

Using Pin Clamps With Outrigger Posts

Large External Fixator— Delta Frame Ankle Bridge

Surgical Technique



LARGE EXTERNAL FIXATOR— DELTA FRAME ANKLE BRIDGE

DePuy Synthes Companies of Johnson & Johnson Large External Fixation devices are labeled MR Conditional according to the terminology specified in ASTM F2503-08, 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 DePuy Synthes Companies labeling, DePuy Synthes Companies Large External Fixation devices are MR Conditional. Representative DePuy Synthes Companies Large External Fixation devices used in a typical construct include clamps, rods and various attachments.

A patient with a DePuy Synthes Companies Large 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 fixator frame is positioned outside the MRI bore at Normal Operator or in First Level Control Mode
- **Static magnetic field of 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

Note: In nonclinical testing, the DePuy Synthes Companies External Fixation Devices were tested in several different configurations. This testing was conducted with the construct positioned at the edge of the MRI bore, with the entire construct outside the MRI bore.

- The results showed a maximum observed heating for a wrist fixator frame of less than 4°C for 1.5T and less than 2°C for 3.0T with a machine reported whole body averaged SAR of 2 W/kg
- The results showed a maximum observed heating for a pelvic frame less than 1°C for 1.5 and 3.0T 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, DePuy Synthes Companies MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of DePuy Synthes Companies 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 DePuy Synthes Companies Large 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 DePuy Synthes Companies Large External Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Companies Large 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.

INDICATIONS AND MRI INFORMATION

INDICATIONS

The DePuy Synthes Large External Fixation Systems are intended to provide treatment for long bone and pelvic fractures that require external fixation. Specifically, the components can be used for:

- Stabilization of soft tissues and fractures
- Polytrauma/multiple orthopaedic trauma
- Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation
- Non-unions/septic non-unions
- Intraoperative reductions/stabilization tool to assist with indirect reduction
- Unilateral rectilinear bone segment transport or leg lengthening

MRI INFORMATION

- 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 5 cm from the device.

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

DEPUY SYNTHES LARGE EXTERNAL FIXATION SYSTEM

Warning:

- DePuy Synthes self-drilling, self-tapping Schanz screws and Steinmann pins are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Precautions:

- To keep from damaging the femoral cutaneous nerve, avoid pin insertion up to 15 mm in a dorsal direction from the superior anterior iliac spine.
- When dealing with the humerus, primary consideration should be given to the radial and axillary nerves. Distally, a dorsal approach to the humerus is appropriate. Proximally, it is recommended to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve.
- Select the appropriate Schanz screw (self-tapping, self-drilling) or Steinmann pin for the patient's bony anatomy.
- 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 of worn bone cutting instruments in an approved sharps container.
- The self-drilling Schanz screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the self-drilling Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Only when bones are osteoporotic does the self-drilling 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.
- 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.
- Implant sites should be meticulously cared for 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 help 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.

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 pin clamp technique to ensure proper pin spacing.

4

Attach pin clamp

Tighten the vise plates.

5

Attach outrigger posts

Thread a post into each vise plate to a hard stop. For angled posts, turn the post counterclockwise to the desired orientation. Lock in position by turning the lock nut clockwise until tight.

6

Attach carbon fiber rods

Attach carbon fiber rods to outrigger posts with combination clamps and to open adjustable clamps on the Steinmann pin.

