Medium External Fixator—Delta Frame Ankle Bridge. For small-statured adults.

Technique Guide

Part of the Medium External Fixation System

SYNTHES® Instruments and implants approved by the AO Foundation

MRI Information

Synthes Medium External Fixation devices are labeled MR Conditional according to the terminology specified in ASTM F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Nonclinical testing demonstrated that, when used in the specific configurations stated in Synthes labeling, Synthes Medium External Fixation devices are MR Conditional. Representative Synthes Medium External Fixation devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Medium External Fixation frame may be scanned safely after placement of the frame under the following conditions.

Static magnetic field of 1.5 Tesla when the fixation 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 Controlled Mode

Static magnetic field of 3.0 Tesla when the fixation 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 Controlled 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 Operatinig 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.

Note: In nonclinical testing, the Synthes external fixation frame was tested in several different configurations. This testing was conducted with the construct positioned 7 cm from within the outside edge of the MRI bore.
– The results showed a maximum observed heating for a wrist fixation 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.

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal 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 is 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, 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, Synthes MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of Synthes external fixation frames must be identified as MR Conditional prior to being placed in or near an MR environment.

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 Synthes Medium External Fixation construct, and it may be necessary to optimize MR imaging parameters, to compensate for the presence of the fixation frame.

Representative devices used to assemble a typical Synthes Medium External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Medium External Fixation devices may present issues if the MR imaging area of interest is in or near the area where the fixation frame is located.
– For FFE sequence: Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

Warning
– Do not place any radio frequency (RF) transmit coils over the external fixation frame.

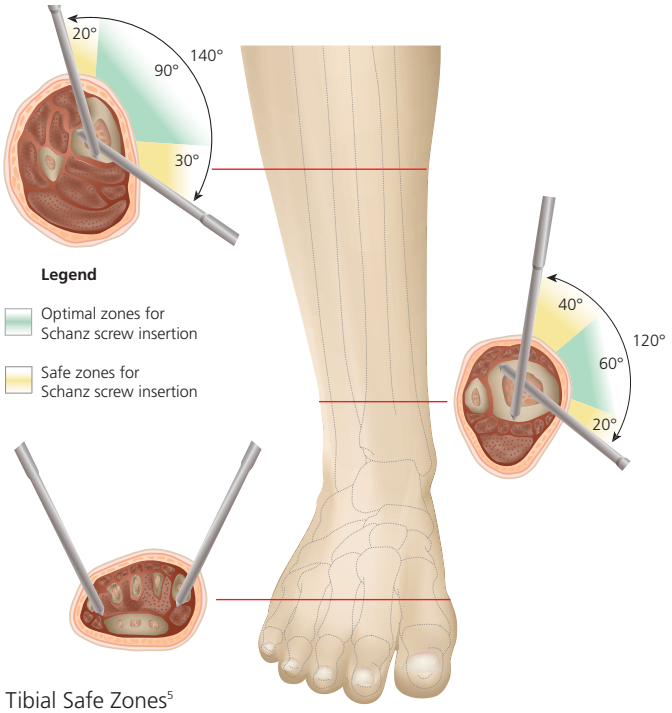
Medium External Fixator—Delta Frame Ankle Bridge

When to use

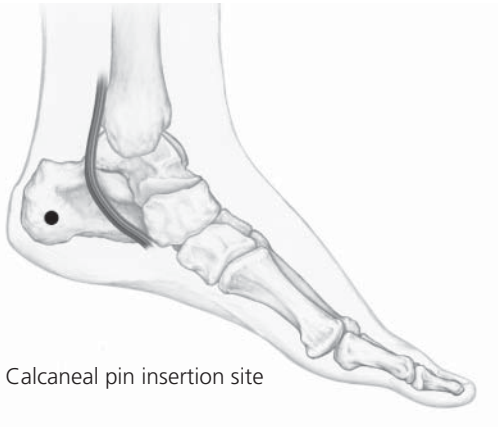
The purpose of this frame is to achieve a closed reduction through ligamentotaxis and maintain it until the soft tissue injury can resolve. The frame is recommended in conjunction with a two-stage treatment protocol for extra- and intra-articular fractures of the distal tibia with soft tissue injury (closed or open). 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.[1,2,3]

Relevant anatomy and pin placement

- In the tibia, insert Schanz screws within the safe zone.[4]
- Tibial Schanz screws should be placed in the AP plane (as shown in the illustrated frame) for maximum stability. Alternatively, they may be placed anteromedially to avoid drilling along the crest.
- Schanz screws are placed proximal to the fracture in the midsagittal plane of the diaphysis, approximately one-half fingerbreadth medial to the tibial crest.
- The proximal Schanz screws should be placed outside the proposed future operative site to avoid the risk of contamination.
- In the calcaneus, a centrally threaded Steinmann pin is placed through the calcaneal tuberosity. To avoid the neurovascular bundle, this pin should be placed well posterior and inferior and can be placed with image intensification. 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.



