Adjustable Large Fixator. For use in the treatment of long bones.

Technique Guide





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Features

- Radiolucent central body facilitates radiographic imaging
- Pin clamp pivots for use in ankle or tibial plateau fractures
- Three tightening points control all planes of movement
- Dual compression/distraction module
- Spring-loaded, 6-position vise plates simplify quick pin placement
- Pivoting clamp includes convergent pin slots for use in the tibial plateau
- Accommodates 4 mm to 6 mm diameter Schanz screws

6-Position Drill Guide Handle

The 6-Position Drill Guide Handle and drill sleeves help space pins properly and protect soft tissue.





Combination T-Wrench

The Combination T-Wrench incorporates two hexagonal wrenches for tightening all fixator adjustment screws.



Reduction Handles

The Reduction Handles aid in manipulation and reduction of fracture fragments. A T-handled grip can be created by inserting the 4.5 mm Pin Wrench through the handle, as shown.



Combination Wrench

The Combination Wrench allows tightening of the multiplanar locking screws and the swivel locking screw.



Relevant anatomy and Schanz screw positioning

The articulating body of the adjustable large fixator facilitates reduction, and its radiolucent construction allows optimal placement of Schanz screw clusters relative to the fracture pattern.

The six pin positions on each of the adjustable large fixator's pin clamps allow optimal pin spacing based on patient anatomy. Place pins as far apart as possible in each clamp. Schanz screws should be placed within the safe zones as illustrated.^{1,2}

Tibial plateau

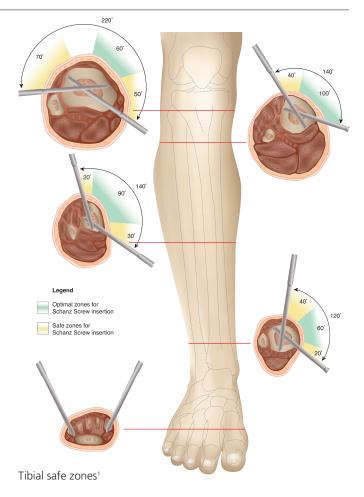
- Schanz screws used in the anterior portion of the proximal tibia should be placed to avoid intracapsular penetration.
- When internal fixation with cannulated screws is employed in addition to external fixation, Schanz screws should be placed in the metaphysis below the cannulated screws.
- Preferred Schanz screw placement in the tibial plateau is achieved by choosing one convergent slot and one straight slot. Configure pin placement to avoid injury to the patellar tendon.

Tibial shaft

- In general, Schanz screws in the tibial shaft are placed anteromedially to avoid drilling along the tibial crest.
- For tibial shaft and plateau fractures, maximum stability can be obtained by placing Schanz screws in the AP plane, depending on patient anatomy and fracture pattern. The radiolucent body of the fixator enables placement of the Schanz screws in the AP plane while facilitating visibility of the fracture site during radiographic imaging.
- When the pivoting clamp is used over the ankle, Schanz screws are placed in the shaft medially or anteromedially.

Hindfoot

- When inserting Schanz screws into the hindfoot, pin placement must be planned to avoid the future surgical site. For this reason, placing both Schanz screws in the calcaneus may be elected.
- Care must be taken to avoid both intra-articular penetration and the neurovascular structures.





Medial calcaneal and medial talar safe zones²

Indications

The adjustable large fixator is indicated for use in the treatment of long bone conditions, including fractures, osteotomies and other bone conditions amenable to treatment with a unilateral external fixator.

Three primary applications of the adjustable large fixator—ankle bridge frame, tibial shaft frame and tibial plateau frame—are discussed on the opposite page.



Ankle Bridge Frame

The adjustable large fixator can be used as definitive treatment or as the first stage of a two-stage treatment protocol for complex pilon fractures. The recommended protocol includes immediate open reduction and internal fixation (ORIF) of the fractured fibula, then application of the spanning external fixator in order to maintain tibial reduction, followed by delayed ORIF of the tibia.^{3,4,5} This frame can also be used as definitive treatment for pilon fractures or for ankle fractures that cannot be treated by ORIF.

