Large and Medium External Fixator

Modular Rod Systems

Surgical Technique

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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Large External Fixator

Modular construction of Large External Fixators makes them flexible

User-oriented handling

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

Free frame design

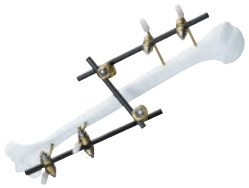
- Frames can be freely assembled
- Free pin placement
- Radiolucent carbon fibre rods ensure fracture visualization

Treatment of the pelvis

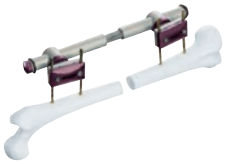
Bridging of ankle

Triangular (for symmetric, balanced ligamentotaxis)

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	 Large External Fixator	 Hybrid Ring Fixator	 Carbon fibre tube
Medium rod ∅ 8 mm	 Medium External Fixator	 External Distal Radius Fixator (DRF)	
Small rod ∅ 4 mm	 Small External Fixator		
Mini rod ∅ 3 mm		 External Mini-Fixator	

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


MEFiSTO Central Body


MEFiSTO Angulator


MEFiSTO Segment Transport

Warnings

▲ WARNINGS:

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

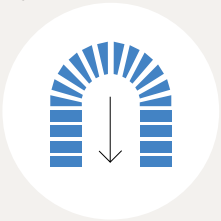
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

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

Large External Fixator

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

■ Notes:

- In nonclinical testing, the Large 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 a pelvic frame of less than 1 °C for 1.5 T and 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 Large 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 Large 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 Large 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 Large 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 Large External Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Large 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.

Medium External Fixator

Medium External Fixator devices used in a typical construct include clamps, rods and various attachments.
A patient with a DePuy Synthes Medium 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:
  - 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 Medium 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 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, DePuy Synthes Medium 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 Medium 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 Medium 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 Medium 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 Medium External Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Medium 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.

Surgical Approaches

The Large and Medium External Fixators must be affixed within the recommended zones described below.

The construction may not hinder the approach for a primary wound debridement or for a secondary operation. Skin transplants, sequestrectomies, bone grafting or a later osteosynthesis must be performable without restriction.

■ Note:

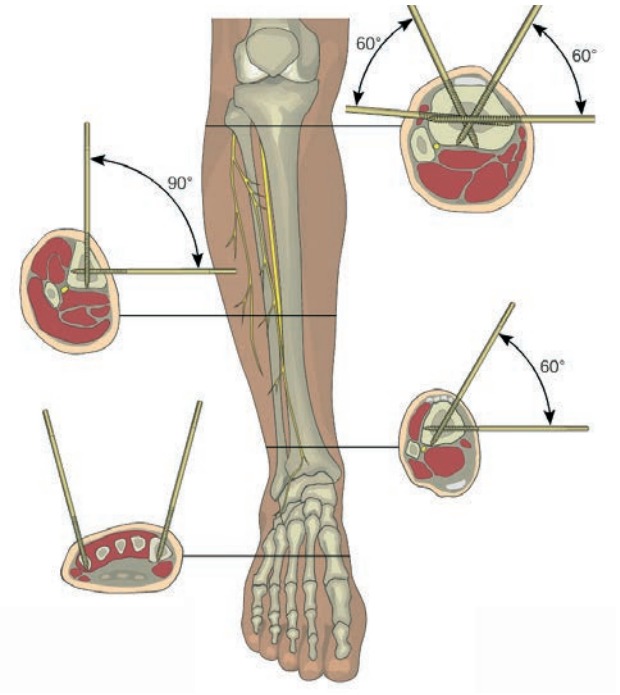
For a detailed handling description of the Schanz screws and the Steinmann pins, refer to the Surgical Technique Schanz Screws and Steinmann Pins.

Surgical approach to the tibia

The soft tissue zone through which Schanz screws can be inserted without damaging important structures (vessels, nerves, muscles and tendons) is anteromedial to the tibia. The angles of this safe zone vary.

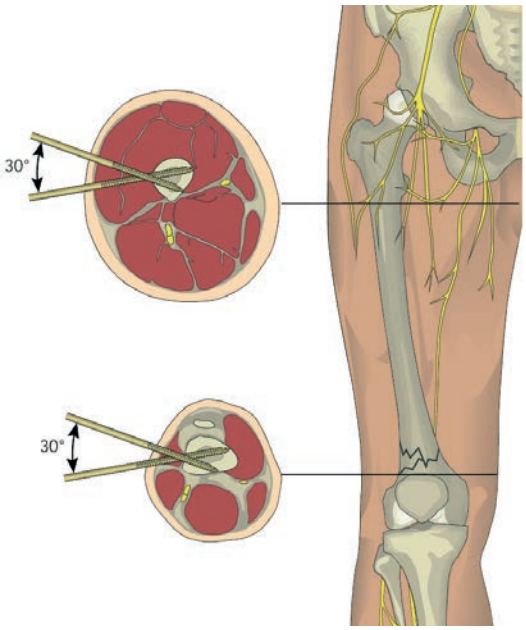
If the lateral surface of the distal third of the tibia is avoided, damage to the anterior tibial artery can be avoided.

When the ventral zone of the distal tibia is avoided, interference with the tendons can also be avoided.



Surgical approach to the femur

A lateral approach to the femur within a 30° angle is recommended. A medial approach is also possible from a distal direction.

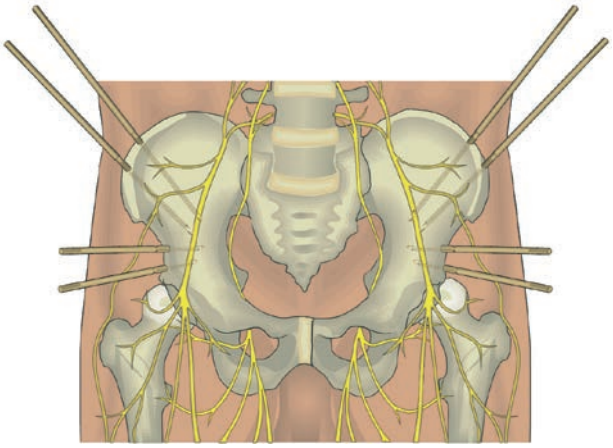


Surgical approach to the pelvis

There are two recommended options for pin placement of the external fixation assembly in the pelvis.

Supraacetabular pin placement

Given the pronounced bone structure, the more technically difficult supraacetabular pin placement is preferred over that of the iliac crest. Proceeding from the superior anterior crest, the site of entry is approximately 4–6 cm in a caudal direction, and 3–4 cm in a medial direction. When the patient is in a supine position, the alignment for drilling the screws is angled approximately 20° in a cranial direction and 30° inward.

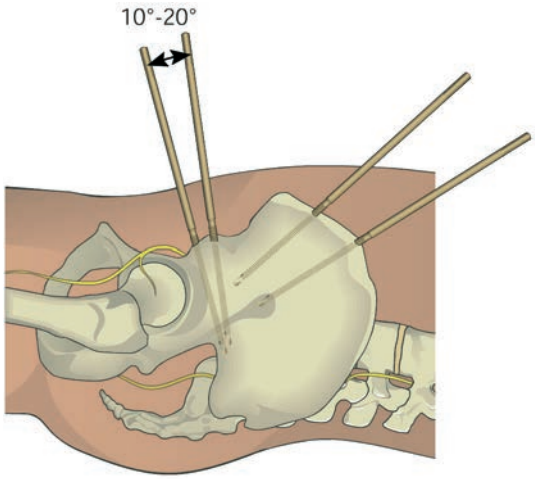


Iliac crest pin placement

▲ Precaution:

To keep from damaging the femoral cutaneous nerve, avoid insertion up to 15 mm in a dorsal direction from the superior anterior iliac spine.

The orientation of the os ilium can be determined by palpation with a finger or an additional instrument. The screws are then inserted delicately between the two laminae of the os ilium.

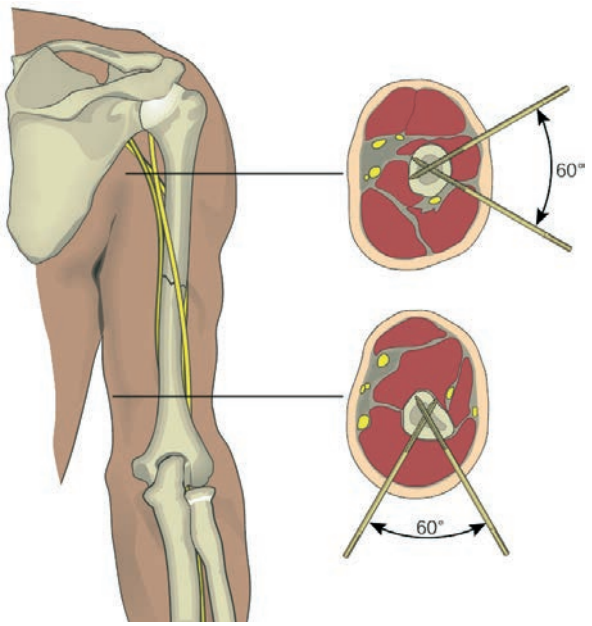


Approach to the humerus

Distally, a dorsal approach to the humerus is appropriate.