Tibial Safe Zones[5]



Calcaneal pin insertion site

1. J. Borrelli, Jr. and L. Catalano. "Open Reduction and Internal Fixation of Pilon Fractures." *Journal of Orthopaedic Trauma*. 1999;13;8. 573–582.
2. 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.
3. 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.
4. F. Behrens and K. Searls. "External Fixation of the Tibia." *Journal of Bone and Joint Surgery*. 1986;68-B. 246–254.
5. A. Fernández. "External Fixation." *AO Principles of Fracture Management*. T. Rüedi and W. Murphy, ed. Dübendorf, Switzerland; AO Publishing. 2000. 239. Illustration modified and used with permission.

Recommended Components for Basic Frame

Product Number	Item	Quantity Needed	
293.xx	5.0 mm Steinmann Pin with Central Thread	**1**	
294.78x	5.0 mm Self-Drilling Schanz Screw	**2**	
390.034	Rod Attachment, for Medium Multi-Pin Clamp	**1**	
390.035	Medium Open Adjustable Clamp	**2**	
390.036	Medium Multi-Pin Clamp, 6 position	**1**	
395.7xx	8.0 mm Carbon Fiber Rod	**2**	
394.993	Protective Caps, for 5.0 mm Fixation Pins	**4**	
395.781	Protective Caps, for 8.0 mm Carbon Fiber Rods	**4**	

Technique Overview

1
Insert Steinmann pin
Insert a centrally threaded Steinmann pin through the calcaneal tuberosity.

2
Attach open adjustable clamps

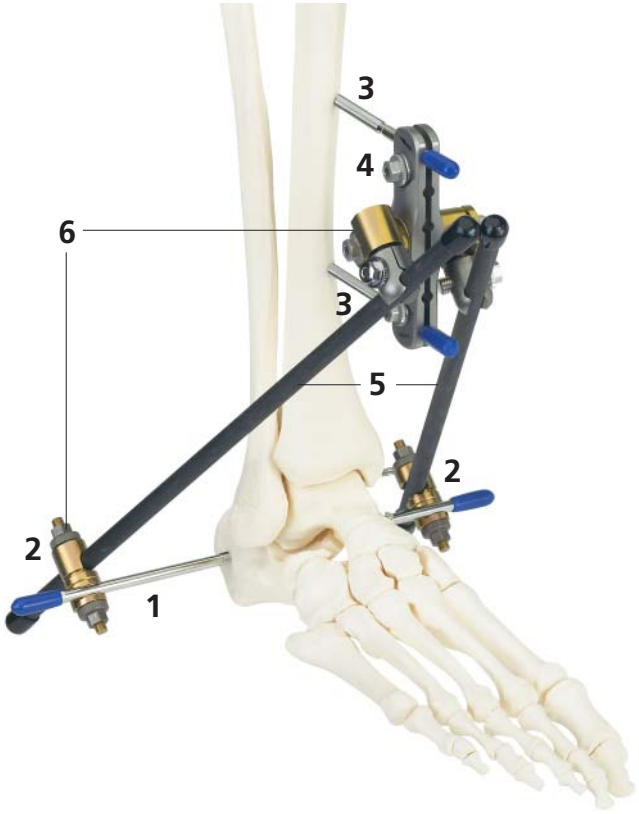
3
Insert Schanz screws
Use the 6-Position Drill Guide Handle (392.963) or multi-pin clamp technique to ensure proper pin spacing.

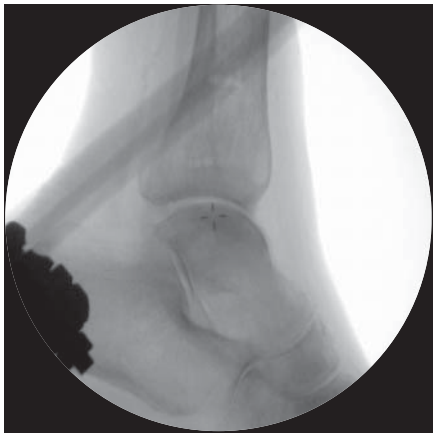
4
Attach multi-pin clamp with rod attachment
Tighten the vise plates.

5
Attach carbon fiber rods

6
Reduce fracture
Reduce the fracture and tighten all clamps.

Note: For ease of reduction, tighten the proximal clamp first and then reduce.





