Elbow Hinge Fixator

Guided Flexion/Extension

Surgical Technique

approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

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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Elbow Hinge Fixator

Guided Flexion/Extension

As a component of the AO family of external fixators, the joint bridging mobile fixator enables flexibility due to its modular frame construction. The free pin placement allows adaptation to the particular circumstances of each injury.

The Elbow Hinge, as the central element is compatible with fixation components of large and medium-size external fixators.

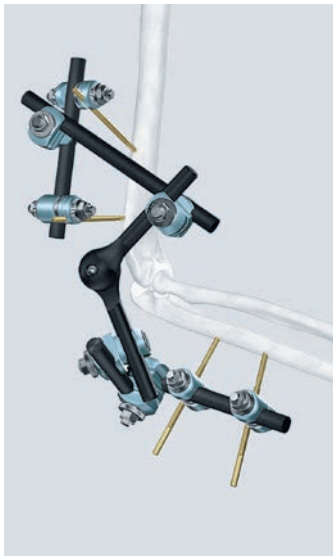
The radiolucency of the Elbow Hinge Fixator helps identify the anatomical joint axis and aids to facilitate the positioning of the mechanical axis of the Elbow Hinge.

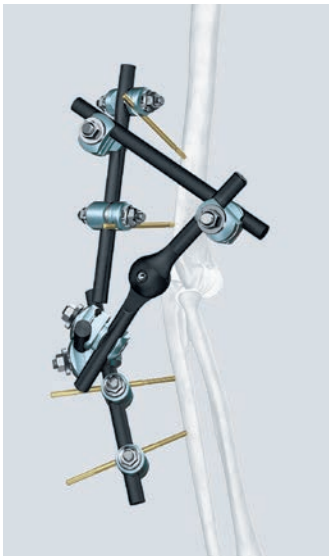
Free frame design

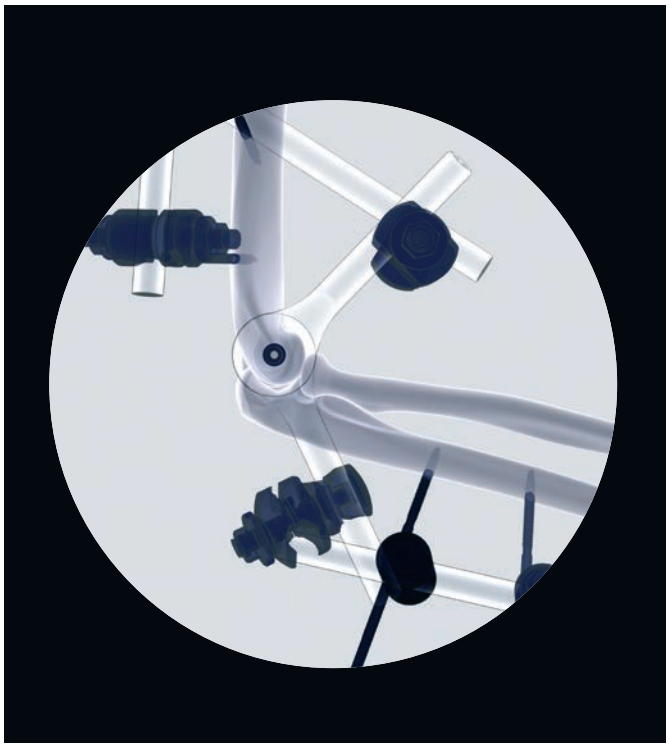
- Patient-specific assembly of the fixation frame
- Free pin placement in the humerus and ulna
- Elbow Hinge Fixator is compatible with 8 and 11 mm carbon fibre rods

Monitored axis determination

- Axis determined with ∅ 2.5 mm guide wire
- Radiolucent materials allow visualization of the musculoskeletal segment







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.
- Patients in whom no screws can 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, Contra-indications, 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

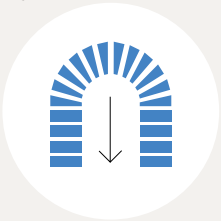
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.

Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[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

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

■ Notes:

- In nonclinical testing, the Elbow Hinge 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 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.

