Small External Fixator—Nonspanning Wrist Frame. For the treatment of wrist fractures.

Technique Guide

Part of the Small External Fixation System

SYNTHERS® Instruments and implants approved by the AO Foundation
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 Synthes labeling, Synthes Small External Fixation devices are MR Conditional. Representative Synthes Small External Fixation devices used in a typical construct include clamps, rods and various attachments.

A patient with a 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.

**Note:**
In non-clinical testing, the Synthes External Fixation Devices were tested in several different configurations. This testing was conducted with the construct positioned at the edge of the MRI bore, with the entire construct outside the MRI bore.

- The results showed a maximum observed heating for a wrist fixator frame of less than 4°C for 1.5T and less than 2°C for 3.0T with a machine reported whole body averaged SAR of 2 W/kg
- The results showed a maximum observed heating for a pelvic frame less than 1°C for 1.5 and 3.0T 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 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 Synthes Small External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by 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
Small External Fixator—Nonspanning Wrist Frame

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 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

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

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
- Extensor carpi radialis brevis
- Extensor carpi radialis longus

Compartment 4
- Extensor digitorum
- 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 the distal and proximal radius fragments, K-wires should converge. This improves fixation by lengthening the bone-pin interface.

If using Schanz screws in the proximal radius fragment, they should be perpendicular to the long axis of the radius. The small adjustable clamp accepts only Schanz screws with 4.0 mm shafts.
1

*Insert pins in the distal radius fragment*

Make a small incision at the site of planned pin insertion.

Make a longitudinal incision through the extensor retinaculum.

Separate the appropriate compartments. Bluntly dissect the soft tissues and push the drill sleeve to the bone. Insert the pins through the drill sleeve, parallel to the articular surface. Avoid penetrating the far cortex with the pin.

When using Schanz screws, insert by hand to avoid damage to soft tissues.

Whenever possible, insert the pins at an angle to the sagittal plane to achieve more bony contact and increase the stability of the frame.

Verify position of the pins with lateral and AP images. They should be parallel to the articular surface.

2

*Build first module*

Connect one small combination clamp to each pin in the distal radius fragment. Connect the clamps with a 4.0 mm carbon fiber rod (straight, curved or angled T-bar).
## 3

**Insert pins in the proximal 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.

**Optional technique**

**Instrument**

| 392.819 | 4.0 mm Parallel Drill Guide |

If using the small adjustable clamp in the proximal segment, insert Schanz screws using the 4.0 mm parallel drill guide.

**Notes**

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

## 4

**Build second module**

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

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

**Optional technique**

If using the small adjustable clamp, place the clamp over parallel Schanz screws and tighten bolts onto Schanz screws.
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.

Optional frame construct
Build the second module with a 4.0 mm carbon fiber rod which is long enough to connect to the first carbon fiber rod. Ensure that all clamps are tight.

See Optional Frame Configurations page for sample frames.

6 Increase stiffness
Use Schanz screws in place of 2.5 mm K-wires and/or add a bar to increase stiffness and to prevent rotation. This bar will also prevent shortening of the distal radius fragment. Connect the fourth bar to the pin in the distal radius fragment and to either the pin or the bar in the proximal radius.
### Recommended Components

<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>390.041</td>
<td>Small Combination Clamp, MR Conditional</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 Caps, for 2.5 mm Kirschner wires</td>
</tr>
<tr>
<td>394.991</td>
<td>Protective Caps, for 4.0 mm Fixation Pins</td>
</tr>
</tbody>
</table>
Small External Fixator—Nonspanning Wrist Frame

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

- Modular frame with angled T-bar
- Modular frame with curved bar
- Modular straight "T" frame
- Modular straight "T" frame with delta bar
- Modular box frame
**Small External Fixator Set with Self-Drilling Schanz Screws**

Stainless Steel (115.755) or Titanium (115.750)

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**Graphic Case**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>690.378</td>
<td>Small External Fixator Graphic Case</td>
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</tbody>
</table>

**Implants in Set 115.755, MR Conditional**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>292.16</td>
<td>1.6 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10</td>
</tr>
<tr>
<td>292.20</td>
<td>2.0 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10</td>
</tr>
<tr>
<td>292.75</td>
<td>2.5 mm Kirschner Wire with Thread, 150 mm, trocar point, 15 mm thread length, 1 pkg. of 10</td>
</tr>
</tbody>
</table>

- **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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>292.16</td>
<td>1.6 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10</td>
</tr>
<tr>
<td>292.20</td>
<td>2.0 mm Kirschner Wire, 150 mm, trocar point, 1 pkg. of 10</td>
</tr>
<tr>
<td>292.75</td>
<td>2.5 mm Kirschner Wire with Thread, 150 mm, trocar point, 15 mm thread length, 1 pkg. of 10</td>
</tr>
</tbody>
</table>

- **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. |

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For detailed cleaning and sterilization instructions, please refer to:

[www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization)

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.
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>
<th>Also Available Sets</th>
</tr>
</thead>
<tbody>
<tr>
<td>391.944 Wire Cutters</td>
<td>105.105 Kirschner Wire Implant Module Set</td>
</tr>
<tr>
<td>392.819 4.0 mm Parallel Drill Guide</td>
<td>115.985 Mini External Fixator Instrument and Implant Set</td>
</tr>
<tr>
<td>392.955 4.0 mm/2.5 mm Drill Sleeve</td>
<td></td>
</tr>
<tr>
<td>393.101 Drive Adaptor with quick coupling, for 4.0 mm Schanz Screws, 2 ea.</td>
<td></td>
</tr>
<tr>
<td>394.183 2.5 mm Trocar</td>
<td></td>
</tr>
<tr>
<td>395.35 Combination Wrench, 7 mm width across flats</td>
<td></td>
</tr>
<tr>
<td>395.36 Socket Wrench, 7 mm width across flats</td>
<td></td>
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<tr>
<td>395.38 Simple T-Handle</td>
<td></td>
</tr>
<tr>
<td>395.911 Drill Sleeve Handle</td>
<td></td>
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<tr>
<td>395.922 4.0 mm Threaded Drill Sleeve</td>
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</table>

<table>
<thead>
<tr>
<th>Fixation Material (for both sets), MR Conditional</th>
<th>Also Available Implants, MR Conditional</th>
</tr>
</thead>
<tbody>
<tr>
<td>390.041 Small Combination Clamp, 12 ea.</td>
<td>294.30 4.0 mm/3.0 mm Schanz Screw, 20 mm thread, 80 mm length</td>
</tr>
<tr>
<td>392.24* Protective Caps, for 2.5 mm Kirschner Wires (light blue), 1 pkg. of 10</td>
<td>294.767 4.0 mm/2.5 mm Schanz Screw, trocar point, 18 mm thread, 65 mm length</td>
</tr>
<tr>
<td>394.991* Protective Caps, for 4.0 mm Fixation Pins (yellow), 1 pkg. of 10</td>
<td>294.768 4.0 mm/2.5 mm Schanz Screw, trocar point, 20 mm thread, 80 mm length</td>
</tr>
<tr>
<td>395.60 60 mm, 2 ea.</td>
<td>294.777 4.0 mm Self-Drilling Schanz Screw, 40 mm thread Length, 125 mm</td>
</tr>
<tr>
<td>395.61 80 mm, 4 ea.</td>
<td>494.777 4.0 mm Titanium Self-Drilling Schanz Screw, 40 mm thread Length, 125 mm</td>
</tr>
<tr>
<td>395.62 100 mm, 4 ea.</td>
<td></td>
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<tr>
<td>395.63 120 mm, 4 ea.</td>
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</tr>
<tr>
<td>395.64 140 mm, 4 ea.</td>
<td></td>
</tr>
<tr>
<td>395.65 160 mm, 2 ea.</td>
<td></td>
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<tr>
<td>395.66 180 mm, 2 ea.</td>
<td></td>
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<tr>
<td>395.67 200 mm, 2 ea.</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Also Available Instruments</th>
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</thead>
<tbody>
<tr>
<td>310.19 2.0 mm Drill Bit, quick coupling, 100 mm</td>
</tr>
<tr>
<td>310.20 2.0 mm Drill Bit, Jacobs chuck, 85 mm</td>
</tr>
<tr>
<td>391.82 Wire-Bending Pliers, 160 mm</td>
</tr>
<tr>
<td>392.00 Bending Iron</td>
</tr>
<tr>
<td>392.819 4.0 mm Parallel Drill Guide</td>
</tr>
<tr>
<td>392.956 4.0 mm Drill Sleeve, 78 mm (long)</td>
</tr>
<tr>
<td>392.957 4.0 mm Drill Sleeve, 42 mm (short)</td>
</tr>
<tr>
<td>394.06 Small Distractor</td>
</tr>
<tr>
<td>394.071 Mini Lengthening Apparatus, 110 mm</td>
</tr>
<tr>
<td>394.08 Mini Lengthening Apparatus, 160 mm</td>
</tr>
<tr>
<td>394.183 2.5 mm Trocar</td>
</tr>
<tr>
<td>394.184 2.5 mm Trocar, 88 mm (long)</td>
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<tr>
<td>394.185 2.5 mm Trocar, 49 mm (short)</td>
</tr>
<tr>
<td>395.51 Open Compressor</td>
</tr>
<tr>
<td>395.931 4.0 mm Threaded Drill Sleeve, 69 mm (long)</td>
</tr>
<tr>
<td>395.932 4.0 mm Threaded Drill Sleeve, 33 mm (short)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Also Available Fixation Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>394.99* 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.*
CAUTION: USA Law restricts these devices to sale by or on the order of a physician.