one or more locating pins **320**, drill bit **330**, and tamp **340**. Instrument tray **350** fits inside instrument outer cover **360**. Both instrument tray **350** and instrument outer cover **360** can be made from transparent plastic so that each instrument is visible from outside. An instrument seal **370** secures over and encloses instrument outer cover **360** using any suitable means such as a heat and pressure activated adhesive. Instrument seal **370** is made from a suitable material for insuring sterility while still allowing air passage. Instrument seal **370** adheres to instrument outer tray **360** to allow instruments **310**, **320**, **330**, and **340** to be sterilized and then maintain sterility. Instrument kit **300** is sterilized by any common method of sterilization such as gas or radiation.

FIG. **5**A shows handle **310** and drill guide **230** being positioned for assembly. Shaft **235** of drill guide **230** slides into

handle **310** to make a connection. FIG. **5**B shows assembled drill guide assembly **390**, consisting of handle **310** and drill guide **23**.

In a second embodiment, shown in FIG. **6**, the orthopedic fixation system now includes an additional component. FIG. **6** shows fixation system **500** consisting of one or more implant kits **200**, **201**. and **202**, instrument kit **300**, and sizing guide **400**. Implant kits **200**, **201**, and **202** and instrument kit **300** functions the same as in the preferred embodiment. Sizing guide **400** is shown in more detail in FIG. **7**. It is a sterile packaged device made from plastic or a similar disposable material, with incremental projections on the perimeter. Representative projections **410** and **411** are shown in FIG. **7**, however, any number of projections could be situated on the perimeter. Projections **410** and **411** have a known separation distance corresponds to the previously described separation distance of legs **206** and **207** on implant **205**. The measurement **415** between projections **410** and **411** is shown on sizing guide **400**.

FIGS. **8**A-**8**J show a sequence of images illustrating the use of a sterile-packaged orthopedic fixation system. FIG. **9** shows a method for using a sterile orthopedic fixation system that corresponds to FIGS. **8**A-**8**J. FIG. **8**A and step **600** of FIG. **9** show sizing guide **400** being used to determine the proper size of implant needed for bones **208** and **209**. FIG. **8**B and step **610** of FIG. **9** show drill guide assembly **390** being created from handle **310** and drill guide **230** by inserting shaft **235** into handle **310**. FIG. **8**C and step **620** of FIG. **9** show drill guide assembly **390** and drill bit **330** being used to drill a hole into bone **209**. FIG. **8**D shows locating pin **320** positioned in drill guide assembly **390** and extending into the hole in bone **209**. Locating pin **320** secures the drill guide assembly **390** in place while drill bit **330** is used to drill a hole in bone **208**. FIG. **8**E and step **630** of FIG. **9** show drill guide assembly **390** with two locating pins **320** securing it to bone. FIG. **8**F shows that the two locating pins **320** are left in bones **208** and **209**. FIG. **8**G and step **640** of FIG. **9** show implant **205** mounted to insertion device **220**, being positioned over bones **208** and **209**. FIG. **8**H and step **650** of FIG. **9** show insertion device **220** being twisted off implant **205** to release implant **205** into bones **208** and **209**. FIG. **8**I and step **660** of FIG. **9** show implant **205** being pressed flush against bones **208** and **209** by tamp **340**. Finally, FIG. **8**J shows multiple implants **205** in position on bones **208** and **209**.

FIG. **10** shows a method for packaging a sterile orthopedic fixation system. Step **700** involves inserting the implant into an insertion device. In step **710**, the insertion device with implant and corresponding drill guide is placed into a storage tray. In step **720**, the components of an instrument kit, including drill bit, location pins, tamp, and instrument handle are placed into an instrument tray. In step **730** both trays are sealed with lids. Finally, in step **740** both trays are sterilized via gas, radiation or other sterilization method.

FIG. **11** shows a method for using a sizing guide to determine the appropriate implant size for an orthopedic surgical procedure. Step **800** describes exposing bones that require surgery. Step **810** describes using a sizing tool by rotating it's projections over the bones. Step **820** involves selecting the proper implant that best fits the bones.

Although the present invention has been described in terms of the foregoing embodiments, such description has been for exemplary purposes only and, as will be apparent to those of ordinary skill in the art, many alternatives, equivalents, and variations of varying degrees will fall within the scope of the present invention. That scope, accordingly, is not to be limited in any respect by the foregoing detailed description; rather, it is defined only by the claims that follow.