▲ Precaution:

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 Elbow Hinge 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 Elbow Hinge 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 Elbow Hinge 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 Elbow Hinge 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 Elbow Hinge Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Elbow Hinge 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.

Approach to the humerus

When dealing with the humerus, primary consideration should be given to the radial and axillary nerves.

▲ Precaution:

Distally, a dorsal approach to the humerus is appropriate. Proximally, it is recommendable to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve.

The following steps are explained with reference to the large external fixator and self-drilling, self-tapping (Seldrill) Schanz screws. Optionally self-tapping Schanz screws can also be used.

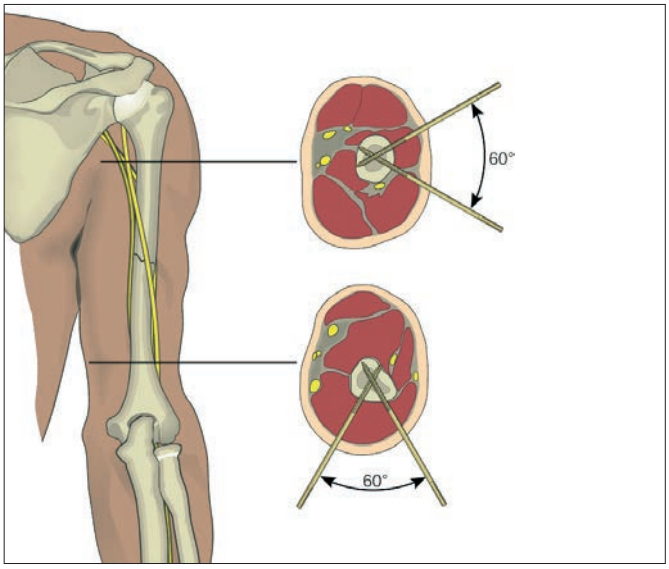
■ Note:

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

The joint bridging mobile fixator for the elbow joint is assembled in modules and is oriented around the pivot of the condyles. Therefore, for correct application, it is necessary to accurately align the upper arm segment prior to connecting the frame to the Schanz screws in e ulna.

▲ 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.



1. Insert the Schanz screws in the humerus

Required components	
Seldrill Schanz Screw ∅ 5 mm	X94.774–779
Handle for Drill Sleeve	395.911
Drill Sleeve 4.0, short with thread	395.922
Drill Sleeve 4.0/2.5	392.955
Trocar ∅ 2.5 mm	394.183
Adapter for Seldrill Schanz Screw ∅ 4 mm	393.101
Drill with attachment for AO/ASIF quick coupling	Type-dependent

Insert the first two Schanz screws in the humerus. Select their position as appropriate for the soft tissue and anatomical situation. When setting the Schanz screws, pay special attention to the radial nerve. It is therefore recommended to spread the tissue with a blunt clamp to the bone, and to use a protection sleeve.

The greater the distance between the Schanz screws, the greater the stability of the frame.

▲ Precautions:

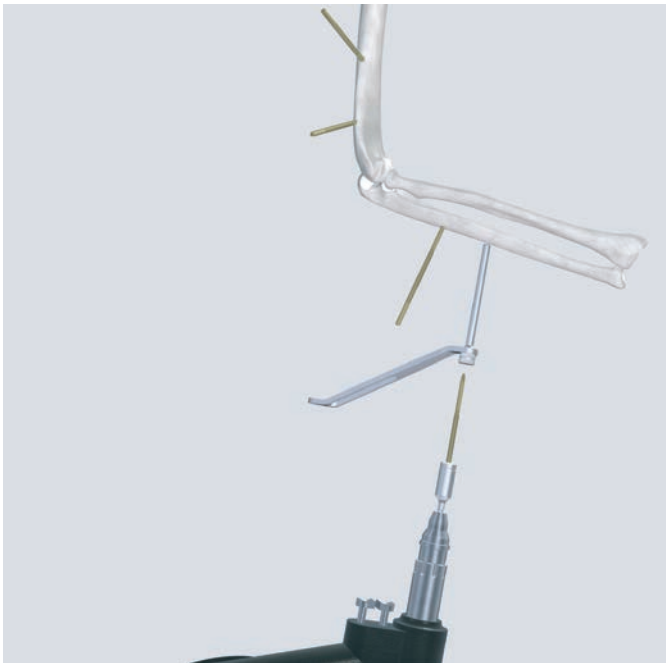
- The Seldrill Schanz Screw has been developed to minimise heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the Seldrill Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and 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.

