



avisa

medical innovators of east

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Dynamic Distal Radius External Fixator

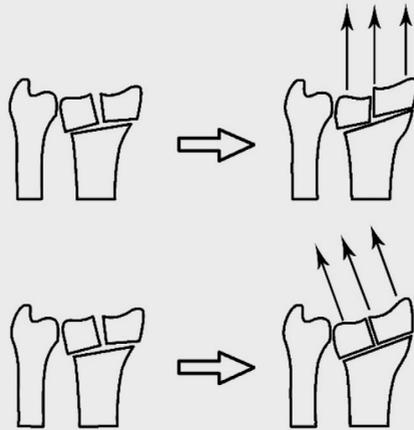
information

Distal radius fractures are among the most common fractures in all age groups. External fixation is one of the best treatment options for management of such fractures. It is useful especially in cases with articular or metaphyseal comminution. Ligamentotaxis is the main mechanism for closed reduction of distal radius fractures. The best reduction is achievable when the axis of traction is ulnar and volar deviated perpendicular to distal radius articular plain. Volar tilt and radial inclination are two important radiologic parameters that determine the orientation of distal radius articular surface. One of most important aspects of dynamic distal radius external fixator is adjustment of traction force axis perpendicular to articular plain. Fine tuning of articular parts of external fixator will be performed according to normal side radiologic parameters. Another important item in closed treatment of distal radius fractures is tension over tendons. Overdistraction of fracture may lead to tension over tendons especially extensors. In these circumstances the finger range of motion will be diminished. The last important aspect of dynamic distal radius external fixator is opportunity to insert schanz pins in any desired distance or direction due to independent clamp system in proximal or distal part of fixator.

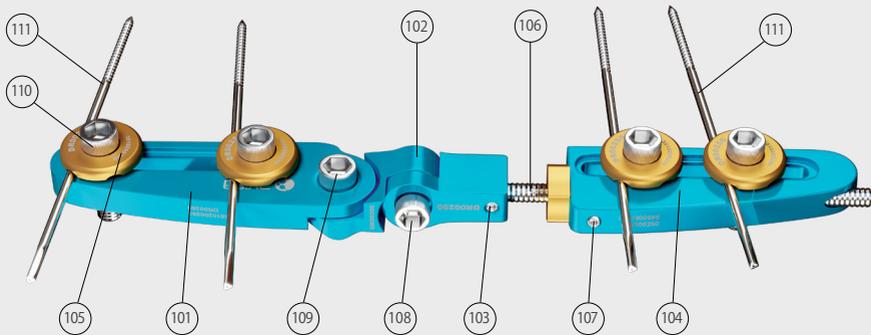
Tips and tricks

Tips and tricks for application:

- It is mandatory to sterile the external fixator before surgery.
- “Dynamic Distal Radius External Fixator” is pre-fabricated for treatment of right sided fractures. Flipping of clamps make the fixator suitable for left sided fractures.
- Four 2.5*150 mm schanzes, perforator and insertion instrument set are necessary for surgery.
- Schanz insertion precautions like predrilling is necessary
- Fluoroscopy is necessary to verify the operation.
- It is better to calculate the exact values of volar tilt and radial inclination according to normal side radiographic parameters.



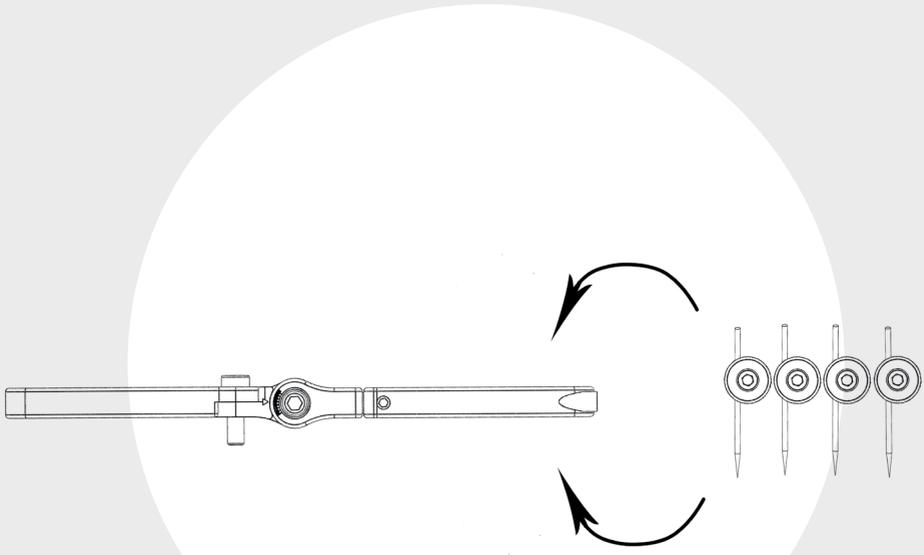
The function of this fixator is mainly based on distraction and ligamentotaxis. In order to acceptable bone reduction, exerting traction must be perpendicular to articular surface not parallel to radius shaft. We design an external Fixator that has the most efficiency with minimal traction. In order to proper placement of broken parts and preventing over distraction, we designed a novel external fixator which is used specially for distal radius fractures and exerts the traction to the joint in a proper perpendicular direction on articular surface not parallel to the radius shaft.



External fixator components

- 101: Radius fixing plate
- 102: Proximal connecting part
- 103: Distal connecting part
- 104: Metacarpal fixing plate
- 105: Schanz clamp
- 106: Distraction rod and nut

- 107: Distraction rod screw
- 108: Palmar tilt hinge screw
- 109: Radial inclination hinge screw
- 110: Schanz clamp screw
- 111: Schanz pin



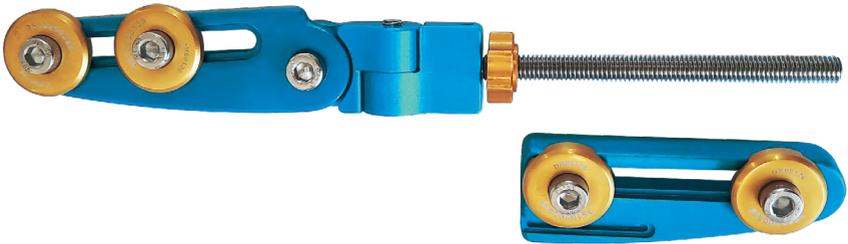
This product is assembled for the right side distal radius fractures. To be used for the left side fractures, the user should reposition the clamps on the other side.

Dynamic Distal Radius External Fixator insertion

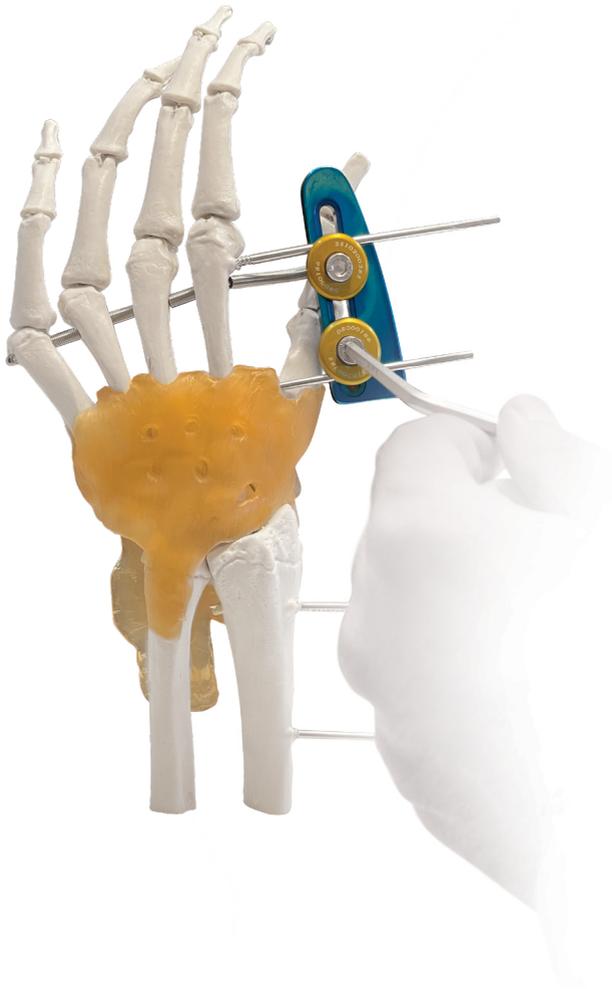
After setting up the operation room (supine positioning of patient, control of C-arm for correct imaging during surgery) preparation and draping will be done. The first 2.5 mm schanz pin will be inserted in the base of 2nd and 3rd metacarpals. The next pin will be inserted distal and parallel to the first pin only in 2nd metacarpal. The first proximal pin is inserted 2 centimeters proximal to fracture line perpendicular to radius alignment from radial to ulnar side. The last schanz will be inserted parallel to the previous pin with a distance of 3 to 5 centimeters to it.



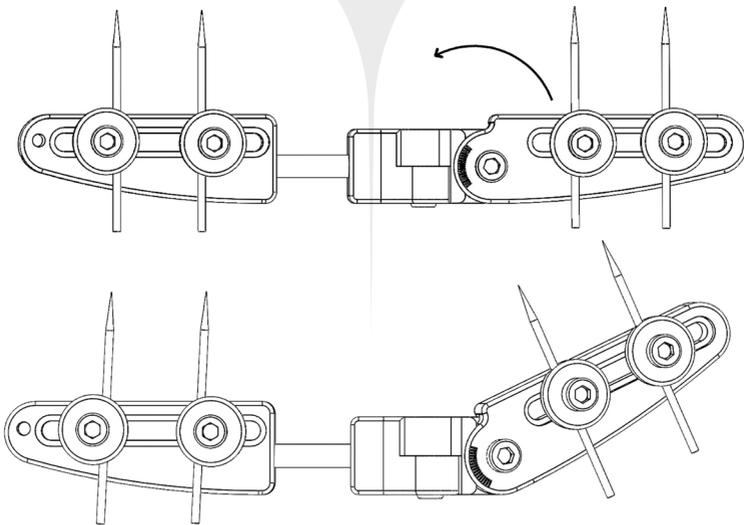
After loosening the distractor rod screw with appropriate screw-driver, the metacarpal plate was detached from the body.