Tibial Shaft Frame

This frame is appropriate for fixation of tibial shaft fractures, particularly those associated with soft tissue injury.

Tibial Plateau Frame

This frame is used when horizontal Schanz screw placement is necessary for the stabilization of proximal tibia fractures.

1 Preoperative planning Instrument

392.961 Adjustable Large Fixator

Preoperative planning helps to ensure that the fixator is placed in the optimal position for each case, as dictated by the soft tissue injury and fracture pattern. First obtain gross manual alignment of the fracture. Place the loosened adjustable large fixator over the limb, with the pivoting clamp positioned distally, to plan approximate pin placement.

2

Determine Schanz screw placement in the hindfoot

Instrument	
392.963	6-Position Drill Guide Handle

Using the 6-position drill guide handle, determine pin placement in both the talus and the calcaneus.

Note: Alternatively, both Schanz screws can be inserted in the calcaneus.



Insert first Schanz screw in the talar neck, parallel to the axis of the talar dome

Use the 6-position drill guide handle and drill sleeves to place the first Schanz screw.

4

Insert second Schanz screw in the calcaneus

Use the 6-position drill guide handle and drill sleeves to insert the second Schanz screw.

Note: Alternatively, once the first Schanz screw has been inserted using the 6-position drill guide handle, the second Schanz screw can be inserted through a drill sleeve in the fixator clamp.

5

Apply fixator

Loosen the pivot locking screw and rotate the pivoting clamp. Slide the pin clamp over the Schanz screws and tighten the pin locking screws.



Insert Schanz screws in proximal fragment

Place the distractor end of the fixator parallel to the limb, oriented for easy access to all adjustment screws.

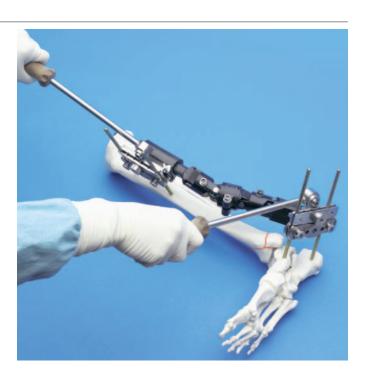
Temporarily finger-tighten fixator joints. Insert Schanz screws through the drill sleeves and the pin clamp, perpendicular to the bone. Remove the drill sleeves. Tighten the pin locking screws.

Alternatively, the 6-position drill guide handle can be used.

7 Reduce fracture

Optional Instrument
392.966* Reduction Handle

Reduction handles can be used for added leverage.



*Also available

Lock fixator into position

Verify that all locking screws are secure.

9

Distract/compress (optional)

Optional Instrument

392.965 Combination T-Wrench

Open distraction locking screw. Turn fine distraction adjustment screw: Clockwise = compression Counterclockwise = distraction One revolution = 1 mm travel

10

Finger-tighten the distraction locking screw





1 Preoperative planning		
Instrumen	t	
392.961	Adjustable Large Fixator	
-		-

Preoperative planning helps to ensure that the fixator will be placed in the optimal position for each case as dictated by the soft tissue injury and fracture pattern. First obtain gross manual alignment of the fracture. Place the loosened adjustable large fixator over the limb to plan approximate pin placement.

2

Insert Schanz screws in proximal fragment

Instrument	
392.963	6-Position Drill Guide Handle

Use the 6-position drill guide handle and the appropriate drill sleeves to insert Schanz screws perpendicular to the bone and in line with the axis of the bone.

Note: Alternatively, once the first Schanz screw has been inserted with the aid of the 6-position drill guide handle, the second Schanz screw can be inserted through a drill sleeve in the pin clamp.

3

Apply fixator

Slide the pin clamp over the Schanz screws in the proximal fragment and tighten the pin locking screws.