We claim:

1. An orthopedic fixation system, comprising:

a sterile packaged implant kit, comprising:

at least one surgical implant, comprising legs movable between a first convergent position and a second substantially parallel position, wherein movement of the legs from the first convergent position to the second substantially parallel position stores a compressive force in the implant, further wherein movement of the legs from the second substantially parallel position to the first convergent position releases the compressive force stored in the implant,

an insertion device adapted to engage the implant with the legs in their second substantially parallel position, wherein the insertion device maintains the legs in their second substantially parallel position such that the implant stores the compressive force, and

an implant package adapted to receive therein the at least one surgical implant mounted on the insertion device such that the insertion device maintains the legs in their second substantially parallel position, whereby the implant package maintains the at least one surgical implant and the insertion device sterile after sterilization of the sterile packaged implant kit; and

a sterile packaged instrument kit, comprising:

one or more instruments necessary to use the sterile packaged implant kit, and

an instrument package adapted to receive the one or more instruments therein, whereby the instrument package maintains the one or more instruments sterile after sterilization of the sterile packaged instrument kit.

2. The orthopedic fixation system of claim **1**, wherein the at least one surgical implant comprises a staple.

3. The orthopedic fixation system of claim **2**, wherein the staple is made from shape-memory material.

4. The orthopedic fixation system of claim **2**, wherein the staple is made from superelastic material.

5. The orthopedic fixation system of claim **1**, wherein the one or more instruments in the instrument kit are manufactured from plastic.

6. The orthopedic fixation system of claim **1**, wherein the one or more instruments comprise a drill bit, locating pins, an instrument handle, and an implant tamp.

7. The orthopedic fixation system of claim **6**, wherein the instrument package, comprises:

an instrument tray shaped to hold the drill bit, locating pins, instrument handle, and implant tamp therein;

an instrument outer cover insertable over the instrument tray; and

an instrument seal securable over the instrument outer cover such that the drill bit, locating pins, instrument handle, and implant tamp remain sterile within the instrument tray and instrument outer cover after sterilization of the sterile packaged instrument kit.

8. The orthopedic fixation system of claim **6**, wherein the sterile packaged implant kit further comprises a drill guide adapted for connection with the instrument handle.

9. The orthopedic fixation system of claim **1**, wherein the sterile packaged implant kit further comprises a drill guide.

10. The orthopedic fixation system of claim **9**, wherein the implant package comprises:

an implant tray shaped to hold therein the at least one surgical implant mounted on the insertion device such that the insertion device maintains the legs in their second substantially parallel position and the drill guide;

an implant outer cover insertable over the implant tray; and

an implant seal securable over the implant outer cover such that the at least one surgical implant, the insertion device, and the drill guide remain sterile within the implant tray and implant outer cover after sterilization of the sterile packaged implant kit.

11. The orthopedic fixation system of claim **1**, wherein there are multiple sizes of implant kits and instrument kits, wherein the choice of implant kit dictates the corresponding instrument kit.

12. The orthopedic fixation system of claim **1**, further comprising a sterile packaged sizing wheel to determine the appropriate size of surgical implant required for a surgical procedure.

13. The orthopedic fixation system of claim **12**, wherein the sizing wheel is made from plastic.

14. The orthopedic fixation system of claim **12**, wherein the sizing wheel includes length measurements on its circumference.

15. An orthopedic fixation system, comprising:

a sterile packaged implant kit, comprising:

at least one surgical implant, comprising legs movable between a first convergent position and a second substantially parallel position, wherein movement of the legs from the first convergent position to the second substantially parallel position stores a compressive force in the implant, further wherein movement of the legs from the second substantially parallel position to the first convergent position releases the compressive force stored in the implant,

an insertion device adapted to engage the implant with the legs in their second substantially parallel position, wherein the insertion device maintains the legs in their second substantially parallel position such that the implant stores the compressive force, and

an implant package adapted to receive therein the at least one surgical implant mounted on the insertion device such that the insertion device maintains the legs in their second substantially parallel position, whereby the implant package maintains the at least one surgical implant and the insertion device sterile after sterilization of the sterile packaged implant kit.

16. The orthopedic fixation system of claim **15**, wherein the at least one surgical implant comprises a staple.

17. The orthopedic fixation system of claim **16**, wherein the staple is made from shape-memory material.

18. The orthopedic fixation system of claim **16**, wherein the staple is made from superelastic material.

19. The orthopedic fixation system of claim **15**, wherein the sterile packaged implant kit further comprises a drill guide.

20. The orthopedic fixation system of claim **19**, wherein the implant package comprises:

an implant tray shaped to hold therein the at least one surgical implant mounted on the insertion device such that the insertion device maintains the legs in their second substantially parallel position and the drill guide;

an implant outer cover insertable over the implant tray; and

an implant seal securable over the implant outer cover such that the at least one surgical implant, the insertion device, and the drill guide remain sterile within the implant tray and implant outer cover after sterilization of the sterile packaged implant kit.

21. The orthopedic fixation system of claim **15**, wherein there are multiple sizes of implant kits.

22. The orthopedic fixation system of claim **15**, further comprising a sterile packaged sizing wheel to determine the appropriate size of surgical implant required for a surgical procedure.

23. The orthopedic fixation system of claim **22**, wherein the sizing wheel is made from plastic.

24. The orthopedic fixation system of claim **22**, wherein the sizing wheel includes length measurements on its circumference.

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