External Distal Radius Fixator.
Supplement to the 8 mm rod fixator system.

Surgical Technique
Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuy.synthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_033827) or refer to:
http://emea.depuy.synthes.com/hcp/reprocessing-care-maintenance
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External Distal Radius Fixator.
Supplement to the 8 mm rod fixator system.

Rapid assembly
- Simple and rapid frame assembly due to a clearly arranged instrument set
- Schanz screws and carbon fibre rods can be secured individually to the clamps, allowing secondary correction in all planes

Excellent fracture visualization
- Radiolucent carbon fibre rods ensure excellent fracture visualization

Distraction
- Compatible with 8 mm rod systems
- Controllable and measurable distraction
- Intraoperative or postoperative use of the distractor possible

SELDRILL™ Schanz Screws
- Radial preload ensures stronger bone anchorage
- Self-drilling and self-tapping drill tips for simple and time-saving insertion of Schanz screws
- Optimal drill tip geometry ensures minimal temperature during insertion
- Available in pure titanium or stainless steel
- Extended range for External Distal Radius Fixator: diameters 4.0/2.5 mm, 4.0/3.0 mm or 4.0 mm
Indications, Contraindications and Warning

Indications
Unstable distal radius fractures
– Intra-articular
– Extra-articular
– Preliminary fixation before open reduction and internal fixation
– Fractures with open and closed soft tissue injury
– Multiple trauma (in terms of “damage control surgery” – injury-adapted care)

Injuries, fractures, dislocations, burns in the area of:
– Hand
– Wrist
– Forearm

Fractures in combination with
– Extensive soft tissue injuries
– Bone loss
– Vascular and/or neural involvement

Fracture dislocation
– Hand

Failed closed reduction with casting resulting in secondary dislocation
– Radial shortening
– Angulation

Contraindications
No specific contraindications.

Warning
The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions:
– Patients who for social and physical reasons are not suitable for an external fixator.
– Agitation.
– Patients in whom screws cannot be inserted due to a bone or soft tissue disease.
Distal Radius Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Distal Radius Fixator frame may be scanned safely after placement of the frame under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator 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 Control 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 Distal Radius Fixator frame was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore. The results showed a maximum observed heating for a wrist fixator 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.

Precautions: Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions, the maximum 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 are 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 in order 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 Distal Radius Fixator devices may have the potential to cause artifact in the diagnostic imaging.

Warnings:
- Only use frame components stated in the surgical technique of the Distal Radius Fixator System
- Potential complications of putting a part in the MR field are:
  - Torsional forces can cause the device to twist in MR field
  - Displacement forces can pull the device into the MR field
  - Induced currents can cause peripheral nerve stimulation
  - Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient
- Do not place any radio frequency (RF) transmit coils over the Distal Radius Fixator frame

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 Distal Radius Fixator System. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame.

Representative devices used to assemble a typical Distal Radius Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Distal Radius Fixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located.

- For FFE sequence: scan duration 3 minutes, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.
Note: For a detailed handling description of the Schanz screws and the Steinmann pin, refer to the Surgical Technique Schanz Screws and Steinmann Pins (DSEM/TRM/0516/0677).

1 First reduction

At the beginning, perform a first reduction of the hand with the fractured radius using gentle ligamentotaxis to minimize soft tissue injuries due to internal pressure.

Precaution: Select the appropriate Schanz screw for the patient’s bony anatomy.

2 Recommended zones for inserting screws

Insert the Schanz screws in the shaft of the second metacarpal.

Precautions:
- 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.

3 Position of screws

Pay attention to the extensor tendon and the radiodorsal neurovascular bundle on the extensor and radiodorsal side.

If the screws are placed too far laterally, they will impede the function of the thumb. For this reason, an angle between 40° and 60° to the horizontal from the orthograde view has proven useful.
4

Insert distal Schanz screws

**Required instruments**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parallel drill guide Ø 4.0 mm</td>
<td>395.967</td>
</tr>
<tr>
<td>Schanz screws Ø 4.0/3.0 mm, Ø 4.0/2.5 mm</td>
<td>(cf. p. 12)</td>
</tr>
</tbody>
</table>

The first Schanz screws to be inserted as a pair can be placed first in the second metacarpal or radius.

Insert the drill guide while protecting and pushing aside the tendons, vessels, and muscles in such a way that the long shaft of the drill guide is in direct contact with the bone. Place the first Schanz screw in described position through the long drill sleeve shaft (A).

Before placing the second screw, remove the drill guide and guide the short shaft over the first Schanz screw; take care here that the long shaft is again in direct contact with the bone (B).

**Notes:**
- Self-drilling, self-tapping Schanz Screws (SELDRIIL) can be inserted without predrilling.
- The thread of the SELDRILL Schanz Screw does not result in irritation of the soft tissue.

5

Insert Schanz screws in the radius shaft

**Required instruments**

<table>
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<tr>
<th>Instrument</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Parallel drill guide Ø 4.0 mm</td>
<td>395.967</td>
</tr>
<tr>
<td>Schanz screws Ø 4.0 mm, Ø 4.0/3.0 mm</td>
<td>(cf. p. 12)</td>
</tr>
</tbody>
</table>

Insert two Schanz screws obliquely in the distal to middle radius as described in step 4. Make sure that the superficial branch of the radial nerve is not damaged.

