Used to Correct Angular Deformity

Large External Fixator—Traveling Traction

Surgical Technique
DePuy Synthes 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 labeling, DePuy Synthes Large External Fixation devices are MR Conditional. Representative DePuy Synthes Large External Fixation devices used in a typical construct include clamps, rods and various attachments.

A patient with a DePuy Synthes 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 non-clinical testing, the DePuy Synthes 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.

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 MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of DePuy Synthes 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 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 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 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.
Indications and MRI Information

Indications
The 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
– Arthrodesis 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

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

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:**
- DePuy Synthes self-drilling, self-tapping Schanz screws and Steinmann pins are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**Precautions:**
- To keep from damaging the femoral cutaneous nerve, avoid pin insertion up to 15 mm in a dorsal direction from the superior anterior iliac spine.
- When dealing with the humerus, primary consideration should be given to the radial and axillary nerves. Distally, a dorsal approach to the humerus is appropriate. Proximally, it is recommendable to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve.
- Select the appropriate Schanz screw (self-tapping, self-drilling), or Steinmann pin for the patient’s bony anatomy.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user’s glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
- The self-drilling Schanz screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the self-drilling Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Only when bones are osteoporotic does the self-drilling Schanz screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability.
- The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Implant sites should be meticulously cared for to avoid pintract infection. Schanz screws and Steinmann pins may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient.
- To help minimize the risk of pin track infection the following points should be observed:
  a. Placement of Schanz screws and Steinmann pins taking anatomy into consideration (ligaments, nerves, arteries).
  b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis.
  c. Release of skin tension at soft tissue entry point of implant.
Insert distal transfixation pin
Insert pin into the calcaneus.

Insert proximal transfixation pin
Ensure that the pin is placed 14 mm distal, and parallel to the articular surface of the proximal tibia.

Add open adjustable clamps
Place one clamp on either side of the transfixation pins.

Attach two carbon fiber rods
As the calcaneal pin lies posterior to the tibial pin, orient the clamps so that the rod will be posterior to the tibial (proximal) pin and anterior to the calcaneal (distal) pin. Tighten nuts.

Add open compressors
Attach open compressors just proximal to the distal open adjustable clamps.

Reduction
Reduction is first performed by manual traction in order to regain length and correct rotation. Clamps are then tightened. Once frame has been locked into place, rotation can no longer be easily adjusted.

Fine adjustment
Fine adjustment of axial and angular deformity is then accomplished using the distally applied open compressor.

Note: Loosening of the rod portion of the open adjustable clamp allows this clamp to slide along the rod. Unilateral distraction corrects angular deformity. Bilateral distraction adjusts length.

Retighten adjustable clamps
Remove open compressors before distal targeting.

The socket wrench with universal joint is used for easy adjustment.
## Recommended Components for Basic Frame

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Item</th>
<th>Quantity Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>294.950</td>
<td>6.0 mm Transfixation Pin, 225 mm</td>
<td>2</td>
</tr>
<tr>
<td>390.008</td>
<td>Large Open Adjustable Clamp</td>
<td>4</td>
</tr>
<tr>
<td>393.76</td>
<td>Open Compressor *</td>
<td>2</td>
</tr>
<tr>
<td>394.8x</td>
<td>11.0 mm Carbon Fiber Rod</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td><strong>Special Instrument</strong></td>
<td></td>
</tr>
<tr>
<td>321.15</td>
<td>Socket Wrench with universal joint</td>
<td></td>
</tr>
</tbody>
</table>

*The Open Compressor is NOT MR Conditional.*
When to use
This frame is used to correct angular deformity and maintain length in preparation for intramedullary nailing of the tibia.

The frame can also be used for pilon fractures, along with a posterior splint, in order to hold the fracture until the soft tissues are stabilized and CT scans can be obtained.

Note: With longer carbon fiber rods and a transfixation pin in the distal femur, a tibial plateau fracture can also be temporarily stabilized.

Patient positioning
The patient should be placed supine on a standard radiolucent operating table. A rolled blanket is placed under the hip of the injured extremity to place the limb in neutral rotation.

Pin placement
The positioning of the distal pin in the calcaneus, as opposed to the distal tibia, allows IM nailing of very distal fractures.

Distal transfixation pin
Insert in the calcaneus, parallel to the coronal plane of the distal tibia.

Proximal transfixation pin
The insertion point is proximal and posterior to the nail entry site.

Insert from lateral to medial, beginning at the level of the tip of the fibular head in line with its anterior border, at least 14 mm distal to and parallel to the tibial articular surface (using the table as a guide can help to ensure that the pin is parallel to the joint).

The proximal pin must be parallel to the distal pin in the transverse plane to ensure correct rotational alignment upon frame assembly.
Basic principles
– The traveling traction frame aids in stabilization of the fracture for AP and lateral x-rays.
– For angular deformities, sterile towels can be placed in the space between the carbon fiber rod and the tibia to help adjust the fragment.
– Be sure to leave sufficient excess rod length at the distal end of the frame to allow the 2 rods to act as a “stand” when the knee is hyperflexed for nail insertion. Put extra towels under the heel so it is supported.
– Any residual distraction can be corrected by applying the open compressors distal to the calcaneal pin, then compressing the fracture before final seating of the nail.

