For the Treatment of Wrist Fractures

Small External Fixator—Wrist Spanning Frame

Surgical Technique

DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
DePuy Synthes Small 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 DePuy Synthes labeling, DePuy Synthes Small External Fixation devices are MR Conditional. Representative DePuy Synthes Small External Fixation devices used in a typical construct include clamps, rods and various attachments.

A patient with a DePuy Synthes Small 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** 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.

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 Small 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 Small External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Small 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

For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15º and SE sequence: Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70º radio echo sequence, worst-case artifact will extend approximately 5 cm from the device.

Warning: Do not place any radio frequency (RF) transmit coils over the external fixation frame.

Indications for Synthes Small External Fixation System

The Synthes Small External Fixation System is intended to stabilize and provide treatment for fractures of the small bones, such as the hand, wrist, forearm, foot, and ankle. Specifically, the components can be used for:

- Preliminary fixation before ORIF
- Unstable fractures of the distal radius (both intra- and extra-articular)
- Open and/or comminuted bilateral fractures
- Fractures in combination with extensive soft tissue injury, bone loss, and vascular and/or neural involvement
- Fracture dislocations
- Failed closed reduction with casting resulting in secondary deformity (radial shortening and angulations)
- Pediatric open fractures with bone loss and osteotomies
Warning:
- DePuy Synthes self-drilling and self-tapping Schanz screws are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Precautions:
- Select the appropriate Schanz screw (self-tapping, self-drilling) 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 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 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 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.
Basic principles and application technique

Although the exact frame construct chosen is dictated by the soft tissue injury and fracture pattern, basic technique principles apply to all AO small external fixator frames.

Fracture reduction can be accomplished manually with longitudinal traction, percutaneous fixation or open reduction and internal fixation prior to the application of an external fixator.

Fracture reduction is also possible after the frame has been assembled using the modular technique, which allows complete freedom of pin placement.

When using the modular technique, the small external fixator frame can be applied as a wrist spanning frame or a nonspanning frame. The fracture location and complexity determine which frame application is appropriate.
Relevant anatomy for Schanz screw or Kirschner wire placement

Dorsal view

- Retinaculum
- Superficial branch of the radial nerve
- Radial artery
- Target area for proximal pins

Dorsal view

- Compartment 1
  - Extensor pollicis brevis
  - Abductor pollicis longus
- Compartment 2
  - Extensor carpi radialis brevis
  - Extensor carpi radialis longus
- Compartment 3
  - Extensor pollicis longus
- Compartment 4
  - Extensor digitorum and extensor indicis
- Compartment 5
  - Extensor digiti minimi
  - Extensor retinaculum
- Compartment 6
  - Extensor carpi ulnaris

References

When constructing a small external fixator frame, choices for pins include:
- 2.5 mm Kirschner wires with thread
- 4.0 mm/2.5 mm self-drilling Schanz screws
- 4.0 mm/3.0 mm self-drilling Schanz screws
- 4.0 mm self-drilling Schanz screws

Schanz screws provide more frame stiffness than 2.5 mm Kirschner wires.

If using 2.5 mm Kirschner wires in either the metacarpal or the radius, K-wires should converge at 40°–60° in the sagittal plane. This improves fixation by lengthening the bone-pin interface.

If using Schanz screws, they should be perpendicular to the long axis of the metacarpal and the radius.

Both K-wires and Schanz screws should also be placed at 40°–60° in the frontal plane, not lateral. Pin placement at 40°–60° in the frontal plane prevents thumb impingement allowing full mobilization of the thumb, avoids soft tissue interference, and makes visualization of the fracture and the wrist joint possible during x-ray.
1

**Insert metacarpal pins**

To avoid entrapping the extensor mechanism in extension, flex the second metacarpophalangeal joint to 90°.

Make a small incision at the site of planned pin insertion. Bluntly dissect the soft tissues and push the drill sleeve to the bone. Insert the pins through the drill sleeve.

The K-wires and Schanz screws should be placed proximally and distally in the diaphyseal bone of the second metacarpal.
**2**

**Build first module**

Connect one small combination clamp to each pin in the metacarpal. Connect the clamps with a short 4.0 mm carbon fiber rod.

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**3**

**Insert pins in the radius**

Make a small incision at the site of planned pin insertion. Bluntly dissect the soft tissues and push the drill sleeve to the bone. Insert the pins through the drill sleeve.

Take care to avoid the superficial branch of the radial nerve.

**Notes:** For accuracy and ease of insertion in hard bone, consider predrilling for the Schanz screws with a 2.0 mm drill bit.

For best stability, pin spacing should be maximized, and the distal pin should be as close to the fracture as possible.
Technique Overview

4
Build second module
Connect one small combination clamp to each pin in the radius. Connect the clamps with a 4.0 mm carbon fiber rod.

Reduce the fracture using partial frames as handles to aid in reduction.

5
Connect modules
Connect the modules with a third rod and two small combination clamps.

Perform final fracture reduction, if required, and tighten the nuts securely.

