

## 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, and tibia) and pelvic fractures that require external fixation. Specifically, the system is intended for:

- Temporary stabilization of open or closed acute fractures with soft tissue injuries;
- Definitive stabilization of open or closed fractures where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Stabilization of fractures in the context of polytrauma;
- Temporary or definitive stabilization of certain pelvic fractures or pelvic ring injuries;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint (knee and ankle) arthroplasty for infection or other failure;
- Neutralization of fractures stabilized with limited internal fixation;
- 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 wire site after wire 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, 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 and wire 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 720 Gauss/cm or less,
- Maximum whole body averaged specific absorption rate (WB SAR) of 1.0 W/kg for 15 minutes of scanning in a 1.5 Telsa scanner
- Maximum whole body averaged specific absorption rate (WB SAR) of 2.0 W/kg for 15 minutes of scanning in a 3 Telsa scanner

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, the XtraFix® External Fixation System produced a temperature rise up to 8.1°C when normalized to a maximum whole body averaged specific absorption rate (WB SAR) of 1 W/kg, as assessed by calorimetry, for 15 minutes of MR scanning in a 1.5T Avanto Siemens MR scanner.

In non-clinical testing, the XtraFix® External Fixation System produced a temperature rise up to 9.9°C when normalized to a maximum whole body averaged specific absorption rate (WB SAR) of 2 W/kg, as assessed by calorimetry, for 15 minutes of MR scanning in a 3T Tim Trio Siemens MR scanner.

In non-clinical testing, the following factors affected the amount of heating:

- Length of scan, where longer scans showed increased heating.
- Shallower depth of pin insertion showed increased heating.
- Lower static magnetic field strength showed increased heating (higher heating was produced in 1.5T MRI versus 3T MRI).
- Increased clamp size showed increased heating.

Larger clamps are typically used on larger bones, and deeper pin penetration is typically used with larger bones. To provide a better understanding of heating seen with typical external fixation frame constructs, additional tests have been conducted. The following are results of tests of the maximum heating measured with sample representative constructs using glass fiber bars along with the specified clamps and pins inserted to the depth listed.

**Heating in 1.5T Avanto Siemens MR Scanner (temperature normalized to a whole body specific absorption rate (WB SAR) of 1.0 W/kg)**

| Construct                                | Length of Scan |            |
|--|----------------|------------|
|  | 6 minutes      | 15 minutes |
| 105mm Clamp with pins inserted 20mm      | 6.2°C          | 8.1°C      |
| 45mm Clamp with pins inserted 20mm       | 1.5°C          | 2.2°C      |
| 45mm Clamp with pins inserted 45mm       | 1.1°C          | 1.4°C      |
| Bar to Pin Clamp with pins inserted 20mm | 1.0°C          | 1.3°C      |

### Heating in 3T Tim Trio Siemens MR Scanner (temperature normalized to a whole body specific absorption rate (WB SAR) of 2.0 W/kg)

| Construct                                | Length of Scan |            |
|--|----------------|------------|
|  | 6 minutes      | 15 minutes |
| 105mm Clamp with pins inserted 20mm      | 8.0°C          | 9.9°C      |
| 105mm Clamp with pins inserted 45mm      | 2.9°C          | 4.1°C      |
| 45mm Clamp with pins inserted 45mm       | 1.9°C          | 2.6°C      |
| Bar to Pin Clamp with pins inserted 45mm | 0.3°C          | 0.5°C      |

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 prepare the implants and ancillary instruments for the next patient, including cleaning and sterilization. All implants in the XtraFix® External Fixation System are single use devices; however, they may be sterilized multiple times. Prior to each use, the following steps should be used to clean and sterilize the implants and ancillary 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. Instruments should not be disassembled, but the modular handles, the tissue protector sleeves and drill sleeves should be separated from the guides. If there is any gross contamination on any of the parts, remove it by rinsing with cold water, wiping and/or brushing. Pre-soaking the parts in cold water should be done for any parts that have been contaminated with blood. All XtraFix® components are fully submersible.

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 fiberglass/epoxy composite). Follow the manufacturer instructions as provided on the detergent labeling. An enzyme detergent may be used for heavy organic soil. 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. 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.


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 implants and ancillary instruments. 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.

| Method               | Time       | Temperature   | Drying Time |
|----------------------|------------|---------------|-------------|
| Gravity Displacement | 15 Minutes | 132°C (270°F) | 30 Minutes  |
| Pre-vacuum           | 4 Minutes  | 132°C (270°F) | 30 Minutes  |

At any time, if any implant 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 implant 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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