LARGE EXTERNAL FIXATOR—DELTA FRAME ANKLE BRIDGE

Using pin clamps with outrigger posts
Large External Fixation devices are labeled MR Conditional according to the terminology specified in ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Nonclinical testing demonstrated that, when used in the specific configurations stated in DePuy Synthes Companies labeling, DePuy Synthes Companies Large External Fixation devices are MR Conditional. Representative DePuy Synthes Companies Large External Fixation devices used in a typical construct include clamps, rods and various attachments.

A patient with a DePuy Synthes Companies Large External Fixation frame may be scanned safely after placement of the frame under the following conditions.

- **Static magnetic field of 1.5-Tesla** when the fixator frame is positioned outside the MRI bore at Normal Operator or in First Level Control Mode
- **Static magnetic field of 3.0-Tesla** when the fixator frame is positioned outside the MRI bore at Normal Operator or in First Level Control Mode
- **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 for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning
- **Use only whole body RF transmit coil**, no other transmit coils are allowed, local receive only coils are allowed
- **Specialty Coils**, such as knee or head coils, should not be used as they have not been evaluated for RF heating and may result in higher localized heating

**Note:** In nonclinical testing, the DePuy Synthes Companies External Fixation Devices were tested in several different configurations. This testing was conducted with the construct positioned at the edge of the MRI bore, with the entire construct outside the MRI bore.

The results showed a maximum observed heating for a wrist fixator frame of less than 4°C for 1.5T and less than 2°C for 3.0T with a machine reported whole body averaged SAR of 2 W/kg

The results showed a maximum observed heating for a pelvic frame less than 1°C for 1.5 and 3.0T with a machine reported whole body averaged SAR of 2 W/kg

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal expected temperature rise is less than 6°C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan is required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible, and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes.

The above field conditions should be compared with those of the user's MR system, to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, DePuy Synthes Companies MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of DePuy Synthes Companies external fixation frames must be identified as MR Conditional prior to being placed in or near an MR environment.

**Artifact information**

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the DePuy Synthes Companies Large External Fixation construct, and it may be necessary to optimize MR imaging parameters, to compensate for the presence of the fixation frame.

Representative devices used to assemble a typical DePuy Synthes Companies Large External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Companies Large External Fixation devices may present issues if the MR imaging area of interest is in or near the area where the fixation frame is located.

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DePuy Synthes Trauma Large External Fixator — Delta Frame Ankle Bridge Surgical Technique
INDICATIONS

The DePuy Synthes Large External Fixation Systems is intended to provide treatment for long bone and pelvic fractures that require external fixation. Specifically, the components can be used for:

- Stabilization of soft tissues and fractures
- Polytrauma/multiple orthopaedic trauma
- Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation
- Non-unions/septic non-unions
- Intraoperative reductions/stabilization tool to assist with indirect reduction
- Unilateral rectilinear bone segment transport or leg lengthening

MRI INFORMATION

- For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 5 cm from the device.

Warning: Do not place any radio frequency (RF) transmit coils over the external fixation frame.
TECHNIQUE OVERVIEW

1  **Insert Steinmann pin**
Insert a centrally threaded Steinmann pin through the calcaneal tuberosity.

2  **Attach open adjustable clamps**

3  **Insert Schanz screws**
Use the 6-Position Drill Guide Handle (392.963) or pin clamp technique to ensure proper pin spacing.

4  **Attach pin clamp**
Tighten the vise plates.

5  **Attach outrigger posts**
Thread a post into each vise plate to a hard stop. For angled posts, turn the post counterclockwise to the desired orientation. Lock in position by turning the lock nut clockwise until tight.

6  **Attach carbon fiber rods**
Attach carbon fiber rods to outrigger posts with combination clamps and to open adjustable clamps on the Steinmann pin.

7  **Reduce fracture**
Reduce the fracture and tighten all clamps.

**Notes:**
For ease of reduction, tighten the proximal clamp first and then reduce.

To prevent equinus contracture, Schanz screws can be placed in the metatarsals as shown on the Optional Frame Configurations page.
**RECOMMENDED COMPONENTS FOR BASIC FRAME**