7

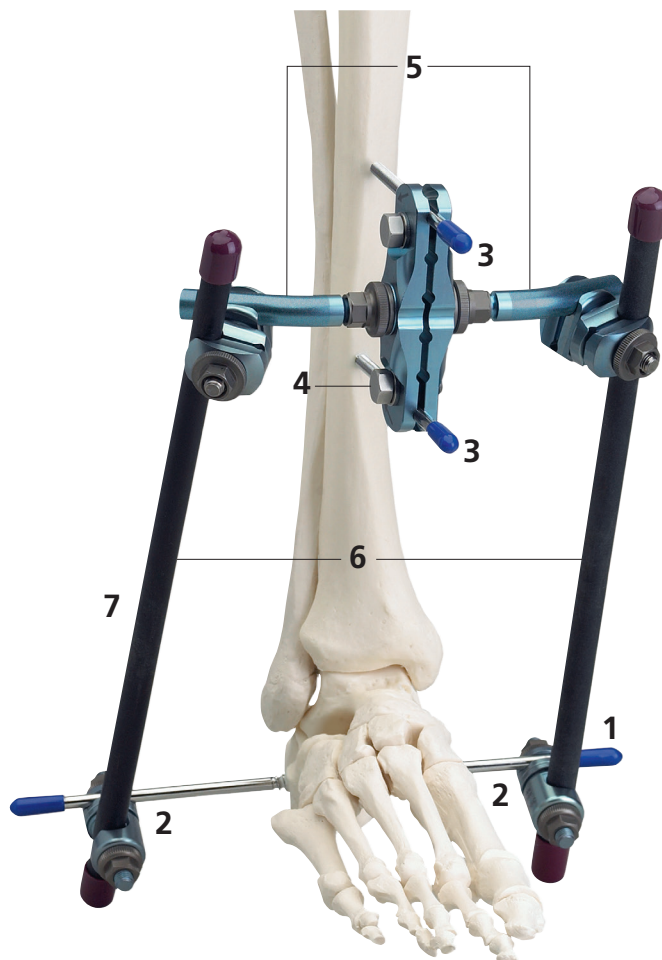
Reduce fracture

Reduce the fracture and tighten all clamps.





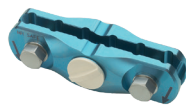




Notes:

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

To prevent equinus contracture, Schanz screws can be placed in the metatarsals as shown on the [Optional Frame Configurations](#) page.



RECOMMENDED COMPONENTS FOR BASIC FRAME

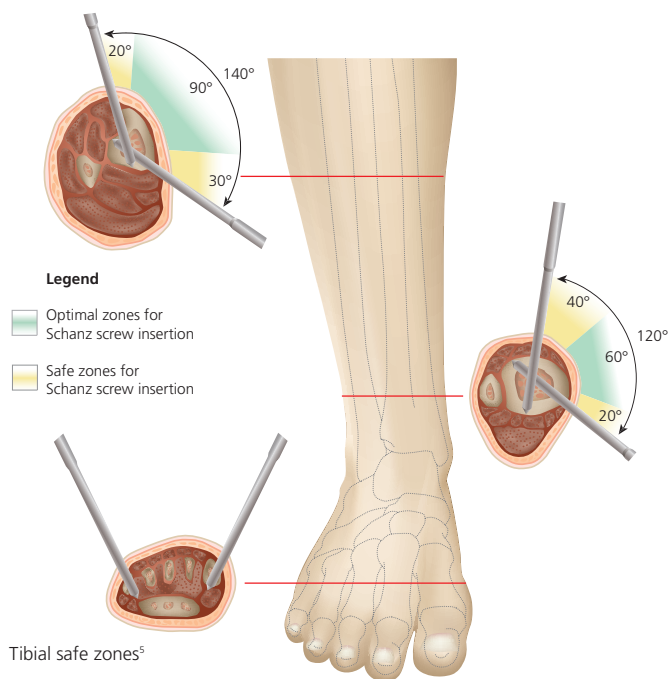
Product Number	Item	Quantity Needed	
293.xx	5.0 mm Steinmann Pin, with central thread	1	
294.78x	5.0 mm Self-Drilling Schanz Screw	2	
390.005	Large Combination Clamp	2	
390.008	Large Open Adjustable Clamp	2	
390.010	Large Pin Clamp, 6 position	1	
390.012	30° Outrigger Post, 11 mm	2	
394.8x	11.0 mm Carbon Fiber Rod	2	
394.97	Protective Cap, for 11.0 mm rods	4	
394.993	Protective Cap, for 5.0 mm Fixation Pins	4	

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. In dense cortical bone, it may be necessary to predrill.
- 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. In order 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.



1. Borrelli J Jr and Catalano L. Open reduction and internal fixation of pilon fractures. *J Orthop Trauma*. 1999;13(8):573–582.
2. Sirkin M, Sanders R, DiPasquale T, Herscovici D Jr. A staged protocol for soft tissue management in the treatment of complex pilon fractures. *J Orthop Trauma*. 1999;13(2):78–84.
3. Patterson MJ and Cole JD. Two-staged delayed open reduction and internal fixation of severe pilon fractures. *J Orthop Trauma*. 1999;13(2):85–91.
4. Behrens F and Searls K. External fixation of the tibia. Basic concepts and prospective evaluation. *J Bone Joint Surg Br*. 1986;68(2):246–254.
5. Fernández A. "External Fixation." In: Rüedi T and Murphy W, eds. *AO Principles of Fracture Management*. ed. Dübendorf, Switzerland; AO Publishing. 2000. 239. Illustration modified and used with permission.

PIN CLAMP TECHNIQUE

1

Insert first Schanz screw

Insert a Schanz screw through the drill sleeve and end position of the Large Pin Clamp (390.009 or 390.010), using the clamp as an insertion guide.

