PANTERA

PROXIMAL HUMERUS FRACTURE FIXATION PLATE SYSTEM

TOBY ORTHOPAEDICS

INSTRUCTIONS FOR USE

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

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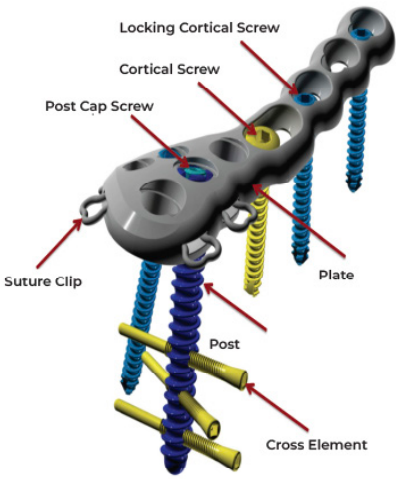
NOMENCLATURE



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 the repair of 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.

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. 50000057) 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	Pre-vacuum
Minimum Temperature	135 ˚C
Full Cycle Time	3 minutes
Drying Time	20 minutes
Configuration	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

- When not in use, store the clean and disinfected PANTERA Plate System within the Sterilization Tray in a cool, dry place, away from direct sunlight.
- Prior to use, inspect the product packaging for any signs of damage, tampering, or contamination. Use the oldest products first (first-in, first-out inventory practice).
- Instruments should be disassembled for cleaning and inspection where appropriate (refer to PANTERA Cleaning and Sterilization Document 50000057).
- 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 reusable instrumentation should be carefully inspected before each use to ensure full functionality.
- Scratches and/or dents may result in breakage during use. Dull cutting edges may

result in poor performance.

- All damaged instrumentation, or instruments suspected of not performing as intended, should be replaced to prevent potential patient injury, including the risk of metal fragments entering the surgical site.
- Care should be taken to remove any debris, tissue, or bone fragments that may accumulate on the instruments.
- It is essential that the surgeon and operating team are fully familiar with the appropriate surgical technique for the PANTERA System.
- Dispose of contaminated implants and instruments in accordance with established healthcare facility procedures for handling contaminated or biohazardous materials.
- Reusable devices that have been inspected and determined to have reached the end of their service life must be disposed of according to institutional procedures.
- Personal Protective Equipment (PPE) must be worn when handling contaminated or potentially contaminated devices.
- Universal precautions are infection control practices designed to reduce the risk of transmission of bloodborne pathogens and must be observed by all healthcare personnel working with contaminated or potentially contaminated devices.
- Exercise caution when handling devices with sharp points and cutting edges.
- Implants must never be reused. Prior stresses from previous use may create imperfections that could lead to device failure.
- All implantable devices should be protected from scratches, nicks, or dents that may create stress concentrations and potentially result in failure.
- Exercise caution to avoid damage to the vasculature of bone fragments during implantation.
- Avoid penetrating the joint during drilling. Drill to a depth that remains 5 mm to 10 mm from the subchondral bone of the joint surface to minimize the risk of joint penetration.
- The patient should be cautioned, preferably in writing, regarding the use, limitations, and possible adverse effects of the device.
- Select Post Screws and Locking Cortical Screws that terminate 5 mm to 10 mm from the subchondral bone of the joint surface to minimize the risk of penetration. Note: The Depth Gauge and screw caddy measuring instruments have ± accuracy tolerances, and the CE scale has an accuracy of ± 2 mm.
- Ensure that the notches on the Cross Elements Guide are properly aligned with the corresponding notches on the Post Screws. Failure to do so may result in improper placement of the Cross Elements.
- Exercise care to avoid damage to the suture clips. Excessive force or bending of the suture clip(s), whether with instruments or suture wire, may degrade clip performance. Use no larger than #2 braided surgical suture to avoid clip damage.
- Avoid measurement errors when selecting the size of the 5.2 mm cannulated post screw, by using the drill bit scale to determine the screw length.
- Reduce the risk of Cross Element migration by maintaining a distance of 5 mm to 10 mm from the far cortex when drilling the pilot hole.
- Use caution when selecting implantable components for patients with severe osteoporosis, as the risk of plate and screw migration may be increased.
- For additional cautions, refer to PANTERA Instructions for Use (Document 60000010).
- For additional cleaning and sterilization instructions, refer to PANTERA Cleaning and Sterilization Instructions (Document 50000057).
- The PANTERA System implants have been evaluated for MR safety. Non-clinical testing under worst-case conditions has demonstrated that the implants are MR Conditional. A patient with a Toby Orthopaedics PANTERA Humerus Bone Plate implant may be safely scanned only under specified MR conditions. Failure to follow these conditions may result in patient injury.

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.	

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)

SYMBOLS LEGEND

	Single Use
MD	Medical Device
	Keep dry
	Keep away from sunlight
	eIFU
MR	MRI conditional
NON STERILE	Non-Sterile
	Refer to Instructions for Use
UDI	Unique Device Identifier
CE	CE mark in compliance with directive on Class IIA or IIb medical devices.
	Manufacturer
	Date of manufacture
EU REP	EU authorized representative
REF	Reference catalogue number
LOT	Lot number

TOBY ORTHOPAEDICS

For more information, questions or to report a complaint and/or an adverse event please contact :

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MD

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PANTERA Proximal Humerus Fracture
Fixation Plate System
Instructions For Use