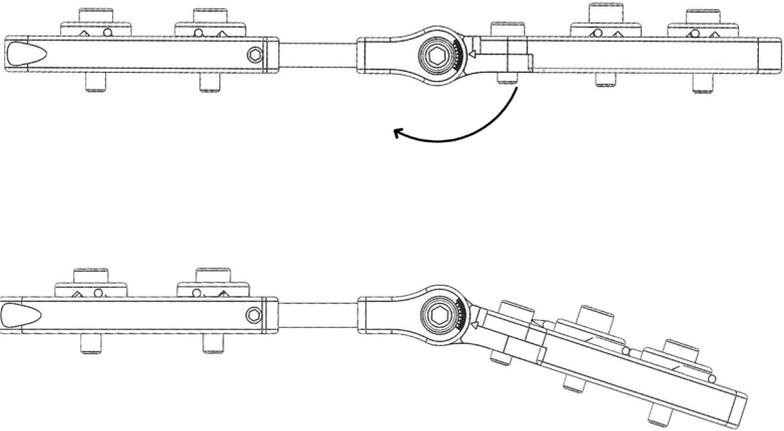
Schanz pins will be fixed to clamp system of the metacarpal plate three centimeters far from the skin.



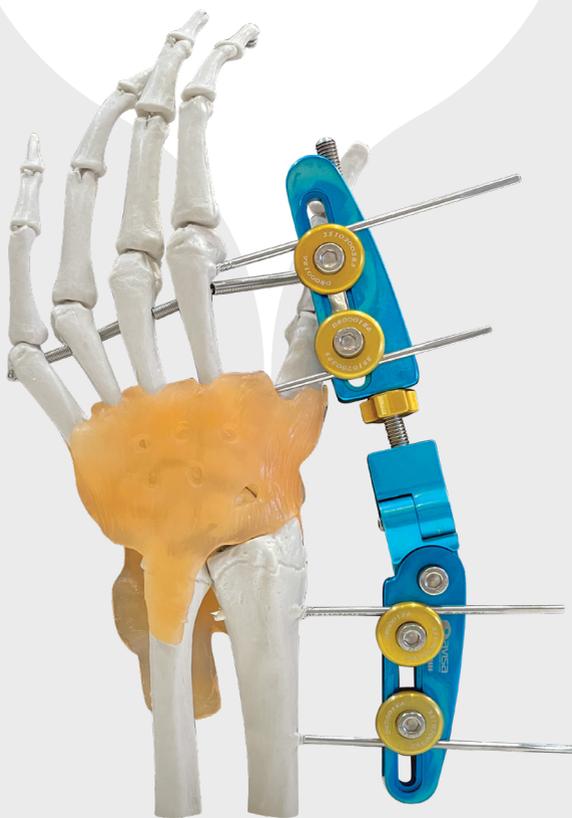
The external fixator contains two joints. The proximal joint moves along coronal plan and help to reduce radial inclination. The distal joint moves along sagittal plan and help in reduction of palmar tilt.



Proximal and distal joints will be adjusted according to radial inclination and palmar tilt of normal side, respectively and tighten with appropriate screw driver.

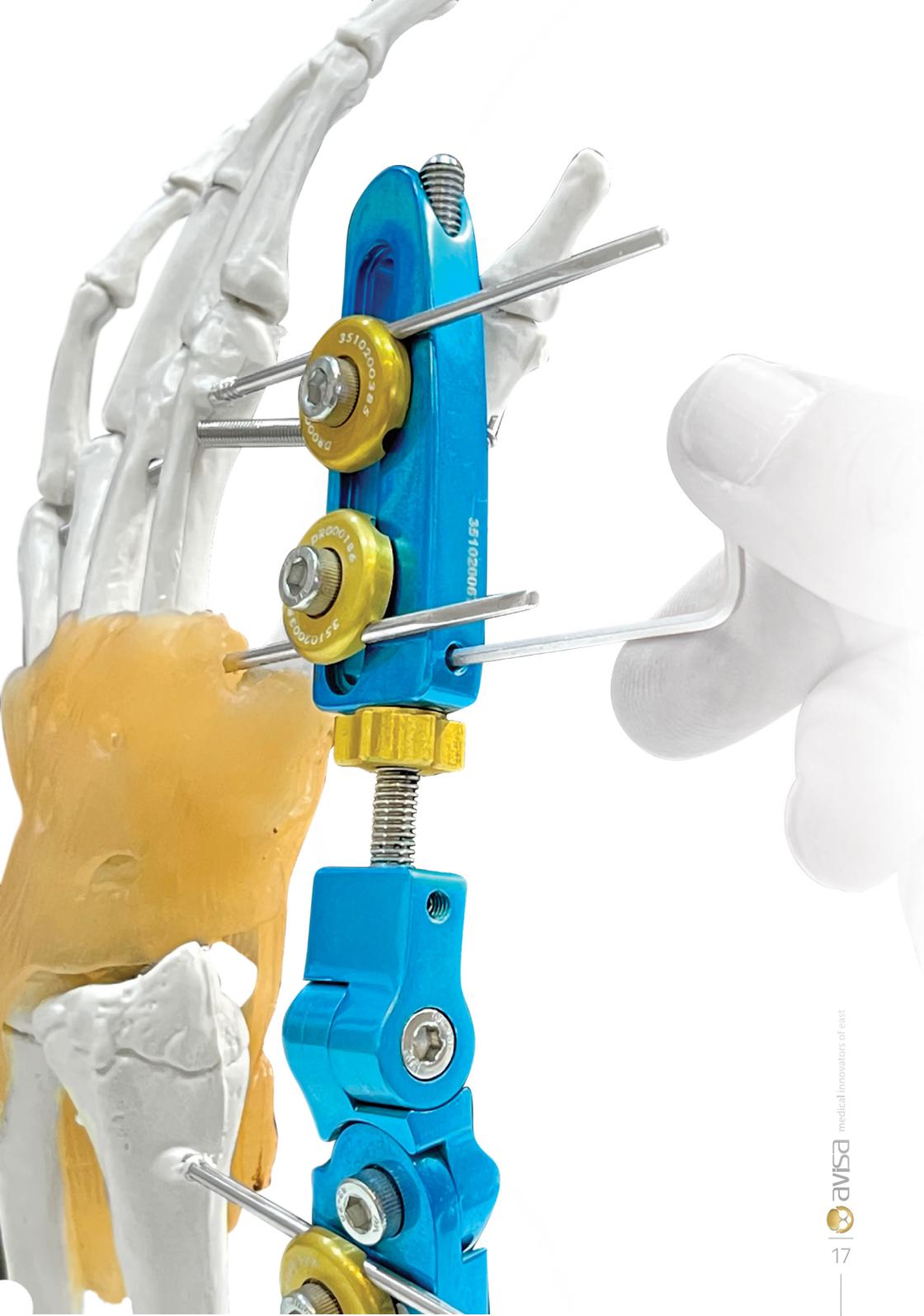


The default values of palmar tilt and radial inclination are 11 and 23 degrees, respectively. We can use the intact side radiographs as well. After adjusting the angles and tightening the related screw, the distractor rod is inserted to the metacarpal plate and the radius clamps are fixed to two proximal schanzes.



With turning the distractor rod nut right wise, you can get the desire tension between proximal and distal schanzes.





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Dynamic Distractor External Fixator

information

The above-mentioned disassembly is a medium-sized and small-sized external fixator. This device can be used for fingers, metacarpals, forearms, arms and all long bones. This is an external fixator for bone lengthening or for joint distraction.

Other applications of this external fixator are similar to other external fixators, such as open fractures and the inability to use the internal fixator. This device is externally used and indicated for bone lengthening and joint distraction.

This device acts like other external fixators and is used outside the body.

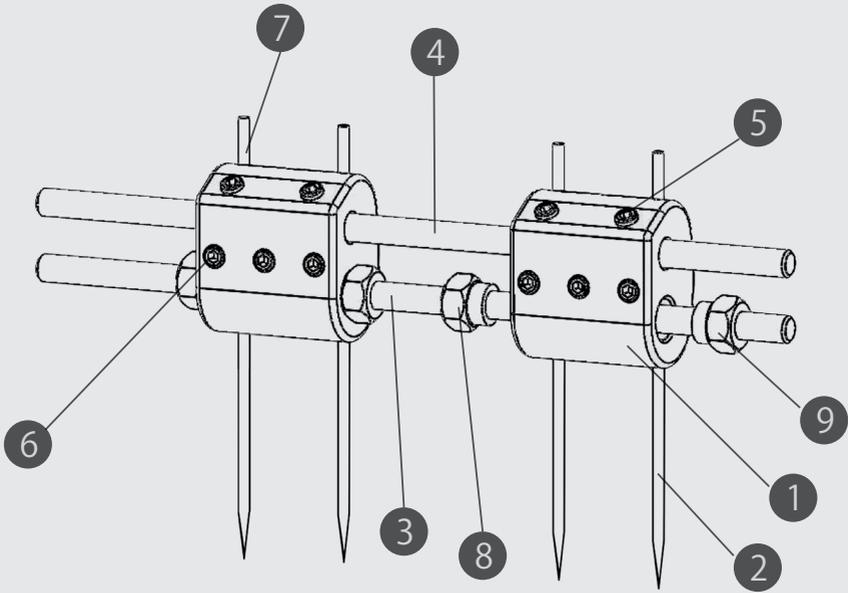
In summary, the product application includes:

1. Bone lengthening and bone shortening
2. Joint spanning especially in old dislocations
3. Similar to other external fixator indications such as open fractures and when internal fixation is impossible.

Tips and tricks

Tips and tricks for application:

- It is mandatory to sterile the external fixator before surgery.
- Four 2.5*150 mm schanzes, perforator and insertion instrument set are necessary for surgery.
- Schanz insertion precautions like predrilling is necessary
- Fluoroscopy is necessary to verify the operation.