2. Insert the Schanz screws into the ulna

Required components	
Seldrill Schanz Screw ∅ 5 mm	X94.774–779*
Handle for Drill Sleeve	395.911
Drill Sleeve 4.0, short with thread	395.922
Drill Sleeve 4.0/2.5	392.955
Trocar ∅ 2.5 mm	394.183
Adapter for Seldrill Schanz Screw ∅ 4 mm	393.101
Drill with attachment for AO/ASIF quick coupling	Type-dependent



Insert two other Schanz screws into the ulna from a dorsal direction.

To optimize lower arm rotation, the two screws in the ulna should lie far in a dorsal direction at the edge of the ulna.

▲ Precaution:

Only when bones are osteoporotic, 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.

* X = 2 Stainless Steel
  X = 4 Titanium (TiCP)

3. Connect the Schanz screws with carbon fibre rods

Required components	
Clamp, clip-on, self-holding	390.008
Carbon Fibre Rod ∅ 11 mm	394.800–394.840
Combination Wrench ∅ 11 mm	321.160

Connect the Schanz screws in the humerus with two clip-on, self holding clamps and a carbon fibre rod. Repeat this process with the Schanz screws in the ulna. Depending on the assembly, make sure that the two rods project somewhat on the joint side to provide sufficient room for the addition frame.

Tighten all the clamp nuts.

■ Note:

If the reduction needs to be secured, it is recommended to hold it during surgery with an additional rod.

4. Determine the anatomical joint axis

Required components	
Kirschner Wire ∅ 2.5 mm with trocar tip, length 280 mm, Stainless Steel	292.260
Drill	Type-dependent

Determine the anatomical axis using the image intensifier, and laterally insert a ∅ 2.5 mm guide wire for reference. To prevent damaging the ulnar nerve, do not drill through the medial cortex.

When it is in the correct position, the guide wire represents a point in the center of the rotational axis.

■ Note:

A skilled practitioner can also determine the joint axis directly by the projection of the two condyles. The hole for the joint rod must represent a concentric circle to the superimposed condyles (see step 7).

5. Position the joint rod and connect to the humerus with a carbon fibre rod

Required components	
Carbon Fibre Rod ∅ 11 mm	394.800–394.840
Hinged Joint Rod for External Fixator	394.055
Combination Clamp, clip-on, self-holding	390.005
Combination Wrench ∅ 11 mm	321.160

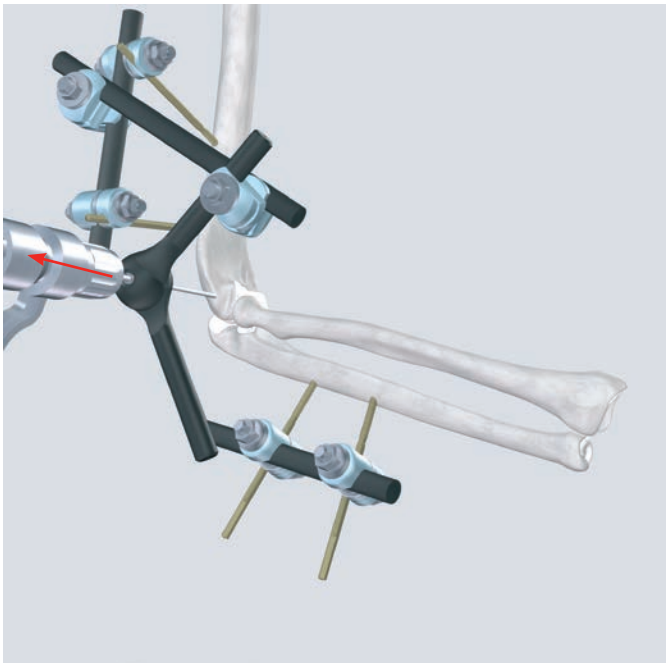
Guide the Elbow Hinge Fixator over the reference wire, and connect it to the partial frame of the humerus using an additional rod and a combination clamps. When connecting Elbow Hinge Fixator to the humoral partial frame, it is important to not bend the reference wire since the anatomical axis would then no longer correspond to the mechanical axis of the joint.

