Using Medium Combination Clamps

Medium External Fixator—Pediatric Femoral Shaft Frame

Surgical Technique
DePuy 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 DePuy Synthes labeling, DePuy Synthes Medium External Fixation devices are MR Conditional. Representative DePuy Synthes Medium External Fixation devices used in a typical construct include clamps, rods and various attachments. A patient with a DePuy 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 DePuy 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, DePuy Synthes MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of DePuy 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 DePuy 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 DePuy Synthes Medium External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy 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 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 physes.* While the physes are 4–6 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.1

The Schanz screws should be perpendicular to the diaphysis, not to the metaphyseal flare, and should be 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.
Warning:
- DePuy Synthes self-drilling, self-tapping Schanz screws and Steinmann pins are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Precautions:
- To keep from damaging the femoral cutaneous nerve, avoid pin insertion up to 15 mm in a dorsal direction from the superior anterior iliac spine.
- When dealing with the humerus, primary consideration should be given to the radial and axillary nerves. Distally, a dorsal approach to the humerus is appropriate. Proximally, it is recommended to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve.
- Select the appropriate Schanz screw (self-tapping, self-drilling), or Steinmann pin for the patient’s bony anatomy.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user’s glove or skin.
- Handle devices with care and dispose of worn bone cutting instruments in an approved sharps container.
- The self-drilling Schanz screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the self-drilling Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Only when bones are osteoporotic does the self-drilling Schanz screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability.
- The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Implant sites should be meticulously cared for to avoid pin-tract infection. Schanz screws and Steinmann pins may be surrounded with antiseptic-coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient.
- To help minimize the risk of pin-tract infection the following points should be observed:
  a. Placement of Schanz screws and Steinmann pins, taking anatomy into consideration (ligaments, nerves, arteries).
  b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis.
  c. Release of skin tension at soft tissue entry point of implant.
## 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>390.031</td>
<td>Medium Combination Clamp</td>
<td>4</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 Rod</td>
<td>2</td>
</tr>
</tbody>
</table>
Technique Overview

Schanz screws must be in the same plane if double-stacking and dynamization are desired.

1
Insert the most distal and proximal Schanz screws, avoiding the growth plates
Use the triple drill sleeve system to insert Schanz screws.

Note: Avoid penetrating the calcar and the distal physis.

2
Attach a medium combination clamp to each Schanz screw

3
Snap in carbon fiber rod

4
Reduce fracture
Reduce the fracture and tighten the clamp bolts.

5
Attach additional medium combination clamps between outer clamps
6 
**Insert Schanz screws**  
Insert Schanz screws through the drill sleeve and clamps. Remove the drill sleeve and tighten the clamps.  
**Note:** Inner Schanz screws should be at least 2 cm from the fracture line.

7 
**Increase stiffness**  
Add a second rod to the frame to increase stiffness. Attach the rod to each Schanz screw using a medium combination clamp.
Optional Techniques

Dynamizing the frame
Dynamization is the process of altering the frame so that the proximal fragment can move axially while movement in all other planes remains restricted. This transfers load to the fracture site while maintaining anatomic alignment. This functional loading appears to increase the strength of the callus and decrease the duration of immobilization after frame removal.²

**Important:** To achieve dynamization, the frame must be double-stacked.

Dynamization technique

1. Loosen the bolts on both upper proximal clamps.

2. Insert Medium Dynamization Clips (390.032) between the rod vise plates and retighten the bolts.

3. Loosen the bolts on both bottom distal clamps.

4. Insert medium dynamization clips between the rod vise plates and retighten the bolts.
**Distraction/compression technique**

For intraoperative, controlled distraction or compression, insert dynamization clips between the rod vise plates as specified in the dynamization technique. Place the Distractor (394.075) onto the rod and against the clamp with the dynamization clip. Tighten the distractor setscrew and turn the adjustment ring in the direction of the arrow. Once distraction/compression is achieved, remove the dynamization clip and tighten the clamp bolt. Loosen the distractor setscrew and remove the distractor.

**Note:** The distractor should always press against the clamp, not against the medium dynamization clip.

**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.
294.777 Self-Drilling Schanz Screws, 4 ea.
294.778 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 Titanium Self-Drilling Schanz Screws, 4 ea.
494.778 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
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 www.synthes.com/cleaning-sterilization or sterilization instructions, if provided.
Medium External Fixator—Pediatric Femoral Shaft Frame Surgical Technique DePuy Synthes

### 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**
  - 390.031, 8 ea.

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

- **Medium Multi-Pin Clamp**
  - 390.033, 4 position, 2 ea.
  - 390.034, 6 position, 2 ea.

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

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

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

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

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

- **8.0 mm Carbon Fiber Rods**
  - 395.779, 160 mm, 2 ea.
  - 395.782, 200 mm
  - 395.784, 220 mm
  - 395.786, 240 mm, 2 ea.
  - 395.788, 280 mm, 2 ea.
  - 395.792, 320 mm, 2 ea.
  - 395.796, 360 mm, 2 ea.
  - 395.797, 400 mm

- **Dynamization Clip, for Medium Combination Clamp**
  - 390.034, 4 ea.

- **Medium Multi-Pin Clamp**
  - 390.033, 4 position, 2 ea.
  - 390.034, 6 position, 2 ea.

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

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

- **8.0 mm Carbon Fiber Rods**
  - 395.779, 160 mm, 2 ea.
  - 395.782, 200 mm
  - 395.784, 220 mm
  - 395.786, 240 mm, 2 ea.
  - 395.788, 280 mm, 2 ea.
  - 395.792, 320 mm, 2 ea.
  - 395.796, 360 mm, 2 ea.
  - 395.797, 400 mm
Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.
Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.
Not all products may currently be available in all markets.

Manufactured or distributed by:
Synthes USA Products, LLC
1302 Wrights Lane East
West Chester, PA 19380

To order (USA): 800-523-0322
To order (Canada): 855-946-8999

Note: For recognized manufacturer, refer to the product label.

www.depuysynthes.com