Large Distractor – Tibia

Provisional reduction and stabilization of tibia fractures prior to definitive fixation

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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Standard Tibial Distraction and Warning

An alternative to the fracture table

In the treatment of multitrauma patients, it is frequently more advantageous to perform surgical procedures on a standard operating table. The use of a fracture table can cause a loss of mobility of the limb, and mandates the surgical approach. The distractor allows free manipulation of the affected limb without the restrictions imposed by the fracture table.

Direct application of force

Unlike the fracture table, where force is applied to the fractured bone through adjacent joints and soft tissue structures, the distractor applies force directly to the bone, thus allowing repositioning of the fractured extremity while adjacent parts of the body remain undisturbed.

Patient positioning

Generally, patients with multiple injuries are placed supine on the fluoroscopy table. The entire limb is assessed with the C-arm in AP and lateral views.

Note:

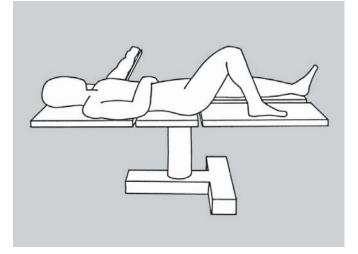
For a detailed handling description of the Schanz screws, refer to the Surgical Technique Schanz Screws and Steinmann Pins.

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



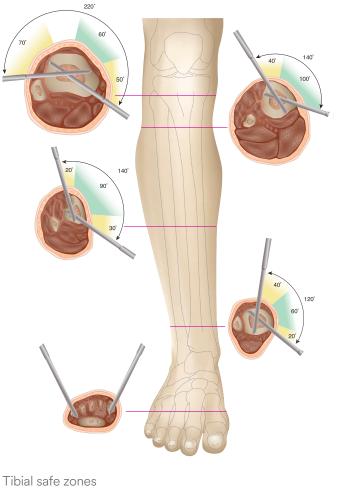
Relevant anatomy and pin placement

Proximal pin insertion

The proximal pin should be inserted from the posterior medial corner of the proximal tibia, aiming for the fibular head. Take care to avoid the medullary canal if IM nailing of the fracture will be attempted.

Distal pin insertion

For insertion in the distal tibia, the distal pin should be placed parallel to, and 5 to 10 mm above the tibia plafond, but distal to the physeal scar, and proximal to the medial malleolus. If IM nailing of very distal fractures will be attempted, the distal pin can also be positioned in the calcaneus, parallel to the coronal plane of the distal tibia. For pin insertion, care must be taken to avoid both intraarticular penetration and relevant neurovascular structures.



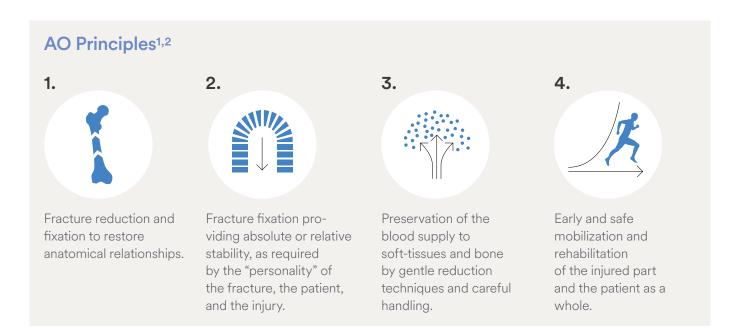
Optimal zones for Schanz Screw insertion

