Medium External Fixator—Humeral Shaft Frame. Modular frame for upper extremity use.
MRI Information

Synthes Medium External Fixation devices 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.

Nonclinical testing demonstrated that, when used in the specific configurations stated in Synthes labeling, Synthes Medium External Fixation devices are MR Conditional. Representative Synthes Medium External Fixation devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Medium 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 fixation frame is positioned:
- 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or;
- Completely outside of the MRI bore in First Level Controlled Mode

Static magnetic field of 3.0 Tesla when the fixation frame is positioned:
- 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or;
- Completely outside of the MRI bore in First Level Controlled Mode

Highest spatial gradient magnetic field of 900 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.

Note: In nonclinical testing, the Synthes external fixation frame was tested in several different configurations. This testing was conducted with the construct positioned 7 cm from within the outside edge of the MRI bore.
- The results showed a maximum observed heating for a wrist fixation frame of 6°C for 1.5 T and less than 1°C for 3.0 T 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 Medium 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 Medium External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Medium 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.
- 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 10 cm from the device.

Warning
- Do not place any radio frequency (RF) transmit coils over the external fixation frame.
When to use
The Medium External Fixation System is indicated for construction of an external fixator frame for the treatment of pediatric and adult fractures. This frame can be used for fixation of humeral shaft fractures.

Relevant anatomy and Schanz screw placement
In the proximal humerus, the axillary nerve is at risk as it passes around the surgical neck. At the midhumerus, the radial nerve crosses posteriorly from medial to lateral. Posterior placement of the Schanz screw in the distal third avoids possible injury to the radial nerve.

Additional reading
**Technique Overview**

1. **Insert proximal Schanz screws laterally**
   Use the triple drill sleeve system to insert Schanz screws.

2. **Build proximal module**
   Connect one medium open adjustable clamp to each Schanz screw in the proximal fragment. Connect with an 8.0 mm carbon fiber rod.

3. **Insert distal Schanz screws posteriorly, avoiding the olecranal fossa**

4. **Build distal module**
   Connect one medium open adjustable clamp to each Schanz screw in the distal fragment. Connect with an 8.0 mm carbon fiber rod.

5. **Connect modules**
   Connect the modules with one rod and two medium combination clamps.

6. **Reduce fracture**
   Use the rods of the proximal and distal modules as “handles” for reduction. Tighten the bolts.
## Recommended Components for Basic Frame

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Item</th>
<th>Quantity Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>494.7xx</td>
<td>4.0 mm Titanium Self-Drilling Schanz Screw</td>
<td>4</td>
</tr>
<tr>
<td>390.031</td>
<td>Medium Combination Clamp</td>
<td>2</td>
</tr>
<tr>
<td>390.035</td>
<td>Medium Open Adjustable Clamp</td>
<td>4</td>
</tr>
<tr>
<td>395.7xx</td>
<td>8.0 mm Carbon Fiber Rod</td>
<td>3</td>
</tr>
<tr>
<td>394.991</td>
<td>Protective Cap, for 4.0 mm Fixation Pins</td>
<td>4</td>
</tr>
<tr>
<td>395.781</td>
<td>Protective Cap, for 8.0 mm Carbon Fiber Rod</td>
<td>6</td>
</tr>
</tbody>
</table>
## Optional Technique

### Reduction with the modular technique

**Note:** Fracture reduction can be adjusted intra- and postoperatively by following three basic steps.

1. **Loosen medium combination clamp bolts on connecting rod clamps only**

2. **Use rods as handles to reduce fracture**

3. **Retighten all bolts**
Optional Frame Configurations

- Humeral frame with medium multi-pin clamps
- Double-stacked modular frame
- Elbow bridging frame
- Shoulder bridging frame
## Medium External Fixator Set with Self-Drilling Schanz Screws
Stainless Steel (01.302.602) or Titanium (01.302.604)

### Graphic Case
- 690.450 Graphic Case, for Medium External Fixator

### Implants in Set 01.302.602
- 293.74 5.0 mm Steinmann Pin with Central Thread, 200 mm, 2 ea.
- 294.777 4.0 mm diameter, 125 mm
- 294.778 4.0 mm diameter, 150 mm
- 294.785 5.0 mm diameter, 175 mm
- 294.786 5.0 mm diameter, 200 mm

### Implants in Set 01.302.604
- 293.74 5.0 mm Steinmann Pin with Central Thread, 200 mm, 2 ea.
- 494.777 4.0 mm diameter, 125 mm
- 494.778 4.0 mm diameter, 150 mm
- 494.785 5.0 mm diameter, 175 mm
- 494.786 5.0 mm diameter, 200 mm

### Instruments (for both sets)
- 310.19 2.0 mm Drill Bit, quick coupling, 100 mm, 2 ea.
- 310.37 3.5 mm Drill Bit, quick coupling, 195 mm, 2 ea.
- 321.158 Combination Wrench, 8 mm width across flats
- 392.955 4.0 mm/2.5 mm Drill Sleeve
- 392.969 Combination T-Wrench, 8 mm
- 393.101 Drive Adaptor with quick coupling, for 4.0 mm Schanz Screws
- 393.103 Drive Adaptor with quick coupling, for 5.0 mm Schanz Screws
- 393.105 Small Universal Chuck with T-Handle
- 394.181 3.5 mm Trocar, short
- 394.182 3.5 mm Trocar, long
- 394.183 2.5 mm Trocar

Note: For additional information, please refer to package insert. For detailed cleaning and sterilization instructions, please refer to [http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm](http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm) or to the below listed inserts, which will be included in the shipping container:
- Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
- Processing Non-sterile Synthes Implants—DJ1304
All Available Implants

- **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

- **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

- **Steinmann Pins with Central Thread**
  - 293.64 5.0 mm diameter, 150 mm
  - 293.69 5.0 mm diameter, 175 mm

Fixation Material (for both sets)

- **Medium Combination Clamp,** 8 ea.
- **Medium Multi-Pin Clamp,** 4 position, 2 ea.
- **Medium Multi-Pin Clamp,** 6 position, 2 ea.
- **8.0 mm/11.0 mm Combination Clamp,** 2 ea.
- **Protective Caps,** for 4.0 mm Fixation Pins, 1 pkg. of 10
- **Protective Caps,** for 5.0 mm Fixation Pins, 1 pkg. of 10
- **Protective Caps,** for 8.0 mm Carbon Fiber Rods, 4 pkgs. of 2

Also Available Instruments

- **Medium Open Compressor**
- **6-Position Drill Guide Handle**

Also Available Fixation Material

- **Medium Pin Clamp,** 4 position
- **Medium Pin Clamp,** 6 position
- **Straight Outrigger Post,** 8 mm
- **30° Outrigger Post,** 8 mm
- **90° Outrigger Post,** 8 mm

Also Available Sets

- **Power Drive Set**
- **ComPact Air Drive II Set**

Also Available for Graphic Case

- **Label Sheet Pack,** for Schanz Screws and Carbon Fiber Rods