▲ Precautions:

- When dealing with the humerus, primary consideration should be given to the radial and axillary nerves.
- Proximally, it is recommendable to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve.



Setting the Schanz Screws

The following steps will be explained with reference to a ∅ 5.0 mm self-drilling, self-tapping (Seldrill) Schanz screw, and a conventional ∅ 5.0 mm Schanz screw inserted in the diaphyseal region of the tibia.

▲ Precaution:

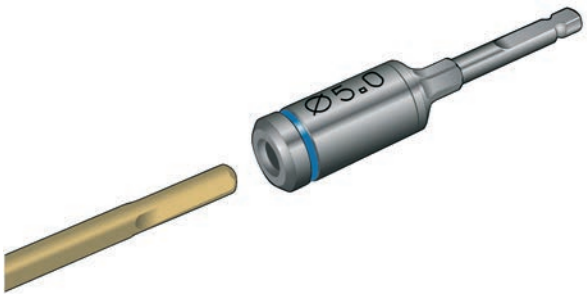
Select the appropriate Schanz screw or Steinmann pin for the patient's bony anatomy.

Seldrill Schanz Screw

The Seldrill Schanz screw is a self-drilling, self-tapping Schanz screw.

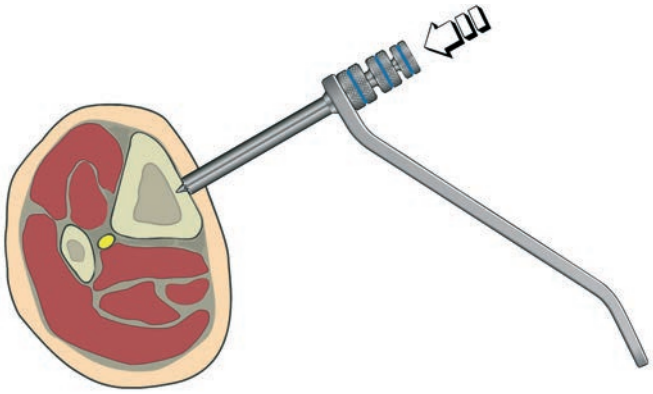
■ Note:

When the new adaptors for Schanz screws are used, the Seldrill Schanz screws do not have to be clamped in the drill chuck. The adapters are compatible with the universal chuck and AO/ASIF Quick Coupling.



1. Set the drill sleeves on the bone

Required instruments	
Handle for Drill Sleeve	395.911
Drill Sleeve 6.0/5.0 short, with thread	395.921
Drill Sleeve 5.0/3.5, short	395.912
Trocar ∅ 3.5 mm, short	394.181



Insert the drill sleeve assembly through a stab incision and set it directly on the bone surface. Then remove the trocar ∅ 3.5 mm and the drill sleeve 5.0/3.5.

▲ 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.

2. Insert Seldrill Schanz Screws

Required instruments	
Seldrill Schanz Screws ∅ 5.0 mm	X94.782–788*
Handle for Drill Sleeve	395.911
Drill Sleeve 6.0/5.0 short, with thread	395.921
Adapter for Seldrill Schanz Screws ∅ 5.0 mm	393.103
Drill with attachment for AO/ASIF Quick Coupling	type-dependent

Insert the Seldrill Schanz screw in the ∅ 5.0 mm adapter, and use the drill to screw it through the drill sleeve 6.0/5.0 until the drill tip is anchored in the distant cortical bone.

If it is difficult to determine whether the screw has entered the opposite side of the cortical bone, it is recommendable to check the screw's penetration depth and position with the image intensifier.

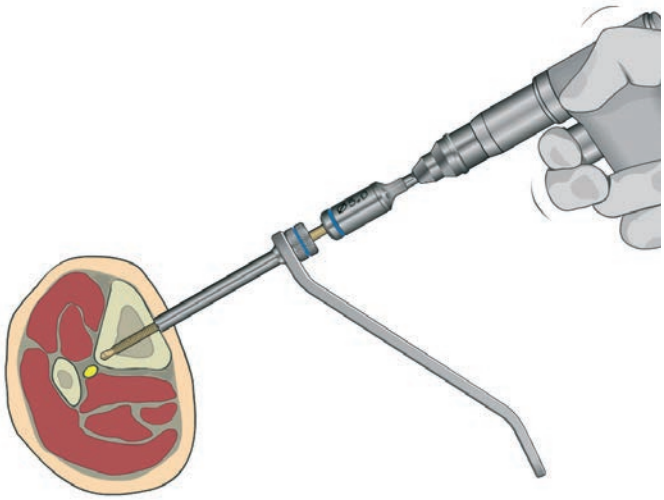
After screwing in the Seldrill Schanz screw, remove the drill sleeve and the drill with the adapter.

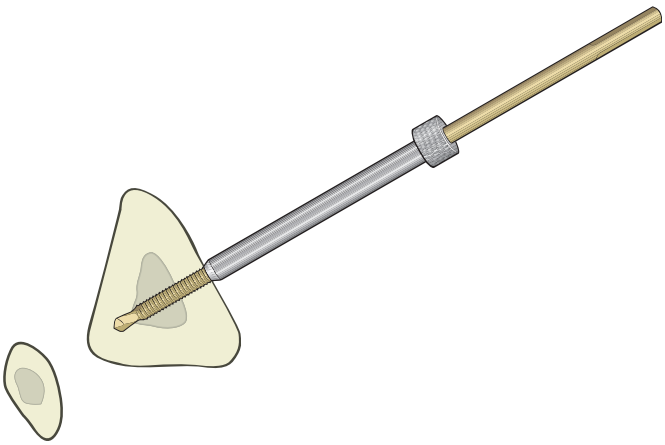
▲ Precautions:

- 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.





The Seldrill Schanz screw should be embedded in the far cortex.

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

Alternative technique:

Required instruments	
Seldrill Schanz Screws ∅ 5.0 mm	X94.782–788*
Handle for Drill Sleeve	395.911
Drill Sleeve 6.0/5.0, short, with thread	395.921
Drill Sleeve 5.0/3.5, short	395.912
Trocar ∅ 3.5 mm, short	394.181
Adapter for Seldrill Schanz Screws ∅ 5.0 mm	393.103
Universal Chuck with T-Handle	393.100
Drill with attachment for AO/ASIF Quick Coupling	type-dependent

Insert the Seldrill Schanz screw ∅ 5.0 mm in the adapter, and use the drill to screw it through the drill sleeve 6.0/5.0 into the near cortical bone.

Remove the drill and replace it with the universal drill chuck with the T-handle (393.100). The screw can now be delicately screwed manually into the middle of the distant cortical bone. It is not necessary to completely penetrate the distant cortical bone since anchoring the thread in the near cortical bone and sinking the drill tip in the distant cortical bone effectively absorbs bending force.

Remove the drill sleeve and the universal chuck with T-handle.

▲ Precaution:

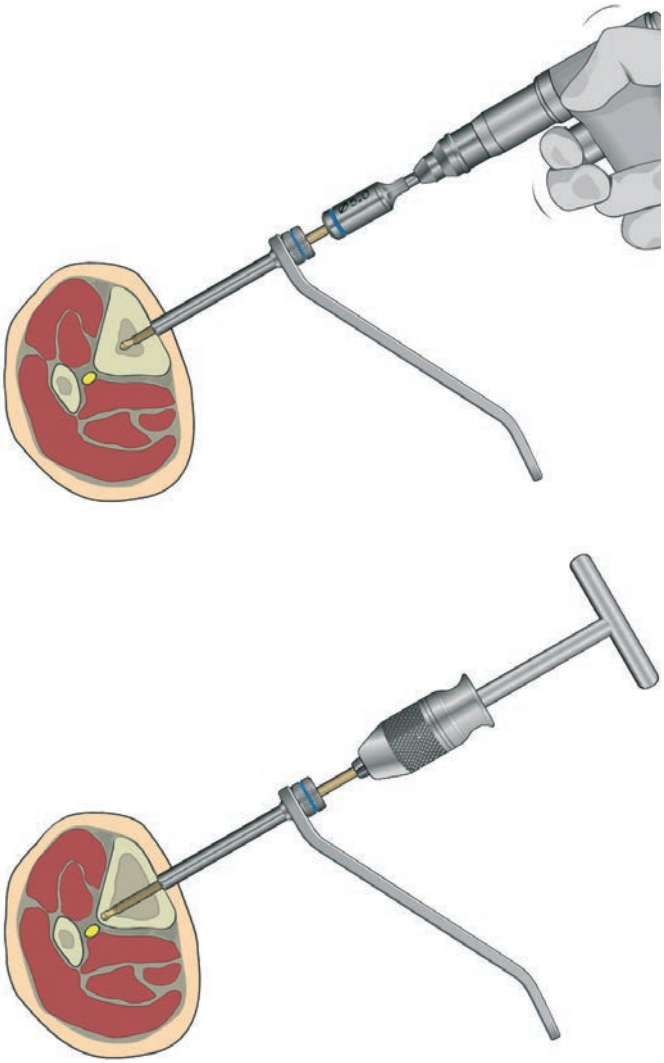
Only when bones are osteoporotic does the Seldrill Schanz screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability.

■ Note:

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

Use in the metaphyseal region

The individual surgical steps are the same as when the screws are used in the shaft area.



