TOBY ORTHOPAEDICS

INSTRUCTIONS FOR USE

PANTERA® Proximal Humerus Fracture Fixation Plate System

Caution: Federal law restricts this device to sale by or on the order of a physician MD

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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INTENDED USE

The PANTERA® Proximal Humerus Fracture Fixation Plate System is intended for the internal fixation of bone fragments about the proximal humerus and includes unique features for enhanced fixation of soft bone.

INDICATIONS

The PANTERA® system is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

CLINICAL BENEFITS

PANTERA® system cross elements enhance the fixation of hardware in bone that is very soft or osteoporotic and whenever there is significant fragmentation or comminution at the fracture site. Cross elements may minimize subsidence of the humeral head with respect to the screws and may minimize the penetration of the screws into the joint.

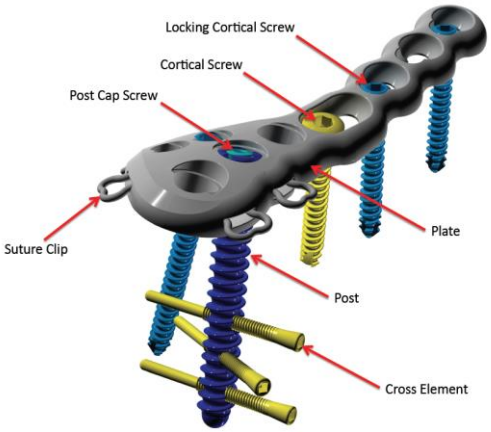
CONTRAINDICATIONS

- Proximal humerus fractures with significant fragmentation of the head where reconstruction is not possible.
- Proximal humerus fractures for which there is a likelihood of development of clinically relevant avascular necrosis of the fracture fragments.

DESCRIPTION

The PANTERA® system contains bone plates for the repair of fractures of the proximal humerus. Included in the system are various posts, cross elements, cortical screws, cortical locking screws, post cap screws, k-wires, and specialized instruments. All components and specialized instruments, which may be purchased independently, are supplied non-sterile in a container suitable for moist heat sterilization.

NOMENCLATURE



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The shoulder plate utilizes Ø5.2mm posts (Cannulated and non-cannulated) to affix the plate to the humeral head and stabilize the fracture. Ø3.5mm cortical screws and cortical locking screws are used to affix the distal segment of the fracture to plate.

MATERIAL SPECIFICATION

PANTERA® implantable components are made of Titanium alloy Ti-6AL-4V ELI. This material meets the requirements of ASTM Designation *F136-02a*, *Standard Specification for Wrought Titanium - 6 Aluminum - 4 Vanadium ELI (Extra*

Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). The PANTERA® implantable components have been evaluated for safety / compatibility in an MRI environment.

TREATMENT BEFORE DEVICE IS USED

Toby products are supplied in a non-sterile condition and must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Please refer to the Cleaning and Sterilization instruction (Doc. 50000133) for further information.

STERILIZATION

PANTERA® system components are supplied non-sterile.

All non-sterile components are intended to be moist heat sterilized at the health-care facility. Prior to use, the product shall be inspected for any signs of damage, tampering, or contamination. Any component suspected of damage should be replaced prior to use. If the tray is deemed satisfactory, it should be wrapped in a 510(k)-approved wrap and sterilized following the Dynamic-Air-Removal moist heat sterilization process identified in the table below, or an equivalent sterilization cycle validated for this type of product. The use of flash sterilization is not recommended for PANTERA®.

Sterilizer Type	Minimum Temperature	Full Cycle Time	Drying Time	Configuration
Pre-vacuum	135˚C	3 minutes	20 minutes	Wrapped Tray

Any method of moist heat sterilization used should be validated in accordance with the current revision of the following standards to demonstrate a sterility assurance level (SAL) of 10^{-6} or better: *ISO 17664, AAMI TIR 12, AAMI TIR 30, AAMI ST 79, AAMI ST 81*.

PANTERA® SYSTEM STORAGE AND INSTRUMENT USE INSTRUCTIONS

When not in use, store the clean and disinfected PANTERA® Proximal Humerus Fixation Plate System within the Sterilization Tray, in a cool dry place away from direct sunlight. Prior to use, inspect the product for any signs of damage, tampering, or contamination. Use the oldest products first. Instrumentation should be disassembled for cleaning and inspection where appropriate (Refer to Pantera Cleaning and Sterilization Doc 50000057). Refer to the PANTERA® Surgical Technique Guide for detailed instrumentation usage instructions (Doc. 50000058).