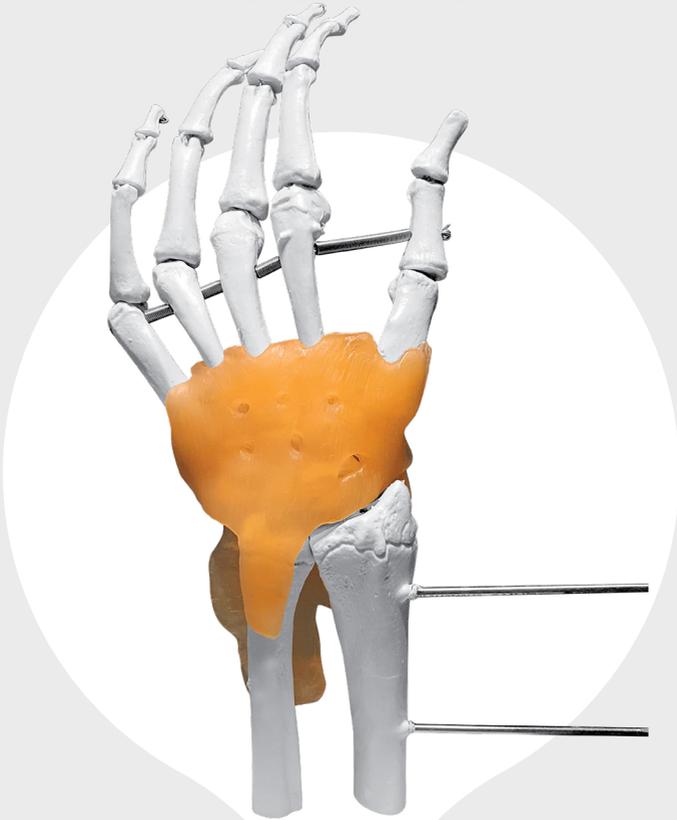


Dynamic Distractor External Fixator components:

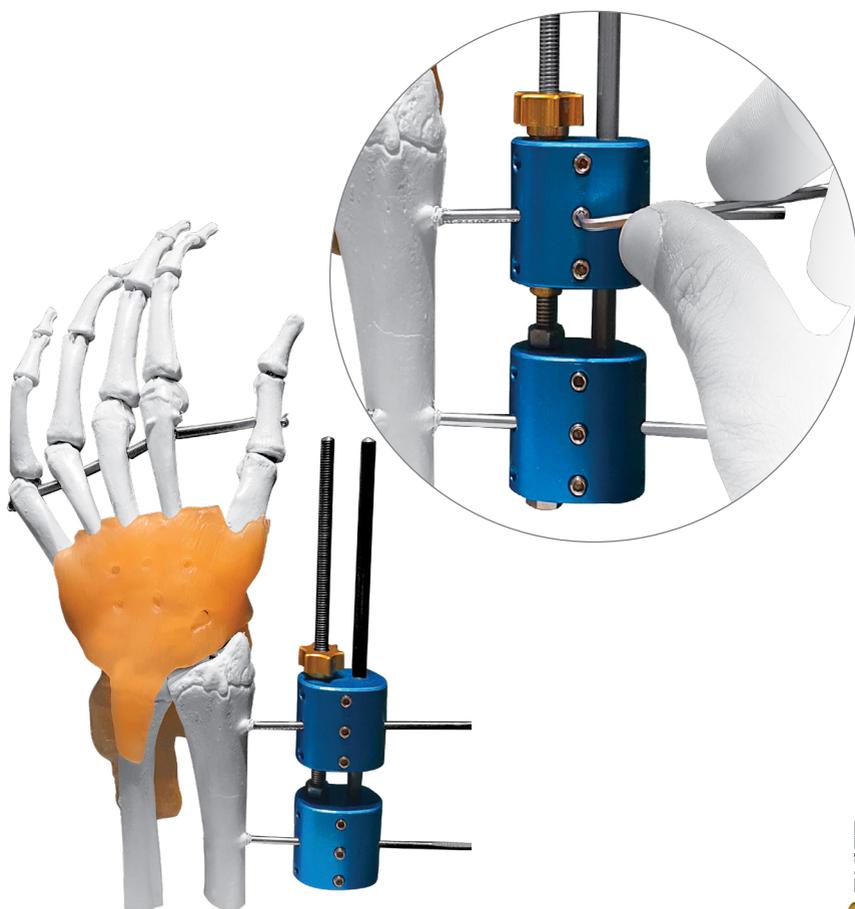
- | | |
|-------------------------|----------------------|
| 1. Clamp | 6. Schanz set screw |
| 2. Schanzes | 7. Schanz Inlet hole |
| 3. Threaded rod | 8. Distracting nut |
| 4. Non-threaded rod | 9. Clamp fixing nut |
| 5. Non-threaded rod set | |

Product placement:

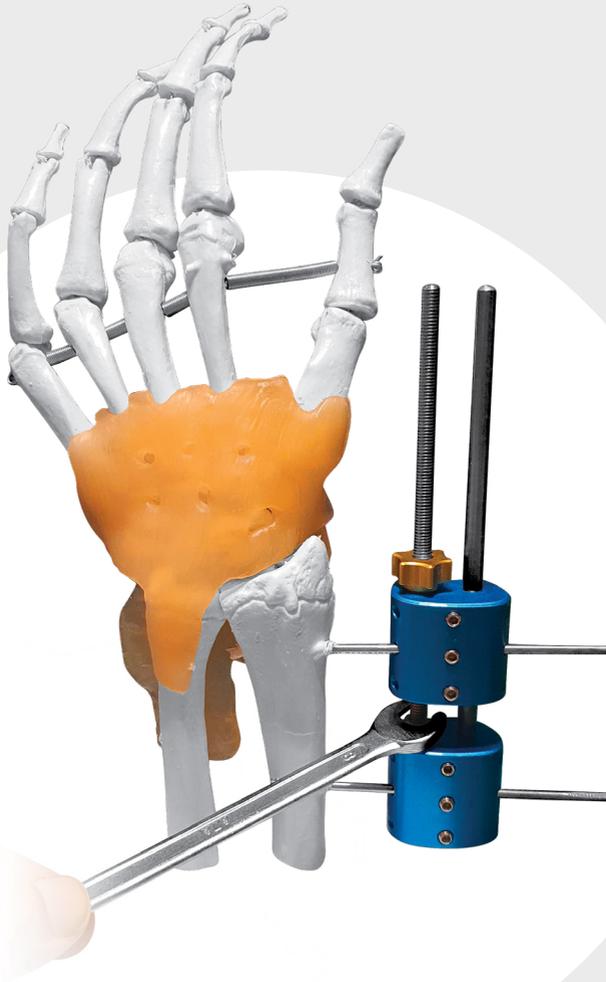
First, insert two Sschanzes are placed parallel to each other and pass through both cortices in the shortest possible distance from the next later osteotomy site (about 2 cm away from the site of the osteotomy), which affects both the cortex.



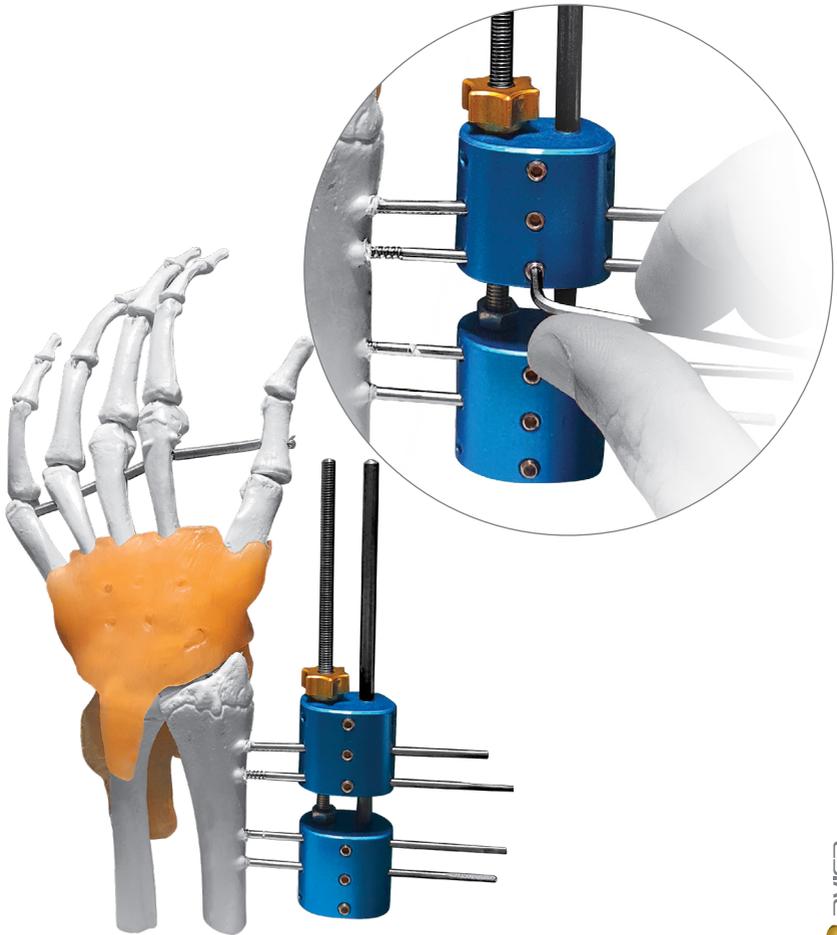
Insert the schanzes from the inner inlet of the schanz in the distal and proximal clamps, after adjusting the span of the two clamps from each other by means of distracting nut and clamp fixing nut. Fix the schanzes 2 cm from the skin with schanz set screws

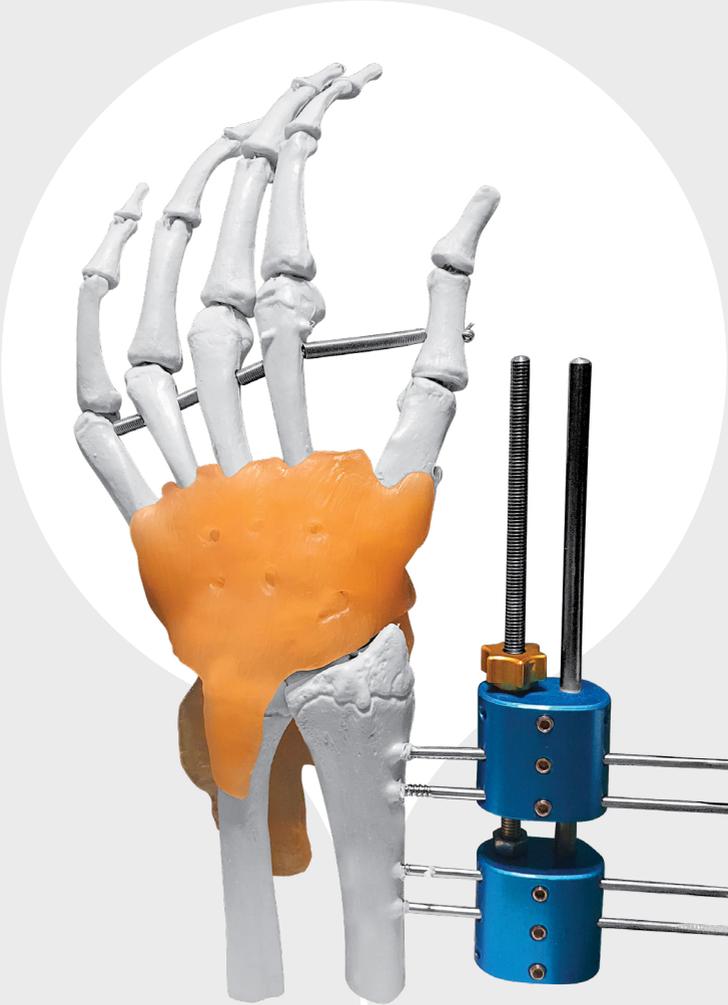


Tighten the nuts of the fix clamp.

