Medium External Fixator—Delta Frame Ankle Bridge. For staged fixation of distal tibia fractures in small-statured adults.
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 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. In dense cortical bone, it may be necessary to predrill.
– 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.

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

2 **Attach open adjustable clamps**

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

4 **Attach pin clamp**
Tighten the vise plates.

5 **Attach outrigger posts**
Thread a post into each vise plate 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.

6 **Attach carbon fiber rods**
Attach carbon fiber rods to outrigger posts with combination clamps and to open adjustable clamps on Steinmann pin.

7 **Reduce fracture**
Reduce the fracture and tighten all clamps.

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

To prevent equinus contracture, Schanz screws can be placed in the metatarsals as shown on the Optional Frame Configurations page.

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><strong>293.xx</strong></td>
<td>5.0 mm Steinmann Pin with Central Thread</td>
<td>1</td>
</tr>
<tr>
<td><strong>294.78x</strong></td>
<td>5.0 mm Self-Drilling Schanz Screw</td>
<td>2</td>
</tr>
<tr>
<td><strong>390.027</strong></td>
<td>Medium Pin Clamp, 6 position</td>
<td>1</td>
</tr>
<tr>
<td><strong>390.029</strong></td>
<td>30° Outrigger Post, 8 mm</td>
<td>2</td>
</tr>
<tr>
<td><strong>390.031</strong></td>
<td>Medium Combination Clamp</td>
<td>2</td>
</tr>
<tr>
<td><strong>390.035</strong></td>
<td>Medium Open Adjustable Clamp</td>
<td>2</td>
</tr>
<tr>
<td><strong>395.7xx</strong></td>
<td>8.0 mm Carbon Fiber Rod</td>
<td>2</td>
</tr>
<tr>
<td><strong>394.993</strong></td>
<td>Protective Cap, for 5.0 mm Fixation Pins</td>
<td>4</td>
</tr>
<tr>
<td><strong>395.781</strong></td>
<td>Protective Cap, for 8.0 mm Carbon Fiber Rods</td>
<td>4</td>
</tr>
</tbody>
</table>
Medium Pin Clamp Technique

1
**Insert first Schanz screw**
Insert a Schanz screw through the drill sleeve and end position of the Medium Pin Clamp (390.026 or 390.027), 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.

**Notes:** Additional Schanz screws may be inserted as needed.

Each side of the Pin Clamp can accept either an Outrigger Post or a Rod Attachment.

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**Outrigger Posts**
- Straight (390.028)
- 30° Post (390.029)
- 90° Post (390.030)

**Pin Clamp**
Medium Pin Clamp, 6 position (390.027)

- Vise plate tightening point
- Stargrind cover: remove to add Outrigger Posts

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Clamp is parallel to bone
Schanz screw is perpendicular to bone
Optional Frame Configurations

The delta frame ankle bridge can also be built using the Straight or 90° Outrigger Posts, as shown.

Enhancing the frame for additional stability
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 metatarsal. 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.
Delta Frame with Medium Multi-Pin Clamp

The two additional posterior carbon fiber rods act as “kick stands” to elevate the foot, protecting the soft tissues.

Schanz screws in metatarsals
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, 4 ea.
294.778 4.0 mm diameter, 150 mm, 4 ea.
294.785 5.0 mm diameter, 175 mm, 4 ea.
294.786 5.0 mm diameter, 200 mm, 4 ea.

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
395.911 Drill Sleeve Handle
395.912 5.0 mm/3.5 mm Drill Sleeve, short
395.913 5.0 mm/3.5 mm Drill Sleeve, long
395.921 6.0 mm/5.0 mm Threaded Drill Sleeve, short
395.922 4.0 mm Threaded Drill Sleeve
395.923 6.0 mm/5.0 mm Threaded Drill Sleeve, long

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
## Medium External Fixator Set with Self-Drilling Schanz Screws

Stainless Steel (01.302.602) or Titanium (01.302.604)

<table>
<thead>
<tr>
<th>Fixation Material (for both sets)</th>
<th>Also Available Implants</th>
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<tbody>
<tr>
<td>390.031 Medium Combination Clamp, 8 ea.</td>
<td>Schanz Screws</td>
</tr>
<tr>
<td>390.032 Dynamization Clip for Medium Combination Clamp, 4 ea.</td>
<td>294.43-.48 4.0 mm, spade point, 60 mm–150 mm</td>
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<tr>
<td>390.033 Medium Multi-Pin Clamp, 4 position, 2 ea.</td>
<td>294.52–.57 5.0 mm, blunted trocar point, 100 mm–250 mm</td>
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<tr>
<td>390.034 Rod Attachment, for Medium Multi-Pin Clamp, 4 ea.</td>
<td>294.71–.76 4.5 mm, blunted trocar point, 80 mm–200 mm</td>
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<tr>
<td>390.035 Medium Open Adjustable Clamp, 4 ea.</td>
<td>Self-Drilling Schanz Screws</td>
</tr>
<tr>
<td>390.036 Medium Multi-Pin Clamp, 6 position, 2 ea.</td>
<td>294.774–.779 4.0 mm, 60 mm–175 mm</td>
</tr>
<tr>
<td>390.037 8.0 mm/11.0 mm Combination Clamp, 2 ea.</td>
<td>294.782–.788 5.0 mm, 100 mm–250 mm</td>
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<tr>
<td>394.991 Protective Caps, for 4.0 mm Fixation Pins, 1 pkg. of 10</td>
<td>Titanium Self-Drilling Schanz Screws</td>
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<tr>
<td>394.993 Protective Caps, for 5.0 mm Fixation Pins, 1 pkg. of 10</td>
<td>494.774–.779 4.0 mm, 60 mm–175 mm</td>
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<tr>
<td>395.781 Protective Caps, for 8.0 mm Carbon Fiber Rods, 4 pkgs. of 2</td>
<td>494.782–.788 5.0 mm, 100 mm–250 mm</td>
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<tr>
<td>395.779 160 mm, 2 ea.</td>
<td>Steinmann Pins with Central Thread</td>
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<tr>
<td>395.782 200 mm</td>
<td>293.64 5.0 mm diameter, 150 mm</td>
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<tr>
<td>395.784 220 mm</td>
<td>293.69 5.0 mm diameter, 175 mm</td>
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<td>395.786 240 mm, 2 ea.</td>
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<td>395.788 280 mm, 2 ea.</td>
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<td>395.792 320 mm, 2 ea.</td>
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<td>395.796 360 mm, 2 ea.</td>
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<td>395.797 400 mm</td>
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<td>8.0 mm Carbon Fiber Rods</td>
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<tr>
<th>Also Available Instrument</th>
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<tr>
<td>392.963 6-Position Drill Guide Handle</td>
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<td>390.026 Medium Pin Clamp, 4 position</td>
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<tr>
<td>390.027 Medium Pin Clamp, 6 position</td>
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<tr>
<td>390.028 Straight Outrigger Post, 8 mm</td>
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<td>390.029 30° Outrigger Post, 8 mm</td>
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<td>390.030 90° Outrigger Post, 8 mm</td>
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<tr>
<td>105.957 Power Drive Set</td>
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<tr>
<td>150.16 ComPact Air Drive II Set</td>
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<th>Accessories for Graphic Case</th>
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<tr>
<td>690.350.13 Label Sheet Pack, for Schanz Screws and Carbon Fiber Rods</td>
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<tr>
<td>690.451 Label Sheet, for Medium External Fixator clamps</td>
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8 Synthes Medium External Fixator—Delta Frame Ankle Bridge Technique Guide