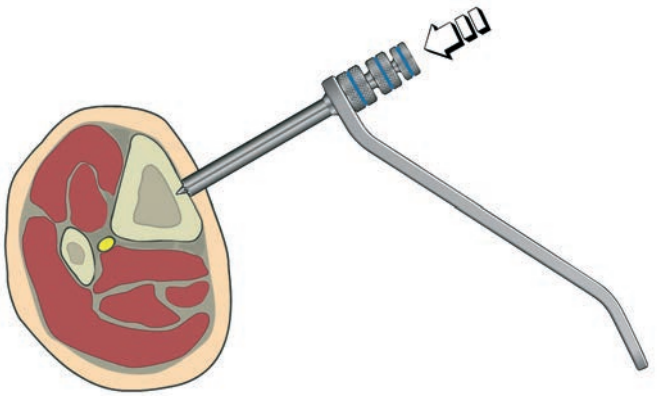
* X=2 Stainless Steel
X=4 Titanium (TiCP)

Self-tapping Schanz Screw

Instead of self-drilling Schanz screws (Seldrill), self-tapping screws can also be used. In contrast to the Seldrill Schanz screws, self-tapping screws must be predrilled.

1. Set the drill sleeve assembly on the bone

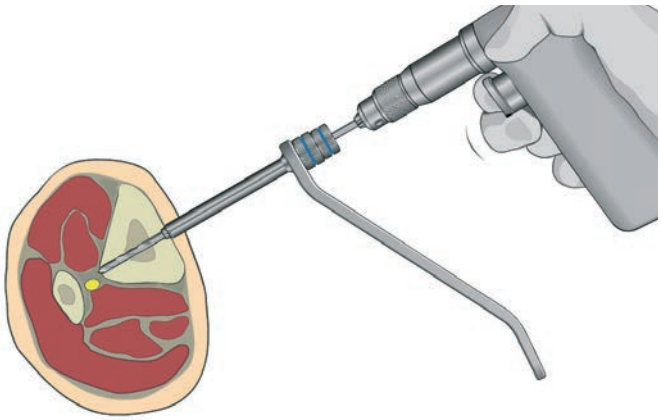
Required instruments	
Handle for Drill Sleeve	395.911
Drill Sleeve 6.0/5.0 short, with thread	395.921
Drill Sleeve 5.0/3.5, short	395.912
Trocar ∅ 3.5 mm, short	394.181



Insert the drill sleeve assembly through a stab incision and set it directly on the bone surface and remove the trocar ∅ 3.5 mm.

2. Predrilling

Required instruments	
Drill Bit ∅ 3.5 mm, length 195/170 mm, 2-flute, for Quick Coupling	310.370
Drill with attachment for AO/ASIF Quick Coupling	type-dependent

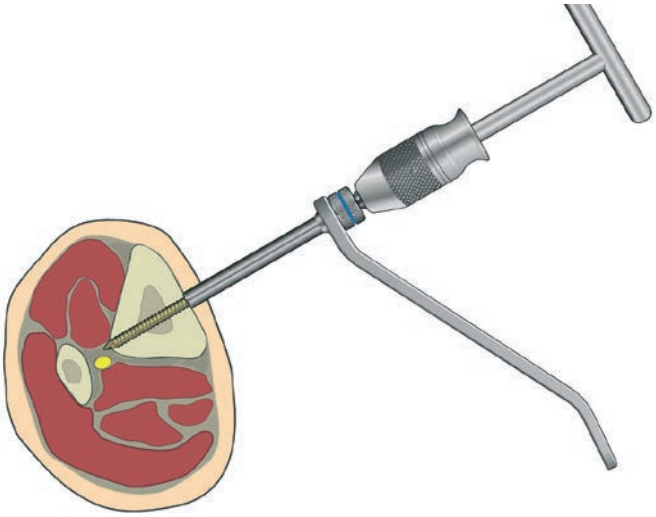


Drill through both sides of the cortical bone with the ∅ 3.5 mm drill bit, then remove the drill sleeve 5.0/3.5.

3. Insert the Self-tapping Schanz screw

Required instruments	
Self-tapping Schanz Screw	X94.520–570*
Handle for Drill Sleeve	395.911
Drill Sleeve 6.0/5.0 short, with thread	395.921
Universal Chuck with T-Handle	393.100

The Schanz screw can now be screwed in through the drill sleeve 6.0/5.0. The tip must be anchored in the distant cortical bone to effectively absorb bending force.



▲ Precaution:

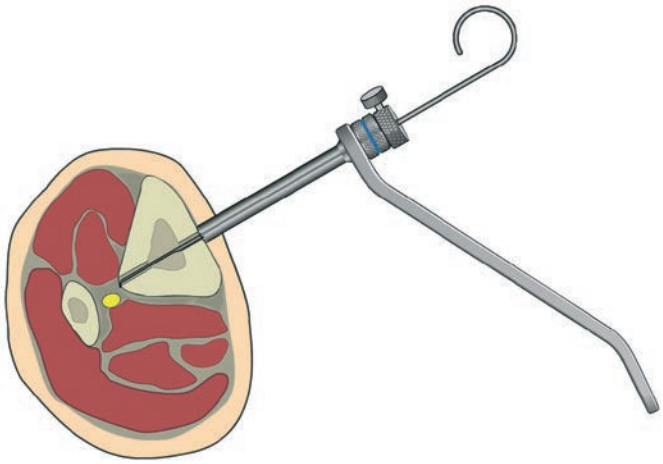
The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.

* X=2 Stainless Steel
  X=4 Titanium Alloy (TAN)

Alternative technique using the length gauge

Alternately, the length of the required Schanz screw can also be precisely checked using the length gauge.

Required instruments	
Handle for Drill Sleeve	395.911
Drill Sleeve 6.0/5.0 short, with thread	395.921
Depth Gauge for Schanz Screws	393.780
Universal Chuck with T-Handle	393.100



After predrilling as described in step 2 of Self-tapping Schanz Screw, the length gauge is guided through the drill sleeve 6.0/5.0 and hooked in the distant cortical bone.

Then move the retaining disk to the height of the drill sleeve and lock it with the locking screw.

Remove the length gauge, and insert the tip of the Schanz screw into the recess of the retaining disk. Slide the universal chuck over the smooth shaft of the Schanz screw to the height of the tip of the length gauge, and tighten the chuck on the Schanz screw. Determining the length in this manner will ensure that the screw will be firmly anchored in the distant cortical bone.

The Schanz screw can now be screwed in through the drill sleeve 6.0/5.0 until the drill chuck stops on the drill sleeve.

■ Note:

If the Schanz screw is screwed in beyond this point, it will strip the thread due to the resistance of the drill sleeve.

▲ Precautions:

- Implant sites should be meticulously cared to avoid pin-tract infection. Schanz screws and Steinmann pins 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 and Steinmann pins 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.

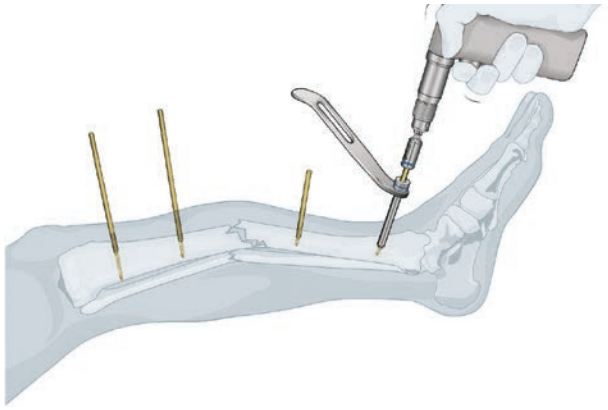
Modular Frame Using the Rod-to-Rod Technique

You can choose between a unilateral or modular frame construction. If a modular frame is chosen, you can freely choose how to set the Schanz screws. This method is recommended by the AO as a standard technique for fractures that require reduction.
Schanz screws, clamps and carbon fibre rods are required to construct the different frames. Instead of radiolucent carbon fibre rods, stainless steel rods can be used for all constructions with Large External Fixators.

1. Set the Schanz screws

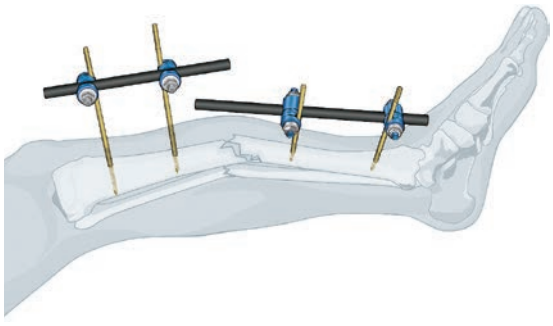
Set two Schanz screws per main fragment using the drill sleeve assembly.

Freely select their position appropriate for the fracture, soft tissue, and anatomical situation. The greater the distance between the Schanz screws, the greater the stability of the frame.