**Precautions:**
- The SELDRILL Schanz Screw has been developed to minimise heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
6
Position the frame

**Required instruments**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clamp</td>
<td>390.051</td>
</tr>
<tr>
<td>Protective cap for the carbon fibre rods</td>
<td>395.781</td>
</tr>
<tr>
<td>Carbon fibre rod</td>
<td>(cf. p. 12)</td>
</tr>
</tbody>
</table>

Loosen all screws on both clamps. Guide the carbon fibre rod of suitable length through the clamps and secure both ends of the rod with the protective caps to prevent the rod from slipping out.

Guide the fixator clamps over the Schanz screws.

**Precaution:** Only when bones are osteoporotic does the 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.

7
Tighten clamps to the screws

**Required instruments**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexagonal screwdriver, large, Ø 3.5 mm, with groove</td>
<td>314.270</td>
</tr>
</tbody>
</table>

Tighten the screw for fixing the clamp to the Schanz screws with the large hexagonal screwdriver.
Surgical Technique

8
Reduce the fracture

Due to the clamps, which permit independent fixation of the Schanz screws and the carbon fibre rod, the fracture can be optimally reduced with the two Schanz screws as a lever using the modular technique.

The reduction can also be performed by conventional traction on the first and second finger (thumb and index finger) and countertraction on the forearm. Keep the two remaining set screws open here and thus allow free play of the DRF construct.

The length can also be adjusted with the distractor (see section 11 for use of the distractor), but the clamp body screws must be closed first.

9
Tighten adjusting points

After reduction, fix both axis set screws (two screws per clamp, see illustration in section 10a) jointly in a single step.
10  
Axis adjustment in small subsequent corrections

Minor axis corrections can be easily made after reduction if necessary.

**Note:** Corrections in one level can lead to loss of reduction in the other levels.

10a

Flexion and extension, as well as radial and ulnar deviations can be easily corrected by loosening the screw on the main body.

10b

The length, supination, and pronation can be easily corrected after the loosening of the fixing screws for the carbon fibre rod.

This manipulation can be performed primarily interoperatively or secondarily. The length adjustment can also be made by hand or with use of the distractor.
11

Use of the distractor

Use of the distractor for reduction is optional

**Prepare the distractor**

**Required instruments**

| Hexagonal screwdriver, large, Ø 3.5 mm, with groove | 314.270 |
| Distractor | 394.075 |

Close the distractor by turning the thumb wheel counter to the direction of the arrow “Distract”.

Align the thumb wheel so that a through opening forms.

**Insert the distractor**

Place the distractor on the carbon fibre rod, so that the conical end of the distractor is next to the clamp for the distal radius fixator.

Secure the distractor on the carbon fibre rod by tightening the screw.

Loosen the fixator clamp in contact with the distractor by turning the rod-to-clamp screw.
Distraction by ligamentotaxis

Distract the fracture by turning the thumb wheel in the direction of the arrow.

One turn corresponds to lengthening by one millimeter.

Remove the distractor

After successful distraction, tighten the screw on the clamp (1). Remove the distractor by aligning the thumb wheel and loosening the screw on the distractor (2).

Precautions:

– Implant sites should be meticulously cared 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 minimize the risk of pin-track 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.
Implants

Self-drilling Schanz screws (SELDRIILL)
- Reinforced bone anchorage due to radial preload
- Minimal temperature during insertion due to optimized drill tip geometry

<table>
<thead>
<tr>
<th>Titanium</th>
<th>Stainless Steel</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>494.769</td>
<td>294.769</td>
<td>4.0/2.5</td>
<td>80</td>
</tr>
<tr>
<td>494.771</td>
<td>294.771</td>
<td>4.0/3.0</td>
<td>80</td>
</tr>
<tr>
<td>494.772</td>
<td>294.772</td>
<td>4.0/3.0</td>
<td>100</td>
</tr>
<tr>
<td>494.774–779</td>
<td>294.774–779</td>
<td>4.0</td>
<td>60–175</td>
</tr>
</tbody>
</table>

Self-tapping Schanz screws

<table>
<thead>
<tr>
<th>Titanium</th>
<th>Stainless Steel</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>494.445</td>
<td>294.445</td>
<td>4.0/2.5</td>
<td>80</td>
</tr>
<tr>
<td>494.300</td>
<td>294.300</td>
<td>4.0/3.0</td>
<td>80</td>
</tr>
<tr>
<td>494.430 – 460</td>
<td>294.430 – 460</td>
<td>4.0</td>
<td>60–125</td>
</tr>
</tbody>
</table>

Fixation Components

390.051 Clamp for the External Distal Radius Fixator
- Freely adjustable settings can be set with the large hexagonal screwdriver
- Permits secondary length adjustment without loss of reduction
- High strength, light titanium alloy
- Suitable for Schanz screws Ø 4.0 mm, 4.0/3.0 mm and 4.0/2.5 mm.

Carbon fibre rods
- Radiolucent

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>395.782</td>
<td>8.0</td>
<td>200</td>
</tr>
<tr>
<td>395.784</td>
<td>8.0</td>
<td>220</td>
</tr>
<tr>
<td>395.786</td>
<td>8.0</td>
<td>240</td>
</tr>
</tbody>
</table>

395.781 Protective cap for carbon fibre rods

Note: For a detailed product information of the Schanz screw, refer to the Surgical Technique Schanz Screws and Steinmann Pins (DSEM/TRM/0516/0677).
<table>
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