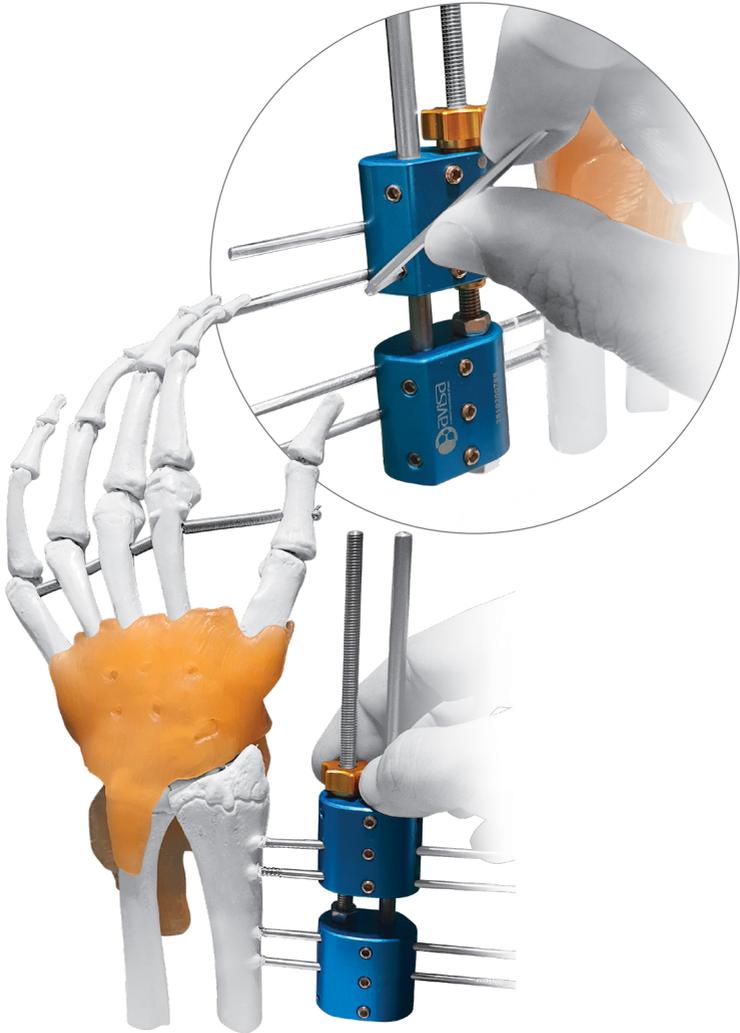


With respect to the bone and the location of the osteotomy we add at least one other schanz to each clamp.



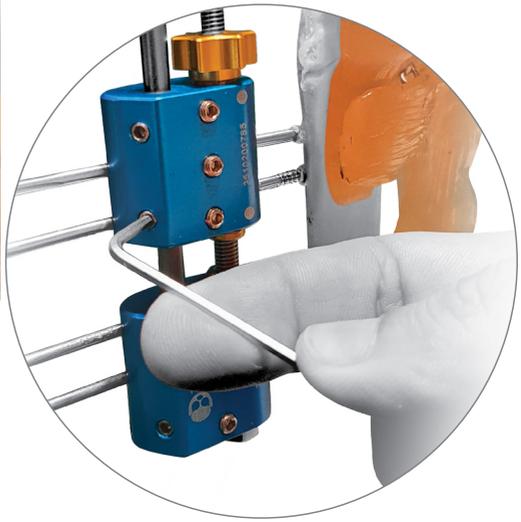
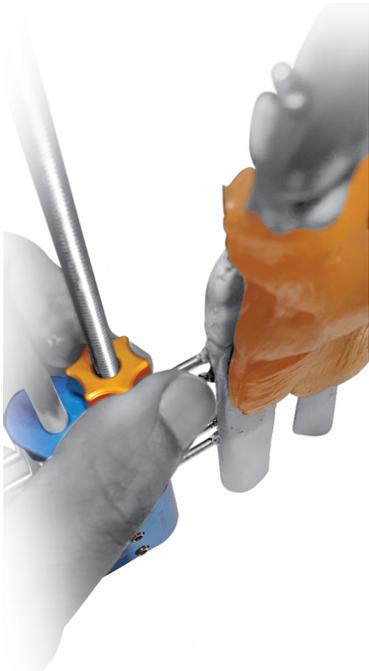


Then we perform osteotomy.



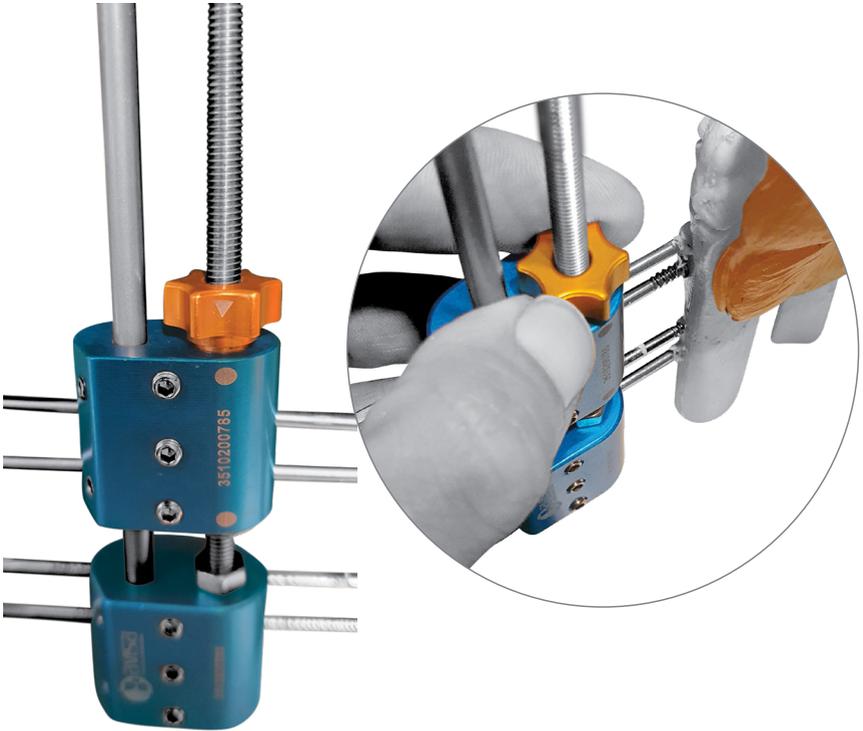
Loose the clamp fixing nut a few rounds and then tighten the distracting nut to ensure that the osteotomy site is distracting.

After one to two weeks from osteotomy, for daily distraction, first loose the non-threaded rod set screw.



Then compress the location of the osteotomy by tightening the distracting nut. Then we tighten non-threaded rod set screw

Tighten non-threaded rod set screw and the above routine be continued daily until optimal distraction.



Turn round the distracting nut one round until the clamp marker and distracting nut marker face to each other.



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Dynamic Hinged Elbow External Fixator

information

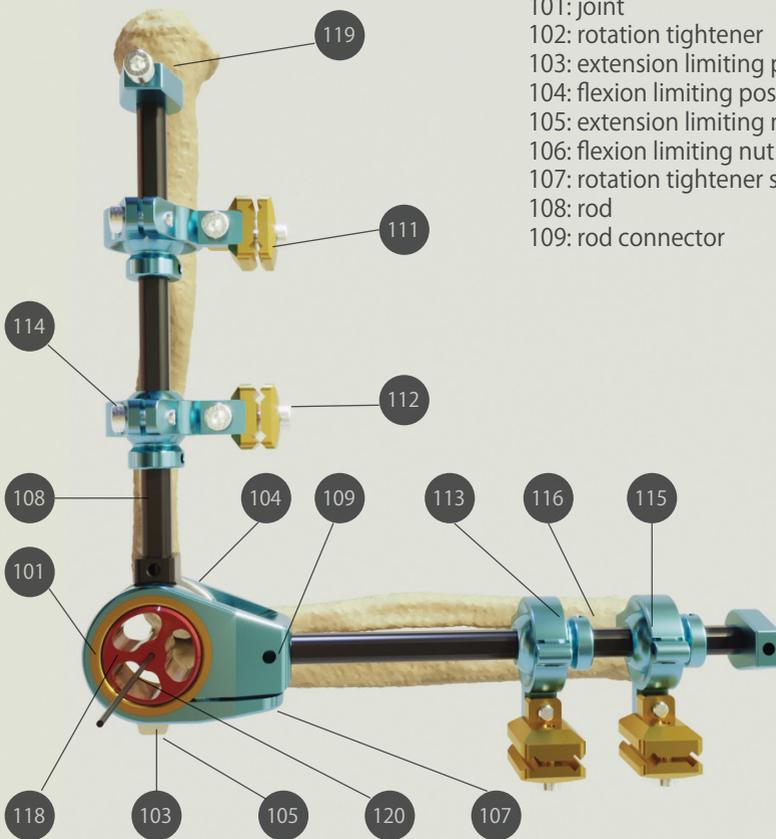
Complex elbow fractures and dislocations are most important traumatic injuries in elbow region with some treatment challenges. In complex elbow injuries it is not possible to address and treat all injured elements. So, elbow instability is a true concern after most surgical treatments in complex elbow injuries. Inherent instability of injured elbow may lead to fixation failure or excessive forces on reduced and fixed constructs. It is necessary to off-load the injured joint during healing phase. The best option to protect the elbow after complex injuries are hinged elbow external fixators. It is connected to upper limb by some schanz screws inserted in humerus and ulnar bones. Alignment of elbow axis of flexion-extension with fixator pivot is necessary to off-load the joint. Dynamic hinged elbow external fixator provides the surgeon to insert schanz screw in any desired direction without any concern about the alignment of other screws. Dynamic hinged elbow external fixator offers progressive active rehabilitation protocols with adjustable tightening of pivot part.