■ Note:

Depending on the position of the partial frame, the joint rod can also be connected directly by means of a rod-to-rod clamp.

6. Remove the reference wire

Remove the reference wire after all the clamps of the proximal part of the fixator have been tightened.



7. Check the axes

The Elbow Hinge position is checked by visualizing the elbow joint in lateral position. When positioned correctly, the center of the fixator and the radial and ulnar condyles project exactly over each other. The center of the Elbow Hinge Fixator will appear as a small circle in the center of the superimposed images of the radial and ulnar condyles.

8. Connect the joint rod to the carbon fibre rod in the ulna

Required components

Combination Clamp, clip-on, self-holding	390.005
Carbon Fibre Rod ∅ 11 mm	394.800–394.840
Combination Wrench ∅ 11 mm	321.160

As a final assembly step after reducing the joint, the end of the Elbow Hinge that is distal from the central guide hole is connected to the ulnar partial frame.

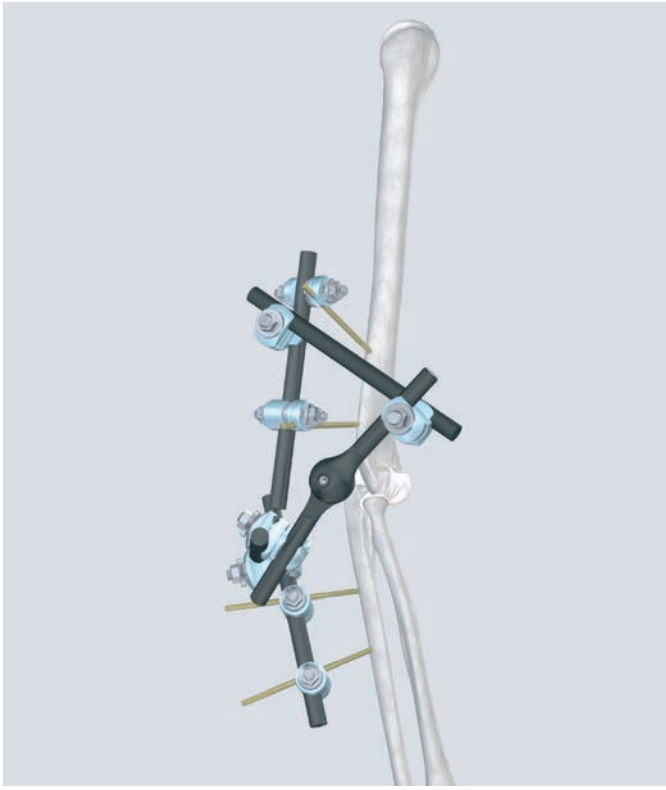
■ Note:

Depending on the position of the partial frame, the joint rod can also be connected directly by means of a rod-to-rod clamp.

9. Check the Mobility of the Joint

After finishing with assembly, check the mobility of the joint and its position.

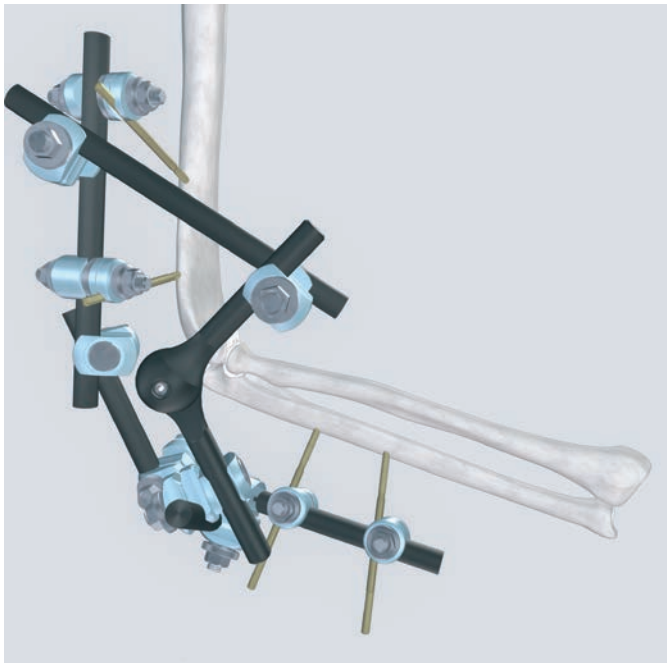
When the position is correct, the central, cannulated metal sleeve of the joint rod projects exactly in the center of the concentric condyles in the form of a circle in a lateral visualization. In the anterior-posterior plane, the central metal sleeve must be parallel to the joint surface since otherwise radial or ulnar deviations of the ulna are generated during movement.