Lateral x-ray showing frame radiolucency

Medium Multi-Pin Clamp Technique

1

Insert first Schanz screw

Insert a Schanz screw through the drill sleeve and end position of the Medium Multi-Pin Clamp (390.036), using the clamp as an insertion guide.

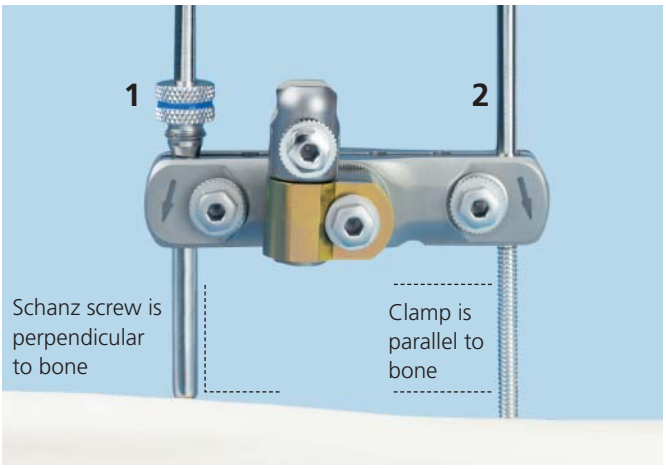
Note: The clamp should be parallel, and the Schanz screws perpendicular, to the bone.

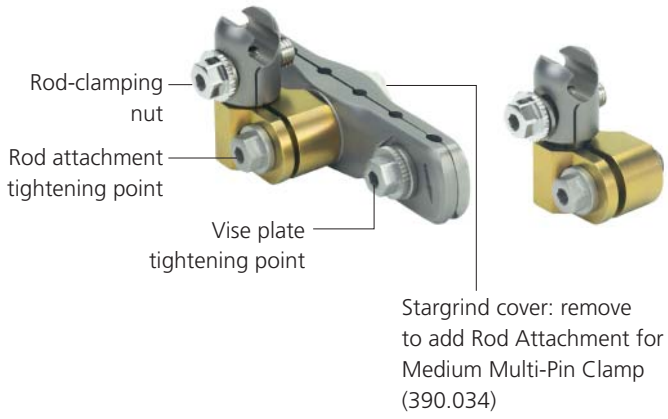
2

Insert second Schanz screw

Insert a second Schanz screw through the opposite end of the clamp. Tighten the vise plates.

Note: Additional Schanz screws may be inserted as needed.





Optional Frame Configurations

Use of the open adjustable clamp for independent pin placement

The delta frame ankle bridge can also be built using Medium Open Adjustable Clamps (390.035) and an additional carbon fiber rod, as shown.

Note: It is important to "close" the frame by adding a short carbon fiber rod between the two proximal Schanz screws.

Enhancing the frame for additional stability

A 4.5 mm or 5.0 mm Schanz screw can be added medially into the talar neck.

To prevent equinus contracture, several options are available. A 4.0 mm Schanz screw can be placed in the proximal-third portion of the first metatarsal, with a second Schanz screw in the third, fourth or fifth metatarsal. These Schanz screws can each be directly connected to the delta frame rods or to each other with a transverse carbon fiber rod. Alternatively, a single Schanz screw can be carefully placed in the middle cuneiform.

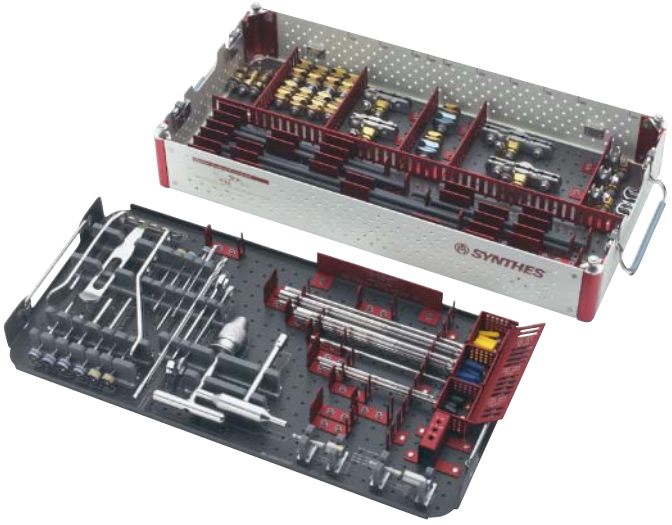
Schanz screw in talar neck

Schanz screw in metatarsal

The two additional posterior carbon fiber rods act as "kick stands" to elevate the foot, protecting the soft tissues.