Flexion and/or ulnar deviation may be required to obtain anatomic reduction.

6
Increase stiffness
Use Schanz screws in place of 2.5 mm K-wires and/or add a fourth bar to increase stiffness and to prevent rotation. The fourth bar should span the length of the frame, connecting the first and second modules.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>292.75</td>
<td>2.5 mm Kirschner Wire with Thread</td>
</tr>
<tr>
<td>294.769</td>
<td>4.0 mm/2.5 mm Self-Drilling Schanz Screw</td>
</tr>
<tr>
<td>294.771</td>
<td>4.0 mm/3.0 mm Self-Drilling Schanz Screw</td>
</tr>
<tr>
<td>294.776</td>
<td>4.0 mm Self-Drilling Schanz Screw</td>
</tr>
<tr>
<td>390.041</td>
<td>Small Combination Clamp, MR Conditional</td>
</tr>
<tr>
<td></td>
<td>Connects rods to rods, rods to Schanz screws or rods to 2.5 mm Kirschner wires</td>
</tr>
<tr>
<td>395.6X</td>
<td>4.0 mm Carbon Fiber Rod, MR Conditional</td>
</tr>
<tr>
<td>392.24</td>
<td>Protective Cap, for 2.5 mm Kirschner Wires</td>
</tr>
<tr>
<td>394.991</td>
<td>Protective Cap, for 4.0 mm Fixation Pins</td>
</tr>
</tbody>
</table>
Nonspanning frames
Do not span the joint.

When to use
– Simple intra-articular distal radius fractures
– Extra-articular distal radius fractures with a relatively large distal fragment
– Corrective distal radius osteotomies due to malunion

Spanning frames
“Bridge” or span of the wrist joint is the most common application for wrist fixators.

Commonly used for
– Intra-articular distal radius fractures
– Extra-articular distal radius fractures
– Adjunct to percutaneous Kirschner wires
AO Fracture Classifications

23-A  Extra-articular fracture

1  Ulna, radius intact
2  Radius, simple and impacted
3  Radius, multifragmentary

23-B  Partial articular fracture

1  Radius, sagittal
2  Radius, frontal, dorsal rim
3  Radius, frontal, volar rim

23-C  Complete articular fracture of radius

1  Articular simple, metaphyseal simple
2  Articular simple, metaphyseal multifragmentary
3  Articular multifragmentary
Optional Frame Configurations

- Single stack frame configuration
- Double stack frame configuration
- Double stack frame configuration with fifth Schanz screw or 2.5 mm K-wire
- Double stack frame configuration
- Modular “Z” frame configuration
- Modular “Z” frame configuration with fourth bar
Small External Fixator Set with Self-Drilling Schanz Screws
Stainless Steel (115.755) or Titanium (115.750)

Graphic Case
690.378  Small External Fixator Graphic Case

Implants in Set 115.755, MR Conditional
292.16  1.6 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10
292.20  2.0 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10
292.75  2.5 mm Kirschner Wire with Thread, 150 mm, trocar point, 15 mm thread length, 1 pkg. of 10

Self-Drilling Schanz Screws
294.769  4.0 mm/2.5 mm, 20 mm thread length, 80 mm, 2 ea.
294.771  4.0 mm/3.0 mm, 20 mm thread length, 80 mm, 4 ea.
294.773  4.0 mm/3.0 mm, 18 mm thread length, 65 mm, 4 ea.
294.775  4.0 mm, 20 mm thread length, 80 mm, 2 ea.
294.776  4.0 mm, 30 mm thread length, 100 mm, 2 ea.

Implants in Set 115.750, MR Conditional
292.16  1.6 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10
292.20  2.0 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10
292.75  2.5 mm Kirschner Wire with Thread, 150 mm, trocar point, 15 mm thread length, 1 pkg. of 10

Titanium Self-Drilling Schanz Screws
494.769  4.0 mm/2.5 mm, 20 mm thread length, 80 mm, 2 ea.
494.771  4.0 mm/3.0 mm, 20 mm thread length, 80 mm, 4 ea.
494.775  4.0 mm, 20 mm thread length, 80 mm, 2 ea.
494.776  4.0 mm, 30 mm thread length, 100 mm, 2 ea.

For detailed cleaning and sterilization instructions, please refer to www.synthes.com/cleaning-sterilization or sterilization instructions, if provided.
Small External Fixator Set with Self-Drilling Schanz Screws
Stainless Steel (115.755) or Titanium (115.750) continued

<table>
<thead>
<tr>
<th>Instruments (for both sets)</th>
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<tbody>
<tr>
<td>391.944</td>
<td>Wire Cutters</td>
</tr>
<tr>
<td>392.819</td>
<td>4.0 mm Parallel Drill Guide</td>
</tr>
<tr>
<td>392.955</td>
<td>4.0 mm/2.5 mm Drill Sleeve</td>
</tr>
<tr>
<td>393.101</td>
<td>Drive Adaptor with quick coupling, for 4.0 mm Schanz Screws, 2 ea.</td>
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<tr>
<td>394.183</td>
<td>2.5 mm Trocar</td>
</tr>
<tr>
<td>395.35</td>
<td>Combination Wrench, 7 mm width across flats</td>
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<tr>
<td>395.36</td>
<td>Socket Wrench, 7 mm width across flats</td>
</tr>
<tr>
<td>395.38</td>
<td>Simple T-Handle</td>
</tr>
<tr>
<td>395.911</td>
<td>Drill Sleeve Handle</td>
</tr>
<tr>
<td>395.922</td>
<td>4.0 mm Threaded Drill Sleeve</td>
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</table>