Tips and tricks

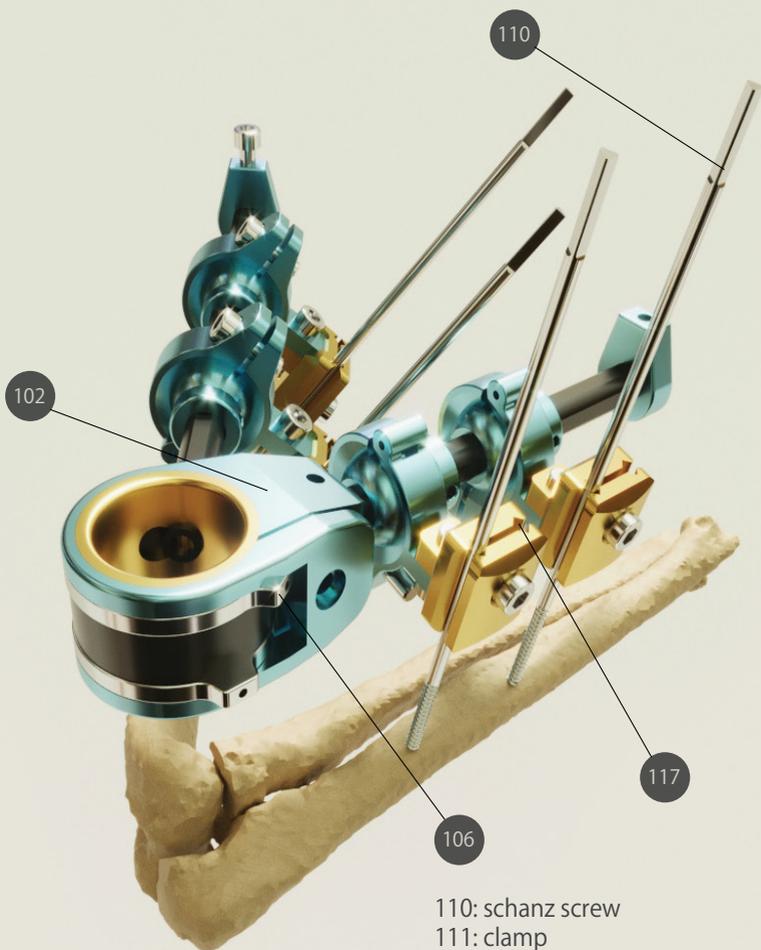
Tips and tricks for application:

- It is mandatory to sterile the external fixator before surgery.
 - Three 4*200 mm schanzes, three 3*200mm schanzes, perforator and insertion instrument set are necessary for surgery.
 - Schanz insertion precautions like predrilling is necessary
 - Fluoroscopy is necessary to verify the operation.
 - It is mandatory to align the axis of elbow flexion-extension with pivot line
- Dynamic Hinged Elbow External Fixator

External fixator components



- 101: joint
- 102: rotation tightener
- 103: extension limiting post
- 104: flexion limiting post
- 105: extension limiting nut
- 106: flexion limiting nut
- 107: rotation tightener screw
- 108: rod
- 109: rod connector

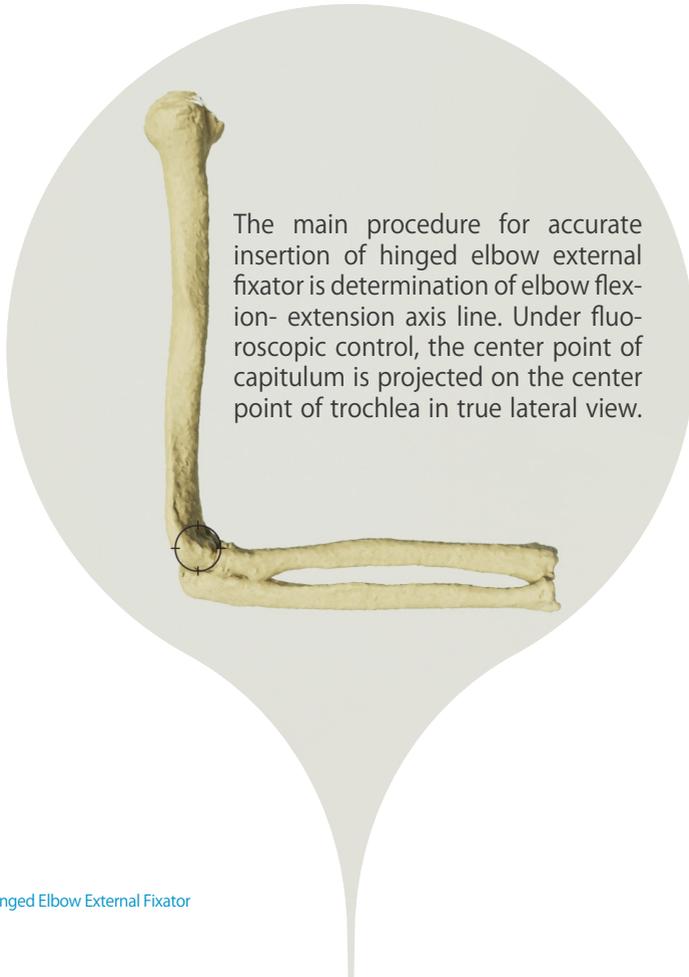


- 110: schanz screw
- 111: clamp
- 112: clamp adjustment screw
- 113: clamp positioner
- 114: clamp position screw
- 115: clamp-rod connector
- 116: clamp-rod connector screw
- 117: schanz sleeve
- 118: pivot jig
- 119: rod end limiter
- 120: axial guide pin

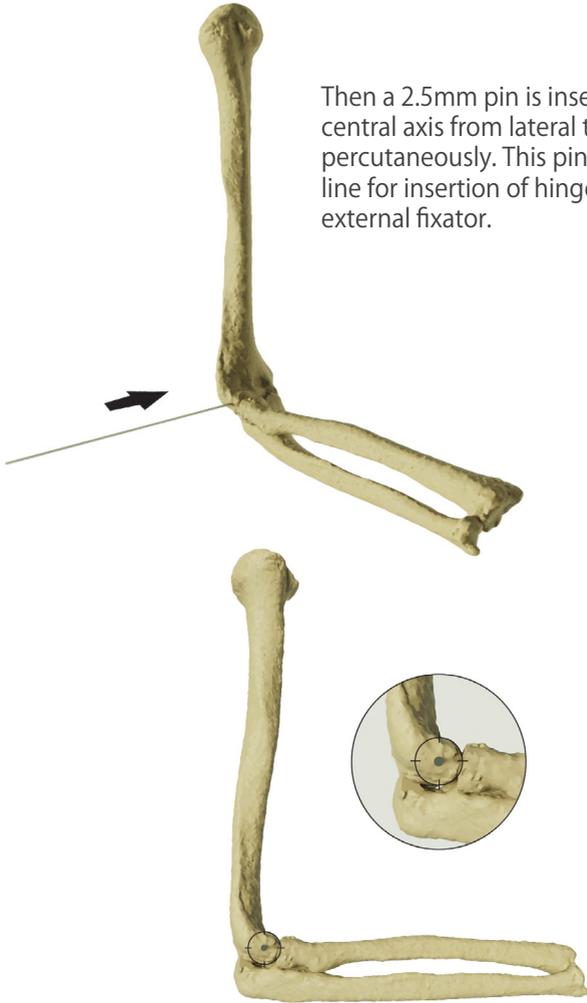
The best function of dynamic hinged elbow external fixator can be expected when the axis of elbow rotation is matched with fixator pivot of rotation. This super-imposed alignment provides the joint surface to off-load from physiologic forces during flexion and extension movements.

Dynamic Hinged Elbow External Fixator insertion

After setting up the operation room (supine positioning of patient, control of C-arm for correct imaging during surgery) preparation and draping will be done. Most cases are scheduled for hinged external fixator insertion at the end of surgical repair of complex elbow fractures or dislocations.

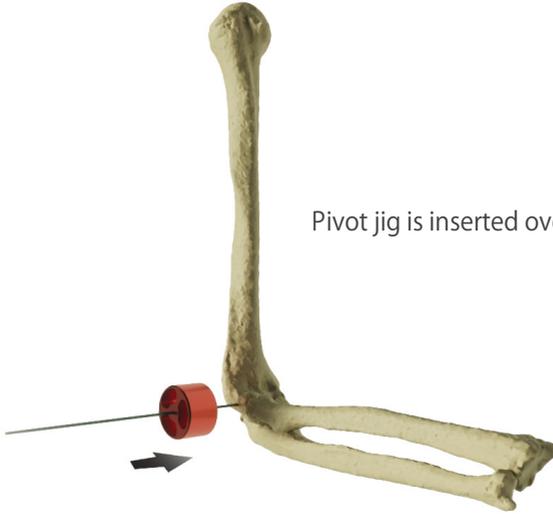


Then a 2.5mm pin is inserted in this central axis from lateral to medial, percutaneously. This pin is the pivot line for insertion of hinged elbow external fixator.



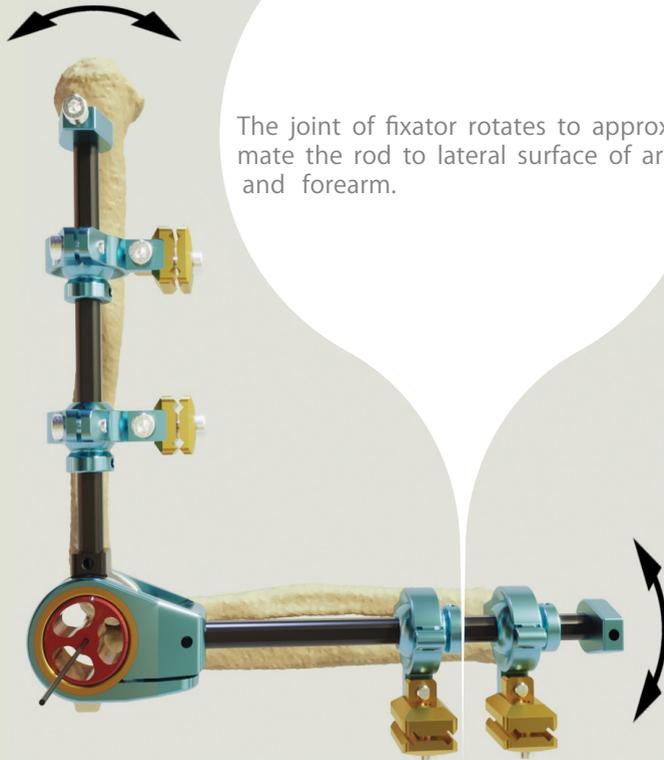
Now, in true lateral view the pin resembles a dot in the center point of elbow flexion – extension axis.

Pivot jig is inserted over pivot axial pin.



Then prefabricated hinged elbow external fixator is aligned over pivot jig.



