INSTRUCTIONS FOR USE

XtraFix® External Fixation System

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

Device Description
The XtraFix® External Fixation System includes various elements including clamps, posts, bars, and fixation pins. The elements are used to create assembled frames. External fixators are intended for single use only.

Material Composition
The elements in the fixator system are made of several materials including: aluminum, stainless steel, titanium, and composite materials. The fixation pins are manufactured from stainless steel (ASTM F 138).

Indications
The XtraFix® External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (foot, femur, tibia and humerus) and pelvic fractures that require external fixation. Specifically, the system is intended for:
• Stabilization of open or closed fractures, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated;
• Arthrodesis and osteotomies with associated soft tissue problems;
• Stabilization of limbs after removal of total joint arthroplasty for infection or other failure;
• Stabilization of non-unions; and
• Intraoperative temporary stabilization tool to assist with indirect reduction.

Contraindications
Following is a list of contraindications for the XtraFix® External Fixation System.
• Active or suspected infection
• Conditions that limit the patient’s ability and/or willingness to follow instructions during the healing process.
• Inadequate skin, bone, or neurovascular status
Contraindications may be relative or absolute and are left to the discretion of the surgeon.

Adverse Events
The following list includes potential complications typically associated with external fixation devices.
• Prolonged healing
• Distraction of the fracture site
• Pin insertion can result in damage to nerves and vessels
• Infection, painful, swollen or inflamed implant site
• Device fracture
• Loosening or dislocation of the implant requiring revision surgery
• Edema
• Loss of range of motion, joint contracture, joint subluxation, and joint dislocation
• Compartment Syndrome
• Septic Arthritis
• Delayed unions and intractable pain
• Initial condition may persist or recur requiring further treatment
• Replacement of apparatus or components resulting in reoperation
• Pin insertion leading to tissue necrosis
• External components leading to skin pressure
• Allergic reaction(s) to implant material(s)
• Muscle tendon impalement and excessive operative bleeding
• Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
• Loss of bone mass
• Abnormal growth plate development
• Bone fractures of regenerated bone after device removal
• Discrepancy in limb length
• Excessive motion at the fracture site to improper device set-up
• Heat build-up and bone necrosis with bone sequestration due to rapid drilling of the bony cortex
• Ankle stiffness due to multiple transfixion pins used in tibial fractures
• Bone deformity
• Thrombosis, late erosion or arteriovenous fistulas
• Osteomyelitis and persistent drainage at pin site after pin removal
• Inability to compress the bone surface due to poorly secured pins seated in the bone

Warnings and precautions
Preoperative
• This device should be used by individuals with adequate training and familiarity with orthopedic surgical techniques.
• If foreign body sensitivity is suspected, testing should be performed to rule out this possibility prior to implantation.
• The patient should be informed of how the device is used and potential complications associated with external fixation devices.
• It is important to correctly select the device components. The type and size should be appropriate and selected based on the patient’s injury, weight, size, and potential compliance, etc.
• Preoperative frame assembly is recommended to decrease OR time and to ensure that components are available as needed. Unless noted otherwise, use only elements from the XtraFix® External Fixation System to create the frame assembly.
• Examine all instruments for damage prior to surgery.

Intra-operative
• Intra-operative fracture or instrument breakage may occur.
• Carefully place pins to avoid damage to nerves, muscles, tendons, and vessels.
• Slowly drill through the bone to avoid heat necrosis of surrounding tissues and bone.

Post-operative
• Instruct patient that daily pin site care management is essential in reducing infections.
• Patient should be instructed that the frame assembly will not be as strong as healthy bone.
• Proper fixation and secure assembly of components are essential. Parts should be securely fastened with the appropriate instruments.
• Assess the gap at the fracture site during healing. Adjustments to the frame assembly should be made as necessary. Regularly check device frame integrity including fixation of the pin to the bone.
• Weight bearing should be avoided for the first three weeks postoperatively. After this time, touch down weight bearing is acceptable when there is bone-to-bone apposition resulting in inherent stability to the limb. In the absence of such stability, all weightbearing should be avoided until bridging callous is visible radiographically.

