Small External Fixator

Surgical Technique

This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation
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**Image intensifier control**

**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
Small External Fixator

Simple handling
– Clamps with clip-on self-holding mechanism
– Color-coded for easy identification
– Shorter operation times
– MR conditional

Flexible system
– The system can be configured to the user’s requirements and the specific anatomic situation
– Free pin placement
– Compatibility with other Synthes external fixator systems
– Suitable for bridging and non-bridging surgical techniques

High stability
The material properties of the TAV clamps, the carbon fibre rods, and pure titanium pins offer safety, high stability, and a light weight.

A clamp for all connection options
– Grips Ø 1.8 – 4.0 mm
– Two nuts for independent fixation of the implant and/or the carbon fibre rod
– Reduced inventory

Combination clamp
– Grips Ø 2.5 – 4.0 mm
– A nut for the fixation of the implant and/or carbon fibre rod

Curved carbon fibre, Ø 4.0 mm
– Ideal for non-bridging fixation of distal radial fractures

Straight carbon fibre rod, Ø 4.0 mm
– For modular frame configurations

Seldrill Schanz screws
– Time-saving and simple placement of Schanz screws
– Reinforced bone anchoring due to radial preloading
– Available in pure titanium and stainless steel
– Compatible with the small external fixator Ø 2.5/4.0, 3.0/4.0 and 4.0 mm

Kirschner wires
– For other application options
– Material: titanium alloy and stainless steel
– Recommended diameter for the system 1.8, 2.0 and 2.5 mm
System Description

The small external fixator is a system for simple or complex configurations.

It is light in weight, consists of only a few components, and offers compatibility with mini, medium, and large external fixators. The clamps with a clip-on, self-holding mechanism allow several types of connection and simplify handling.

A large number of construct variants allows for treatment in all indications.

The main benefits are: independent pin placement, modular primary and secondary reduction options, good stability, and consideration of (adaptation to) the soft tissue situation.
Indications

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

Other indications

Injuries, fractures, dislocations, burns
- Carpal region
- Wrist
- Forearm
- Ankle (possibly in combination with a medium or large fixator)

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

Fracture dislocation
- Carpal bones

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

Contraindications
- 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.
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
- 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
The assembly of the small external fixator is described here using the 3-rod modular technique on the distal radius as the example.

At the start, perform an initial reduction on the hand with the fractured radius by gentle ligamentotaxis to minimize soft tissue injuries through internal pressure.

1

Angle for screw insertion

Implant the Schanz screws into the second metacarpal.

Note: For a better purchase, it is recommended to insert these at a slight angle. An angle of 40° to 60° between the proximal and distal pin has proven to be best.

2

Position of the 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° with respect to the horizontal has proven best when viewed from the orthograde position.
3

Insertion of screws

The Schanz screws can be placed first in the second metacarpal or radius. Insert the drill sleeve in the radius and particularly in the second metacarpal, while protecting and pushing aside the extensor tendon. Maintain a secure bone contact when implanting the Schanz screws with the drill sleeve.

4

Screw diameters

Insert two Schanz screws each into the second metacarpal and the radius. Depending on the size of the skeleton, select Schanz screws with a diameter between 2.5 mm and 4.0 mm for the second metacarpal and Schanz screws with a diameter of 4.0 mm for the radius.

It is recommended for the shaft that cooling be provided for the drilling or insertion of the Seldrill Schanz screw. To accomplish this, the connector on the drill sleeve can be connected to a tube and a syringe.

5

Construction of partial frames

Connect the pairs of Schanz screws in the radius and the second metacarpal using short rods. Firmly tighten the clamps of these partial frames.

Note: Select the rod length so that the ends near the fracture do not interfere with each other during the later reduction but there is sufficient room at the end of the rods to attach the middle modular rod to the partial frames with two additional clamps (modular clamps).

This is achieved, for example, by placing the rod in the second metacarpal on the ulnar side and in the radius on the radial side (or vice versa).
Partial frames as reduction handles

Use the partial frames as handles for every main bone to be reduced. The fracture can be reduced in all six degrees of freedom (longitudinal-ligamentotaxis, translation, and rotation). This technique protects soft tissues from unnecessary pressure and compression and can be easily performed.

Alternative with reduction rods
7

**Insert modular rod and verify reduction**

Place the third rod before the final reduction.

**Note:** If the rod slips out during the reduction manoeuvre, it can be reinserted later.

Loosely connect the two “modular clamps” at the end of the fracture by means of the third rod (similar to two connected universal joints).

After the fracture has been reduced, verify this clinically by palpation and radiographically with the image intensifier in two planes and if necessary in oblique planes.

**Note:** The two “modular clamps” can be tightened slightly before the radiographic verification to avoid unnecessary exposure to X-rays.

