Large External Fixator—Tibial Shaft Box Frame. Using pin clamps with outrigger posts.
Synthes Large External Fixator—Tibial Shaft Box Frame Technique Guide

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

A patient with a 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 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
- 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, Synthes MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of 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 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 Synthes Large External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by 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

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
- 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

For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15º and SE sequence: Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70º 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.

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Technique Overview

1
Insert Schanz screws
Use the 6-Position Drill Guide Handle (392.963) or pin clamp technique to ensure proper pin spacing.

2
Attach pin clamps
Tighten the vise plates.

3
Attach outrigger posts
Thread the posts into the vise plates 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.

4
Attach carbon fiber rod
Attach carbon fiber rod to outrigger posts with combination clamps.

5
Reduce fracture
Reduce the fracture and tighten all clamps.

Note: To increase stiffness, add a second rod by repeating Steps 3 and 4 on the opposite side of the pin clamps.
### Recommended Components for Basic Frame

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Item</th>
<th>Quantity Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>294.78x</td>
<td>5.0 mm Self-Drilling Schanz Screw</td>
<td>4</td>
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<tr>
<td>390.005</td>
<td>Large Combination Clamp, MR Conditional</td>
<td>2</td>
</tr>
<tr>
<td>390.010</td>
<td>Large Pin Clamp, 6 position, MR Conditional</td>
<td>2</td>
</tr>
<tr>
<td>390.012</td>
<td>30° Outrigger Post, 11 mm, MR Conditional</td>
<td>2</td>
</tr>
<tr>
<td>394.8x</td>
<td>11.0 mm Carbon Fiber Rod, MR Conditional</td>
<td>1</td>
</tr>
<tr>
<td>394.97</td>
<td>Protective Cap, for 11.0 mm rods</td>
<td>2</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
This frame is a treatment option that can be utilized for the fixation of tibia shaft fractures with open or closed soft tissue injury. The 6-position large pin clamp allows full adjustability for fracture reduction.

Relevant anatomy
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.

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.

Reference
Optional Frame Configurations

Box frame with straight outrigger posts

Box frame with 90° outrigger posts

Box frame with diagonal crossbar for additional stiffness

Knee and ankle spanning frame with Schanz screw in metatarsal
Synthes

Large External Fixator Set with Self-Drilling Schanz Screws
Stainless Steel (115.720) or Titanium (115.740)

Graphic Case
690.315 Large External Fixator Graphic Case

Implants in Set 115.720, MR Conditional
293.74 5.0 mm Steinmann Pin with Central Thread, 200 mm, 4 ea.
294.56 5.0 mm Schanz Screw, blunted trocar point, 200 mm, 8 ea.
294.784 60 mm thread/150 mm, 4 ea.
294.785 60 mm thread/175 mm, 8 ea.
294.786 80 mm thread/200 mm, 8 ea.
294.950 6.0 mm Transfixation Pin, 225 mm, 4 ea.

Implants in Set 115.740, MR Conditional
293.74 5.0 mm Steinmann Pin with Central Thread, 200 mm, 4 ea.
294.56 5.0 mm Schanz Screw, blunted trocar point, 200 mm, 8 ea.
294.950 6.0 mm Transfixation Pin, 225 mm, 4 ea.

5.0 mm Titanium Self-Drilling Schanz Screws
494.784 60 mm thread/150 mm, 4 ea.
494.785 60 mm thread/175 mm, 8 ea.
494.786 80 mm thread/200 mm, 8 ea.

Instruments (for both sets)
310.37 3.5 mm Drill Bit, quick coupling, 195 mm, 2 ea.
310.48 4.5 mm Drill Bit, quick coupling, 195 mm, 2 ea.
321.20 Ratchet Wrench, 11 mm width across flats, 2 ea.
355.14 Cannulated Socket Wrench
392.951 8.0 mm/6.0 mm Threaded Drill Sleeve, short
392.952 8.0 mm/6.0 mm Threaded Drill Sleeve, long
392.963 6-Position Drill Guide Handle
393.10 Universal Chuck with T-Handle
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

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.
## Instruments (for both sets) continued

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>393.746</td>
<td>Split Tissue Protection Sleeve, 5.0 mm</td>
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<tr>
<td>393.76</td>
<td>Open Compressor, 2 ea.</td>
</tr>
<tr>
<td>394.181</td>
<td>3.5 mm Trocar, short</td>
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<tr>
<td>394.182</td>
<td>3.5 mm Trocar, long</td>
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<tr>
<td>395.911</td>
<td>Drill Sleeve Handle</td>
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<tr>
<td>395.912</td>
<td>5.0 mm/3.5 mm Drill Sleeve, short</td>
</tr>
<tr>
<td>395.913</td>
<td>5.0 mm/3.5 mm Drill Sleeve, long</td>
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<tr>
<td>395.921</td>
<td>6.0 mm/5.0 mm Threaded Drill Sleeve, short</td>
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<tr>
<td>395.923</td>
<td>6.0 mm/5.0 mm Threaded Drill Sleeve, long</td>
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## Fixation Material (for both sets), MR Conditional

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

11.0 mm Carbon Fiber Rods, 4 ea.

<table>
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<th>Description</th>
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<tr>
<td>394.80</td>
<td>100 mm</td>
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<tr>
<td>394.82</td>
<td>150 mm</td>
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<td>394.83</td>
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<td>394.85</td>
<td>300 mm</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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Protective Caps

<table>
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<th>Description</th>
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<tbody>
<tr>
<td>394.97*</td>
<td>For 11.0 mm Rods, 1 pkg. of 10</td>
</tr>
<tr>
<td>394.993*</td>
<td>For 5.0 mm Fixation Pins, 1 pkg. of 10</td>
</tr>
<tr>
<td>394.994*</td>
<td>For 6.0 mm Fixation Pins, 1 pkg. of 10</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, diamond 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

- 390.009 Large Pin Clamp, 4 position
- 390.010 Large Pin Clamp, 6 position
- 390.011 Straight Outrigger Post, 11 mm
- 390.012 30° Outrigger Post, 11 mm
- 390.013 90° Outrigger Post, 11 mm
- 394.796 11.0 mm Carbon Fiber Bridging Rods, 190 mm, short
- 394.797 11.0 mm Carbon Fiber Bridging Rods, 190 mm, long
- 394.798 11.0 mm Carbon Fiber Bridging Rods, 220 mm, short
- 394.799 11.0 mm Carbon Fiber Bridging Rods, 220 mm, long

### Fixation Material

- 393.43* Spring-Loaded Nut
- 393.64* Adjustable Clamp
- 393.69* Open Clamp
- 393.71* Universal Joint for Two Tubes
- 393.75* Universal Clamp

**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

*This item has not been tested for safety in the MR Environment. Note: Implants and Fixation Materials are MR Conditional unless noted otherwise.
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
CAUTION: USA Law restricts these devices to sale by or on the order of a physician.