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.
Medium External Fixator—Pediatric Femoral Shaft 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 the fixation of pediatric femoral shaft fractures.

Relevant anatomy for pediatrics
Using fluoroscopic imaging, place the most distal and the most proximal Schanz screws at least 2 cm from the physis.* While the physes are 4 mm–6 mm in width, they have undulating shapes. Therefore, to be in the safe zone and avoid injury to a growth plate, allow 1 cm for its total width.†

The Schanz screws should be perpendicular to the diaphysis, not to the metaphyseal flare, and 2 cm from the fracture site.

* Illustration adapted from an original with permission from James Aronson, M.D., author, and W.B. Saunders Company, publisher.
Recommended Components for Basic Frame

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Item</th>
<th>Quantity Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>294.7xx</td>
<td>4.0 mm Self-Drilling Schanz Screw</td>
<td>4</td>
</tr>
<tr>
<td>390.033</td>
<td>Medium Multi-Pin Clamp, 4 position</td>
<td>2</td>
</tr>
<tr>
<td>395.7xx</td>
<td>8.0 mm Carbon Fiber Rod</td>
<td>1</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 Rods</td>
<td>2</td>
</tr>
</tbody>
</table>
1
**Insert Schanz screws, avoiding the growth plates**
Use the triple drill sleeve system to insert the Schanz screws.

*Note:* Avoid penetrating the calcar and the distal physis. Inner Schanz screws should be at least 2 cm from the fracture line.

2
**Attach medium multi-pin clamps**
Tighten the vise plate bolts.

3
**Snap in carbon fiber rod**

4
**Reduce fracture**
Reduce the fracture and tighten the rod clamping bolt and rod attachment bolt.
1
Insert first Schanz screw
Insert the Schanz screw through the drill sleeve and the end position of the Medium Multi-Pin Clamp (390.033), using the clamp as an insertion guide.

Note: The clamp should be parallel to the bone.

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

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

Additional reading


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.

Self-Drilling Schanz Screws, 4 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.

Titanium Self-Drilling Schanz Screws, 4 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
395.911 Drill Sleeve Handle

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 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
### Also 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

### Also Available Instruments
- **Medium Open Compressor**
  - 03.302.001

- **6-Position Drill Guide Handle**
  - 392.963

### Also Available Fixation Material
- **Medium Combination Clamp, 8 ea.**
  - 390.031

- **Dynamization Clip, for Medium Combination Clamp, 4 ea.**
  - 390.032

- **Medium Multi-Pin Clamp, 4 position, 2 ea.**
  - 390.033

- **Rod Attachment, for Medium Multi-Pin Clamp, 4 ea.**
  - 390.034

- **Medium Open Adjustable Clamp, 4 ea.**
  - 390.035

- **Medium Multi-Pin Clamp, 6 position, 2 ea.**
  - 390.036

- **8.0 mm/11.0 mm Combination Clamp, 2 ea.**
  - 390.037

- **Protective Caps, for 4.0 mm Fixation Pins, 1 pkg. of 10**
  - 394.991

- **Protective Caps, for 5.0 mm Fixation Pins, 1 pkg. of 10**
  - 394.993

- **Protective Caps, for 8.0 mm Carbon Fiber Rods, 4 pkgs. of 2**
  - 395.781

### Also Available Sets
- **Medium Pin Clamp, 4 position**
  - 390.026

- **Medium Pin Clamp, 6 position**
  - 390.027

- **Straight Outrigger Post, 8 mm**
  - 390.028

- **30° Outrigger Post, 8 mm**
  - 390.029

- **90° Outrigger Post, 8 mm**
  - 390.030

### Also Available for Graphic Case
- **Label Sheet Pack, for Schanz Screws and Carbon Fiber Rods**
  - 690.350.13