Small External Fixator, Radiolucent, Sterile. Specific design for distal radius fractures.
Warning
This description alone does not provide sufficient background for direct use of
the instrument set. Instruction by a surgeon experienced in handling these
instruments is highly recommended.

Reprocessing, Care and Maintenance of
Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments,
please refer to: www.synthes.com/reprocessing
The small external fixator is available as a sterile-packed system. Individual sterile clamps can also be ordered.

The system is distinguished by its light, completely radiolucent clamp. The clamp enables the pins to be freely placed, and is easy to use due to its snap mechanism. Consisting of single-use items, the system is also easy to maintain, hygienic and logistically advantageous.

The single clamp made of high-quality plastic can also be used as the perfect radiolucent supplement to existing, small external fixators with metal clamps. Compatibility is ensured.

**Note:** The product is designed for single use and cannot be resterilised.
176.440S Small external fixator, radiolucent, sterile
- Single-use set for distal radius fractures
- Set contains sterile-packed single-use products
- Simple handling
- Simplifies hospital logistics
- Enables rapid initial care
- MR conditional

898.000S Clamp, radiolucent, sterile
- Radiolucent
- MR conditional
- Light (approx. 5 g)
- High stability
- Simple handling reduces operative time
Indications and contraindications

Indications

Unstable distal radius fractures
– Intraarticular
– Extraarticular
– Fractures with open and closed soft tissue injury
– Multiple trauma (in terms of “damage controlled surgery” – injury-adapted care)

Injuries, fractures, luxations, burns
– Wrist area
– Carpal bone
– Forearm

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

Fracture dislocation
– Wrist

Paediatric traumatology
– Open fractures with bone loss

Contraindications
– Patients who for social and physical reasons are not suitable for an external fixator.
– Agitation
– Patients in whom no screws can be inserted due to a bone or soft tissue disease.
The Small External Fixator System 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 Fixator devices are MR Conditional. Representative Small External Fixator devices used in a typical construct include clamps, rods and various attachments.

A patient with a Synthes Small External 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 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 nonclinical testing, the Small External 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 the wrist fixator frame of less than 4°C for 1.5 T and less than 2°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 MR Conditional Small External 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 Small External Fixator System
- Potential complications of putting a non-MR safe or non-MR conditional 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 Small External 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 Small External Fixator frame. 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 Small External Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Small External 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
Possible fractures according to AO fracture classification

Non-bridging technique

23-A Extraarticular fracture

Ulna, intact radius
Radius, simple and compressed
Radius, multifragmented

Bridging surgical technique

23-B Partial articular fracture

Radius, sagittal
Radius, frontal, dorsal
Radius, frontal, volar

23-C Complete articular radius fracture

Simple articular, simple metaphyseal
Simple articular, multifragmental
Full articular, multifragmental
The assembly of the radiolucent, small external fixator will be illustrated using an example of a 3-rod modular technique for the distal radius.

The hand with the fractured radius is first reduced via gentle ligamentotaxis to minimize soft-tissue damage from internal pressure.

1

**Angle for introducing the screws**

Implant the Schanz screws in metacarpal II.

**Note:** To increase retention, it is recommended to insert the screws at a slight angle with the proximal and distal pins at a proven angle of 40° to 60°.
2

Position of the screws

From the extension side and radiodorsal side, pay attention to the radiodorsal tendon and nerve fibre bundle.

Screws too far to the side impair the functioning of the thumb. From an orthograde perspective, an angle of 40° to 60° in reference to the horizontal plane has proven to be useful.

3

Insert screws

The Schanz screws can first be inserted in metacarpal II or in the radius. Insert the drill guide under protection while displacing the tendons, veins, arteries and muscles (on the radius). When screwing in the Schanz screws using the drill guide, maintain distinct contact with the bone.
4

**Screw diameters**

Insert two Schanz screws in metacarpal II, and two in the radius. Depending on the size of the skeleton, use Schanz screws with a diameter of 2.5 mm to 4.0 mm for metacarpal II; for the radius, Schanz screws with a diameter of 3.0 to 4.0 mm can be used.

If possible, cool the shaft while drilling or inserting the Seldrill Schanz screws.

5

**Construct a partial frame**

Connect the pair of Schanz screws in the radius and metacarpal II with short rods. Tighten the clamps of this partial frame with the open-ended wrench or the torque wrench with 3.0 Nm.

**Note:** Select the rod lengths so that the ends close to the fracture are not problematic during later reduction. Also leaving enough room at the ends of the rods to later affix a middle, modular rod with two additional clamps (modular clamps) to the partial frame (see step 6).