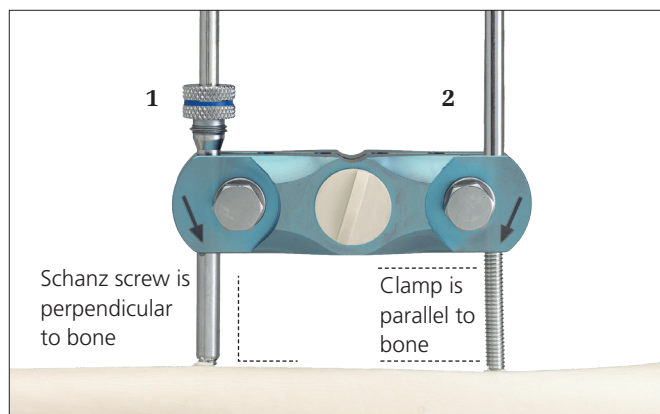
Note: The clamp should be parallel, and the Schanz screws perpendicular, to the bone.

2

Insert second Schanz screw

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

Note: Additional Schanz screws may be inserted as needed.



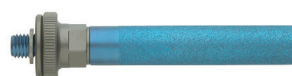
Pin clamp

Large Pin Clamp, 6 position (390.010)



Note: Each side of the pin clamp can accept either an outrigger post or a rod attachment.

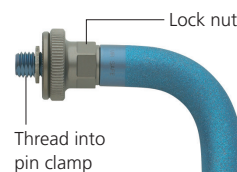
Outrigger posts



Straight (390.011)



30° Post (390.012)



90° Post (390.013)

OPTIONAL FRAME CONFIGURATIONS

The delta frame ankle bridge can also be built using the straight or 90° outrigger posts, as shown.



Straight outrigger posts



90° outrigger posts

Enhancing the frame for additional stability

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.



A carbon fiber bridging rod acts as a “kickstand” to elevate the foot, protecting the soft tissues.



Schanz screws in metatarsals

Conversion to a hybrid frame



If ORIF cannot be performed due to the degree of soft tissue injury or because of the amount of metaphyseal or articular comminution, the delta frame can be converted to a hybrid frame.

With the delta frame in position, place two spade-point reduction wires through the distal bony fragment. Attach a 3/4 ring and connect to the previously placed outrigger posts. Remove the Steinmann pin from the calcaneus.

For further information, please refer to the *Distal Tibia Hybrid Frame Technique Guide*.



Note: The hybrid frame is NOT MR Conditional. MR Conditional frames are composed of:

- color-coded clamps etched 
- carbon fiber rods etched 
- DePuy Synthes Companies stainless steel or titanium Schanz screws labeled MR Conditional

LARGE EXTERNAL FIXATOR SET WITH SELF-DRILLING SCHANZ SCREWS

Stainless Steel (115.720) or Titanium (115.740)

Graphic Case

690.315 Large External Fixator Graphic Case

Implants in Set 115.720, MR Conditional

293.74 5.0 mm Steinmann Pin with Central Thread,
200 mm, 4 ea

294.56 5.0 mm Schanz Screw, blunted trocar
point, 200 mm, 8 ea

5.0 mm Self-Drilling Schanz Screws

294.784 60 mm thread/150 mm, 4 ea

294.785 60 mm thread/175 mm, 8 ea

294.786 80 mm thread/200 mm, 8 ea

294.950 6.0 mm Transfixation Pin, 225 mm, 4 ea

Implants in Set 115.740, MR Conditional

293.74 5.0 mm Steinmann Pin with Central Thread,
200 mm, 4 ea

294.56 5.0 mm Schanz Screw, blunted trocar
point, 200 mm, 8 ea

294.950 6.0 mm Transfixation Pin, 225 mm, 4 ea

5.0 mm Titanium Self-Drilling Schanz Screws

494.784 60 mm thread/150 mm, 4 ea

494.785 60 mm thread/175 mm, 8 ea

494.786 80 mm thread/200 mm, 8 ea

Instruments (for both sets)

