



INSTRUCTIONS FOR USE

PANTERA® Proximal Humerus Fracture Fixation Plate System

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

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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 also 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 not been evaluated for safety / compatibility in an MRI environment.

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

NOMENCLATURE

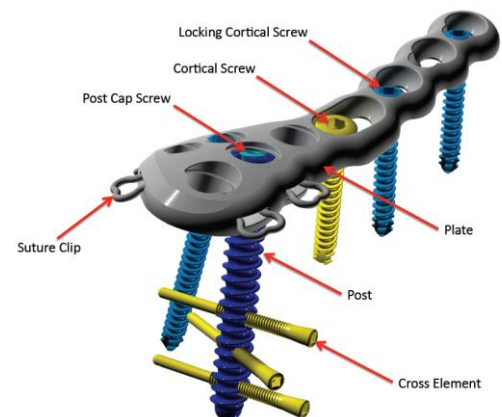


Figure 1



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

The PANTERA® system should be stored 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 oldest products first. Instrumentation should be disassembled for cleaning and inspection where appropriate (Refer to Doc 50000057). Refer to the PANTERA® Surgical Technique Guide for detailed instrumentation usage instructions (Refer to Doc 50000058).

PRECAUTIONS

- 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 suspect 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.
- 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 ± 1 mm accuracies and the CE scale has a ± 2 mm 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 not been evaluated for safety and compatibility in the MR environment and the PANTERA® system has not been tested for heating or migration in the MR environment.

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

Caution: Re-using Implantable Components may result in an increase risk for infection.

For implantation instructions, refer to the PANTERA® Surgical Technique Guide (50000058)



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