This is accomplished for example by having the rod lie on the ulnar side of metacarpal II, and on the radial side of the radius (or visa versa).
Insert the modular rod and monitor reduction

After the two partial frames are mounted and fixed, check the reduction.
  – visually
  – clinically by using your sense of touch
  – radiologically with the image intensifier in two, possibly angled planes

If the reduction is satisfactory, have a medical assistant mount and affix the modular rod. This can prevent the clamps from popping off.

Do not tighten the clamps more than 3.0 Nm. It is advantageous to use the torque wrench (Art. No. 324.305) with an 11 mm nut (324.308).

Advantages
The 3-rod modular technique allows fast and reliable reduction and retention that protects soft tissue.
**Additional stabilization**

A neutralization rod stabilizes the assembly. Depending on the position, it is sufficient to grasp a screw end of the distal and proximal groups. Metal clamps can also be used.

This neutralization rod can be affixed to any site of the partial frame. One clamp per partial frame is sufficient.

Whether or not to use a neutralization rod depends on various factors:

– Patient weight
– Fracture configuration/instability
– Distances to the fragment
– Free lengths of the Schanz screws
– Length of the modular intermediate rods

The construction becomes weaker and more elastic as angle of the rods and their spacing increases. The neutralization rod can be affixed to improve stabilization.

Recheck to see if all the clamps are sufficiently tight.
Safety zones in the wrist

In the forearm, wrist, and fingers, affix Schanz screws or Kirschner wires in the safe zones apart from tendons, nerves and vessels.

For the fragment close to the wrist, the following holds true especially for non-bridging constructions for distal radius fractures:
Narrow safe zones exist between the dorsal and dorsoradial extensor regions. Corresponding anatomical knowledge is required to place the fixator in these critical zones. If the swelling permits, the tendon zones can be palpated before the Schanz screws and/or Kirschner wire are inserted.

Create a small, lengthwise incision, and use a suitable instrument (such as a small curved clamp, or small curved and unopened scissors) to follow the channel until the bone is firmly contacted. Cautiously advance the drill guide in this channel until it securely contacts the bone.

Place the spreader and the drill guide safely between the tendon zones using slight spreading and back-and-forth movements.
To prevent ambiguity, the bone must provide a definite response upon being contacted, or the bone surface must be visible.

Insert the Schanz screw while the drill guide maintains continuous contact with the bone.

Note: Self-tapping Schanz screws (Seldrill) and Kirschner wires can be introduced without predrilling; conventional screws require predrilling.
Modular technique with Schanz screws

Different combinations are possible with or without metal clamps.

Insert two Schanz screws in the radius shaft, and two in the distal radius fragment. Connect the main fragments with a 4 mm carbon fibre rod, and tighten the clamps.

A curved carbon fibre rod can also be used for the distal fragment. Each main fragment is thereby provided with its own frame, enabling it to be manipulated and reduced.

A modular intermediate rod is normally added. However, it can also be affixed after reduction. This intermediate rod connects the distal and proximal frames at any desired site.

After reduction, tighten the clamps of this intermediate rod.

Additionally stabilize these modular frames with a neutralization rod.

1

Initial patient positioning

The patient is positioned and covered according to conventional and local guidelines. If the dislocation is severe, the fracture can be initially reduced while preparing for surgery.
2

Insert screws in the radius shaft

Insert two Schanz screws in the radius shaft from a dorsoradial direction. Create sufficiently large stab incisions, spread the incision to the bone, displace the muscles, tendons, vessels and nerves by feel and partially by sight.

Insert the single-use drill guide until it definitely contacts the bone. Then implant the Schanz screws.

Note: Only screw in Seldrill screws. Predrilling is required for conventional screws which are then screwed in. An angle of 10º to a max. 45º is recommended for thin bones. This can be advantageous for weak bones. The angle of the screws depends on the situation.

It is recommended that coolant be used when inserting Schanz screws, or pre-drilling.
3

**Connect the screws in the radius shaft**

Connect the screws with a straight 4 mm carbon fibre rod. The intermediate rod can also be placed diagonally across the Schanz screws; i.e., against the radial side of one screw, and against the ulnar side of the other. This produces a small angle, and the end collides less with the distal frame. The projection from the fracture should be 1 to 2 cm to allow room for a clamp.

Tighten all nuts using the single-use wrench or torque wrench 3.0/4.0 Nm (Art. No. 324.305) together with the nut, width-across-flats 11.0 mm (324.308).
4

Insert the screws in the distal fragment

Insert two Schanz screws in the safe zones between the tendons and vascular regions of the distal fragment. Create sufficient but not overly large stab incisions in the correct location.

Spread the incision; displace soft tissue, tendons, nerves, and vessels until the bone is definitely contacted. Insert the drill guide system (ensure continuous contact with the bone), and insert the Schanz screws.

