PANTERA®
Cleaning and Sterilization Instructions

CAUTION: Federal law restricts this device to sale by or on the order of a Physician

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	Medical Device
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Product	**PANTERA®** Fracture Fixation Plate System consists of shoulder plates, Posts, Cross Elements, Locking and Non-Locking screws, Post Cap Screws, Suture Clips, K-wires, and Surgical Instrumentation contained in a Sterilization tray.
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. • The plates and screws contained within the system are single use devices, which are designed for implantation per the relevant surgical procedure. • The drill bits, drill guides, depth gauges, k-wire, drivers, and other instrumentation are designed for use during the surgical procedure and require decontamination and cleaning prior to reuse. The instruments typically contact blood, bone, tissue, and bodily fluids during normal use, and therefore, require that the cleaning and processing steps are completed for each usage.

<table>
<tr><td>Cautions</td><td>

Implantable devices (plates, screws, etc.) are single use only.
Reusable instruments that are provided clean and ready to use are non-sterile unless the packaging indicates otherwise.
Clean and sterilize prior to each use, unless device is already provided in clean / sterile packaging.
Where applicable, disassemble instruments prior to cleaning.
For additional Cautions, reference the PANTERA® Instructions for Use (Doc 60000010).
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.

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.
<table>
<tr><td>Name/Identification of device</td><td>Toby Orthopaedics PANTERA® Proximal Humerus Fraction Plate System</td></tr>
<tr><td>Nominal value(s) of Static Magnetic Field [T]</td><td>1.5 T or 3 T</td></tr>
<tr><td>Maximum Spatial Field Gradient [T/m and gauss/cm]</td><td>30 T/m (3000 gauss/cm)</td></tr>
<tr><td>RF Excitation</td><td>Circularly Polarized (CP)</td></tr>
<tr><td>RF Transmit Coil Type</td><td>Whole body transmit coil, Head RF transmit-receive coil</td></tr>
<tr><td>Maximum Whole Body SAR [W/kg]</td><td>2.0 W/kg (Normal Operating Mode)</td></tr>
<tr><td>Limits on Scan Duration</td><td>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.</td></tr>
<tr><td>MR Image Artifact</td><td>The presence of this implant may produce an image artifact of 19 mm.</td></tr>
<tr><td colspan="2">If information about a specific parameter is not included, there are no conditions associated with that parameter.</td></tr>
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<tr><td>Reprocessing Limitations</td><td>

Implantable devices are single use only and may <u>not</u> be reused once in contact with bodily fluid, soft tissue, bone, or other sources of contamination.
Repeated processing has minimal effect on reusable PANTERA® surgical instruments. End of life is normally determined by wear and damage due to the use of the instruments.

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<tr><td>Point of Use</td><td>

Remove gross soiling by submerging the instrument into cold water (<40ºC) immediately after use.
Don't use a fixating detergent or hot water (>40ºC) as this can cause the fixation of residue, which may influence the result of the reprocessing process.
Remove surface contamination with paper tissue.

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<tr><td>Containment / Transportation</td><td>

Dispose of contaminated implants and instruments per established Healthcare facility precautions for the handling of contaminated / bio-hazardous 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

