

## External Fixation Systems

### IMPORTANT MEDICAL INFORMATION

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#### SPECIAL NOTE

External fixation should be used only under the directions of physicians who have a thorough knowledge of the anatomy, physiology and surgical principles involved. Physicians are strongly encouraged to obtain instruction from experienced clinicians or to observe surgical application of the apparatus prior to its initial use.

#### DESCRIPTION

External Fixation Systems consist of various components used to build constructs to treat the indications listed below. External Fixation Systems are modular, therefore, different frame configurations are possible. An individualized configuration should be designed for each case to suit the specific application. Refer to supporting instruction information provided by Smith & Nephew or component information assembly instructions, and surgical techniques for each individual external fixation system. ***All External Fixation System components are designed for single use only.***

Unless outlined in supporting instructional information, each External Fixation System is designed as a system and does not allow the substitution of components from other systems or manufacturers.

External Fixation Systems are made from various types of metal, plastic, and composite materials. The component material is provided on the outside carton label.

The COMPASS<sup>®</sup> Universal Hinge is used with the ILIZAROV<sup>™</sup> External Fixator to control distraction and rotation of an injured joint to regain, maintain, or increase the range of motion of the joint. It utilizes circular frame and half-pin fixation techniques and procedures for placement of the device. The device is intended to be centered on the axis of rotation. The device allows some adjustability to permit adjustment on the axis. Please refer to the surgical technique for complete details of the recommended procedures.

The TAYLOR SPATIAL FRAME<sup>®</sup> Fixator utilizes computer software to recommend adjustments to the fixation frame based on surgeon-derived measurements and examination.

#### INDICATIONS

1. Post-Traumatic joint contracture which has resulted in loss of range of motion (not applicable for Smith & Nephew Rail System)
2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
3. Open and closed fracture fixation

4. Pseudoarthrosis of long bones
5. Limb lengthening by epiphyseal or metaphyseal distraction (not applicable for COMPASS Universal Hinge or JET-X<sup>®</sup> Fixator)
6. Correction of bony or soft tissue deformities (not applicable for COMPASS Universal Hinge)
7. Correction of segmental bony or soft tissue defects
8. Joint arthrodesis (not applicable for Smith & Nephew Rail System)
9. Infected fractures or nonunions
10. Mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius (not applicable for Smith & Nephew Rail System)
11. Calandruccio devices are indicated for arthrodesis of the ankle or subtalar joints, as well as some select fractures, nonunion, or osteotomy of the distal tibia; and acute transverse fractures or nonunion of the distal tibia (not applicable for Smith & Nephew Rail System)

## **CONTRAINDICATIONS**

External fixation devices are contraindicated for use in uncooperative or mentally incompetent patients who are unable to follow the postoperative regimen.

Calandruccio devices are also contraindicated for fractures that will most likely heal satisfactorily with noninvasive conservative management, either casting or cast bracing without loss of joint function. Other contraindications include fractures or nonunions which do not permit multiple pin fixation in the coronal plane and patients with medical problems that require weight-bearing on the extremity.

## **WARNINGS**

1. The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient based on injury, weight, compliance, etc.
2. Preliminary frame assembly is recommended to reduce operative times and to assure an adequate supply of components prior to surgery.
3. Intraoperative fracture or instrument breakage can occur. Instruments which have been used extensively or with excessive force are susceptible to fracture. Examine all instruments for wear and damage prior to surgery. Replace where necessary. Single use devices should not be reused due to risks of breakage, failure or patient infection.
4. Correction of varus, valgus, procurvatum, and recurvatum movement of limb segments during distraction should be planned preoperatively by selecting an appropriate prophylactic ring tilt and strategically positioning wires with stoppers, fulcrums, half pins, and hinges.
5. Wire and pin placement requires strict anatomical consideration to avoid damage to nerves, muscles, tendons, and vessels. Wires should be gently pushed through soft tissue, not drilled, to reduce the possibility of injury.
6. Wire drilling through the bone should be done slowly to avoid heat necrosis of surrounding tissues and bone.
7. Use caution when handling the sharp tips of wires. The tip of the wire should be held when clipped. Eye protection is recommended for operating room personnel.
8. Pin/wire site care is crucial in reducing infections.
9. Periodic postoperative follow-up and radiographs are recommended during the distraction phase.