Note: Use Seldrill screws without pre-drilling; pre-drill for conventional screws. Observe the safe zones (see anatomical picture on page 12).

The modular technique can be used for Schanz screws as desired.

In this surgical technique, the screws can be positioned in the distal fragment in two ways that can be varied at any time depending on the situation.

4a

Position the Schanz screws in the distal fragment

Position the Schanz screws at an angle of 60° to 90° in relation to each other; one radial, one dorsal
5 Connect the screws in the distal fragment

Connect the two Schanz screws of the distal fragment. A straight 4 mm carbon fibre rod or a 4 mm curved carbon fibre rod can be used. By using the curved carbon fibre rod, the 2 Schanz screws can be connected to circumvent soft tissue.

**Note:** In regard to the surgical technique, it does not matter to which side the rod is attached. Make sure that the frame of the distal fragment and the frame of the shaft fragment do not interfere with each other when reducing the fracture.

Tighten the nuts of the distal frame to 3 Nm using the single-use wrench or the torque wrench. The nuts of both partial frames must be well-tightened.
6

Connect the rods with an intermediate rod

Connect the partial frames with an intermediate rod. Various modular and freely-selectable positions can be used.

Create connections that are easiest to assemble based on anatomy, the injury, and construction.

Insert the modular rod and monitor reduction.

After the two partial frames are mounted and fixed, check the reduction.

– visually
– clinically by using your sense of touch
– radiologically with the image intensifier in two, possibly angled planes

If the reduction is satisfactory, affix the modular rod. This can prevent the clamps from coming off the rod.

Do not tighten the clamps more than 3 Nm. It is advantageous to use the torque wrench (Art. No. 324.305) with an 11 mm nut (324.308).
Affix the neutralization rod

The system can be additionally stabilized with a neutralization rod.

Affix the neutralization rod to any site on the partial frame. One clamp per partial frame is sufficient.

Whether or not to use a neutralization rod depends on various factors:
- Patient weight
- Fracture configuration/instability
- Distances to the fragment
- Free lengths of the Schanz screws
- Length of the modular intermediate rods

The construction becomes weaker and more elastic as angle of the rods and their spacing increases. The neutralization rod can be affixed to improve stabilization.

Check to ensure all clamps are tight.
Components

898.0005 Radiolucent clamps
- Radiolucent, MR conditional and light (approx. 5 g).
- Optimally grasps Ø 2.0–4.0 mm
- Simple connection variations possible such as pin to rod or rod to rod

395.610 Connecting Rod Ø 4.0 mm, length 80 mm,
Carbon Fibre
  - Radiolucent

395.620 Connecting Rods Ø 4.0 mm, length 100 mm,
Carbon Fibre
  - Radiolucent

494.769 Seldrill Schanz Screw Ø 4.0/2.5 mm,
length 80 mm, Pure Titanium
  - Reinforced bone anchorage due to radial preload

494.771 Seldrill Schanz Screw Ø 4.0/3.0 mm,
length 80 mm, Pure Titanium
  - Reinforced bone anchorage due to radial preload

Instruments

Single use T-handle Ø 4.0 mm
Single-use wrench, 11 mm

Single-use drill guide, Ø 4.0 mm

Optional

898.000S  Additional clamp, radiolucent, sterile

324.304  Carbon fibre rod Ø 4.0 mm, curved, radius 60mm
  – Ideal for the non-bridging fixation of distal radius fractures
  – Radiolucent

324.305  Torque wrench, 3.0/4.0 Nm, steel
  – Easy to handle
  **Warning:** 3.0 Nm is the optimum torque to transfer to the radiolucent clamp. (Details can be found in instructions 69001).

324.308  Nut, width across flats 11.0 mm for the torque wrench.
  Used with the handle to prevent applying excessive torque to the nut.
Combination options

The radiolucent clamp is an outstanding supplement to the small external fixator system.

Use: for example, near the wrist where the fracture must be radiologically monitored.

The radiolucent plastic clamp is sterile, individually packaged, and is not suitable for resterilisation.

Handling the clamp requires a sensitive touch: It should not be overly tightened. When first using the clamp, it is recommendable to have a few additional radiolucent clamps at hand beyond the contents of the set.

Important instructions

When removing the radiolucent clamp, it may be useful to use the fork of combination wrench 11 mm (Art. No. 321.160).

Do not use the radiolucent clamp together with stainless steel screws or rods since the holding force cannot be ensured. The clamp only functions optimally with titanium implants and carbon fibre rods.

To prevent improper assembly, the clamp may not be disassembled into its individual components.
## Ordering information

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<th>Article No.</th>
<th>Description</th>
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<td>6 clamps, radiolucent, Sterile</td>
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<td>1 x Single-Use T-Handle Ø 4 mm</td>
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### Optional

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