2. Connect the Schanz screws with carbon fibre rods

Required instruments	
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Wrench ∅ 11.0 mm	321.160



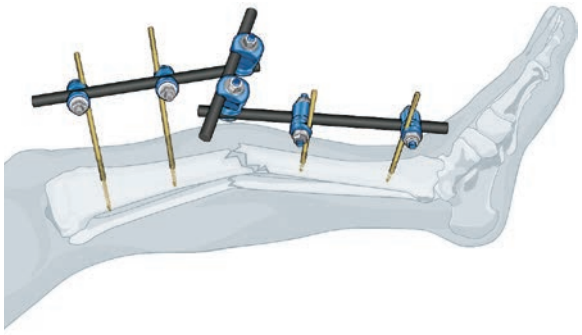
The two Schanz screws per main fragment are connected with a rod. Clip-on, self-holding clamps are used. Make sure that the rods project a bit beyond the fracture zone so that sufficient length remains for the combination clamp.

Tighten all the clamp nuts.

3. Connect the carbon fibre rods

Required instruments	
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Combination Clamp, clip-on, self-holding	390.005

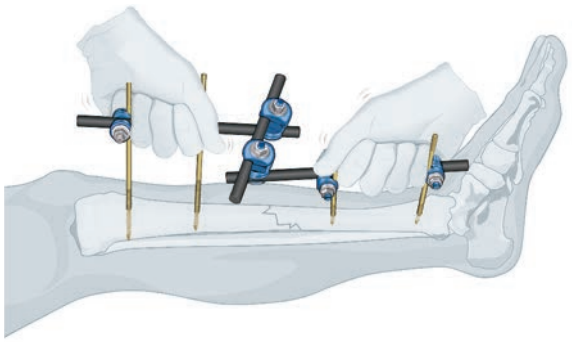
Connect the two ends of the rods near the fracture to a third rod using two self-holding combination clamps. Do not yet tighten the nuts for the combination clamps.



4. Reduce the fracture

Use the two partial frames as handles to reduce the fracture.

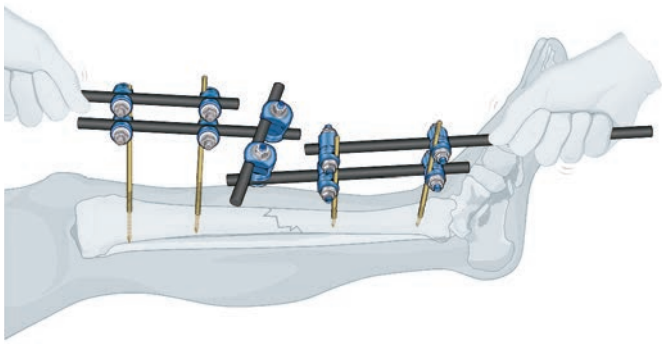
After checking the reduction, alternately tighten the nuts of the combination clamps in the image intensifier while manually holding the reduction.



Alternative technique:

Required instruments	
Clamp, clip-on, self-holding	390.008
Combination Wrench ∅ 11.0 mm	321.160
Carbon Fibre Rod ∅ 11.0 mm	394.800–870

For each fragment, additionally affix one long rod that can be used as a temporary lever for reduction. The leverage can be used for controlled reduction that requires less force (particularly recommended for the femur). In addition, your hands will remain safely outside the X-rays when this technique is applied.



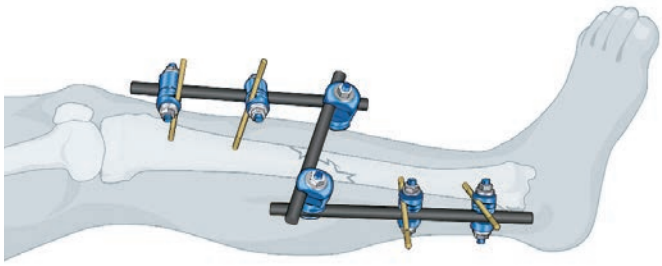
5. Tighten nuts

Required instruments

Combination Wrench ∅ 11.0 mm	321.160

Finally, recheck all the nuts with the wrench to ensure they are all tight.

Retighten all the nuts after 24 hours.



6. Secondary reduction

A secondary correction of the reduction can be performed within the first few days after surgery. Only the two combination clamps are released. The correction can then be made using the partial frames that move relative to each other.

After the correction, retighten the two combination clamps.

▲ Precautions:

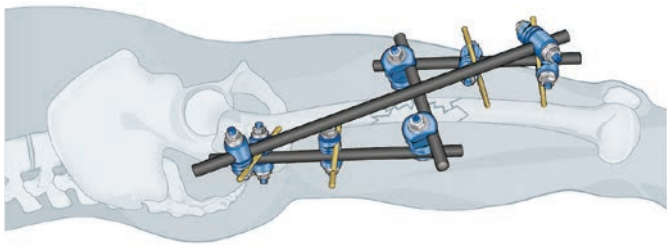
- Implant sites should be meticulously cared to avoid pin-tract infection. Schanz screws and Steinmann pins may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient.
- To minimize the risk of pin tract infection, the following points should be observed:
  a. Placement of Schanz screws and Steinmann pins 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.

Additional Treatment Options Using the Rod-to-Rod Technique

∅ 11.0 mm system

Adult femur

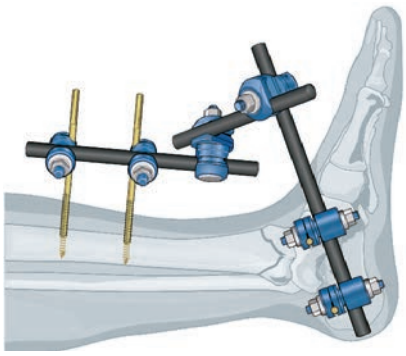
Insert 2–3 Schanz screws into the proximal and distal main fragment from a lateral direction. With adipose patients, it is recommendable to use 6.0 mm screws. The stability of the rod-to-rod assembly can be increased with an additional neutralization rod.



Bridging the ankle

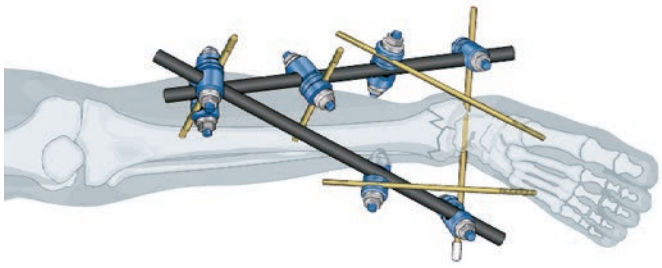
Unilateral

Insert the screws into the calcaneus and talus from a medial direction. In the tibia, set the screws at an anteromedial to medial angle, and connect them using the rod-to-rod technique.



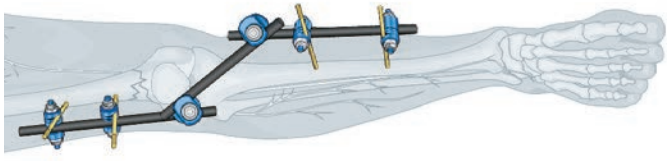
Triangular

Insert the first screw from an anteromedial direction into the tibial shaft. Insert the Steinmann pin through the calcaneus, and affix the rods in the form of a tent between the first screw and Steinmann pin. Then reduce the fracture by pulling lengthwise with balanced ligamentotaxis. Then insert two screws into the tibia starting from the medial rod. For prophylaxis of pes equines, insert an additional Schanz screw at an angle from above into the first and fifth metatarsal bone.



Bridging the knee joint

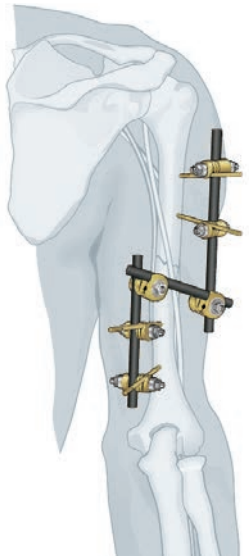
Insert two Schanz screws into the distal femur from a lateral or ventral direction, and into the proximal tibia from an anterome-dial direction. Connect them using the rod-to-rod technique.



∅ 8.0 mm system

Humerus

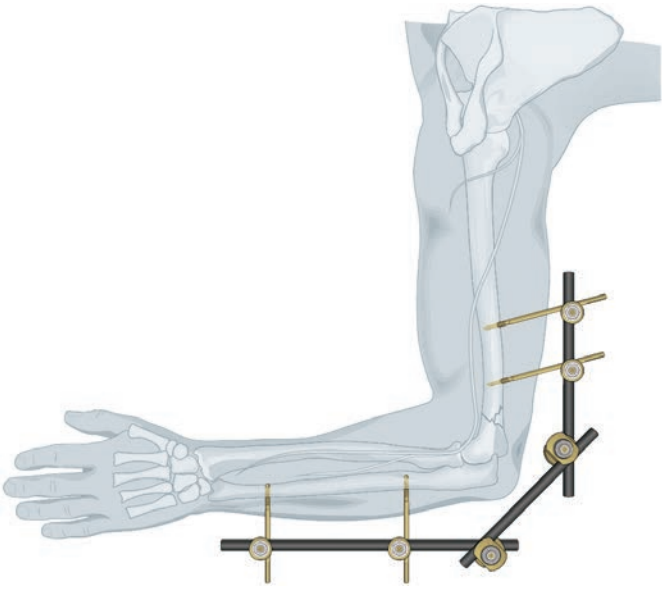
Insert the Schanz screws in the proximal humerus from a lateral direction and into the distal humerus from a dorsal direction, avoiding injury to the radial nerve. Connect the Schanz screws using the rod-to-rod technique.



