Low-Profile Wrist Fixator.
For stabilization of fractures of the distal radius.

Technique Guide

Part of the External Fixation System

SYNTHESES® Instruments and implants approved by the AO Foundation
**Indications**
Intended for stabilization of fractures of the distal radius.

**Low-Profile Wrist Fixator Clamp**
- Independently locks to Schanz screws while allowing universal joint motion for reduction in all planes
- Allows secondary adjustment of length without loss of reduction

**6.0 mm Carbon Fiber Rod**
- Includes a choice of 200 mm or 220 mm length carbon fiber rod
- Lightweight for patient comfort
- Radiolucent for improved intra- and postoperative radiographic visualization

**Disposable Parallel Drill Guide**
- Lightweight plastic handle with stainless steel drill sleeves
Synthes Low-Profile Wrist Fixator 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 Low-Profile Wrist Fixator devices are MR Conditional. Representative Synthes Low-Profile Wrist Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Low-Profile Wrist Fixator may be scanned safely after placement of the fixator 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 the 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 the 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 before 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 Low-Profile Wrist Fixator 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 Low-Profile Wrist Fixator frame have been evaluated in the MRI chamber and worst case artifact information is provided below. Overall, artifacts created by Synthes Low-Profile Wrist Fixator 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.
Technique Overview

1

**Insert distal Schanz screws**
To avoid entrapping the extensor mechanism in extension, flex the second metacarpophalangeal joint to 90°.

Make a 25 mm longitudinal incision over the radial aspect and dissect the soft tissue.

Using the parallel drill guide, insert 4.0 mm/3.0 mm self-drilling Schanz screws or 4.0 mm/2.5 mm Schanz screws into the second metacarpal. Placement should be in the proximal and distal diaphyseal bone, 40°–60° to the frontal plane.

**Note:** The basic self-drilling Schanz screw insertion technique requires the tip to be embedded in the far cortex to resist cantilever forces. It is not necessary for the tip to penetrate through the far cortex. However, the screw may be inserted so that it protrudes slightly through the far cortex in some cases such as osteopenic bone.

2

**Insert proximal Schanz screws**
Repeat Step 1 in the distal radius, taking care to avoid the sensory branch of the radial nerve.
Technique Overview

3

Apply frame
With the clamps loosened, place the assembled frame over the Schanz screws.

The clamps should always be positioned with the carbon fiber rod lying on the ulnar side of the Schanz screws to allow easy adjustment and clearance for the thumb.

4

Secure clamps on Schanz screws
Tighten each of the Schanz screw locking screws using the offset wrench.
5

**Reduce fracture**
Reduce the fracture and tighten the remaining adjustment points.

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6

**Perform secondary adjustments**
Supination/pronation may be adjusted by loosening a clamp on the carbon fiber rod.

Flexion/extension, and radial/ulnar deviation may be adjusted by loosening the ball joint screw.
Components Included in Sterile Package

### Fixation Material, MR Conditional

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>294.768</td>
<td>4.0 mm/2.5 mm Schanz Screw</td>
</tr>
<tr>
<td>or 294.771</td>
<td>4.0 mm/3.0 mm Self-Drilling Schanz Screw</td>
</tr>
</tbody>
</table>

- ![Low-Profile Wrist Fixator Clamp](image)
- ![6.0 mm Carbon Fiber Rod](image)

### Low Profile Wrist Fixator Instruments, MR Unsafe*

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>321.263</td>
<td>Offset Wrench, 3.5 mm hex</td>
</tr>
</tbody>
</table>

- ![Disposable Parallel Drill Guide](image)

### General Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>395.769</td>
<td>Protective Cap, for 6.0 mm Carbon Fiber Rods</td>
</tr>
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</table>

*MR Unsafe: An item that is known to pose hazards in all MR environments
03.304.220S    Low-Profile Wrist Fixator, with 4.0 mm/2.5 mm Schanz screws and 200 mm carbon fiber rod, sterile

03.304.222S    Low-Profile Wrist Fixator, with 4.0 mm/2.5 mm Schanz screws and 220 mm carbon fiber rod, sterile

03.304.320S    Low-Profile Wrist Fixator, with 4.0 mm/3.0 mm self-drilling Schanz screws and 200 mm carbon fiber rod, sterile

03.304.322S    Low-Profile Wrist Fixator, with 4.0 mm/3.0 mm self-drilling Schanz screws and 220 mm carbon fiber rod, sterile

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