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<tr><td></td><td>observed by all Healthcare Facility Personnel that work with contaminated or potentially contaminated devise.
• Exercise caution when handling devices with sharp points and cutting edges.
• Instruments should be cleaned within 30 minutes after use to minimize the potential of staining, damage, and drying.</td></tr>
<tr><td>Preparation for Decontamination</td><td>If possible, the devices must be reprocessed in a disassembled or opened state.
1. Disassemble the Depth Gauge to clean each component of the assembly: Depth Gauge Tip, Slide and Housing.
a. Fully retract the Slide into the Housing so that the scale reads zero.
b. Apply angular pressure on the Tip until the groove is visible.
c. Fully separate the Tip from the Housing while taking care to not bend the Slide.
2. Remove the K-Wire sleeve(s) from the corresponding Post Drill Guide and Cross Element Guide by turning the threaded sleeve counterclockwise.</td></tr>
<tr><td>Pre-Cleaning</td><td>Rinse with cold water for approximately 3 minutes.</td></tr>
<tr><td>Manual Cleaning Procedure</td><td>Applicable towards reusable devices and instrumentation. All reusable instrumentation shall be considered critical, especially the items with small lumens / cannula or silicone surfaces.
<table>
<tr><th colspan="4">Automated Cleaning Cycle Parameters</th></tr>
<tr><th>Program Step</th><th>Medium</th><th>Temperature (ºC)</th><th>Time</th></tr>
<tr><td>Pre-rinse</td><td>Cold Water</td><td>N/A</td><td>3 minutes</td></tr>
<tr><td>Wash</td><td>Cold and Warm Water</td><td>35-60ºC, 60+ºC</td><td>4 minutes heating from 35 to 60ºC,
4 minutes > 60ºC</td></tr>
<tr><td>Rinse 1</td><td>Warm Water</td><td>N/A</td><td>3 minutes</td></tr>
<tr><td>Rinse 2</td><td>Warm Water</td><td>N/A</td><td>1 minute</td></tr>
<tr><td>Thermal Disinfection</td><td>Purified Water</td><td>30-80ºC, 80+ºC</td><td>5 minutes heating from 30 to 80ºC,
5 minutes > 80ºC</td></tr>
<tr><td>Drying</td><td>Air</td><td>120ºC</td><td>11 minutes</td></tr>
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1. Immerse the device(s) in an enzymatic detergent solution prepared in warm (30-35ºC) tap water (8 mL EcoLab Neutral Enzymatic Detergent per liter or equivalent detergent solution) and allow device(s) to soak for not less than five (5) minutes.
2. Aspirate not less than sixty (60) mL of the detergent solution through any lumens present, as applicable, using an appropriate sized syringe.
3. Brush all lumens present on device(s), as applicable, using an appropriately sized nylon bristled channel brush. Wet the brush in the detergent solution and run the brush down the entire length of each lumen and back, not less than five (5) times. The brush should also be used to remove any visible soil.
4. Brush any silicone surface with a nylon bristled instrument cleaning brush for not less than two (2) minutes per device where silicone material is present.
5. Prepare an enzymatic detergent solution in a sonicating water bath (35 kHz has shown to be effective) using purified water (2 mL EcoLab Neutral Enzymatic Detergent per liter of water or equivalent detergent solution).
6. Sonicate the device(s) for not less than ten (10) minutes in the enzymatic detergent solution.
7. Upon completion of the manual brushing and sonication steps, process the device(s) through a standard washer / disinfector surgical instruments cycle with the following parameters (or equivalent):
8. Perform a final rinse of the device(s) in running purified water, not less than ~250 mL per device, and allow the device(s) to air dry.
Perform a visual inspection of the device(s) to ensure that all contaminants have been</td></tr>
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	removed. Residual bodily fluids, excessive discoloration, unacceptable corrosion, etc., are typical reasons to further process the device(s). If the device(s) are determined to not be visually clean, the above relevant steps shall be repeated. If the device cannot be cleaned effectively, then it shall be disposed of safely, and contact your local Toby representative for replacement.
Automated Cleaning Procedure	Automated systems are only recommended for the PANTERA® surgical instruments when combined with the manual cleaning procedure detailed in the section above.
Disinfection	1. Submerge instruments in a disinfection detergent according to the detergent manufacturer's instructions. 2. Rinse the instruments with sterile water to remove the detergent. Note: Disinfection is only a supplementary step and does NOT replace the steam sterilization.
Drying	Dry the instruments with a lint-free towel. The instruments may never be heated up >140ºC. To avoid water residues, insufflate cavities of instruments by using sterile compressed air. It is critical that all areas of the devices are completely dry, as residual moisture causes possible corrosion and premature deterioration of the instrument.
Inspection / Function Testing	1. Carefully inspect each device to ensure that all visible blood and soil has been removed. 2. Visually inspect for damage, corrosion and/or wear. 3. Check the action of moving parts to ensure smooth operation throughout the intended range of motion. 4. Check instruments with long slender features (particularly rotating instruments) for distortion. 5. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components. Note: If damage or wear is noted that may compromise the function of the instrument, contact your Toby Orthopaedics® representative for a replacement.
Maintenance	Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear.
Reuse Life	• Implantable components may not be reused, but may be re-sterilized, as required, through the moist heat method described herein. The implantable components have been validated for undergoing at least 15 sterilization cycles without loss of performance. • Drill guides, drill guide sleeves, drivers, and similar instruments may be reused as long as the functionality of the device is sufficient to perform the intended use. Typically, these types of instruments have a lifetime of 50+ surgical cases unless the threads or driver tip is damaged during use. • The depth gauge assembly and drill bits / k-wires may be reused as long as the functionality of the device is sufficient, and any marking used for measurements are clearly legible. The depth gauge scale and other similar laser markings on these devices begin to deteriorate after 10 to 15 sterilization / cleaning cycles and should be visually inspected to ensure accuracy is still guaranteed. The cutting edges of the drill bits / k-wires deteriorate at various times based on use, and the drill bits should be safely discarded once the edges become dull. The edges can become dull after one use or may last 10 to 15 surgical cases. Dull drill bits should be safely discarded to prevent localized burning of the bone during use. Similarly, it is not recommended that K-wire or drill bits be reused for multiple cases due to the high velocity rotation of the devices causing possible deformation of the item and deterioration of performance. • The sterilization trays are designed to last hundreds of sterilization / cleaning

	cycles and only require replacement when functionality is lost or excessive contamination cannot be remedied.
Packaging	• Instruments shall be loaded into the dedicated PANTERA® sterilization tray for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method (ANSI/AAMI ST79).
Sterilization	• Steam sterilize using a pre-vacuum cycle for 3 minutes at a minimum temperature of 135ºC. 20 Minute minimum drying time in accordance with ANSI/AAMI ST79. Note: Flash Sterilization is not recommended for PANTERA®.
Storage	When not in use, store the clean and disinfected PANTERA® Proximal Humerus Fracture Fixation Plate System, within the Sterilization Tray, in a cool, dry place, away from sunlight.
Additional Information	For more information, questions or to report a complaint and/or an adverse event please contact Toby Orthopaedics, Inc. by: Phone: 305.665.8699 Email: sales@tobyortho.com Mail: 6355 SW 8th Street, Unit 101 Miami, FL 33144 USA