Bridging the elbow

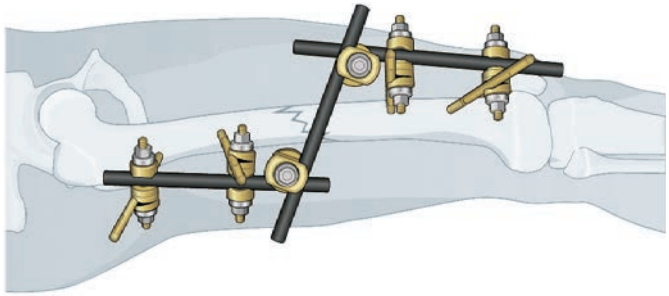
Insert Schanz screws into the distal humerus from a dorsal direction. The screws can be introduced into the forearm from a dorsal direction into the ulna. Connect the Schanz screws using the rod-to-rod technique.

It is only recommendable to insert an additional screw in the radius to stabilize the radio-ulnar joint.



Child femur

Insert 2–3 Schanz screws into the proximal and distal main fragment from a lateral direction. The stability of the rod-to-rod assembly can be increased with an additional neutralization rod.

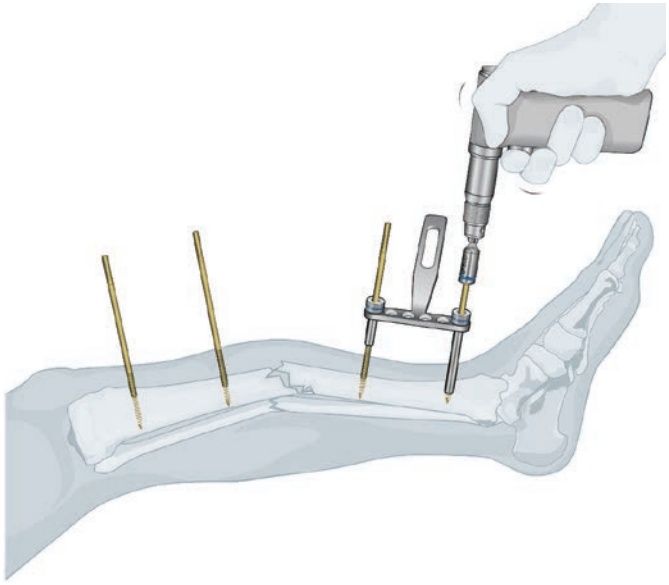


Using multi pin clamps

The advantage of multi pin clamps is that reduction can be carried out using the above-described rod-to-rod technique. The Schanz screws with clamps serve as an external reduction instrument system. Additional reduction levers may be used to lengthen the lever arm (see alternative technique).

1. Set the Schanz screws for multi pin clamps

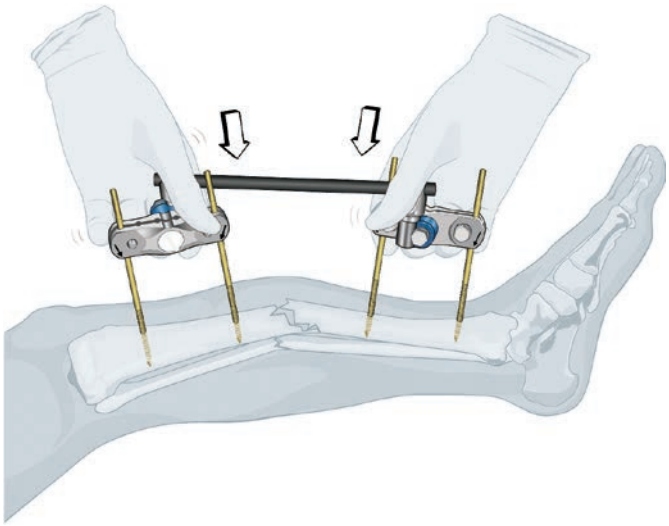
Required instruments	
Seldrill Schanz Screws	X94.782–788*
Drill Guide Handle, 6 positions	392.963
Drill Sleeve 6.0/5.0, short, with thread	395.921
Drill Sleeve 5.0/3.5, short	395.912
Trocar ∅ 3.5 mm, short	394.181
Drill Sleeve 6.0/5.0 long, with thread	395.923
Drill Sleeve 5.0/3.5, long	395.913
Trocar ∅ 3.5 mm, long	394.182
Adapter for Seldrill Schanz Screws ∅ 5.0 mm	393.103
Universal Chuck with T-Handle	393.100
Drill with attachment for AO/ASIF Quick coupling	type-dependent



Insert two Schanz screws into the distal and proximal fragments using a parallel drill sleeve.

2. Assembling the Fixator

Required instruments	
Multi Pin Clamp, 6 positions, large	390.002
Carbon Fibre Rod ∅ 11.0 mm	394.800–870
Combination Wrench ∅ 11.0 mm	321.160

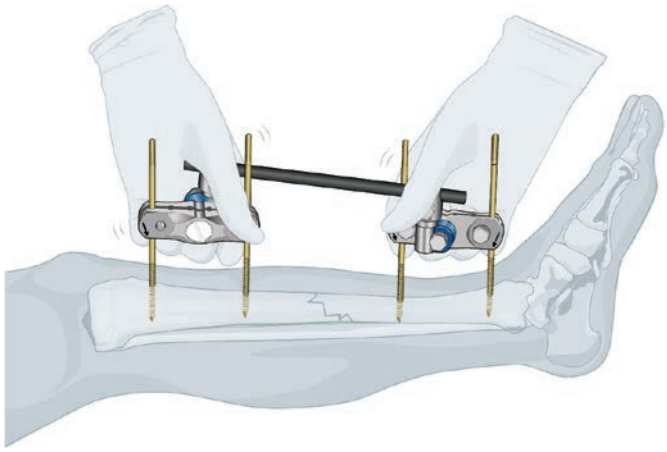


Guide the clamps of the premounted clamp-rod construction over the Schanz screws, and tighten the clamps on the screws with the ∅ 11.0 mm combination wrench.

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

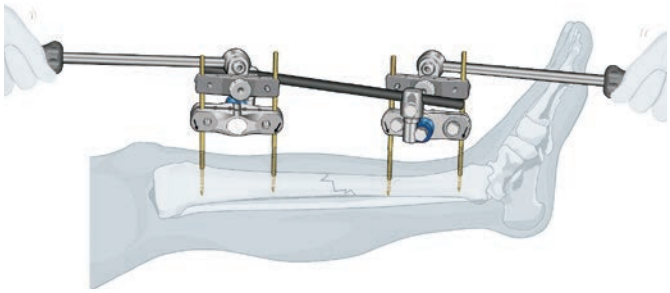
3. Reduction

Due to the clamps that enable the Schanz screws and carbon-fibre rod to be independently fixed, the fracture can be optimally reduced using the modular technique with the double Schanz screws as levers.



Alternative technique:

Required instruments	
Reduction Handle for Large Multi Pin Clamp	392.966
Combination Wrench ∅ 11.0 mm	321.160
Wrench, hexagonal ∅ 5.0 mm, long, angled	392.919

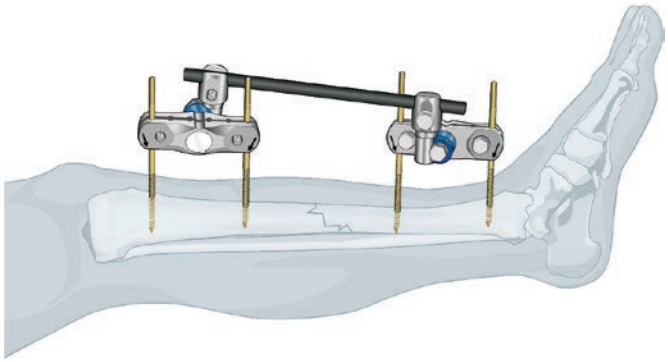


In certain cases, it is recommendable to use additional reduction levers. Greater force can be applied from the increased leverage. In addition, the levers enable free image intensifier control.

4a. Unilateral single frame with multi pin clamps

Required instruments	
Combination Wrench ∅ 11.0 mm	321.160

After reduction, tighten all the screws of the clamps.

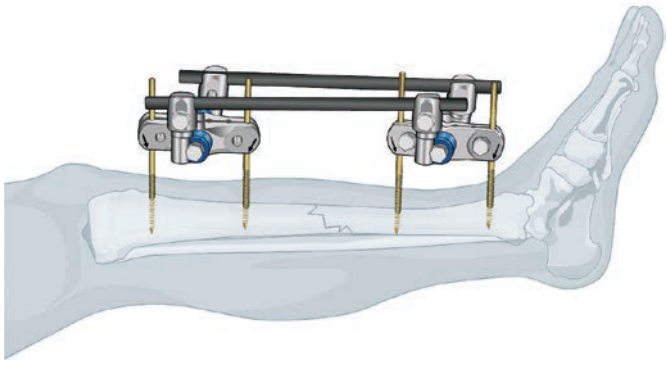


4b. Unilateral double frame construction with Multi Pin clamps

Required instruments

Rod Attachment for large Multi Pin Clamp	390.003
Combination Wrench ∅ 11.0 mm	321.160

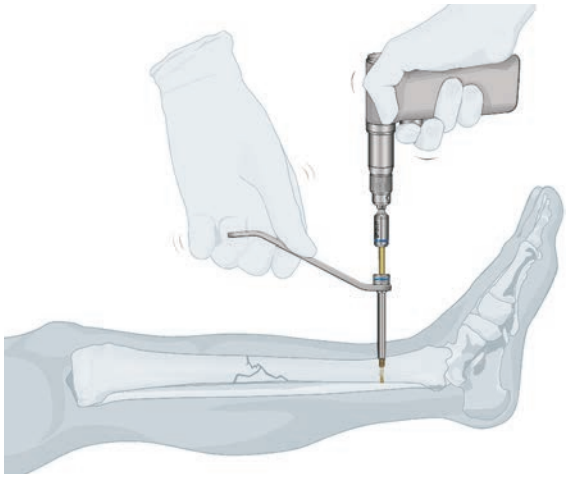
If additional rod connectors are attached to the frame, a double-frame construction can be created to increase the stability of the frame.