After successful reduction, gradually tighten the two “modular clamps”.

---

8

**Benefits of the 3-rod modular technique**

The 3-rod modular technique allows rapid and secure reduction and retention with protection of soft tissue.

A secondary correction or adjustment can also be made easily at any time by opening the two “modular clamps”.

---

9

**Additional stabilisation**

The construct can be stabilised as needed by using a “neutralization rod”. Depending on the position, it is sufficient to grasp one end of the screw from the distal and proximal group.

Finally, verify again whether all clamps have been tightened well.
Non-bridging Surgical Technique

Safety zones in the wrists

Schanz screws or Kirschner wires are to be used in the forearm and wrist and finger region in the safe zones not involving tendons, nerves, and vessels.

The following apply to the fragment near the wrist, particularly if a non-bridging construct technique is used for distal radius fractures:

There are narrow safety zones between the extensor compartments dorsally and dorsonally. Placing the fixator in these critical zones requires appropriate background knowledge of anatomy. Before the Schanz screws and/or Kirschner wire can be inserted, the tendon compartments are palpated, except when swelling makes this impossible.

Make a small longitudinal incision and palpate the channel through this incision with a suitable instrument (small curved clamp, small curved, unopened scissors, or the like) until there is secure contact with the bone surface. Cautiously advance the multidrill sleeve with the protective trocar into this channel, so that this sleeve assembly is securely in contact with bone.

With slight spreading and pendular motions, place both the separator and the drill sleeve assembly securely between the tendon compartments. To avoid any uncertainty, the tactile contact must provide definite feedback or the bone surface must be visible.

Insert the Schanz screw with the drill sleeve assembly being in constant contact with the bone.

Note: Self-drilling Schanz screws (Seldrill) and Kirschner wires can be inserted without conventional screws with predrilling.
Variant A: Modular Technique with Schanz Screws

Insert 2 Schanz screws each into the radial shaft and the distal radius fragment. Connect the main fragments with a 4 mm carbon fibre rod and tighten the clamps firmly.

A curved carbon fibre rod can also be used in the distal fragment. Each main fragment thus has its individual frame and can be manipulated and repositioned using its frame.

As a rule, use the modular intermediate rod. This rod can also be inserted for the first time after the reduction. This intermediate rod connects the distal and proximal frames at any desired place.

The reduction can be made easier by long rods (with 1 or 2 clamps), which are attached temporarily during the surgery. The long rods point away from the fracture so that the reduction is easier and more differentiated and contact with the X-ray beam of the image intensifier can be avoided.

After the reduction the clamps lock this intermediate rod.

Depending on the situation, this modular frame can be stabilised still further with a neutralization rod.

1

First positioning

The positioning and covering follow general and local guidelines. Initial reduction in a very severe dislocation can be performed during the preparation for surgery.
Inserting the screws in the radial shaft

Insert two Schanz screws in the radial shaft from the dorso-radial direction. Make sufficiently large stab incisions, spread the tissue to the bone, and push aside muscles, tendons, vessels, and nerves by feel and to some extent by sight.

Always insert the 3-part drill sleeve assembly until there is secure contact with the bone. Then implant the Schanz screws.

Note: When using Seldrill screws, merely drill in the screws. With conventional screws, first predrill holes and then insert the screws. An angle of 10° to a maximum of 45° (in the radius) is recommended if the bones are thin. This is a benefit but not essential with weak bones. Select the pitch of the screws to fit the actual conditions.

It is recommended for the shaft that cooling be provided for the drilling or insertion of the Seldrill Schanz screw. To accomplish this, the connector on the drill sleeve can be connected to a tube and a syringe.

Connecting the screws in the radial shaft

Connect the screws with a straight 4 mm carbon fibre rod. The position of the distal frame is readily evident.

The intermediate rod can also be selected “diagonally” through the Schanz screws, sometimes on the radial and sometimes on the ulnar side. A certain pitch results and the end collides less with the distal frame. The projection relative to the fracture should be 1 to 2 cm, so that there is room for a clamp.

Tighten all nuts firmly.
4

Inserting screws in the distal fragment

Insert two Schanz screws in the safe zones between the tendons and the vascular compartments of the distal fragment. Make adequate but not too large stab incisions at the correct place.

Spread and push aside the soft tissues, tendons, nerves, and vessels until there is secure contact with the bone. Position the drill sleeve assembly (make sure that there is constant contact with the bone) and insert the Schanz screws.

**Note:** Use self-drilling Seldrill screws without conventional screws with predrilling. Bear in mind the safe zones (see anatomic diagram on page 8).

Schanz screws can be used with the modular technique in any manner.

There are two variants of the surgical technique; these can be varied at any time according to requirements.

4a

Schanz screws at a 60 to 90° to each other, one from the radial and the other from the dorsal direction
Both Schanz screws from the radial direction

The further surgical technique is identical for a and b; this is an outstanding feature of the modular technique.