Ensure that the fixator is oriented for easy access to all adjustment screws.

Note: It is suggested that the distractor end be placed on the proximal fragment to facilitate access to the fine distraction adjustment screw.



Insert Schanz screws in distal fragment

Temporarily finger tighten fixator joints. Insert Schanz screws through the drill sleeves and the second pin clamp, then tighten pin locking screws.

Alternatively, the 6-position drill guide handle can be used for pin placement.

5 Reduce fracture

Optional Instrument

392.966* Reduction Handle

Reduction handles can be used for added leverage.

6

Lock fixator in position

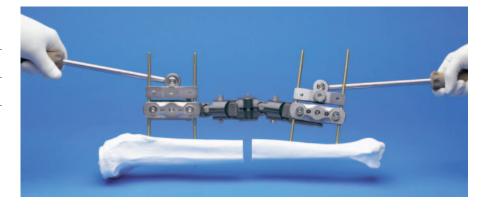
Verify that all locking screws are secure.

7 Distract/compress (optional)

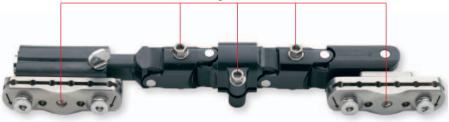
Optional Instrument

392.965 Combination T-Wrench

Open distraction locking screw. Turn fine distraction adjustment screw: Clockwise = compression Counterclockwise = distraction One revolution = 1 mm travel



locking screws





*Also available

Finger-tighten the distraction locking screw

9

Dynamize (optional)

Unlock the gross distraction locking screw to provide dynamization.

10

Optional Frame Configurations

Optional Sets

Large External Fixator Set
Small External Fixator Set
Medium External Fixator Set

For connection of the adjustable large fixator to the small, medium or large external fixator systems, ensure that the Schanz screws used are long enough to allow connection of an additional clamp.



Tibial shaft frame with additional Schanz screws in the first and fifth metatarsals to prevent equinus deformity, using Medium External Fixator Set



Tibial shaft frame with additional Schanz screws in each pin clamp

1 Preoperative planning Instrument

392.961	Adjustable Large Fixator
JJZ.JUI	Aujustable Laige i Mator

Preoperative planning helps to ensure that the fixator will be placed in the optimal position for each case, as dictated by the soft tissue injury and fracture pattern. First obtain gross manual alignment of the fracture. Place the loosened adjustable large fixator over the limb, with the pivoting clamp positioned proximally, to plan approximate pin placement.

It is preferred to have one of the proximal Schanz screws in an anterior/ posterior position through a straight slot and the second Schanz screw in a convergent slot.

2

Prepare fixator for Schanz screw insertion in the proximal fragment

Loosen the pivot locking screw and rotate the pivoting clamp. Tighten at 90° to the fixator body.



3 Determine Schanz screw placement in the tibial plateau Instrument 395.923 6.0 mm/5.0 mm Threaded Drill Sleeve

Ensure that the pin clamp is parallel to the joint surface. Place two long 6.0 mm/5.0 mm threaded drill sleeves in the pin clamp, one in the most appropriate straight slot and the other in the most appropriate convergent slot.

Tighten the vise plates onto the drill sleeves at the appropriate distance from the bone.

Note: The convergent pin slots are the outermost slots on the pin clamp, as indicated by the arrows on the clamp.

4

Insert first Schanz screw into straight slot

Insert the Schanz screw through the drill sleeve and pin slot. Slide the pin clamp to the desired position on the Schanz screw.

This determines the final position of the pin clamp and the insertion point for the convergent Schanz screw.

5

Insert convergent Schanz screw

Insert the convergent Schanz screw through the drill sleeves and the second pin slot. Loosen the pin clamp and remove the drill sleeves. Tighten the pin locking screws.



Insert Schanz screws in distal fragment

Align the distractor end of the fixator parallel to the limb and in line with the axis of the bone, oriented for easy access to all adjustment screws.