Recommended zones for Schanz Screw insertion

The AO Principles of Fracture Management

Mission

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

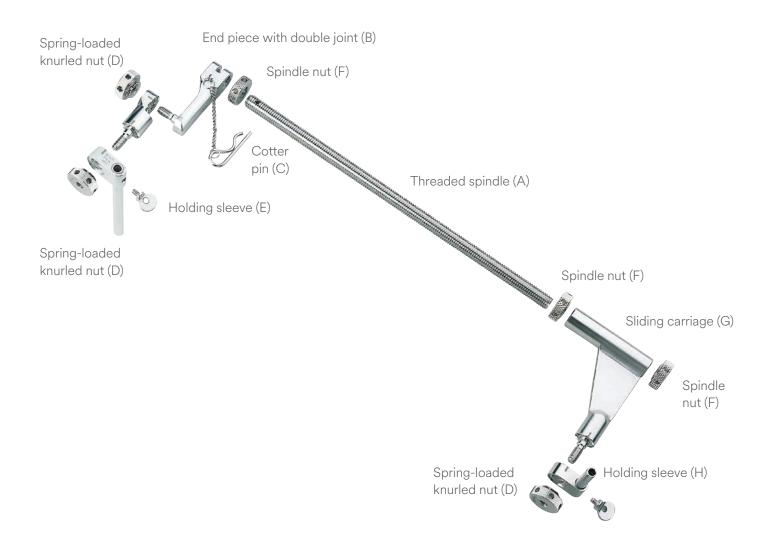


¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991. ² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Prepare Distractor

Preparing the distractor for use

The exact configuration of the large distractor assembly depends on the particular details of each case, such as patient anatomy and which bone is involved, i.e. right or left tibia. The surgeon must consider these factors when assembling the device.



Universal Joint Assembly

1.

Select a 14.0 mm threaded spindle (A) of appropriate length. A transverse hole will be in the distal end when applied to the tibia.

2.

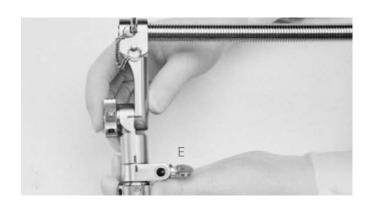
Turn the end piece with double joint (B) onto the threaded spindle so that the rod and end piece are flush. If the end piece is positioned correctly, the transverse hole will be centered in the slot of the end piece.

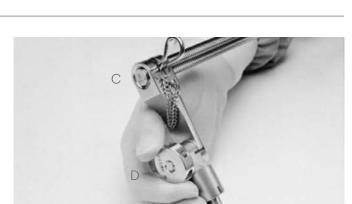
3.

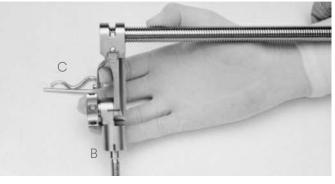
To lock rotation of the end piece with double joint, push the cotter pin (C) through the hole until it snaps into place. Extend the end piece so that the reference marks align, and hand-tighten the spring-loaded knurled nut (D).

4.

Mount the appropriate length holding sleeve (E) onto the end piece so that the serrated ends interface and the reference marks align. To secure the holding sleeve, put the spring-loaded knurled nut on the end piece and hand-tighten.





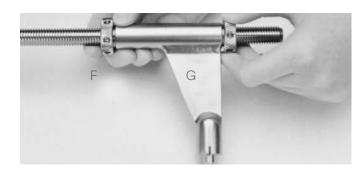


А

Sliding Carriage Assembly

5.

Thread a spindle nut (F) partway down the 14.0 mm threaded spindle. Place the sliding carriage (G) over the threaded spindle, and secure it with a second spindle nut.

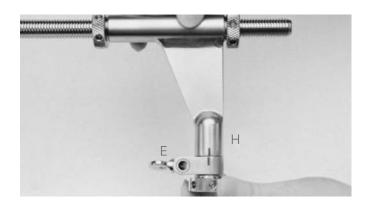


6.

Mount the other holding sleeve (H or E) onto the sliding carriage. The serrated ends must interface and the reference marks must align. Put the spring-loaded knurled nut on the sliding carriage to secure the holding sleeve and hand-tighten.

▲ 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.



Tibial Distraction Technique Overview

1. Insert proximal Schanz screw

Instruments	
294.540	Schanz Screw \oslash 5.0 mm, length 150/50 mm, Stainless Steel
294.550	Schanz Screw \varnothing 5.0 mm, length 175/50 mm, Stainless Steel
294.560	Schanz Screw \varnothing 5.0 mm, length 200/50 mm, Stainless Steel
393.100	Universal Chuck with T-Handle

The proximal Schanz screw should be placed 14 mm inferior and parallel to the tibial plateau. Starting from the posterior medial corner of the proximal tibia, insert the Schanz screw laterally, aiming for the fibular head.