CAUTIONS

- PANTERA® instrumentation does not have an infinite functional life. Because the instrumentation is subjected to repeated stresses related to impaction, bone contact, routine cleaning, and sterilization processes, all re-usable instrumentation should be carefully inspected before each use to ensure that they are fully functional. Scratches and/or dents may result in breakage during use. Dullness of cutting edges can result in poor functionality. All damaged instrumentation and those suspected to not perform as required should be replaced to prevent any potential patient injury such as metal fragments falling into the surgical site. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instruments. It is important that the surgeon and operating theater staff be fully conversant with the appropriate surgical technique for the PANTERA® system.
- All implantable devices must never be reused. Previous stresses from prior use may cause imperfections that can potentially lead to device failure. All implantable devices should be protected from scratches, nicking, or dents that may lead to stress concentrations that would potentially result in failure.
- Dispose of contaminated implants and instruments per established Healthcare facility precautions for the handling of containment / biohazardous materials.
- Safe disposal of Reuseable devices that have been inspected and have reached the end of their lifetime should be disposed of according to institutional procedures.

- Safety precautions Personal Protective Equipment (PPE) should be worn when handling or working with contaminated devices. Universal precautions are standards of infection control practices designed to reduce the risk of transmission of bloodborne infections. Universal precautions should be observed by all Healthcare Facility Personnel that work with contaminated or potentially contaminated devices.
- Exercise caution when handling devices with sharp points and cutting edges.
- The patient shall be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this device.
- Exercise caution to avoid damaging the vasculature of the bone fragments.
- Avoid penetrating into the joint anytime when drilling. It is advisable to drill only up to 5mm or 10mm away from the subchondral bone of the joint surface to minimize the risk of joint penetration.
- It is advisable to elect Post screws and Locking Cortical Screws that are 5mm to 10mm away from the subchondral bone of the joint surface to minimize risk of penetration. Note: The Depth Gauge and screw caddy measuring instruments have ±1mm accuracies and the CE scale has a ±2mm accuracy.
- Ensure that the notches on the Cross Element Guide are properly aligned with the reciprocal notches on the Post screws. Failure to do so will result in improper placement of the Cross Elements.
- Exercise care to avoid damage to the suture clips. Use of excessive force or bending on the suture clip(s), with instruments or suture wire, may result in degraded performance of the clip(s). It is advisable to use no larger than #2 braided surgical suture to avoid clip damage.
- When deciding the size of a POST, avoid measurement errors by making a direct measurement with a depth gauge instead of using scale on a Drill Bit.
- Reduce the possibility of Cross Element migration by remaining 5mm to 10mm away from the far cortex when drilling the pilot hole.
- Use caution when choosing implantable components for patients with severe osteoporosis, as risk of plate and screw migration is increased.
- The PANTERA® system has been evaluated for MR Safety. Non-clinical testing of the worst-case scenario has demonstrated that the implants of the system are MR Conditional. These implants can be scanned safely under the following Conditions:

MRI Safety Information

A patient with a Toby Orthopaedics PANTERA® Proximal Humerus Fraction Plate System implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Toby Orthopaedics PANTERA® Proximal Humerus Fraction Plate System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 30 minutes of continuous RF (a sequence or back-to-back series/scan without breaks), followed by a 15-minute resting period, followed by an additional 15-minute scan.
MR Image Artifact	The presence of this implant may produce an image artifact of 19 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

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ADVERSE EFFECTS

Potential complications/adverse events associated with the use of implantable shoulder plates include, but are not limited to, the following:

- Postoperative pain (shoulder)
- Screw perforation into glenohumeral joint
- Postoperative discomfort
- Numbness
- Inflammation
- Humeral head collapse/fracture due to aseptic necrosis after the fracture healed.
- General infection
- Avascular necrosis

Note: PANTERA® Implantable components are Single Use Only. Do not re-use. 
For implantation instructions, refer to the PANTERA® Surgical Technique Guide (Doc. 50000058)

For more information, questions or to report a complaint and/or an adverse event please contact Toby Orthopaedics, Inc. by:
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Symbols Legend

	**Single use**
	**Medical Device**
	**Keep dry**
	**Keep away from sunlight**
 **www.tobyortho.com**	**eIFU**
	**MRI conditional**
	**Non-Sterile**
	**Refer to Instructions for Use.**

	**Unique Device Identifier**
	**Manufacturer**
	**Date of Manufacture**
	**CE mark in compliance with directive on Class IIA or IIb medical devices,**
	**EU authorized representative.**
	**UK authorized representative.**
	**Lot number**
	**Reference catalogue number.**

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