310.37 3.5 mm Drill Bit, quick coupling, 195 mm,
2 ea

310.48 4.5 mm Drill Bit, quick coupling, 195 mm,
2 ea

321.20 Ratchet Wrench, 11 mm width across flats,
2 ea

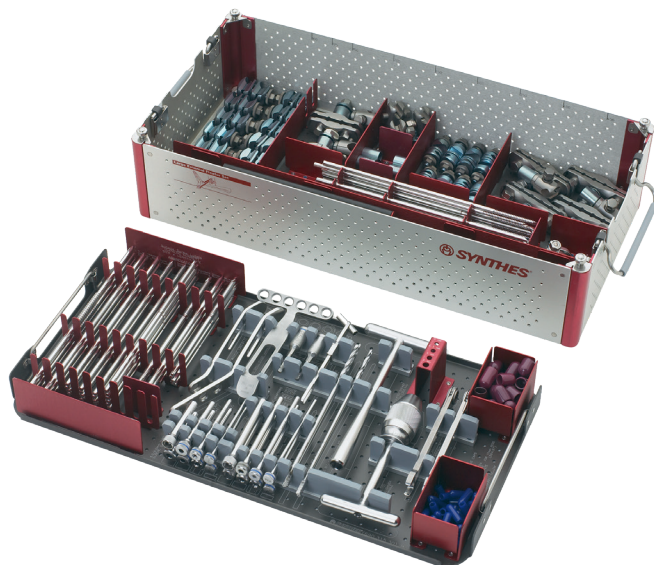
355.14 Cannulated Socket Wrench

392.951 8.0 mm/6.0 mm Threaded Drill Sleeve, short

392.952 8.0 mm/6.0 mm Threaded Drill Sleeve, long

392.963 6-Position Drill Guide Handle

393.10 Universal Chuck with T-Handle



Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuySynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Large External Fixator Set with Self-Drilling Schanz Screws
Stainless Steel (115.720) or Titanium (115.740)

393.103	Drive Adaptor with quick coupling, for 5.0 mm Schanz Screws
393.104	Drive Adaptor with quick coupling, for 6.0 mm Schanz Screws
393.746	Split Tissue Protection Sleeve, 5.0 mm
393.76	Open Compressor, 2 ea
394.181	3.5 mm Trocar, short
394.182	3.5 mm Trocar, long
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
395.923	6.0 mm/5.0 mm Threaded Drill Sleeve, long

Fixation Material (for both sets), MR Conditional

390.002	Large Multi-Pin Clamp, 6 position, 4 ea
390.003	Rod Attachment, for Large Multi-Pin Clamp, 6 ea
390.004	Large Multi-Pin Clamp, 4 position, 2 ea
390.005	Large Combination Clamp, 12 ea
390.006	Dynamization Clip, for Large Combination Clamp, 4 ea
390.007	Tube-to-Tube Clamp, 2 ea
390.008	Large Open Adjustable Clamp, 8 ea
393.66*	Transverse Clamp, 2 ea
	11.0 mm Carbon Fiber Rods, 4 ea
394.80	100 mm
394.82	150 mm
394.83	200 mm
394.84	250 mm
394.85	300 mm
394.86	350 mm
394.87	400 mm
	Protective Caps
394.97*	For 11.0 mm Rods, (10/pkg)
394.993*	For 5.0 mm Fixation Pins, (10/pkg)
394.994*	For 6.0 mm Fixation Pins, (10/pkg)

*This item has not been tested for safety in the MR environment.

ALSO AVAILABLE

Implants, MR Conditional

	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
294.792–.798	6.0 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
494.792–.798	6.0 mm, 100 mm–250 mm

Fixation Material, MR Conditional

390.009	Large Pin Clamp, 4 position
390.010	Large Pin Clamp, 6 position
390.011	Straight Outrigger Post, 11 mm
390.012	30° Outrigger Post, 11 mm
390.013	90° Outrigger Post, 11 mm
	11.0 mm Carbon Fiber Bridging Rods
394.796	190 mm, short
394.797	190 mm, long
394.798	220 mm, short
394.799	220 mm, long

Fixation Material

393.43*	Spring-Loaded Nut
393.64*	Adjustable Clamp
393.69*	Open Clamp
393.71*	Universal Joint for Two Tubes
393.75*	Universal Clamp
	Protective Caps
394.991*	For 4.0 mm Fixation Pins (10/pkg)
394.992*	For 4.5 mm Fixation Pins (10/pkg)



03.301.011S

Sterile-Packaged Large External Fixator Kits

03.301.010S	Large External Fixator Ankle Frame Kit, sterile
03.301.011S	Large External Fixator Trauma Kit, sterile
03.301.012S	Large External Fixator Pelvic Frame Kit, sterile

Sets

105.957	Power Drive Set
150.16	ComPact Air Drive II Set

Accessories for Graphic Case

690.315.12	Label Sheet Pack, for Large External Fixator Clamps
690.315.13	Label Sheet Pack, for Schanz Screws
690.315.14	Replacement Brackets (3 sizes)
690.315.15	Replacement Screws (10/pkg)
690.315.17	Label Sheet, for Large External Fixator MR Conditional clamps

*This item has not been tested for safety in the MR environment.

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