Temporarily finger-tighten fixator joints. Insert the Schanz screws through the drill sleeves and the second pin clamp. Remove the drill sleeves.

Tighten the pin locking screws.

Alternatively, the 6-position drill guide handle can be used.

7 Lock fixator in position

Verify that all locking screws are secure.

8

Distract/compress (optional)

Optional Instrument

392.965 Combination T-Wrench

Open distraction locking screw. Turn fine distraction adjustment screw: Clockwise = compression Counterclockwise = distraction One revolution = 1 mm travel

9 Finger-tighten the distraction locking screw





Optional Frame Configuration

Optional Sets		
115.720 or	Large External Fixator Set	
115.992	Medium External Fixator Set	

For connection of the adjustable large fixator to the medium or large external fixator systems, ensure that the Schanz screws used are long enough to allow connection of an additional clamp.



Additional plane of fixation into the tibial plateau, using the large or medium external fixation sets.

Distraction/Compression

392.965	Combination	T-Wrench

Manual gross length adjustment is achieved by loosening the gross distraction locking screw. This will allow the pin clamp to slide freely up to 45 mm.

To allow sufficient room for fine distraction and compression, ensure that the fine distractor is not positioned at either end of its full travel (35 mm) before applying the fixator.

Fine distraction is achieved by turning the fine distractor adjustment screw counterclockwise until the desired length is obtained. Four markings around the fine distraction lock indicate 0.25 mm increments of distraction. The total amount of distraction achieved can be measured with the progressive markings on the telescoping arm. Each mark represents 1 mm.

Fine compression can be achieved by turning the fine distraction adjustment screw clockwise.

Note: When the fine distractor reaches the end of its travel, a red line appears at the end of the markings. Further distraction using the fine distractor adjustment screw should not be attempted.



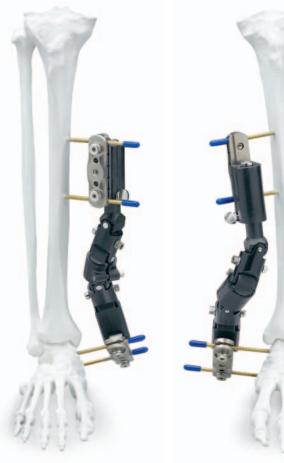




Adjustments continued

Versatility

The adjustable large fixator is packaged ready for use on either the right or the left side of the body.



Ankle frame Right





Tibial shaft frame Right



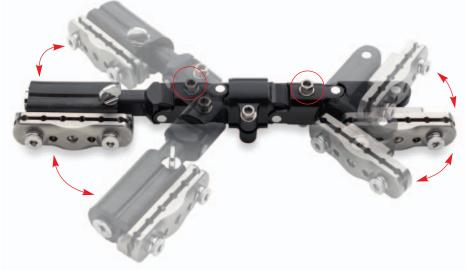
Tibial shaft frame Left

Adjustment Screws

The swivel locking screw controls rotation about the axis of the fixator.



The multiplanar locking screws control varus/valgus and anterior/posterior movement.



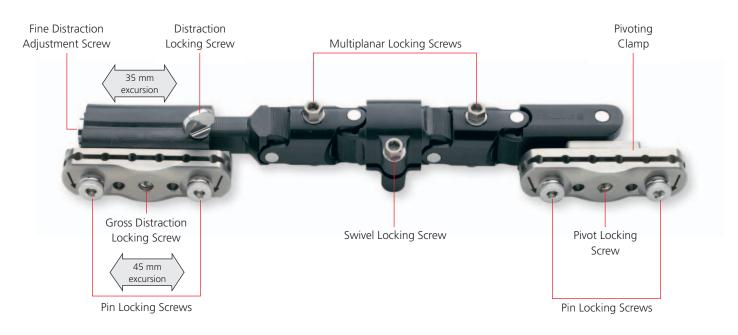
Varus/valgus movement



Anterior/posterior movement

Adjustments continued

Adjustment Points



After application of the fixator, most alignment corrections require adjustment in more than one plane, as follows:

Rotational Correction

For correction of rotational malalignment about the axis of the bone, loosen both multiplanar locking screws, the swivel locking screw and the gross distraction locking screw.

