

Minimally Invasive Bunion Plating System

Instructions for Use

enovis[™]

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Description

The Minimally Invasive Bunion Plating System is comprised of titanium plates designed for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus. The Minimally Invasive Bunion Plating System utilizes 2.4mm locking and non-locking screws with lengths of 16-24mm from the Gridlock Plating System and 2.4mm cannulated screws with lengths of 22-28mm from the Tiger Cannulated Screw System. Available plates, screws, and instrumentation will be packaged as a single system. The system instruments include handles, drill bits, drill guides, placement guides, broach, guide wires, depth gauges, countersinks, retractor, screw removal tool, and screwdrivers to facilitate the placement of the plates. The implants and guide wires are intended for single use only.

Implant Materials

All Minimally Invasive Bunion Plating System plates are made from commercially pure Titanium (ASTM F-67). All screws included in the Minimally Invasive Bunion Plating System are made from Titanium Alloy (ASTM F-136). The instrumentation is made from stainless steel, anodized aluminum and plastic.

Indications

The Minimally Invasive Bunion Plating System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

Contraindications

Use of the Minimally Invasive Bunion Plating System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of internal fixation.

Warnings

1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
3. Instruments, guide wires and screws are to be treated as sharps.
4. Re-use of devices indicated as single use can result in decreased mechanical and clinical performance of devices.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of plating systems.
2. The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.
3. The Minimally Invasive Bunion Plating System is not intended to endure excessive abnormal functional stresses.
4. The Minimally Invasive Bunion Plating System is intended for temporary fixation only until osteogenesis occurs.
5. All Minimally Invasive Bunion Plating System implants and instrumentation may be required for each surgery. Failure to use dedicated, unique Trilliant Surgical instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
6. Carefully inspect the screws and plates prior to use, inspect the instruments before and after each procedure to assure they are in proper operation condition. Instruments which are faulty, damaged or suspect should not be used.
7. Trilliant Surgical recommends the use of Trilliant Surgical products in a sterile environment.

Instructions for Use, Minimally Invasive Bunion Plating System

1. Identify, expose, prepare the surgical site, and perform the osteotomy.
2. Assemble plate construct by securing the desired plate to the appropriate placement guide using the threaded drill guides.
3. Manually, or with the use of a small mallet, broach at the apex of the deformity in the proximal medullary canal while distracting the distal bone segment.
4. Remove the broach, and using plate assembly, insert plate into broached region and temporarily secure placement utilizing two guide wires inserted to the correct length through the wire guide holes in the assembly. Precaution: K-wire must protrude through the distal/lateral cortex.
5. Pilot drill through one of the threaded drill guides for distal screw placement. Utilize the calibrations on the threaded drill guide and drill bit, or the provided depth gauge to determine the necessary screw length.
6. Remove threaded drill guide and insert appropriate length locking screw into the pilot hole through the placement guide using the hexalobe driver.
7. Repeat steps 5 and 6 for remaining distal screw.
8. Remove distal guide wire from the plate assembly and remove the guide assembly by sliding back over the remaining proximal guide wire.
9. Insert the interfrag drill guide into the remaining plate screw hole and pilot drill for an interfrag screw. Utilize the calibrations on the interfrag drill guide and drill bit, or the provided depth gauge to determine the necessary screw length.
10. Remove the interfrag drill guide and insert appropriate length solid core, non-locking screw into pilot hole using the hexalobe driver. OPTIONAL: A cannulated screw with guide wire may be utilized here instead.
11. Slide the countersink over the remaining guide wire until the countersink tip contacts bone. Rotate the countersink back and forth to create the necessary recess in the bone.
12. Measure for the necessary screw length by examining the end of the guide wire in relation to the marks on the cannulated depth gauge.
13. Slide the appropriate length cannulated screw over the guide wire and insert the screw using the cannulated screw driver until desired compression is achieved.
14. Remove and discard guide wire.

Plate Removal (If necessary)

1. Locate plate and screws with intra-operative imaging.
2. Palpate plate and remove surrounding soft tissue to gain maximum exposure.
3. Engage screw heads with appropriate driver and rotate counterclockwise until screws are removed.
4. Use a forcep or pickup to remove plate.
5. Once the plate and screws are removed they should be treated as medical waste and disposed of accordingly.

Cleaning

Non-sterile products must be carefully cleaned promptly prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents. For cleaning instructions, please reference document 900-06-018, Minimally Invasive Bunion Plating System Cleaning and Sterilization Protocol.

Packaging and Sterility

NON-STERILE PRODUCT

The Minimally Invasive Bunion Plating System (Instruments and implants) can be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer’s user instructions. The user facility must clean instruments promptly prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed.

Sterilization Method	Pre-Vacuum Steam	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270° F (132° C)	270° F (132° C)
Time	4 minutes	40 minutes
Recommended Dry Time	50 minutes**	50 minutes**

*The system shall be packaged for sterilization by double wrapping in an FDA cleared wrap and wrapping techniques outlined per ANSI/AAMI ST79, then adhered with FDA cleared chemical indicator autoclave tape.

**Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.

***Do not stack trays during sterilization.

Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Do not attempt a surgical procedure with faulty, damaged or suspect Trilliant Surgical instruments or implants.

Inspect all components preoperatively to assure utility.

MRI Safety Information

The Minimally Invasive Bunion Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Minimally Invasive Bunion Plating System is unknown. Scanning a patient who has this device may result in patient injury.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2016
	Catalog Number	5.1.5
	Batch Code	5.1.6
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
	Non-Sterile	5.2.7
	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Caution	5.4.4
	Consult instructions for use	5.4.3

*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements. Note: QTY is an abbreviation of “QUANTITY”.

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

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