Unilateral Frame with Single- or Double-Rod Construction

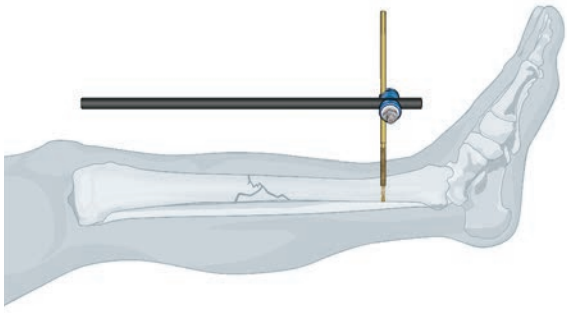
1. Provisionally reduce the fracture, and set the first Schanz screw

Provisionally reduce the fracture, and insert the first Schanz screw in a main fragment. From a ventrolateral direction, locate the first screw as distally as possible.



2. Mount the carbon fibre rod and clamp

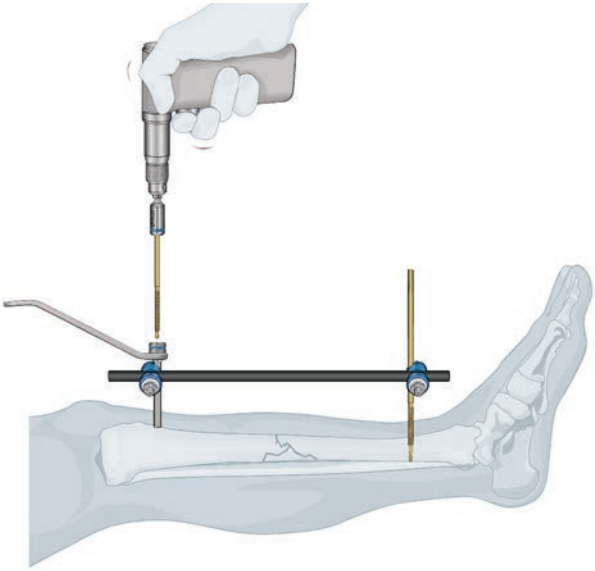
Required instruments	
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Wrench ∅ 11.0 mm	321.160



Mount the rod with the assistance of a clip-on, self-holding clamp.

3. Definitively reduce the fracture, and set the second Schanz screw

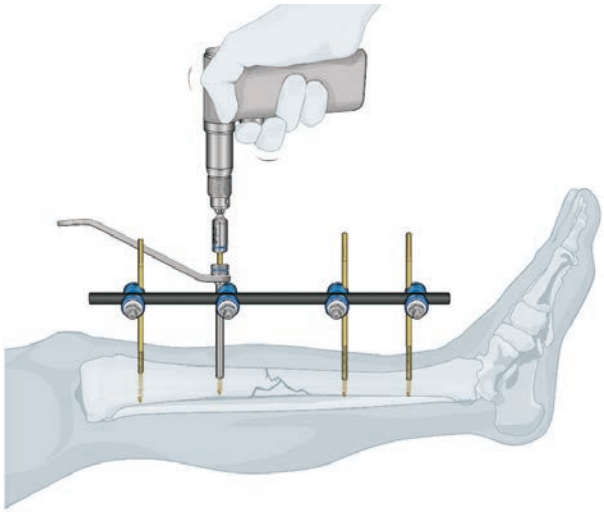
After reducing the fracture, set the second Schanz screw as proximally as possible. Secure the reduction by tightening the proximal and distal clamp, yet continue to hold the reduction until the fracture is definitively fixed (see following pages).



4a. Unilateral frame with single-rod construction

Required instruments	
Clamp, clip-on, self-holding	390.008
Combination Wrench ∅ 11.0 mm	321.160

Insert the remaining Schanz screws, and place the required clip-on, self-holding clamps on the rod to the side of the screws. Tighten all the clamp nuts.

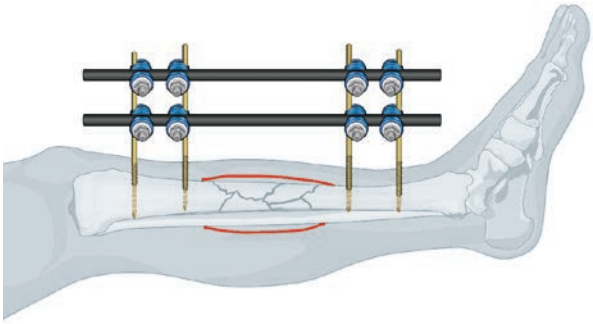


4b. Unilateral frame with double-rod construction

Required instruments	
Clamp, clip-on, self-holding	390.008
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Combination Wrench ∅ 11.0 mm	321.160

Use the same procedure as for single-rod construction; however, after setting the first two Schanz screws, place the second rod over the first.

The double-rod construction should be standard for the femur.



Pelvic Use – Supraacetabular Assembly

Particular care is required with external fixation assemblies in the pelvis.

The pelvis can be stabilized with an external fixator both at the iliac crest and the supraacetabular region. Although the point of entry for the Schanz screw is easier to find on the iliac crest, it is frequently difficult or impossible to attain a permanent and secure seat for the Schanz screws in the curved ala of the ilium. For this reason, the treatment of the pelvis will be illustrated first with reference to supraacetabular fixation in the following surgical instructions.

Supraacetabular pin placement

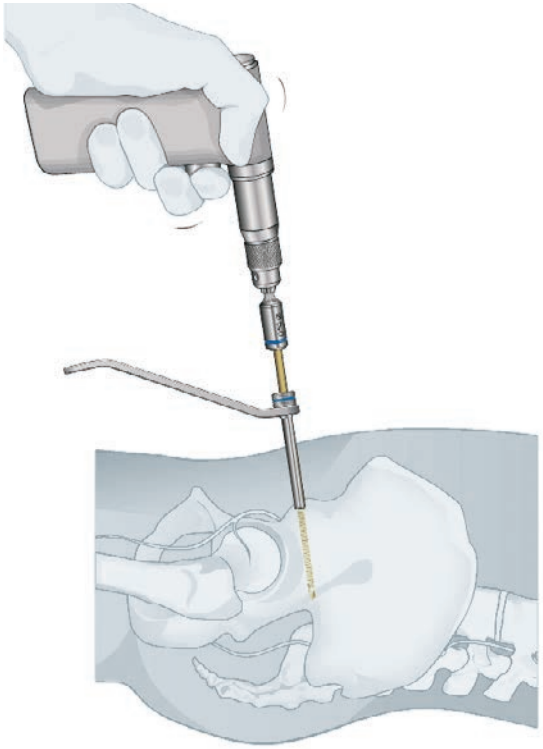
1. Setting the first two Schanz screws

Anatomical landmarks for the supraacetabular placement of the Schanz screws are the superior anterior iliac crest and inferior anterior iliac crest.

Set a self-drilling/self-tapping Schanz screw (Seldrill) on the right and left between the inferior anterior iliac spine, and the ventral labrum of the acetabulum. Proceeding from the superior anterior iliac crest, this site of entry is 4 to 6 cm in a caudal direction, and 3 to 4 cm in a medial direction. When inserting the screw, make sure that the lateral femoral cutaneous nerve is not damaged.

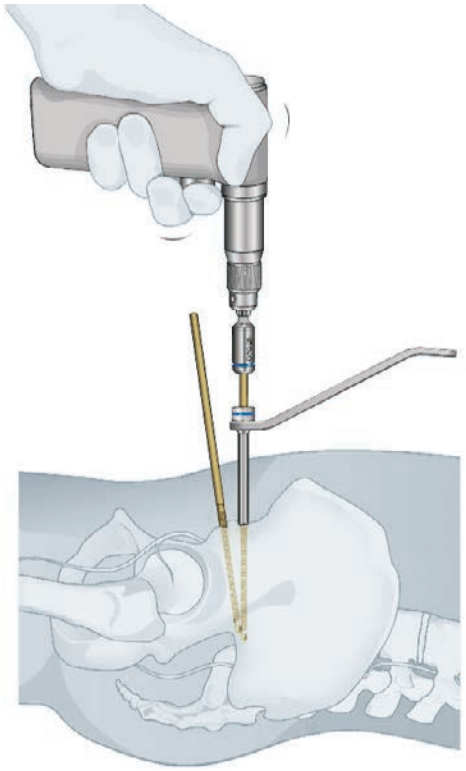
To prevent the screws from penetrating the acetabulum, make sure that the screw is aligned 20–30° medially and 10–20° cranially. When the screws are mechanically inserted, concentrate on feeling if the screw is properly screwing into the bone substance. Monitor the site of entry and the advance of the self-drilling screws with the image intensifier.