Connecting screws in the distal fragment

Connect the two Schanz screws of the distal fragment. Use a straight 4 mm carbon fibre rod, a 4 mm stainless steel rod, or a 4 mm curved carbon fibre rod here. The last rod makes it easy to connect the 2 Schanz screws elegantly around the soft tissue.

Note: The side on which the rod is placed is not important for the surgical technique. Care must be taken that the frame construct of the distal fragment and the frame of the shaft fragment do not interfere with each other during the reduction manoeuvre.

Tighten the nuts of the distal frame firmly. The nuts of both partial frames must be tightened well.
Position of the Schanz screws in the distal fragment:

5a
Schanz screws at a 60 to 90° to each other, one radial and the other dorsal

5b
Both Schanz screws radial

The remaining surgical technique applies to both 5a and 5b. However, the technique is shown in the drawings only for 5a.
6
Connecting the rods with the intermediate rod

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

Connections can be selected which can be assembled most easily due to anatomy, the pattern of injury, and construction.

The clamps of "the modular intermediate rod" must be kept open until the reduction has been completed. But the clamps for the individual frames must remain closed!
7

Reduction

The partial frames can be grasped and used to reposition the bone. The reduction may not be performed over already injured soft tissue.

This step can be supplemented with “accessory reduction rods”: 4 mm rods (200 mm), which point away from the fracture, are used on the partial frames with 1 or 2 clamps. It is beneficial if these rods are parallel to the radial shaft and parallel to the metacarpal. The reduction can be performed in a differentiated and tissue-sparing manner with use of these rods, put in place temporarily during surgery. Hands must be outside the central beam of the X-ray image intensifier during intraoperative X-ray image intensifier verification!

Reduction can be verified clinically or if necessary radiographically (X-ray image intensifier).
8

**Attaching the neutralization rod**

A neutralization rod can provide the system with additional stability. It can be attached anywhere in the partial frame. One clamp per partial frame is sufficient. The use of an additional clamp depends on various factors:

- the patient’s weight
- fracture configuration / instability
- distance to the fragment
- the free lengths of the Schanz screws
- the length of the modular intermediate rods

The more angled the rod and the greater the distances, the weaker and more elastic the construct. A neutralization rod can be attached here for better stabilisation.

Finally, verify again whether all clamps have been tightened.

---

9

**Tightening of the clamps of the intermediate rod**

Tighten the two clamps, which connect the modular rod between the partial frames. Take care that the tightening proceeds sequentially to allow the shaft to make contact with the cogs.

Verify the achieved reduction manoeuvre clinically and radiographically. If it is not satisfactory, steps 7 and 8 can be repeated as often as desired.
**Variant B: with Kirschner wires**

Before stabilising with Kirschner wires, reposition using the bridging technique. If a sufficient reduction can be achieved with gentle pulling, the repositioning can be omitted.

In this variant, the frame for stabilising the fracture is configured according to the bridging surgical technique with the already described modular technique.

The neutralization rod in step 9 usually does not need to be attached.

---

1

**Bridging modular technique for reduction**

Perform steps 1 to 8 of the surgical technique of the bridging variant without prior reduction and temporary stabilisation using the 3-rod modular technique.

---

2

**Inserting the Kirschner wires**

Insert 2, 3, or 4 Kirschner wires and stabilise the fracture. Bridge a intraarticular fracture with 1 Kirschner wire. Place the other two Kirschner wires from distal area into the shaft region. Connect all Kirschner wires with a curved carbon fibre rod. The ends of the Kirschner wires can be bent so that they point in the same direction.
3

Removing part of the construct

Loosen the bridging and remove the front part of the construct. The construct now no longer bridges. The Kirschner wires used in the distal fragment remain connected to the frame of the shaft fragment.

If the fracture is very unstable, the bridging construct can also be removed later.

Note: For instructional reasons, a diagram is not provided for this procedure.

4

Connecting the Kirschner wires

Connect all Kirschner wires using a rod. Only minor fine reductions are possible with Kirschner wires, which bridge the main fracture and open into the shaft. These can be performed using the modular technique.
5

Connecting the partial frames
After making the connection between the Kirschner wires, tighten all clamps.

5a

Connect the partial frames (distal radial fragment and radial shaft). If a fine reduction is no longer necessary, the distal partial frame can be connected with a 4 mm rod and Schanz screws.

5b

If a fine reduction or later reduction and correction are anticipated, the use of a modular intermediate rod between the partial frames at the distal fragment and shaft is recommended in this case as well.
Attaching the neutralization rod

Depending on need and actual conditions, a neutralization rod can be attached between any places on any partial frame.

This gives the system additional stability.
## Small External Fixator

### Ordering Information

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