Medium External Fixator Set with Self-Drilling Schanz Screws

Stainless Steel (01.302.602) or Titanium (01.302.604)



Graphic Case

690.450 Graphic Case, for Medium External Fixator

Implants in Set 01.302.602

293.74 5.0 mm Steinmann Pin with Central Thread, 200 mm, 2 ea.

Self-Drilling Schanz Screws, 4 ea.

294.777 4.0 mm diameter, 125 mm
294.778 4.0 mm diameter, 150 mm
294.785 5.0 mm diameter, 175 mm
294.786 5.0 mm diameter, 200 mm

Implants in Set 01.302.604

293.74 5.0 mm Steinmann Pin with Central Thread, 200 mm, 2 ea.

Titanium Self-Drilling Schanz Screws, 4 ea.

494.777 4.0 mm diameter, 125 mm
494.778 4.0 mm diameter, 150 mm
494.785 5.0 mm diameter, 175 mm
494.786 5.0 mm diameter, 200 mm

Instruments (for both sets)

310.19 2.0 mm Drill Bit, quick coupling, 100 mm, 2 ea.
310.37 3.5 mm Drill Bit, quick coupling, 195 mm, 2 ea.
321.158 Combination Wrench, 8 mm width across flats
392.955 4.0 mm/2.5 mm Drill Sleeve
392.969 Combination T-Wrench, 8 mm
393.101 Drive Adaptor with quick coupling, for 4.0 mm Schanz Screws
393.103 Drive Adaptor with quick coupling, for 5.0 mm Schanz Screws
393.105 Small Universal Chuck with T-Handle
394.181 3.5 mm Trocar, short
394.182 3.5 mm Trocar, long
394.183 2.5 mm Trocar

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

Instruments (for both sets) continued

395.911	Drill Sleeve Handle
395.912	5.0 mm/3.5 mm Drill Sleeve, short
395.913	5.0 mm/3.5 mm Drill Sleeve, long
395.921	6.0 mm/5.0 mm Threaded Drill Sleeve, short
395.922	4.0 mm Threaded Drill Sleeve
395.923	6.0 mm/5.0 mm Threaded Drill Sleeve, long

Fixation Material (for both sets)

390.031	Medium Combination Clamp, 8 ea.
390.032	Dynamization Clip, for Medium Combination Clamp, 4 ea.
390.033	Medium Multi-Pin Clamp, 4 position, 2 ea.
390.034	Rod Attachment, for Medium Multi-Pin Clamp, 4 ea.
390.035	Medium Open Adjustable Clamp, 4 ea.
390.036	Medium Multi-Pin Clamp, 6 position, 2 ea.
390.037	8.0 mm/11.0 mm Combination Clamp, 2 ea.
	Protective Caps
394.991	4.0 mm Fixation Pins, 1 pkg. of 10
394.993	5.0 mm Fixation Pins, 1 pkg. of 10
395.781	8.0 mm Carbon Fiber Rods, 4 pkgs. of 2
	8.0 mm Carbon Fiber Rods
395.779	160 mm, 2 ea.
395.782	200 mm
395.784	220 mm
395.786	240 mm, 2 ea.
395.788	280 mm, 2 ea.
395.792	320 mm, 2 ea.
395.796	360 mm, 2 ea.
395.797	400 mm

Also Available Implants

	Schanz Screws
294.43–.48	4.0 mm, spade point, 60 mm–150 mm
294.52–.57	5.0 mm, blunted trocar point, 100 mm–250 mm
294.71–.76	4.5 mm, blunted trocar point, 80 mm–200 mm
	Self-Drilling Schanz Screws
294.774–.779	4.0 mm, 60 mm–175 mm
294.782–.788	5.0 mm, 100 mm–250 mm
	Titanium Self-Drilling Schanz Screws
494.774–.779	4.0 mm, 60 mm–175 mm
494.782–.788	5.0 mm, 100 mm–250 mm
	Steinmann Pins with Central Thread
293.64	5.0 mm diameter, 150 mm
293.69	5.0 mm diameter, 175 mm

Also Available Instrument

03.302.001	Medium Open Compressor
392.963	6-Position Drill Guide Handle

Also Available Fixation Material

390.026	Medium Pin Clamp, 4 position
390.027	Medium Pin Clamp, 6 position
390.028	Straight Outrigger Post, 8 mm
390.029	30° Outrigger Post, 8 mm
390.030	90° Outrigger Post, 8 mm

Also Available Sets

105.957	Power Drive Set
150.16	ComPact Air Drive II Set

Also Available for Graphic Case

690.350.13	Label Sheet Pack, for Schanz Screws and Carbon Fiber Rods
690.451	Label Sheet, for Medium External Fixator clamps

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