The final turns and fine adjustment of the Schanz screw should be done manually with the universal handle.



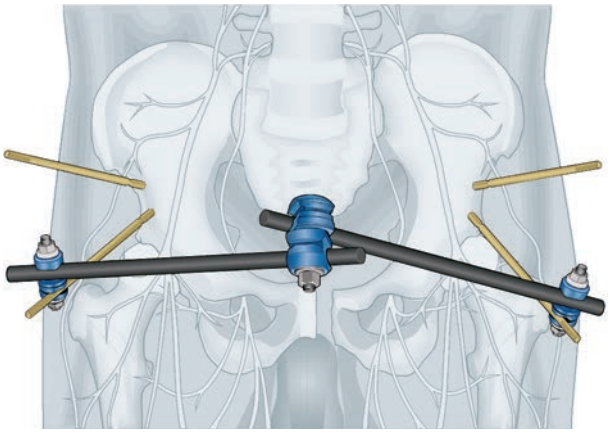
2. Setting the second two Schanz screws

The second Schanz screws to be set on both sides are introduced somewhat cranially to the first set of screws. The two tips can slightly converge.



3. Ventral connection

Required instruments	
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Clamp, clip-on, self-holding	390.005
Combination Wrench ∅ 11.0 mm	321.160



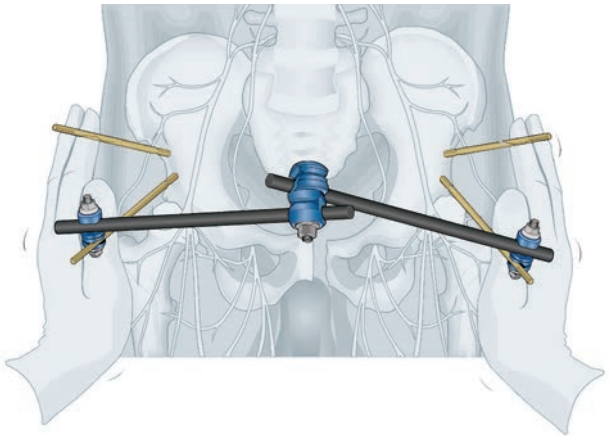
Initially, the two caudal screws of the bilaterally set Schanz screws are connected with two carbon fibre rods and a self-holding combination clamp. It is important for the assembly to be large enough to allow a sufficient degree of freedom to accommodate swelling of the abdomen.

The rods are held with a combination clamp but are not tightened.

4. Reduction

Required instruments	
Combination Wrench ∅ 11.0 mm	321.160

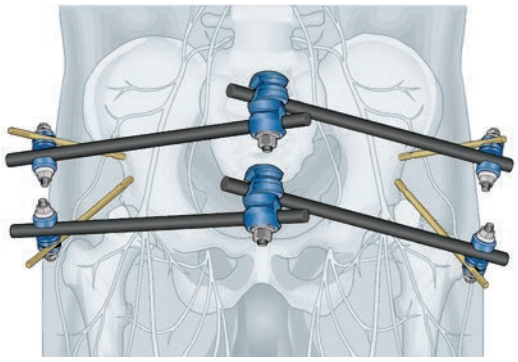
Manually reduce the pelvic ring by pressure, stretching, or using the Schanz screws as levers. In certain cases, distraction by pulling on a leg can be advantageous. After reduction, tighten the combination clamp.



5. Connect the second pair of screws

Required instruments	
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Clamp, clip-on, self-holding	390.005
Combination Wrench ∅ 11.0 mm	321.160

If the reduction of the pelvis has been correctly carried out, the two top Schanz screws can be connected with each other.

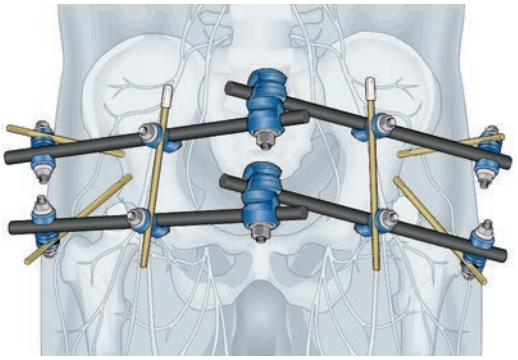


■ Note:

Instead of the rods and combination clamps, a curved carbon fibre rod 394.790 can be used for both the first and second pair of screws.

6. Connecting the partial frames

Required instruments	
Connecting Rod ∅ 5.0 mm, Stainless Steel	393.900–393.940
Self-tapping Schanz Screw	X94.520–570*
Protective Cap, for Schanz Screws and Steinmann Pins ∅ 5.0 mm	393.420



To increase the stability of the construction, the two partial frames are connected with additional 4.0 mm cross-braces (such as 4.0 mm carbon fibre rods or Schanz screws with a protective cap). The clip-on, self-holding clamps are particularly suitable for mounting an additional cross-brace.

* X=2 Stainless Steel
X=4 Titanium Alloy (TAN)

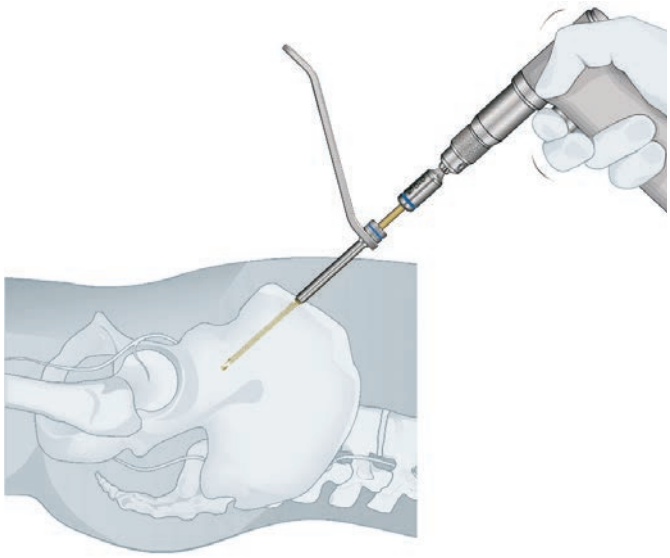
Placing pins in the Iliac crest

1. Setting the first two Schanz screws

The iliac crests serve as landmarks for introducing the Schanz screws. Marking the inner and outer surfaces of the ala of the ilium with Kirschner wires can help establish the alignment for placing the first Schanz screw.

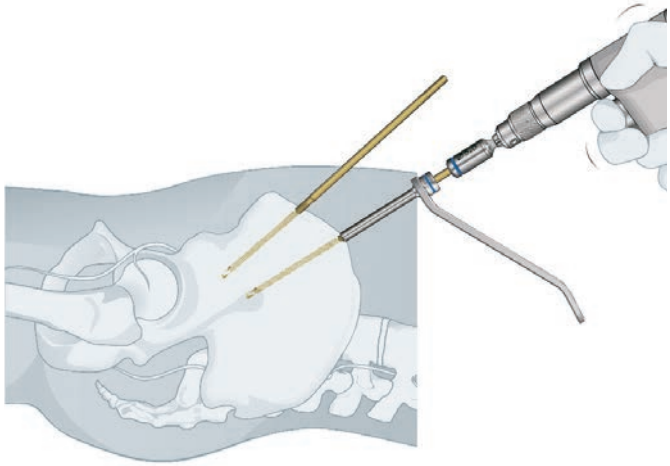
■ Note:

It is advantageous to place at least one screw in the margin of the os ilium on both sides.



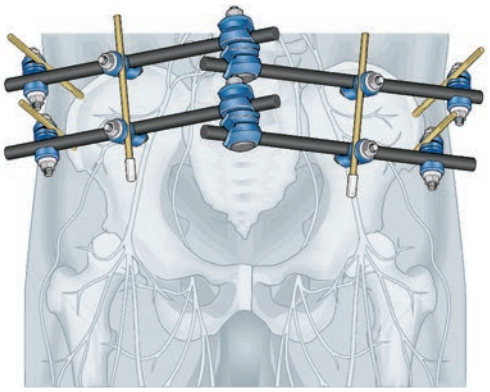
2. Setting the second two Schanz screws

The second screw is set slightly posterior (approximately 2 cm) to the first Schanz screw.



3. Reduction and definitive assembly

Required instruments	
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Clamp, clip-on, self-holding	390.005
Combination Wrench ∅ 11.0 mm	321.160
Self-tapping Schanz Screw	X94.520–570*
Protective Cap, for Schanz Screws and Steinmann Pins ∅ 5.0 mm	393.420



The additional steps for fixing the pelvis are analogous to points 3–6 under sections
2. Setting the second two Schanz screws,
3. Ventral connection,
4. Reduction,
5. Connect the second pair of screws and
6. Connecting the partial frames

■ Note:

In individual cases, the supraacetabular assembly and crest assembly can be combined.