Optional: Use of the large distractor
A modified version of this frame, using the Large Distractor (394.35)* instead of one of the carbon fiber rods, can be used for the correction of excessive rotational deformity related to nonparallel pin placement and for fractures that are more than two weeks old. In this situation, the distractor is placed on the concave side of the deformity with the threaded spindle rotated to a posterior location to prevent obstruction of lateral radiography.

For further information, please refer to The Large Distractor—Tibia Technique Guide.

*Also available.

Bibliography
## Traveling Traction Sets

Standard (01.301.200) or Extended Length (01.301.100)

### Graphic Cases

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>690.462</td>
<td>Traveling Traction Graphic Case, standard</td>
</tr>
<tr>
<td>690.461</td>
<td>Traveling Traction Graphic Case, extended length</td>
</tr>
</tbody>
</table>

### Implants (in both sets), MR Conditional

- 5.0 mm Steinmann Pins with central thread
  - 4 ea.
- 293.840  250 mm
- 293.890  275 mm
- 293.940  300 mm
- 294.950  6.0 mm Transfixation Pin, 225 mm,
  - 4 ea.

### Instruments (in both sets)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>310.37</td>
<td>3.5 mm Drill Bit, quick coupling, 195 mm</td>
</tr>
<tr>
<td>310.48</td>
<td>4.5 mm Drill Bit, quick coupling, 195 mm</td>
</tr>
<tr>
<td>321.15</td>
<td>Socket Wrench with universal joint,</td>
</tr>
<tr>
<td></td>
<td>11 mm width across flats</td>
</tr>
<tr>
<td>321.16</td>
<td>Combination Wrench, 11 mm width across flats</td>
</tr>
<tr>
<td>392.951</td>
<td>8.0 mm/6.0 mm Threaded Drill Sleeve, short, 2 ea.</td>
</tr>
<tr>
<td>393.103</td>
<td>Drive Adaptor with quick coupling,</td>
</tr>
<tr>
<td></td>
<td>for 5.0 mm Schanz screws, 2 ea.</td>
</tr>
<tr>
<td>393.105</td>
<td>Small Universal Chuck with T-Handle</td>
</tr>
<tr>
<td>393.76</td>
<td>Open Compressor, 4 ea.</td>
</tr>
<tr>
<td>394.181</td>
<td>3.5 mm Trocar, short, 2 ea.</td>
</tr>
<tr>
<td>395.911</td>
<td>Drill Sleeve Handle, 2 ea.</td>
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<tr>
<td>395.912</td>
<td>5.0 mm/3.5 mm Drill Sleeve, 77 mm (short), 2 ea.</td>
</tr>
<tr>
<td>395.921</td>
<td>6.0 mm/5.0 mm Threaded Drill Sleeve, 68 mm (short), 2 ea.</td>
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</table>

For detailed cleaning and sterilization instructions, please refer to [www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization) or sterilization instructions, if provided.
## Traveling Traction Sets
Standard (01.301.200) or Extended Length (01.301.100) continued

### Fixation Material (in set 01.301.200), MR Conditional

<table>
<thead>
<tr>
<th>Code</th>
<th>Item Description</th>
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<tbody>
<tr>
<td>390.008</td>
<td>Large Open Adjustable Clamp, 6 ea.</td>
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<tr>
<td></td>
<td>11.0 mm Carbon Fiber Rods, 2 ea.</td>
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<tr>
<td>394.86</td>
<td>350 mm</td>
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<td>394.87</td>
<td>400 mm</td>
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<tr>
<td>394.88</td>
<td>450 mm</td>
</tr>
<tr>
<td>394.89</td>
<td>500 mm</td>
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</tbody>
</table>

**Protective Caps**

- 394.97* For 11.0 mm Carbon Fiber Rods, 1 pkg. of 10
- 394.993* For 5.0 mm Fixation Pins, 1 pkg. of 10
- 394.994* For 6.0 mm Fixation Pins, 1 pkg. of 10

### Fixation Material (in set 01.301.100), MR Conditional

<table>
<thead>
<tr>
<th>Code</th>
<th>Item Description</th>
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<tbody>
<tr>
<td>390.008</td>
<td>Large Open Adjustable Clamp, 6 ea.</td>
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<td>11.0 mm Carbon Fiber Rods, 2 ea.</td>
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<td>394.89</td>
<td>500 mm</td>
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<td>394.90</td>
<td>550 mm</td>
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<tr>
<td>394.91</td>
<td>600 mm</td>
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<tr>
<td>394.92</td>
<td>650 mm</td>
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**Protective Caps**

- 394.97* For 11.0 mm Carbon Fiber Rods, 1 pkg. of 10
- 394.993* For 5.0 mm Fixation Pins, 1 pkg. of 10
- 394.994* For 6.0 mm Fixation Pins, 1 pkg. of 10

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*This item has not been tested for use in the MR environment.*
Also Available

Instruments
321.20 Ratchet Wrench, 11 mm width across flats
355.14 Cannulated Socket Wrench, 11 mm width across flats
393.10 Universal Chuck with T-Handle
393.746 Split Tissue Protection Sleeve
394.35 Large Distractor, complete

Fixation Material, MR Conditional
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

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

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
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Note: For recognized manufacturer, refer to the product label.

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