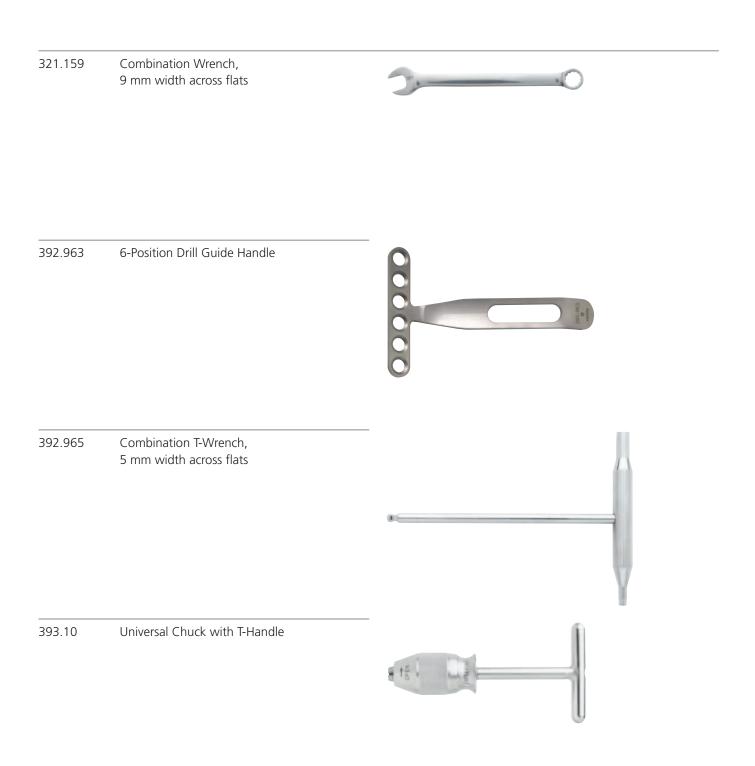
Angular Correction and Translation

For varus/valgus and anterior/posterior corrections, loosen both multiplanar locking screws and the gross distraction locking screw.





Instruments from Adjustable Large Fixator Set (105.016 or 105.017)



393.103	Drive Adaptor with quick coupling, for 5.0 mm Schanz screws	05.0
394.181	3.5 mm Trocar, 88 mm (short)	
394.182	3.5 mm Trocar, 118 mm (long)	
395.912	5.0 mm/3.5 mm Drill Sleeve, 77 mm (short)	
395.913	5.0 mm/3.5 mm Drill Sleeve, 107 mm (long)	
395.921	6.0 mm/5.0 mm Threaded Drill Sleeve, 68 mm (short)	
395.923	6.0 mm/5.0 mm Threaded Drill Sleeve, 98 mm (long)	

Adjustable Large Fixator Set

with Titanium Self-Drilling Schanz Screws (105.016) with Stainless Steel Self-Drilling Schanz Screws (105.017)

Graphic Case

690.305 Adjustable Large Fixator Graphic Case

Implant in set 105.017

294.7855.0 mm Self-Drilling Schanz Screw,
60 mm thread length, 175 mm, 8 ea.

Implant in set 105.016

494.7855.0 mm Titanium Self-Drilling Schanz Screw,
60 mm thread length, 175 mm, 8 ea.