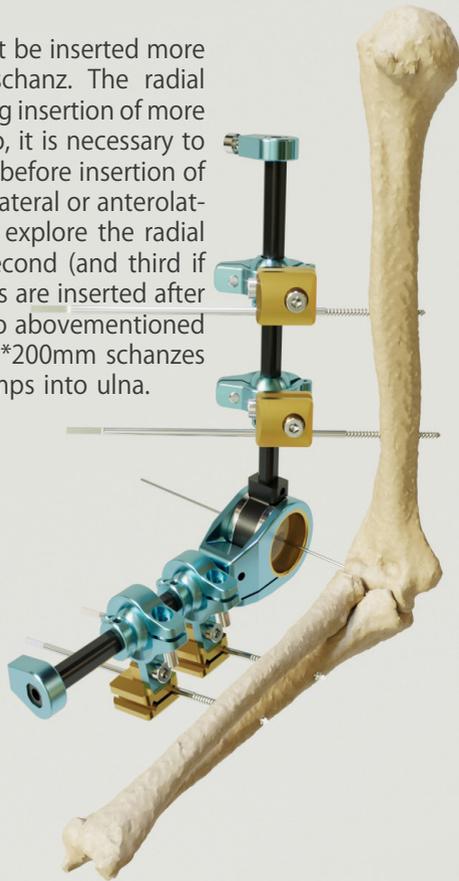


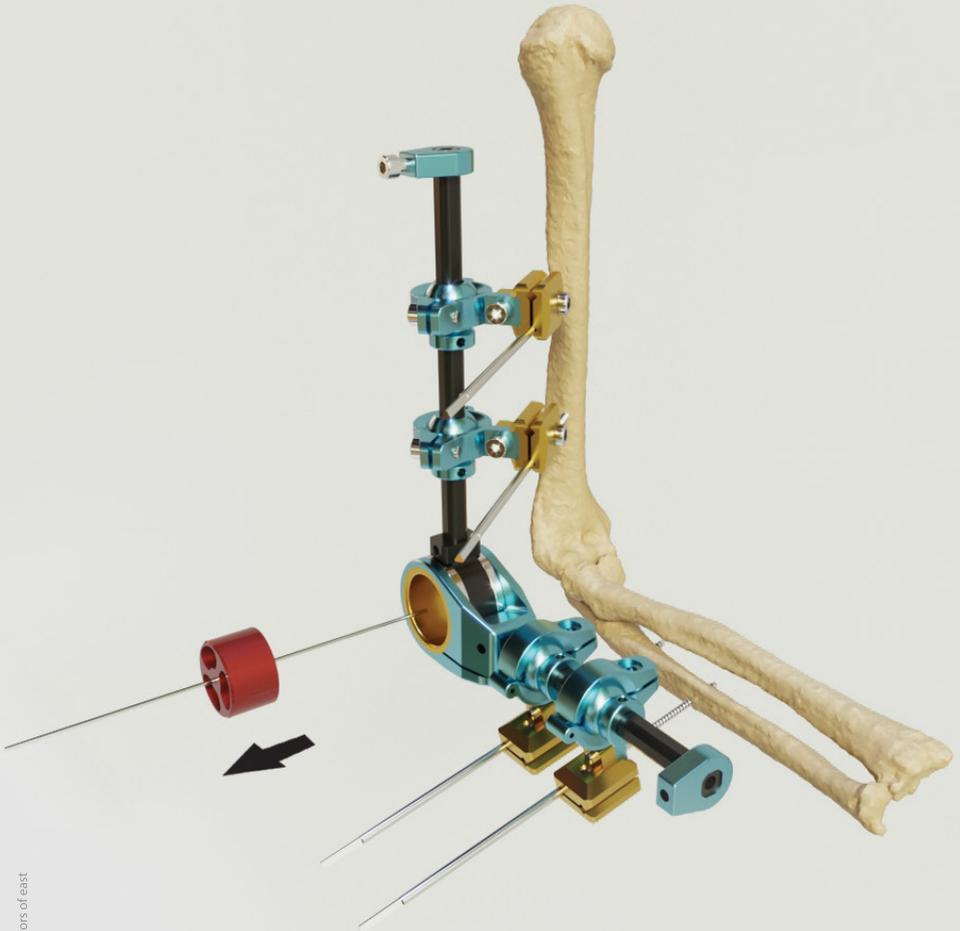
The joint of fixator rotates to approximate the rod to lateral surface of arm and forearm.

The location of first schanz pin is selected in distal arm region. Stab wound is made with scalpel no 11. one sleeve is adjusted from distal clamp to stab wound to drill the distal humerus with a 3.2mm drill bit. After predrilling of distal humerus, one 4*200 mm schanz screw with bi-cortical purchase is inserted under the guidance of sleeve.

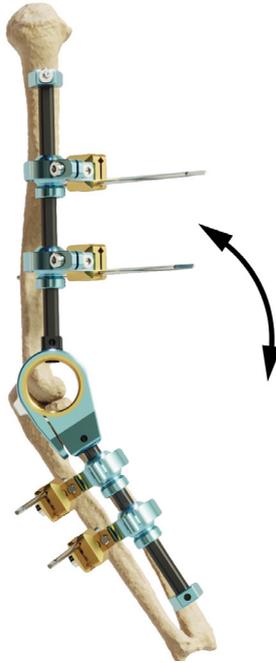


The other schanzes must be inserted more proximal to this first schanz. The radial nerve is vulnerable during insertion of more proximal schanz pins. So, it is necessary to explore the radial nerve before insertion of proximal schanzes. The lateral or anterolateral incision is made to explore the radial nerve. After that, the second (and third if necessary) schanz screws are inserted after predrilling step similar to abovementioned method. Two or three 3*200mm schanzes inserted from distal clamps into ulna.

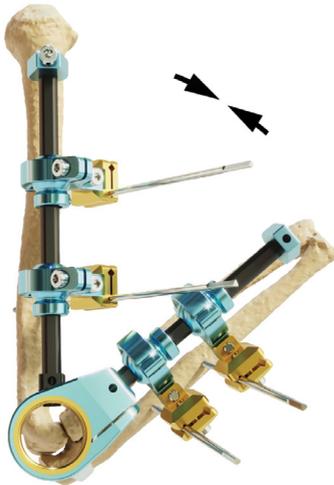


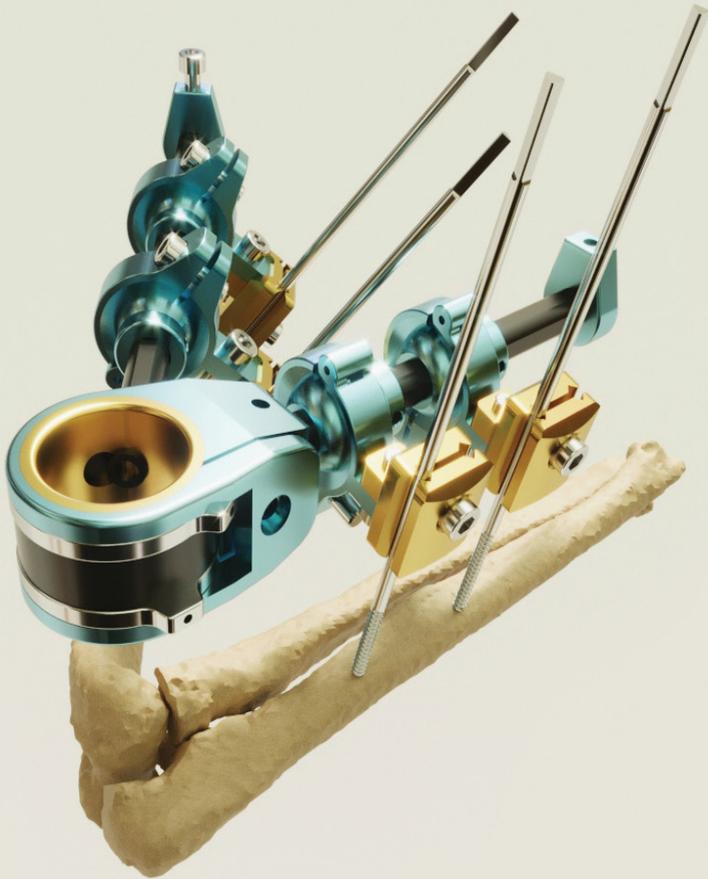


Finally, Pivot jig is removed from fixator joint. The elbow range of motion is started. Congruency of elbow joint during motion is evaluated.



Finally, elbow range of motion performed. As the axis of rotation of hinged elbow external fixator aligned with true flexion-extension axis, congruent elbow motion anticipated.





It is possible to limit the range of flexion or extension. Flexion or extension limiting posts are fixed in desired angles to limit the range of motion, if necessary.

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Dynamic Hip External Fixator

information

Hip fractures especially intertrochantric fractures are among the most common fractures in elderly population. Due to comorbidities such as diabetes, cardiovascular diseases or hypertension, the risk of perioperative mortality rate is high. Open reduction and internal fixation that is known as the gold standard for treatment of such fractures leads to more bleeding during operation and elevated risk of surgery. Decreased compliance of old patients with such medical morbidities make the fatal complications inevitable. So, most surgeons hesitate to do open surgeries.

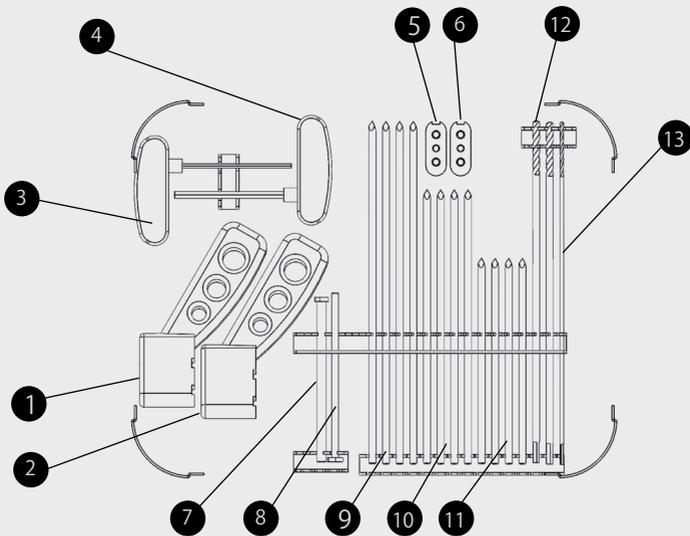
Most patients will be the candidates for non-operative treatment with several complications like thromboembolism, bed sore, malunion or death. The best solution to deal with this scenario is external fixation. We developed the “Dynamic Hip External Fixator (DHEF)” to overcome this complicated situation.

“Dynamic Hip External Fixator” will be inserted with a sedation or local anesthesia. Dynamic sliding part of apparatus provides us the compression of fracture externally.

Tips and tricks

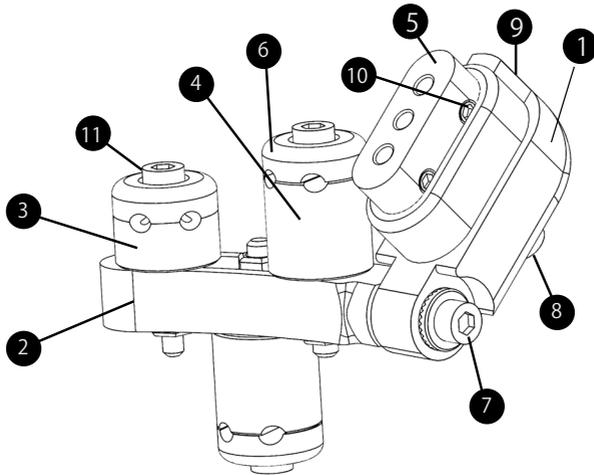
Tips and tricks for application:

- It is mandatory to sterile the DHEF before surgery.
- “Dynamic Hip External Fixator” is pre-fabricated for treatment of right sided fractures. Flipping of half-ring makes it suitable for left sided fractures
- Two 250*5 mm schanzes, three 150*5 mm schanzes, 3.2mm drill bit, perforator and insertion instrument set are necessary for surgery.
- Schanz insertion precautions such as predrilling is necessary
- Short schanz hole is used in cases with short femoral neck diameter.
- The patient will be operated on fracture table like conventional method of fracture fixation with DHS.
- Fluoroscopy is necessary to verify the operation.
- Traction on operated leg should be released to achieve compression during fastening the sliding head.