## PRECAUTIONS

1. Use extreme care in handling and storing components. Cutting, bending, or scratching the surface of components can reduce the strength and fatigue life of the device. Any components damaged during the course of the treatment should be replaced. Wire bending can be avoided by using various types of washers to build the ring to the wire.
2. Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.
3. Unless specified, only components from the same system should be used together. Refer to supporting instruction information for details on each external system.
4. Proper fixation and assembly of components are essential. All wires and miscellaneous parts should be securely fastened with the appropriate instrument. Wires should be tensioned as specified in product literature.
5. The proper wire diameter should be used to ensure sufficient wire strength and to maintain appropriate axial stiffness of the apparatus. The 1.8 mm wires are usually recommended for the tibia and femur in normal adults, while the 1.5 mm wires are usually recommended for the upper limbs and pediatric lower limb applications.
6. The diameter of the rings, assembled half rings or frames, are recommended to be about 4 cm larger than the maximum diameter of the operated limb segment to accommodate swelling.
7. Wire/pin security in bone, wire tension, and device frame integrity should be routinely checked. The gap at a fracture site should be reassessed during healing. Adjustments should be made as necessary.
8. The patient should be instructed to report any adverse or unanticipated effects to the physician as soon as possible and should also be advised of the distraction and adjustment requirement.
9. Preoperative planning for the TAYLOR SPATIAL FRAME Fixator requires special software and programs. Accurate inputs are critical for accurate results. Verify and double check all input parameters. The computer program should be run twice to verify that the parameters have been correctly entered into the software. The TAYLOR SPATIAL FRAME Fixator can be used as a template to compare the adjusted frame to the deformity to verify fit. Output of strut lengths from the program can exceed any strut length for a particular preassembled frame. If this occurs, refer to Surgical Technique and Instruction Manuals.
10. Intraoperative placement of the TAYLOR SPATIAL FRAME Fixator according to preoperative plans is imperative to achieve predetermined results. If intraoperative conditions require a change to frame placement (eccentricity) or size (parameters), new strut lengths should be calculated by entering the new inputs into the program. Small changes may affect accuracy of outcome.
11. Touch down weight bearing may be allowed postoperatively. Weight bearing may be increased as the callus thickens.
12. For patients with Calandruccio devices, postoperative care and physical therapy should be structured to prevent weight bearing on the operated leg until sufficient healing is evident on the x-ray.

### 13. MRI Information

JET-X Bar System fixator components are labeled **MR Conditional** according to the terminology specified in ASTM F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Non-clinical testing demonstrated that the JET-X Bar System fixator components, when used in the specific configuration stated herein, are **MR Conditional**. Representative JET-X Bar System fixator components used in

a typical construct included bar/pin clamps, multi-pin clamps, composite bars and metal half pins. A patient with the JET-X Bar System fixator can be scanned safely immediately after placement under the following conditions:

- **Static magnetic field** of 1.5-Tesla with the center of the JET-X Bar fixator frame positioned at least 30cm from the isocenter of the bore
- **Static magnetic field** of 3.0-Tesla with no restriction for the position of the JET-X Bar fixator frame
- **Highest spatial gradient magnetic field** of 720-Gauss/cm or less
- Maximum MR system reported, whole-body-averaged **specific absorption rate (SAR)** of 2 W/kg, (i.e. normal operating mode only).

Note: In non-clinical testing, a JET-X Bar System Tibia Frame fixator construct (comprised of 4 bar/pin clamps, 4 stainless steel half pins and a 350mm long composite bar) was combined with a JET-X Bar System Knee Spanning fixator construct (comprised of 4 bar/pin clamps, 3 bar/bar clamps, 1 multiple pin clamp, 4 stainless steel half pins and 3 composite bars ranging from 150mm to 600mm in length) to produce the worst-case “conduction loop”. In this non-clinical testing, the maximum observed heating was 19°C for 1.5T and 5.7°C for 3.0T. Because higher in vivo heating could be possible, close patient monitoring and communication with the patient during scanning is required.

Patients may be safely scanned in the MRI chamber when the center of the JET-X Bar fixator frame is positioned at least 30cm from the isocenter/longitudinal center of the bore of the magnet. To maintain this distance, patients may need to be positioned differently dependent on the anatomic placement of the JET-X Bar fixator frame (e.g. on the Upper or Lower extremity).

All other Smith & Nephew External Fixation Systems do not claim MRI safety or conditionality and no testing has been performed to evaluate the products for safety and compatibility in the MR environment. The External Fixation Systems have not been tested for heating or migration in the MR environment.

### **Artifact Information**

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the JET-X Bar System fixator construct. Therefore, it may be necessary to optimize MR imaging parameters in order to compensate for the presence of the JET-X Bar System fixator construct.

Representative components used to assemble a typical JET-X Bar System fixator construct have been evaluated in the MRI chamber. Artifact test results are summarized below. Overall, artifacts created by JET-X Bar System fixator components may present problems if the MR imaging area of interest is in or near the area where the JET-X Bar System fixator construct is located. See Table 1 below for artifact information.