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Item</th>
<th>Quantity Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>293.xx</td>
<td>5.0 mm Steinmann Pin, with central thread</td>
<td>1</td>
</tr>
<tr>
<td>294.78x</td>
<td>5.0 mm Self-Drilling Schanz Screw</td>
<td>2</td>
</tr>
<tr>
<td>390.005</td>
<td>Large Combination Clamp</td>
<td>2</td>
</tr>
<tr>
<td>390.008</td>
<td>Large Open Adjustable Clamp</td>
<td>2</td>
</tr>
<tr>
<td>390.010</td>
<td>Large Pin Clamp, 6 position</td>
<td>1</td>
</tr>
<tr>
<td>390.012</td>
<td>30° Outrigger Post, 11 mm</td>
<td>2</td>
</tr>
<tr>
<td>394.8x</td>
<td>11.0 mm Carbon Fiber Rod</td>
<td>2</td>
</tr>
<tr>
<td>394.97</td>
<td>Protective Cap, for 11.0 mm rods</td>
<td>4</td>
</tr>
<tr>
<td>394.993</td>
<td>Protective Cap, for 5.0 mm Fixation Pins</td>
<td>4</td>
</tr>
</tbody>
</table>
When to use
The purpose of this frame is to achieve a closed reduction through ligamentotaxis and maintain it until the soft tissue injury can resolve. The frame is recommended in conjunction with a two-stage treatment protocol for extra- and intra-articular fractures of the distal tibia with soft tissue injury (closed or open). The recommended protocol includes immediate open reduction and internal fixation (ORIF) of the fractured fibula, then application of the spanning external fixator in order to maintain tibial reduction, followed by delayed ORIF of the tibia.¹,²,³

Relevant anatomy and pin placement
• In the tibia, insert Schanz screws within the safe zone.⁴
• Tibial Schanz screws should be placed in the AP plane (as shown in the illustrated frame) for maximum stability. Alternatively, they may be placed anteromedially to avoid drilling along the crest. In dense cortical bone, it may be necessary to predrill.
• Schanz screws are placed proximal to the fracture in the midsagittal plane of the diaphysis, approximately one-half fingerbreadth medial to the tibial crest.
• The proximal Schanz screws should be placed outside the proposed future operative site to avoid the risk of contamination.
• In the calcaneus, a centrally threaded Steinmann pin is placed through the calcaneal tuberosity. In order to avoid the neurovascular bundle, this pin should be placed well posterior and inferior and can be placed with image intensification. Typically, the ideal insertion site lies two fingerbreadths from the plantar aspect of the heel and two fingerbreadths anterior to the dorsal aspect of the heel.

PIN CLAMP TECHNIQUE

1
Insert first Schanz screw
Insert a Schanz screw through the drill sleeve and end position of the Large Pin Clamp (390.009 or 390.010), using the clamp as an insertion guide.

Note: The clamp should be parallel, and the Schanz screws perpendicular, to the bone.

2
Insert second Schanz screw
Insert a second Schanz screw through the opposite end of the clamp. Tighten vise plates.

Note: Additional Schanz screws may be inserted as needed.
The delta frame ankle bridge can also be built using the straight or 90° outrigger posts, as shown.
Enhancing the frame for additional stability
To prevent equinus contracture, several options are available. A 4.0 mm Schanz screw can be placed in the proximal-third portion of the first metatarsal, with a second Schanz screw in the third, fourth or fifth metatarsal. These Schanz screws can each be directly connected to the delta frame rods or to each other with a transverse carbon fiber rod. Alternatively, a single Schanz screw can be carefully placed in the middle cuneiform.

Conversion to a hybrid frame
If ORIF cannot be performed due to the degree of soft tissue injury or because of the amount of metaphyseal or articular comminution, the delta frame can be converted to a hybrid frame.

With the delta frame in position, place two spade-point reduction wires through the distal bony fragment. Attach a 3/4 ring and connect to the previously placed outrigger posts. Remove the Steinmann pin from the calcaneus.

For further information, please refer to the Distal Tibia Hybrid Frame Technique Guide.

Note: The hybrid frame is NOT MR Conditional. MR Conditional frames are composed of:
- color-coded clamps etched
- carbon fiber rods etched
- DePuy Synthes Companies stainless steel or titanium Schanz screws labeled MR Conditional
LARGE EXTERNAL FIXATOR SET WITH SELF-DRILLING SCHANZ SCREWS
Stainless Steel (115.720) or Titanium (115.740)

<table>
<thead>
<tr>
<th>Graphic Case</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>690.315</td>
<td>Large External Fixator Graphic Case</td>
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</table>

<table>
<thead>
<tr>
<th>Implants in Set 115.720, MR Conditional</th>
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<tbody>
<tr>
<td>293.74</td>
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<td>294.56</td>
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<td>294.950</td>
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<table>
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<tr>
<th>Implants in Set 115.740, MR Conditional</th>
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<tbody>
<tr>
<td>293.74</td>
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<table>
<thead>
<tr>
<th>Instruments (for both sets)</th>
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<tbody>
<tr>
<td>310.37</td>
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<td>310.48</td>
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<tr>
<td>321.20</td>
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<td>355.14</td>
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<td>392.951</td>
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<td>392.963</td>
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<tr>
<td>393.10</td>
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</table>

For detailed cleaning and sterilization instructions, please refer to:
www.synthes.com/cleaning-sterilization
In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.
**Large External Fixator Set with Self-Drilling Schanz Screws**