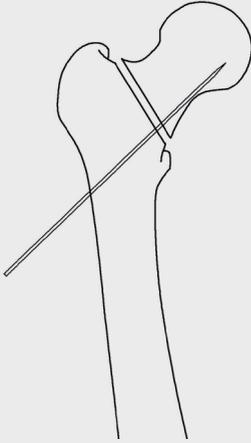
Insertion set components:

- | | |
|-------------------------|-------------------|
| 1- 20 mm distance jig | 8- Thin sleeve |
| 2- 16 mm distance jig | 9- Schanz 250*50 |
| 3- Small screw driver | 10- Schanz 200*50 |
| 4- Large screw driver | 11- Schanz 150*50 |
| 5- Sliding core (20 mm) | 12- Drill bit 3.2 |
| 6- Sliding core (16 mm) | 13- pin |
| 7- Thick sleeve | |



Dynamic Hip External Fixator components:

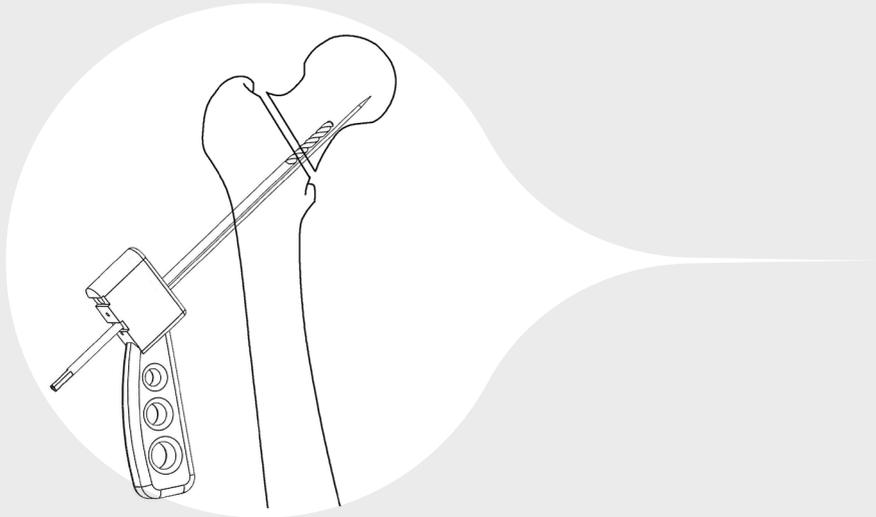
- 1- Head
- 2- Semi-lunar part
- 3- Short rod
- 4- Long rod
- 5- Sliding core
- 6- Pulley
- 7- Semi-lunar part-head connecting screw
- 8- Compression screw
- 9- Above the head screw
- 10- Nutting screw
- 11- Rod screw



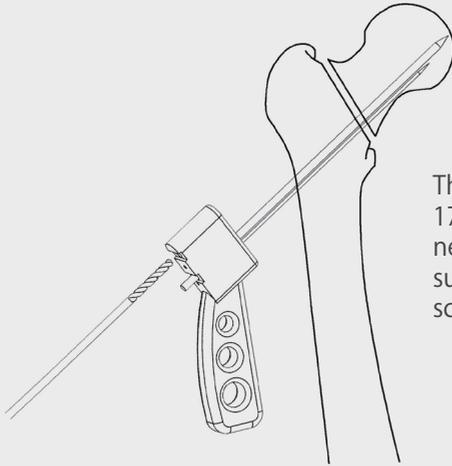
DHEF insertion

After setting up the operation room (patient transport to fracture table, control of C-arm for correct imaging during surgery and closed reduction maneuvers) preparation and draping will be done.

One 20mm Steinmann pin will be inserted percutaneously just superior to inferior calcar region angled between 120-150 degrees under fluoroscopic control. It is better that pin will be suited in center of femoral neck under lateral view of fluoroscopy.



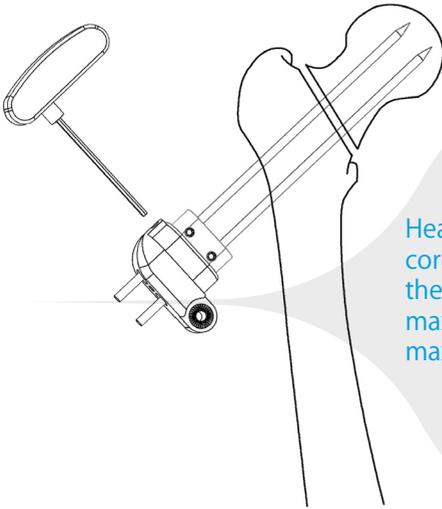
The pin should be passes through the pin hole in inferior site of the jig. Predrilling through inferior schanz hole should be performed with 3.2mm drill bit. Then, a 250*5mm schanz pin is inserted up to 5 mm to articular surface of femoral head.



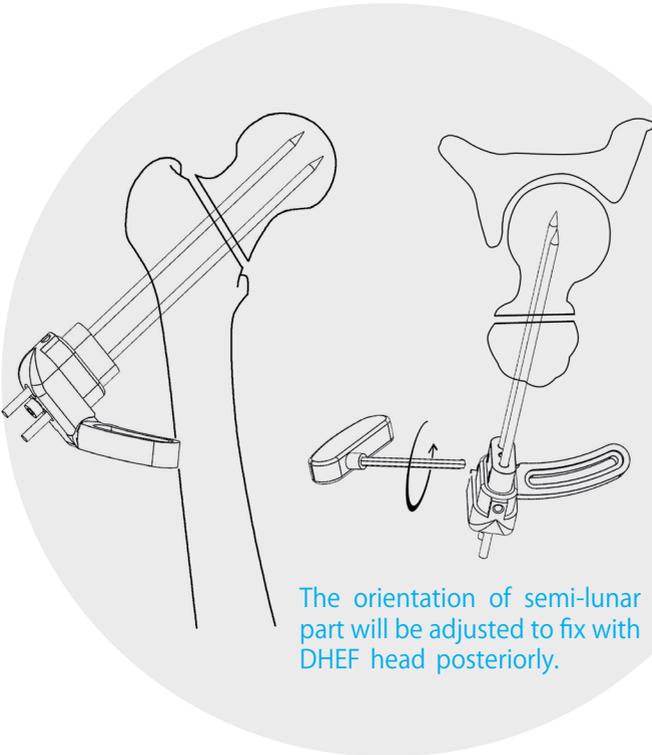
The surgeon can select sliding core of 17mm or 20 mm depends on femoral neck diameter. The suitable jig helps the surgeon to predrill and insert the next schanz pin.



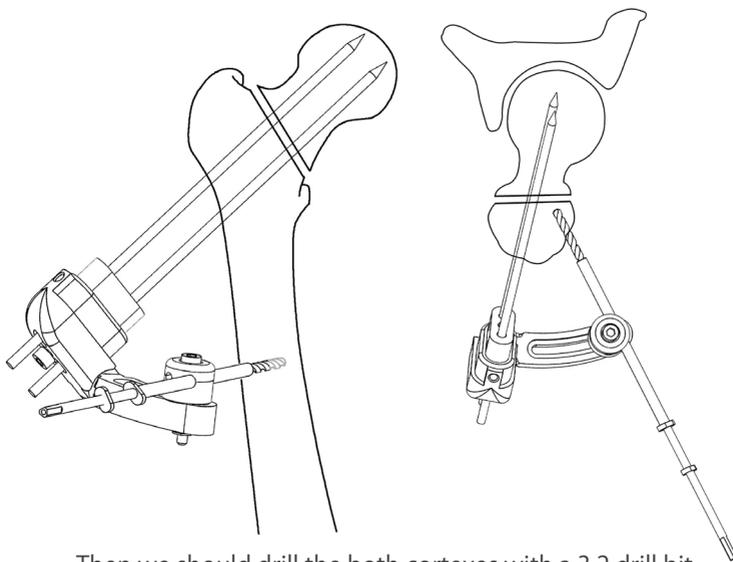
Nutting screws can tighten sliding core over schanz pins 5-7 centimeters close to skin.



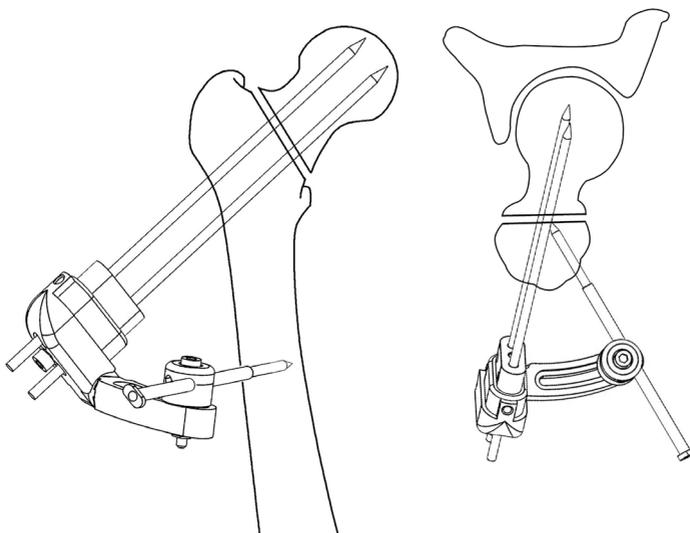
Head of DHEF will be suited over sliding core. Fixing screw above the head fixes the sliding core within DHEF head with maximal allowed distance to permit maximal compression at fracture line.