MR Conditional
Non-clinical testing has demonstrated the XtraFix External Fixation System with glass fiber bars only is MR Conditional. It can be scanned safely under the following conditions:
• static magnetic field of 1.5 or 3 Tesla,
• spatial gradient field of 1500 Gauss/cm or less,
• maximum whole body averaged specific absorption rate (WB SAR) of 2.0 W/kg for 15 minutes of scanning in a 1.5 or 3 Tesla scanner,
• normal operating mode only,
• all bars in the external fixation construct should be glass-fiber/epoxy bars.

Testing of the XtraFix External Fixation System with bars other than those made of glass fiber has not been performed. Scans should only be done with glass fiber bars. All other bar materials, in particular carbon fiber bars, can lead to substantial heating of the devices and scans should not be performed. The following data on heating is based on testing done with glass fiber bars:

In non-clinical testing in a 1.5T or 3T MR scanner the XtraFix External Fixation System produced a temperature rise of less than 8°C at a maximum whole-body averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of MR scanning. The largest image artifact extends approximately 60 mm from the device when scanned in nonclinical testing using the Spin Echo (SE) sequence in a 3T Siemens Medical Systems Tim Trio (running Syngo MR V17 software) using the Body RF Coil.

Cleaning and Sterilization
All products associated with the XtraFix® External Fixation System are provided nonsterile. The following instructions describe how to clean and sterilize the system components.

All external fixation components (clamps, posts, bars and pins) and drills in the XtraFix® External Fixation System are single use devices. Single use devices may be sterilized multiple times; however, single use devices should not be reprocessed if they have been contaminated with blood, any body fluid or debris. Possible risks associated with reprocessing of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Prior to each use, the following instructions should be used to clean and sterilize the external fixation system components and instruments. All components should be removed from the packaging and shipping material prior to cleaning and sterilization. Prior to sterilization the parts should be thoroughly cleaned. Clamps should be loosened but not disassembled. The modular handles should be removed from clamps, the tissue protector sleeves should be removed from any clamps or handles, and trocars, drills, and pins should be removed from the sleeves. All other instruments should not be disassembled.

Parts should be manually cleaned using lukewarm water (between 27°C and 44°C) with an appropriate detergent that is labeled as safe for use on the materials in the XtraFix® system (stainless steel, aluminum alloy, titanium alloy, silicone rubber and carbon-fiber or glass-fiber/epoxy composite). An enzyme detergent may be used for heavy organic soil. Follow the manufacturer instructions as provided on the detergent labeling.

All parts can be wiped or brushed with a soft cleaning cloth or brush. The lumens in the tissue protectors and drill sleeves should be cleaned with an appropriate sized cleaning brush and flushed. Any movable parts should be actuated as they are flushed, cleaned and rinsed. After cleaning, the parts should be thoroughly rinsed to remove debris and detergent residue, including rinsing of all lumens. A final rinse with treated water (i.e. de-ionized,
distilled or reverse osmosis water) is recommended. Dry the instruments with a clean, disposable, absorbent cloth. For reusable instruments that have been contaminated with blood, the parts should be pre-soaked in cold water. If contamination is found on the reusable instruments, remove it by rinsing with cold water, wiping and/or brushing. All XtraFix® components are fully submersible.

The parts should be visually inspected (internal and external) to assure cleanliness. If necessary, the steps above should be repeated until the part is visibly clean.

The following steps should be used to sterilize the external fixation components and instruments. Populate the tray with the appropriate XtraFix external fixation components and instruments only. The system tray is not a sterile barrier and must be wrapped. The system may be steam sterilized in its tray using a pre-vacuum cycle at 132°C (270°F) for 4 minutes or using gravity displacement at the same temperature for 15 minutes, both followed by 30 minutes drying time.

<table>
<thead>
<tr>
<th>Method</th>
<th>Time</th>
<th>Temperature</th>
<th>Drying Time</th>
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<tbody>
<tr>
<td>Gravity Displacement</td>
<td>15 Minutes</td>
<td>132°C (270°F)</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Pre-vacuum</td>
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<td>30 Minutes</td>
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At any time, if any external fixation component appears to have any pitting, corrosion or other signs of degradation, the implant should be disposed of or returned to the manufacturer and a new component should be used. If alternative cleaning and/or sterilization methods are used, it is the user’s responsibility to qualify these methods in conjunction with the XtraFix® system.

Single Use Only

MR Conditional

Storage Conditions
All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.
For additional information, contact:

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