Stainless Steel (115.720) or Titanium (115.740)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
</table>
| 393.103 | Drive Adaptor with quick coupling,  
for 5.0 mm Schanz Screws |
| 393.104 | Drive Adaptor with quick coupling,  
for 6.0 mm Schanz Screws |
| 393.746 | Split Tissue Protection Sleeve, 5.0 mm |
| 393.76 | Open Compressor, 2 ea |
| 394.181 | 3.5 mm Trocar, short |
| 394.182 | 3.5 mm Trocar, long |
| 395.911 | Drill Sleeve Handle |
| 395.912 | 5.0 mm/3.5 mm Drill Sleeve, short |
| 395.913 | 5.0 mm/3.5 mm Drill Sleeve, long |
| 395.921 | 6.0 mm/5.0 mm Threaded Drill Sleeve, short |
| 395.923 | 6.0 mm/5.0 mm Threaded Drill Sleeve, long |

**Fixation Material (for both sets), MR Conditional**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.002</td>
<td>Large Multi-Pin Clamp, 6 position, 4 ea</td>
</tr>
</tbody>
</table>
| 390.003 | Rod Attachment, for Large Multi-Pin Clamp,  
6 ea |
| 390.004 | Large Multi-Pin Clamp, 4 position, 2 ea |
| 390.005 | Large Combination Clamp, 12 ea |
| 390.006 | Dynamization Clip, for Large Combination  
Clamp, 4 ea |
| 390.007 | Tube-to-Tube Clamp, 2 ea |
| 390.008 | Large Open Adjustable Clamp, 8 ea |
| 393.66* | Transverse Clamp, 2 ea |

- 11.0 mm Carbon Fiber Rods, 4 ea
- 100 mm
- 150 mm
- 200 mm
- 250 mm
- 300 mm
- 350 mm
- 400 mm

**Protective Caps**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>394.97*</td>
<td>For 11.0 mm Rods, (10/pkg)</td>
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<tr>
<td>394.993*</td>
<td>For 5.0 mm Fixation Pins, (10/pkg)</td>
</tr>
<tr>
<td>394.994*</td>
<td>For 6.0 mm Fixation Pins, (10/pkg)</td>
</tr>
</tbody>
</table>

*This item has not been tested for safety in the MR environment.*
ALSO AVAILABLE

Implants, MR Conditional

- **Schanz Screws**
  - 294.43–.48  4.0 mm, spade point, 60 mm–150 mm
  - 294.52–.57  5.0 mm, blunted trocar point, 100 mm–250 mm
  - 294.71–.76  4.5 mm, blunted trocar point, 80 mm–200 mm

- **Self-Drilling Schanz Screws**
  - 294.774–.779  4.0 mm, 60 mm–175 mm
  - 294.782–.788  5.0 mm, 100 mm–250 mm
  - 294.792–.798  6.0 mm, 100 mm–250 mm

- **Titanium Self-Drilling Schanz Screws**
  - 494.774–.779  4.0 mm, 60 mm–175 mm
  - 494.782–.788  5.0 mm, 100 mm–250 mm
  - 494.792–.798  6.0 mm, 100 mm–250 mm

Fixation Material, MR Conditional

- **Large Pin Clamp**
  - 390.009  4 position
  - 390.010  6 position
  - 390.011  11 mm
  - 390.012  30° Post, 11 mm
  - 390.013  90° Post, 11 mm

  - 11.0 mm Carbon Fiber Bridging Rods
    - 394.796  190 mm, short
    - 394.797  190 mm, long
    - 394.798  220 mm, short
    - 394.799  220 mm, long

Fixation Material

- **Spring-Loaded Nut**
  - 393.43*

- **Adjustable Clamp**
  - 393.64*

- **Open Clamp**
  - 393.69*

- **Universal Joint for Two Tubes**
  - 393.71*

- **Universal Clamp**
  - 393.75*

- **Protective Caps**
  - 394.991*  For 4.0 mm Fixation Pins (10/pkg)
  - 394.992*  For 4.5 mm Fixation Pins (10/pkg)

Sterile-Packaged Large External Fixator Kits

- 03.301.010S  Large External Fixator Ankle Frame Kit, sterile
- 03.301.011S  Large External Fixator Trauma Kit, sterile
- 03.301.012S  Large External Fixator Pelvic Frame Kit, sterile

Sets

- 105.957  Power Drive Set
- 150.16  ComPact Air Drive II Set

Accessories for Graphic Case

- 690.315.12  Label Sheet Pack, for Large External Fixator Clamps
- 690.315.13  Label Sheet Pack, for Schanz Screws
- 690.315.14  Replacement Brackets (3 sizes)
- 690.315.15  Replacement Screws (10/pkg)
- 690.315.17  Label Sheet, for Large External Fixator MR Conditional clamps

*This item has not been tested for safety in the MR environment.

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Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.