10. Blocking the Joint

Required components	
Combination Clamp, clip-on, self-holding	390.005
Carbon Fibre Rod ∅ 11 mm	394.800–394.840
Combination Wrench ∅ 11 mm	321.160

Depending on the situation, the elbow joint can be temporarily blocked directly after surgery with an additional rod that connects the two partial frames proximal and distal from the joint. The duration of the blocking depends on the patient's situation.



▲ 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

Implants

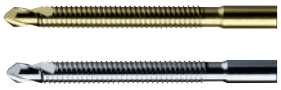
■ Note:

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

Seldrill Schanz Screws

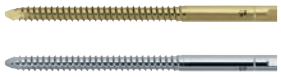
Reinforced bone anchorage

Titanium*	Stainless Steel	Diameter (mm)	Length (mm)
494.771	294.771	4.0/3.0	80
494.772	294.772	4.0/3.0	100
494.774–779	294.774–779	4.0	60–175



Self-Tapping Schanz Screws

Titanium alloy**	Stainless Steel	Diameter (mm)	Length (mm)
494.300	294.300	4.0/3.0	80
494.430–460	294.430–460	4.0	60–125



Guide Wire

The guide wire is used to determine the anatomical joint axis during surgery and position the Elbow Hinge Fixator in reference to this axis.

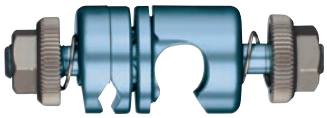
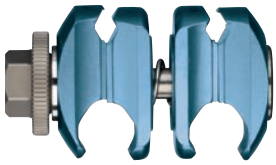
292.260	Kirschner Wire ∅ 2.5 mm with trocar tip, length 280 mm, Stainless Steel

* (TiCP)
** (TAN)

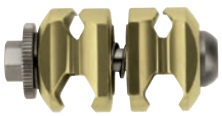
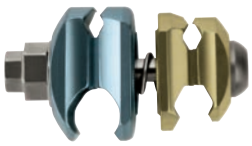
Fixation Components

394.055	Hinged Joint Rod for External Fixator	

Fits the large External Fixator

390.008	Clamp, clip-on, self-holding	
390.005	Combination Clamp, clip-on, self-holding	
394.800 – 394.840	Carbon Fibre Rod ∅ 11 mm	

Fits the medium External Fixator

390.035	Clamp, clip-on, self-holding	
390.031	Combination Clamp, clip-on, self-holding	
390.037	Combination Clamp, 8.0/11.0, clip-on, self-holding	
395.779 – 395.786	Carbon Fibre Rod ∅ 8 mm	

Instruments

Adapter

393.101	Adapter for Seldrill Schanz Screw ∅ 4 mm	
393.103	Adapter for Seldrill Schanz Screw ∅ 5 mm	

Combination Wrenches

321.160	Combination Wrench 11 mm	
321.158	Combination Wrench 8 mm	

Drill Guide System

395.911	Handle for Drill Sleeve	

Drill Sleeves 5.0 mm

395.921	Drill Sleeve 6.0/5.0, short, with thread	
395.912	Drill Sleeve 5.0/3.5, short	
394.181	Trocar ∅ 3.5 mm, short	

Drill Sleeves 4.0 mm

395.922	Drill Sleeve 4.0, with thread	
392.955	Drill Sleeve 4.0/2.5	
394.183	Trocar ∅ 2.5 mm	

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Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.

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