Large External Fixator—Delta Frame Ankle Bridge. For staged fixation of the distal tibia.
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

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.
Technique Overview

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

2
**Attach combination clamps**

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

4
**Attach multi-pin clamp with rod attachment**
Tighten vise plates.

5
**Attach carbon fiber rods**

6
**Reduce fracture**
Reduce fracture and tighten all clamps.

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

Lateral x-ray showing frame radiolucency
## Recommended Components for Basic Frame

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Item</th>
<th>Quantity Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>494.78x</td>
<td>5.0 mm Titanium Self-Drilling Schanz Screw</td>
<td>2</td>
</tr>
<tr>
<td>293.xx</td>
<td>5.0 mm Steinmann Pin, with central thread</td>
<td>1</td>
</tr>
<tr>
<td>390.002</td>
<td>Large Multi-Pin Clamp, 6 position</td>
<td>1</td>
</tr>
<tr>
<td>390.003</td>
<td>Rod Attachment, for Large Multi-Pin Clamp</td>
<td>1</td>
</tr>
<tr>
<td>390.005</td>
<td>Large Combination Clamp</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.
- 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.

---

Multi-pin clamp technique

1
Insert first Schanz screw
Insert Schanz screw through the drill sleeve and end position of the Large Multi-Pin Clamp (390.002), 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 second Schanz screw through the opposite end of the clamp. Tighten vise plates.

Note: Additional Schanz screws may be inserted as needed.
Optional Frame Configurations

**Use of the open adjustable clamp for independent pin placement**

The delta frame ankle bridge can also be built using Large Open Adjustable Clamps (390.008) and an additional carbon fiber rod, as shown.

**Note:** It is important to “close” the frame by adding a short carbon fiber rod between the two proximal Schanz screws.

---

**Enhancing the frame for additional stability**

A 4.5 mm or 5.0 mm Schanz screw can be added medially into the talar neck.

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 metatarsals. 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 tibial shaft Schanz screws. 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
- Synthes stainless steel or titanium Schanz screws labeled MR Conditional

A carbon fiber bridging rod acts as a "kickstand" to elevate the foot, protecting the soft tissues.
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.

5.0 mm Self-Drilling Schanz Screws
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.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>393.746</td>
<td>Split Tissue Protection Sleeve, 5.0 mm</td>
</tr>
<tr>
<td>393.76</td>
<td>Open Compressor, 2 ea.</td>
</tr>
<tr>
<td>394.181</td>
<td>3.5 mm Trocar, short</td>
</tr>
<tr>
<td>394.182</td>
<td>3.5 mm Trocar, long</td>
</tr>
<tr>
<td>395.911</td>
<td>Drill Sleeve Handle</td>
</tr>
<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>
</tr>
<tr>
<td>395.921</td>
<td>6.0 mm/5.0 mm Threaded Drill Sleeve, short</td>
</tr>
<tr>
<td>395.923</td>
<td>6.0 mm/5.0 mm Threaded Drill Sleeve, long</td>
</tr>
</tbody>
</table>

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

11.0 mm Carbon Fiber Rods, 4 ea.

Choose from:
- 394.80 100 mm
- 394.82 150 mm
- 394.83 200 mm
- 394.84 250 mm
- 394.85 300 mm
- 394.86 350 mm
- 394.87 400 mm

Protective Caps

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<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, 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 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
  - 390.796 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*
- **For 4.0 mm Fixation Pins**
  - 394.991* (10/pkg.)
- **For 4.5 mm Fixation Pins**
  - 394.992* (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
- **Power Drive Set**
  - 105.957
- **ComPact Air Drive II Set**
  - 150.16

### Accessories for Graphic Case
- **Label Sheet Pack**
  - 690.315.12 for Large External Fixator Clamps
  - 690.315.13 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.

**CAUTION: USA Law restricts these devices to sale by or on the order of a physician.**