Fixation Material (both sets)

392.961	Adjustable Large Fixator
394.993	Protective Caps, for 5.0 mm Fixation Pins,
	1 pkg. of 10

Instruments (both sets)

321.159	Combination Wrench,
	9 mm width across flats
392.963	6-Position Drill Guide Handle
392.965	Combination T-Wrench,
	5 mm width across flats, 2 ea.
393.10	Universal Chuck with T-Handle
393.103	Drive Adaptor with quick coupling,
	for 5.0 mm Schanz Screws
394.181	3.5 mm Trocar, 88 mm (short)
394.182	3.5 mm Trocar, 118 mm (long)
395.912	5.0 mm/3.5 mm Drill Sleeve,
	77 mm (short)
395.913	5.0 mm/3.5 mm Drill Sleeve,
	107 mm (long)
395.921	6.0 mm/5.0 mm Threaded Drill Sleeve,
	68 mm (short), 2 ea.
395.923	6.0 mm/5.0 mm Threaded Drill Sleeve,
	98 mm (long), 2 ea.

Also Available Sets

105.954	Small Battery Drive with 14.4V Battery Set
115.720	Large External Fixator Set,
	with self-drilling Schanz screws
115.982	Small External Fixator Set,
	with carbon fiber rods
115.992	Medium External Fixator Set,
	with self-drilling Schanz screws
	-

Note: For additional information, please refer to package insert.

For detailed cleaning and sterilization instructions, please refer to http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm

or to the below listed inserts, which will be included in the shipping container:

---Processing Synthes Reusable Medical Devices---Instruments, Instrument Trays

and Graphic Cases—DJ1305

-Processing Non-sterile Synthes Implants-DJ1304



Also Available Instruments

310.37	3.5 mm Drill Bit, quick coupling, 195 mm
321.17	4.5 mm Pin Wrench, 120 mm
392.919	Hexagonal Wrench, 5 mm
392.951	8.0 mm/6.0 mm Threaded Drill Sleeve,
	58 mm (short)
392.952	8.0 mm/6.0 mm Threaded Drill Sleeve,
	88 mm (long)
392.966	Reduction Handle

References

- Alberto Fernandez Dell'Occa. "External Fixation." AO Principles of Fracture Management. Thomas P. Rüedi and William M. Murphy, ed. Dübendorf, Switzerland; AO Publishing. 2000. 239. Illustration modified and used with permission.
- M.D. Santi and M.J. Botte. "External Fixation of the Calcaneus and Talus: An Anatomical Study for Safe Pin Insertion." *Journal of Orthopaedic Trauma*. 1996; 10,7. 487–491. Illustration modified and used with permission.
- 3. J. Borrelli, Jr. and L. Catalano. "Open Reduction and Internal Fixation of Pilon Fractures." *Journal of Orthopaedic Trauma*. 1999; 18,8. 573–582.
- M. Sirkin et al. "A Staged Protocol for Soft Tissue Management in the Treatment of Complex Pilon Fractures." *Journal of Orthopaedic Trauma*. 1999; 13,2. 78–84.
- M.J. Patterson and J.D. Cole. "Two-Staged Delayed Open Reduction and Internal Fixation of Severe Pilon Fractures." *Journal of Orthopaedic Trauma*. 1999; 13,2. 85–91.

Additional Reading

Bal G.K., R.S. Kuo, J.R. Chapman, et al. "The Anterior T-Frame External Fixator for High-Energy Proximal Tibial Fractures." *Clinical Orthopaedics and Related Research*. 2000: 380. 234–240.

Reid, J.S., M.A. Vanslyke, M.J.R Moulton et al. "Safe Placement of Proximal Tibial Transfixation Wires with Respect to Intracapsular Penetration." *Journal of Orthopaedic Trauma*. 2001; 15,1. 10–17.

DeCoster, T.A., Crawford, M.K., and Steven Kraut M.A. "Safe Extracapsular Placement of Proximal Tibia Transfixation Pins." *Journal of Orthopaedic Trauma*. 1999; 13,4. 236–240.

J.L. Marsh, Smith, S.T., Do, T.T. "External Fixation and Limited Internal Fixation for Complex Fractures of the Tibial Plateau." *Journal of Bone and Joint Surgery.* 1995; 77-A;5. 661–673.



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