2. Insert distal Schanz screw

The distal Schanz screw should be placed 10 mm above and parallel to the tibial plafond.

Note:

For extreme distal tibia fractures, there is the option of inserting the distal pin through the tuberosity of the calcaneus. To avoid the neurovascular bundle in this area, the pin should be placed well posterior and inferior on the calcaneus. Typically, the ideal insertion site lies two fingerbreadths from the plantar aspect of the heel, and two fingerbreadths anterior to the dorsal aspect of the heel. The pin should be parallel to the coronal plane of the distal tibia.

▲ Precautions:

- The tip of the Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Only when bones are osteoporotic, the Schanz screw has 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.



3. Attach distractor

Instruments321.170Pin Wrench Ø 4.5 mm, length 120 mm394.350Large Distractor, complete

Handling the preassembled distractor as a unit, slide the proximal holding sleeve (on the sliding carriage) over the proximal Schanz screw. The 14.0 mm threaded spindle should be medial and posterior to the axis of the tibia. Slide the distal holding sleeve (with double-jointed end piece) onto the distal Schanz screw. Temporarily loosen the spring-loaded knurled nut or the spindle nuts, as needed. The holding sleeves should be placed firmly against the bone.

4. Tighten wing screws

Instruments	
321.170	Pin Wrench \varnothing 4.5 mm, length 120 mm
393.100	Universal Chuck with T-Handle

Securely tighten the holding sleeves on the Schanz screws by tightening the wing screws using the 4.5 mm pin wrench. If the distractor is positioned properly, the threaded spindle will parallel the axis of the distal tibia. Tighten all spring-loaded knurled nuts in the neutral position.

Note:

For segmental fractures, an additional Schanz screw can be inserted into the middle fracture segment, and manipulated into position with the aid of the universal chuck with T-handle.



Adjustment Technique

With all connections loose (except wing screws), obtain approximate alignment and rotation. When the position is acceptable, securely tighten all loose connections with the 4.5 mm pin wrench.

1. Distraction

Instrument

321.170	Pin Wrench \oslash 4.5 mm, length 120 mm

Loosen the proximal spindle nut (1). Under image intensification, apply distraction by moving the distal spindle nut (2) proximally.

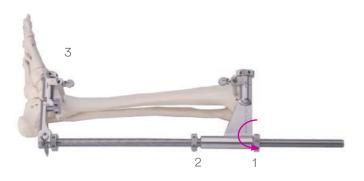


2. Rotation

Instrument

321.170 Pin Wrench \emptyset 4.5 mm, length 120 mm

Loosen both spindle nuts (1 and 2) and the spring-loaded knurled nut (3) on the end piece with double joint. Correct rotation by simultaneously rotating the sliding carriage and the 14.0 mm threaded spindle.



3. Valgus-Varus

Instrument

321.170 Pin Wrench Ø 4.5 mm, length 120 mm

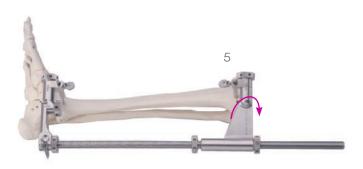
Loosen the spring-loaded knurled nut on the distal holding sleeve (4). Correction is achieved by manipulating the distal Schanz screw with the universal chuck with T-handle.



4. Anterior-posterior angulation

321.170 Pin Wrench \emptyset 4.5 mm, length 120 mm

Loosen the wing screw (5) that secures the proximal Schanz screw in the proximal holding sleeve and correct the anterior-posterior angulation.



5. Compression

Instrument	
321.170	Pin Wrench \varnothing 4.5 mm, length 120 mm

Loosen the distal spindle nut (2). Under image intensification, apply compression by moving the proximal spindle nut (1) distally.