* X=2 Stainless Steel
X=4 Titanium Alloy (TAN)

Bilateral Frame for Arthrodesis and Osteotomies

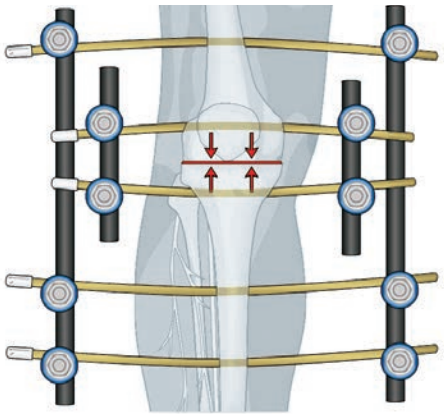
Arthrodesis and osteotomies generally require symmetrical compression that is best generated using a bilateral frame construction.

Bilateral frames for arthrodesis

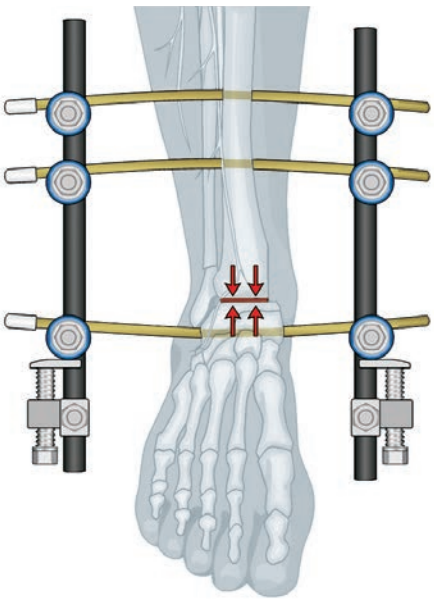
Required instruments	
Steinmann Pin ∅ 5.0 mm with trocar tip	X93.500–X93.590*
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Wrench ∅ 11.0 mm	321.160
Protective Cap, for Schanz Screws and Steinmann Pins ∅ 5.0 mm	393.420
Compressor, open	393.760
Drill Bit ∅ 3.5 mm, length 195/170 mm, 2-flute, for Quick Coupling	310.370

The large external fixator enables effective compression by pretensioning the Steinmann pins in relation to each other. Maximum stability is attained by first untightening the relevant clamp nuts, then generating the desired compression using the open compressor, and then retightening the nuts.

Knee arthrodesis



Ankle arthrodesis



* X=2 Stainless Steel
X=4 Titanium Alloy (TAN)

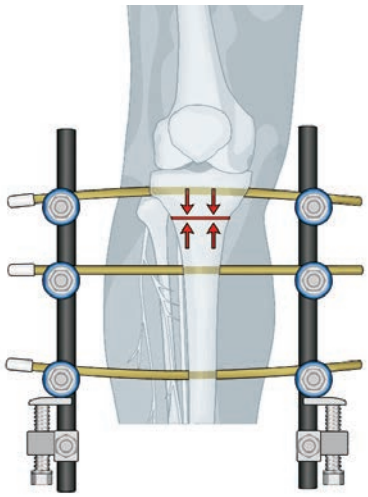
Bilateral frames for Osteotomies

Required instruments	
Steinmann Pin ∅ 5 mm with trocar tip	X93.500–X93.590*
Carbon Fibre Rod ∅ 11.0 mm	394.800–394.870
Clamp, clip-on, self-holding	390.008
Combination Wrench ∅ 11.0 mm	321.160
Protective Cap, for Schanz Screws and Steinmann Pins ∅ 5.0 mm	393.420
Compressor, open	393.760
Drill Bit ∅ 3.5 mm, length 195/170 mm, 2-flute, for Quick Coupling	310.370

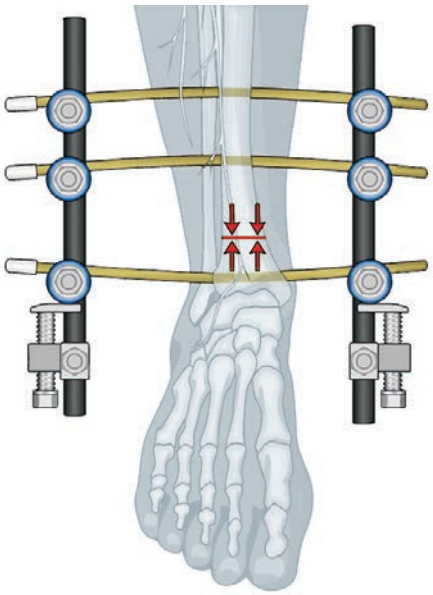
In the case of osteotomies of the proximal and distal tibia, inner fixation is generally preferred if there are no associated soft-tissue problems.

Compression osteotomies with a bilateral frame construction are supportive of the metaphysis of rapid bone healing.

Proximal tibia osteotomy



Distal tibia osteotomy



* X=2 Stainless Steel
X=4 Titanium Alloy (TAN)

Implants

■ Note:

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

For the Large External Fixator

Seldrill Schanz Screws

Titanium*	Stainless Steel	Diameter (mm)	Length (mm)
494.782–788	294.782–788	5.0	100–250
494.792–798	294.792–798	6.0	100–250

Self-Tapping Schanz Screws

Titanium alloy **	Stainless Steel	Diameter (mm)	Length (mm)
494.520–570	294.520–570	5.0	100–190
494.650–680	294.650–680	6.0	100–190

For the Medium External Fixator

Seldrill Schanz Screws

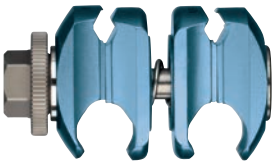
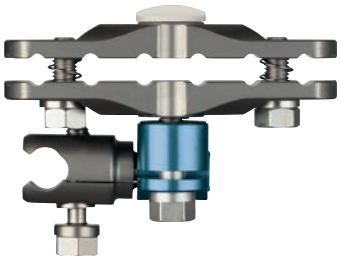
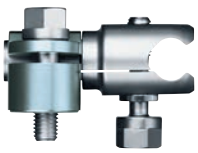
Titanium*	Stainless Steel	Diameter (mm)	Length (mm)
494.769	294.769	4.0/2.5	80
494.771	294.771	4.0/3.0	80
494.772	294.772	4.0/3.0	100
494.774–779	294.774–779	4.0	60–175

Self-Tapping Schanz Screws

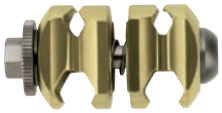
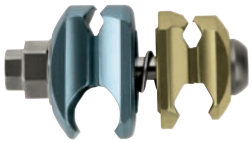
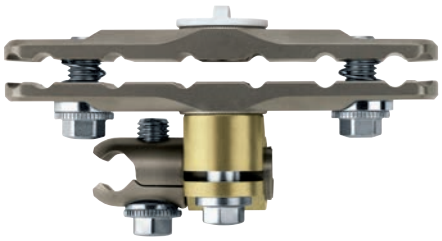
Titanium alloy **	Stainless Steel	Diameter (mm)	Length (mm)
494.445	294.445	4.0/2.5	80
494.300	294.300	4w.0/3.0	80
494.430–460	294.430–460	4.0	60–125

* (TiCP)
** (TAN)

Fixation Components for the Large External Fixator

390.008	Clamp, clip-on, self-holding	
390.005	Combination Clamp, clip-on, self-holding	
390.002 390.004	Multi Pin Clamp, 6 positions, large Multi Pin Clamp, 4 positions, large	
390.007	Rod-to-rod Clamp	
390.003	Rod Attachment for large Multi Pin Clamp	
394.800–870	Carbon Fibre Rod, ∅ 11.0 mm, lengths 100–400 mm	

Fixation Components for the Medium External Fixator

390.035	Clamp, medium, clip-on, self-holding	
390.031	Combination Clamp, medium, clip-on, self-holding	
390.037	Combination Clamp 8.0/11.0, clip-on, self-holding	
390.033 390.036	Multi Pin Clamp, 4 positions, medium Multi Pin Clamp, 6 positions, medium	
390.034	Rod Attachment for medium Multi Pin Clamp	
390.051	Clamp for External Fixator for Distal Radius	
395.779–797	Carbon Fibre Rod, ∅ 8.0 mm, length 160–400 mm	

Instruments

Adapters

393.101	Adapter for Seldrill Schanz Screw ∅ 4.0 mm	
393.103	Adapter for Seldrill Schanz Screw ∅ 5.0 mm	
393.104	Adapter for Seldrill Schanz Screw ∅ 6.0 mm	

Protective caps

393.400	Protective Cap for Schanz Screws and Steinmann Pins ∅ 4.0 mm	
393.420	Protective Cap for Schanz Screws and Steinmann Pins ∅ 5.0 mm	

Combination wrenches

321.160	Combination Wrench ∅ 11.0 mm	
321.158	Combination Wrench ∅ 8.0 mm	

Handles for drill sleeves

392.963	Drill Guide Handle, 6 positions

395.911	Handle for Drill Sleeve

Drill sleeves

Drill sleeves 6.0 mm (for use with 5.0 mm system)

392.951	Drill Sleeve 8.0/6.0, short, with thread

392.952	Drill Sleeve 8.0/6.0, long, with thread

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

395.923	Drill Sleeve 6.0/5.0, long, with thread

395.913	Drill Sleeve 5.0/3.5, long

394.182	Trocar ∅ 3.5 mm, long

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	

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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