Small External Fixator 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.depuysynthes.com/hcp/reprocessing-care-maintenance For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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Small External Fixator

Simple handling

- Clamps with clip-on self-holding mechanism
- Color-coded for identification

Flexible system

- The system can be configured to the user's requirements
- Free pin placement
- Compatibility with other DePuy Synthes external fixator systems
- Suitable for bridging and non-bridging surgical techniques

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

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, \varnothing 4.0 mm

• Ideal for non-bridging fixation of distal radial fractures

Straight carbon fibre rod, \varnothing 4.0 mm

• For modular frame configurations

Seldrill Schanz screws

- Reinforced bone anchoring due to radial preloading
- Available in commercially 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

- Material: titanium alloy and stainless steel
- Recommended diameter for the system 1.8, 2.0 and 2.5 mm

Stability

The material properties of the TAV clamps, the carbon fibre rods, and pure titanium pins provide stability, and are light weight.





Overview of available Fixator systems

	Rod Fixators External Fixation Family (clip-on)	Supplements to the External Fixation Family	Monolateral Systems MEFiSTO Systems
Large rod ∅ 11 mm	the state		Acres and a
	Large External Fixator	Hybrid Ring Fixator	Carbon fibre tube
Medium rod ∅ 8 mm	++++		
Small rod Ø 4 mm	Medium External Fixator	External Distal Radius Fixator (DRF)	
	Small External Fixator		
Mini rod ∅ 3 mm		-sites	
		External Mini-Fixator	

* MEFiSTO central body, MEFiSTO angulator, and MEFiSTO segment transport are also available



MEFiSTO Central Body



MEFiSTO Angulator



MEFiSTO Segment Transport

Warning

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.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.



¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991. ² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

MRI Information

Small External Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a DePuy 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, DePuy Synthes 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 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 DePuy 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 DePuy 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

Bridging Surgical Technique

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.

Notes:

- 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.
- For a detailed handling description of the Schanz Screws, refer to the Surgical Technique Schanz Screws and Steinmann Pins.



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.

A 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.



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.

A 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 Seldrill Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.

Note:

Less experienced users are advised to use a hand drill when placing the Seldrill Schanz screw in the far cortex.



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).



6. 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 pressure and compression.



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 reduction and retention.

A secondary correction or adjustment can also be made 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

Recommended zones in the wrists

Schanz screws or Kirschner wires are to be used in the forearm and wrist and finger region in the recommended 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 recommended zones between the extensor compartments dorsally and dorsoradially. 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:

For a detailed handling description of the Schanz screws, refer to the Surgical Technique Schanz Screws and Steinmann Pins.



Variant A: Modular Technique with Schanz Screws

A Precaution:

Select the appropriate Schanz screw for the patient's bony anatomy.

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.



2. Inserting the screws in the radial shaft

Insert two Schanz screws in the radial shaft from the dorsoradial 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 Schanz 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.

▲ Precaution:

Only when bones are osteoporotic does the Seldrill 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.

Note:

A Seldrill Schanz screw can be turned back without loosening as the thread is not conical.



3. 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 recommended 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.

A Precaution:

The tip of the Self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.

Note:

Use self-drilling Seldrill Schanz screws without conventional screws with predrilling.

Bear in mind the recommended zones (see anatomic diagram under Recommended zones in wrist).

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



4b.

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.

5. 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 connect to the 2 Schanz screws.

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-rayimage intensifier verification!

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





8. 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.



9. Attaching the neutralization rod

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.

▲ 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 tract 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.



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 stps 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.



6. Attaching the neutralization rod

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

▲ 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 tract 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.



Product Information

Set	U	nits
186.430	Small External Fixator in Vario Case	
Case		
686.430	Vario Case for Small External Fixator, without Lid, without Contents	1
Instruments		
395.360	Socket Wrench, Ø 7.0 mm	1
395.350	Combination Wrench \varnothing 7.0 mm	1
324.300	Drill Sleeve Assembly, complete, Stainless Steel	1
Fixation Com	ponents	
395.578	Clamp, clip-on, self-holding, Titanium Alloy (TAV)	12
390.041	Combination Clamp, clip-on, self-holding, Titanium Alloy (TAV)	4
395.600	Connecting Rod \varnothing 4.0 mm, length 60 mm, Carbon Fibre	4
395.610	Connecting Rod \varnothing 4.0 mm, length 80 mm, Carbon Fibre	4
395.620	Connecting Rod \varnothing 4.0 mm, length 100 mm, Carbon Fibre	4
395.630	Connecting Rod \varnothing 4.0 mm, length 120 mm, Carbon Fibre	4
395.640	Connecting Rod Ø 4.0 mm, length 140 mm, Carbon Fibre	2
395.650	Connecting Rod Ø 4.0 mm, length 160 mm, Carbon Fibre	2
395.660	Connecting Rod ∅ 4.0 mm, length 180 mm, Carbon Fibre	2
395.670	Connecting Rod ∅ 4.0 mm, length 200 mm, Carbon Fibre	2
324.304	Carbon Fibre Rod ∅ 4.0 mm, curved, radius 60 mm	2

Implants	Ur	nits
494.769	Seldrill Schanz Screw ∅ 4.0/2.5 mm Iength 80/20 mm, Pure Titanium	6
494.771	Seldrill Schanz Screw ∅ 4.0/3.0 mm, length 80/20 mm, Pure Titanium	6
494.775	Seldrill Schanz Screw ∅ 4.0 mm, Iength 80/20 mm, Pure Titanium	6
492.170	Kirschner Wire ∅ 1.8 mm with trocar t length 150 mm, Titanium Alloy (TAV)	ip, 10
492.200	Kirschner Wire ∅ 2.0 mm with trocar length 150 mm, Titanium Alloy (TAV)	tip, 10
Optional		

324.305	Torque Wrench, 4.0 Nm, Stainless Steel
395.510	Compressor, open
324.306	Allen Nut, width across 7.0 mm, for No. 324.305, Stainless Steel

Note:

For a detailed product information of the Schanz screw, refer to the Surgical Technique Schanz Screws and Steinmann Pins.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

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