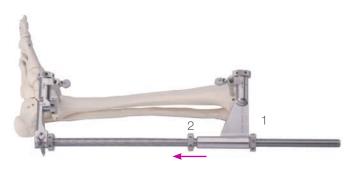
After reduction, secure distractor joints by tightening all connections.

Note:

Manipulation of the distractor for reduction of the tibia is similar to that of the femur, although the instrumentation is oriented in the opposing direction. These steps need not be performed in the order given, except for Step 5 (compression), which should be performed last. To avoid loss of correction, retighten all loosened nuts after each step.

▲ 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.



Instruments

Schanz Screw \emptyset 5.0 mm, 294.540 length 150/50 mm, Stainless Steel Schanz Screw \emptyset 5.0 mm, 294.550 length 175/50 mm, Stainless Steel Schanz Screw \emptyset 5.0 mm, 294.560 length 200/50 mm, Stainless Steel Drill Bit \emptyset 3.5 mm, length 195/170 mm, 310.370 2-flute, for Quick Coupling Combination Wrench \varnothing 11.0 mm 321.160 321.170 Pin Wrench \varnothing 4.5 mm, length 120 mm Universal Chuck with T-Handle 393.100

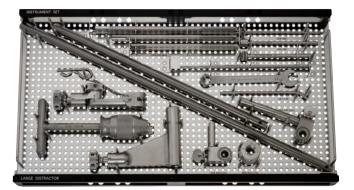
393.790	Drill Sleeve 5.0/3.5, long	(P3)
393.830	Drill Sleeve 6.0/5.0, long	
394.182	Trocar Ø 3.5 mm, long	I
394.350	Large Distractor complete	
394.400	Threaded Rod ∅ 14.0 mm, length 480 mm, for Large Distractor	
394.410	Threaded Rod ∅ 14.0 mm, length 330 mm, for Large Distractor	
394.420	Nut, knurled, for Large Distractor	

394.430	Sliding Carriage with Adjusting Nut, for Large Distractor	
394.440	Double Joint, complete, for Large Distractor	- Durand
394.450	Holding Sleeve with Wing Screw, length 55 mm, internal diameter 6.0 mm, for Large Distractor	
394.460	Holding Sleeve with Wing Screw, length 105 mm, internal diameter 6.0 mm, for Large Distractor	
395.913	Drill Sleeve 5.0/3.5, long	
395.923	Drill Sleeve 6.0/5.0, long with thread	

Set List

68.120.051 Modular Tray for Instrument Set for Large Distractor, without Contents

 310.370 Drill Bit Ø 3.5 mm, length 195/170 mm, 2-flute, for Quick Coupling 321.160 Combination Wrench Ø 11.0 mm 321.170 Pin Wrench Ø 4.5 mm, length 120 mm 393.100 Universal Chuck with T-Handle 393.790 Drill Sleeve 5.0/3.5, long 393.830 Drill Sleeve 6.0/5.0, long 394.160 Trocar Ø 3.5 mm, long 394.400 Threaded Rod Ø 14.0 mm, length 480 mm, for Large Distractor 394.410 Threaded Rod Ø 14.0 mm, length 330 mm, for Large Distractor 394.420 Nut, knurled, for Large Distractor 394.430 Sliding Carriage with Adjusting Nut, for Large Distractor 394.440 Double Joint, complete, for Large Distractor 394.450 Holding Sleeve with Wing Screw, length 55 mm, internal diameter 6.0 mm for Large Distractor 394.460 Holding Sleeve with Wing Screw, length 105 mm, internal diameter 6.0 mm for Large Distractor 394.450 Schanz Screw Ø 5.0 mm length 150/50 mm, Stainless Steel 294.540 Schanz Screw Ø 5.0 mm, length 175/50 mm, Stainless Steel 294.560 Schanz Screw Ø 5.0 mm, length 175/50 mm, Stainless Steel 	Content of	Instrument Set U	nits
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MRI Information

The "Large Distractor – Tibia" is MR unsafe. Do not use this device in any MR environment. This device is known to pose hazards in all MR environments as per discussion with RA.

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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