<table>
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<tr>
<th>Also Available Sets</th>
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<tbody>
<tr>
<td>105.105</td>
<td>Kirschner Wire Implant Module Set</td>
</tr>
<tr>
<td>115.985</td>
<td>Mini External Fixator Instrument and Implant Set</td>
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<tr>
<td>294.30</td>
<td>4.0 mm/3.0 mm Schanz Screw, 20 mm thread, 80 mm length</td>
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<tr>
<td>294.767</td>
<td>4.0 mm/2.5 mm Schanz Screw, trocar point, 18 mm thread, 65 mm length</td>
</tr>
<tr>
<td>294.768</td>
<td>4.0 mm/2.5 mm Schanz Screw, trocar point, 20 mm thread, 80 mm length</td>
</tr>
<tr>
<td>294.777</td>
<td>4.0 mm Self-Drilling Schanz Screw, 40 mm thread length, 125 mm</td>
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<tr>
<td>494.777</td>
<td>4.0 mm Titanium Self-Drilling Schanz Screw, 40 mm thread length, 125 mm</td>
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<thead>
<tr>
<th>Fixation Material (for both sets), MR Conditional</th>
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<tbody>
<tr>
<td>390.041</td>
<td>Small Combination Clamp, 12 ea.</td>
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<tr>
<td>392.24*</td>
<td>Protective Caps, for 2.5 mm Kirschner Wires (light blue), 1 pkg. of 10</td>
</tr>
<tr>
<td>394.991*</td>
<td>Protective Caps, for 4.0 mm Fixation Pins (yellow), 1 pkg. of 10</td>
</tr>
<tr>
<td>395.60</td>
<td>60 mm, 2 ea.</td>
</tr>
<tr>
<td>395.61</td>
<td>80 mm, 4 ea.</td>
</tr>
<tr>
<td>395.62</td>
<td>100 mm, 4 ea.</td>
</tr>
<tr>
<td>395.63</td>
<td>120 mm, 4 ea.</td>
</tr>
<tr>
<td>395.64</td>
<td>140 mm, 4 ea.</td>
</tr>
<tr>
<td>395.65</td>
<td>160 mm, 2 ea.</td>
</tr>
<tr>
<td>395.66</td>
<td>180 mm, 2 ea.</td>
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<td>395.67</td>
<td>200 mm, 2 ea.</td>
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<tr>
<td>395.60</td>
<td>60 mm, 2 ea.</td>
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<th>Also Available Instruments</th>
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<tbody>
<tr>
<td>310.19</td>
<td>2.0 mm Drill Bit, quick coupling, 100 mm</td>
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<tr>
<td>310.20</td>
<td>2.0 mm Drill Bit, Jacobs chuck, 85 mm</td>
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<tr>
<td>391.82</td>
<td>Wire-Bending Pliers, 160 mm</td>
</tr>
<tr>
<td>392.00</td>
<td>Bending Iron</td>
</tr>
<tr>
<td>392.819</td>
<td>4.0 mm Parallel Drill Guide</td>
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<tr>
<td>392.956</td>
<td>4.0 mm Drill Sleeve, 78 mm (long)</td>
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<tr>
<td>392.957</td>
<td>4.0 mm Drill Sleeve, 42 mm (short)</td>
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<tr>
<td>394.06</td>
<td>Small Distractor</td>
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<tr>
<td>394.071</td>
<td>Mini Lengthening Apparatus, 110 mm</td>
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<tr>
<td>394.08</td>
<td>Mini Lengthening Apparatus, 160 mm</td>
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<tr>
<td>394.184</td>
<td>2.5 mm Trocar, 88 mm (long)</td>
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<tr>
<td>394.185</td>
<td>2.5 mm Trocar, 49 mm (short)</td>
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<tr>
<td>395.51</td>
<td>Open Compressor</td>
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<tr>
<td>395.931</td>
<td>4.0 mm Threaded Drill Sleeve, 69 mm (long)</td>
</tr>
<tr>
<td>395.932</td>
<td>4.0 mm Threaded Drill Sleeve, 33 mm (short)</td>
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</table>

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<thead>
<tr>
<th>Also Available Fixation Material</th>
<th></th>
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<tbody>
<tr>
<td>394.99*</td>
<td>Protective Caps, for 4.0 mm Connecting Bars and Carbon Fiber Rods (black), (10/pkg.)</td>
</tr>
</tbody>
</table>

*This item has not been tested for safety in the MR environment.*
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Not all products may currently be available in all markets.