Table 1 – Summary of MRI Artifacts @ 3-Tesla for Components of the JET-X Bar System

Artifact Information				
<b>JET-X Bar-to-Pin Clamp</b> (51mm x 32mm x 25mm)				
Pulse Sequence	T1 - SE	T1 - SE	GRE	GRE
Signal Void Size	13,652 mm <sup>2</sup>	11,555 mm <sup>2</sup>	21,494 mm <sup>2</sup>	21,809 mm <sup>2</sup>
Imaging Plane	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)
<b>JET-X 350mm Composite Bar</b> (10.5mm diameter x 350mm long)				
Pulse Sequence	T1 - SE	T1 - SE	GRE	GRE
Signal Void Size	1,726 mm <sup>2</sup>	109 mm <sup>2</sup>	1,823 mm <sup>2</sup>	112 mm <sup>2</sup>
Imaging Plane	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)
<b>JET-X Long Titanium Nitride Half Pin</b> (6mm diameter x 232mm long)				
Pulse Sequence	T1 - SE	T1 - SE	GRE	GRE
Signal Void Size	6,311 mm <sup>2</sup>	2,446 mm <sup>2</sup>	12,073 mm <sup>2</sup>	6,115 mm <sup>2</sup>
Imaging Plane	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)
<b>JET-X Multi-Pin Clamp</b> (102mm x 32mm x 25mm)				
Pulse Sequence	T1 - SE	T1 - SE	GRE	GRE
Signal Void Size	26,643 mm <sup>2</sup>	12,200 mm <sup>2</sup>	25,538 mm <sup>2</sup>	23,800 mm <sup>2</sup>
Imaging Plane	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)

T1 – SE = T1-weighted spin echo      GRE = gradient echo

#### ADVERSE EFFECTS

1. Damage to nerves or vessels resulting from insertion of wires and pins
2. Infection including persistent drainage of the pin tracts, or after wire removal; chronic pin/wire site osteomyelitis
3. Edema or swelling, possible compartment syndrome
4. Joint contracture, loss of range of motion or reduction, joint subluxation or dislocation
5. Septic arthritis and osteomyelitis
6. Loosening or breakage of the pins, wires, or other components including inadvertent injury to the patient or operating room personnel caused by the wire (e.g. projective wire from tip cutting during surgery)
7. Intractable pain or delayed unions or both
8. Persistence or reoccurrence of the initial condition requiring treatment
9. Reoperation to replace a component or the entire apparatus
10. Foreign body reaction to pins, wires, or other components
11. Tissue necrosis occurring during pin or wire insertion or at the pin/wire tissue junction
12. Excessive operative bleeding or muscle tendon impalement
13. Skin pressure problems caused by external components
14. The intrinsic risks associated with anesthesia

15. Premature consolidation during bone elongation
16. Secondary equinus contracture
17. Failure of bone to regenerate satisfactorily; development or persistence of nonunion or pseudoarthrosis
18. Fracture of regenerated bone or fracture through a hole after removal of the device
19. Abnormal growth plate development in patients who are not skeletally mature, including premature fusion, and slowed or accelerated growth
20. Loss of bone mass due to “stress shielding”
21. Limb length discrepancy
22. Bone sequestration secondary to rapid drilling of the bony cortex, with heat build-up and bone necrosis
23. Excessive motion at the fracture site due to failure to tighten the component parts of the device; improper tensioning of wires, flexion from use of too few pins or pins that are too small
24. Ankle stiffness if multiple transfixion pins are used in tibial fractures
25. Thrombosis, late erosion or arteriovenous fistulas
26. Persistent drainage after wire removal; chronic wire site osteomyelitis
27. Bone deformity
28. Inability to compress the bone surface if the pins are not securely seated in bone

## **PACKAGING AND LABELING**

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. For implants that are provided sterile, if the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

## **STERILIZATION**

For components provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of  $10^{-6}$ . Sterile packaged implant components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

If not specifically labeled sterile, the components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile external fixation devices, remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization. Please also see the document, “Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices,” which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

DO NOT REUSE implant components or single use disposable instruments.

**HA coated half pins are provided STERILE packaged and cannot be resterilized.**

## **RECOMMENDED STEAM STERILIZATION CYCLE PARAMETERS (for devices provided non-sterile)**

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes, and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C (273°F) for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance to HTM 2010).

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

### **RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS**

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.

If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

### **INFORMATION**

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

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

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### **Manufacturing facilities and EC representative:**

Smith & Nephew Inc.  
1450 Brooks Road  
Memphis, TN 38116 U.S.A.  
Tel.: 901-396-2121

Smith & Nephew Orthopaedics GmbH  
Alemannenstrasse 14  
78532 Tuttlingen, Germany  
Tel.: 07462/208-0  
Fax: 07462/208-135

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