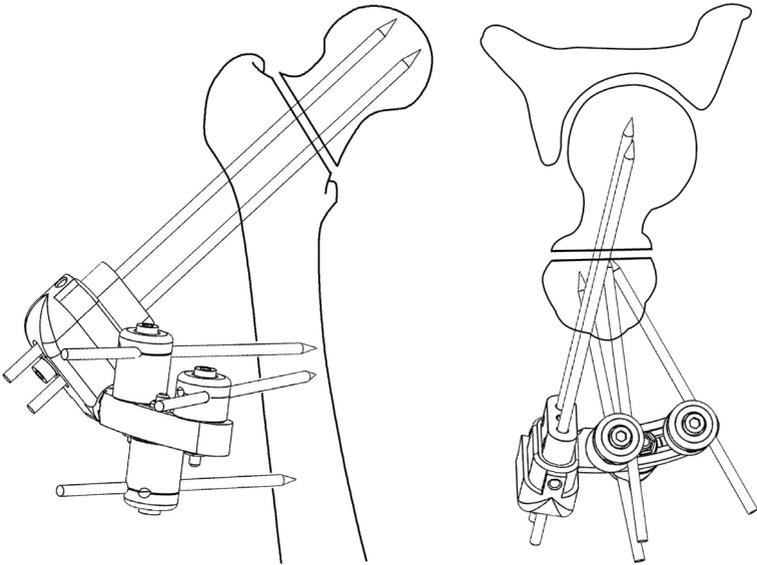
The orientation of semi-lunar part will be adjusted to fix with DHEF head posteriorly.



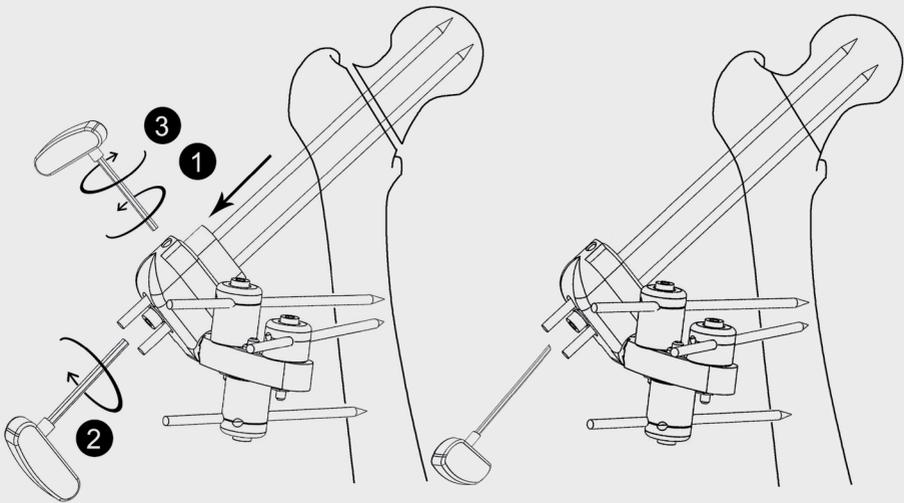
Then we should drill the both cortexes with a 3.2 drill bit.



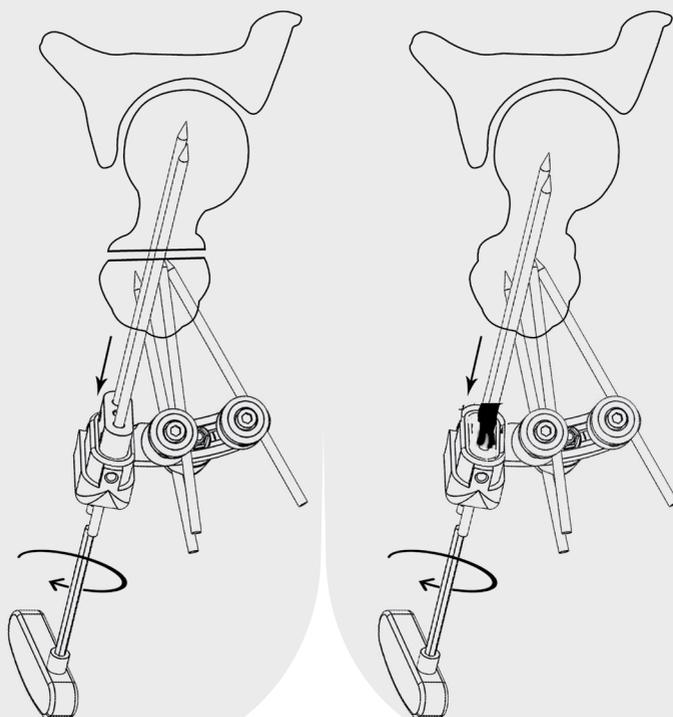
After removal of the thinner sleeve and the drill bit, we can place the 5*150 schanz.



We will do the same for other rods.



To compress the fracture line, traction from leg will be released. Then tightening the compression screw will pull the sliding core into DHEF head and compress the femoral neck into trochanteric metaphyseal bone.



Tightening the nut screw will fix the position of sliding core in head. Compressive dressing around pins will be applied. Finally, the patient transferred to recovery room.

Gait training with walker started the day after surgery. The protocol of partial weight bearing is toe-touch weight bearing with walker until radiographic and clinical union. Compressive dressing should change daily. Nut screw can be released two weeks after surgery to allow more dynamic compression in patient who able to walk. For non-ambulatory patients, we get compression with tightening of the compression screw at this time. Estimated time to achieve radiologic union is about 2.5 months in ambulatory patients and 3.5 months in non-ambulatories. External fixator will be removed after union.



Dynamic Universal External Fixator

information

Universal external fixators consist of four parts: Schanz, Rod, schanz to rod clamp and Rod to rod clamp. Avisamediacal produced the universal external fixator in two sizes: small and large. Small size is appropriate for forearm fractures and the large size is for arm, leg and etc.

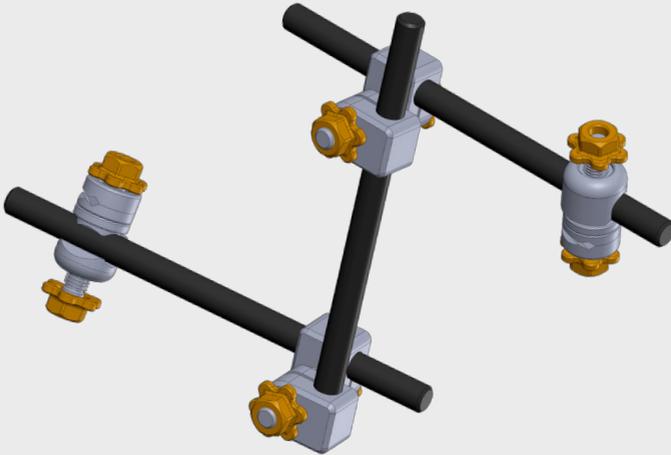
Tips and tricks

Tips and tricks for application:

- It is mandatory to sterile the DUEF before surgery.
- Schanz insertion precautions such as predrilling is necessary

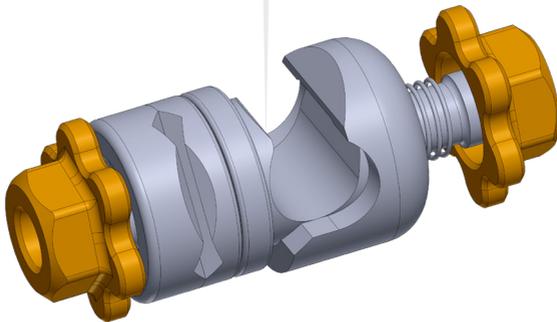
Schanz screws:

- Schanz screws are available in different diameters of 2, 2.5, 3, 4 and 5 millimeters
- The schanz are available in both simple and Hydroxyapatite coated forms.



Pin to rod clamps:

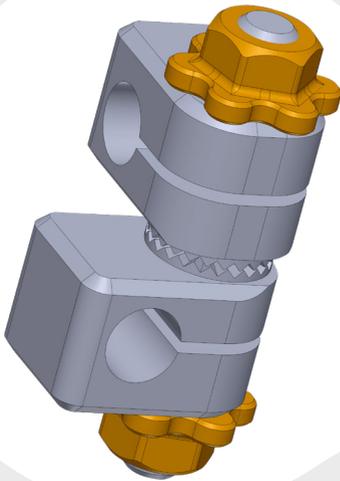
- The pin to rod clamps have an open structure so the surgeon can simply add it to rod in any time
- The pin to rod clamps have to sizes: small and large
- The pin to rod clamps have equipped to a small compressive spring allowing to device to catch the rod provisionally.

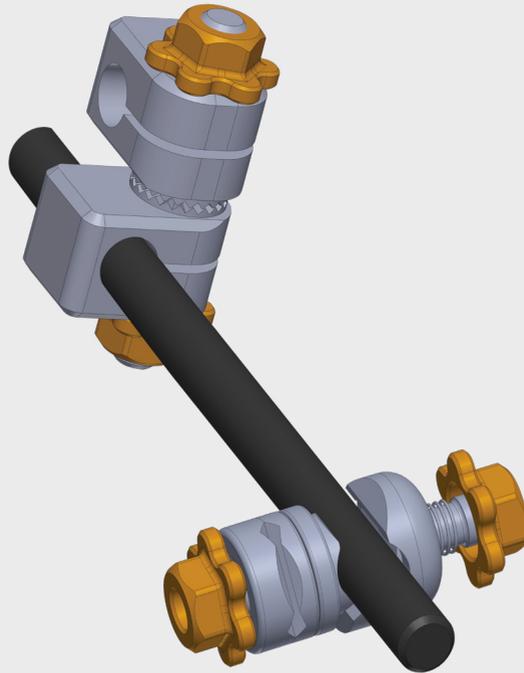


Rod to rod clamps:

The pin to rod clamps have two sizes: small and large

The pin to rod clamps allow the surgeon to set up a rod frame. The twin clamp structure locks simply with one screw.





Rods:

Rods have two sizes: small (5mm) and large diameter (20mm)
Rods have different length: 100mm, 200mm, 300mm, and 400mm.
The rods are ultra-light and made out of Carbon fibers.

More information about product

The external fixator parts will be produced in two colors in single package

- Some useful information is registered on external fixator parts with Laser marking according to ASTM F86 standards:
- Company logo
- Catalogue number(ref. no)
- Identification and tracking number (lot no)

Material Quality

Cr 0.042	Ni 0.009	Cu 0.705	Mn 0.209	Ca 0.008	Si 0.463
Mg 1.964	P 0.002	Sn 0.008	Ti 0.016	Pb 0.056	Fe 1.140
Sb 0.008	Al Rem	Zn 4.793			

Quality of materials:

External fixators are made from aluminum alloy with standard coding of ISIRI-10979 Ingredients (based on elements)

Labeling and packaging

-Label of external fixator printed in green color. Information that printed on labels are:

- name, logo and address of company
- manufacturing date
- reference number
- IMed code
- material of external fixator parts
- single-use mark
- non-sterile mark
- cautions information
- ISO 13485 2016 mark

- Label is provided in three hard copies. One label is adhered on external fixator package. Two copies are within package to attach in medical records sheet.

Sterilization

Sterilization

The product package is non-sterile. It is mandatory to sterile it before use.

Sterilization methods

Time	Method	Pressure	Temperature (C)
30 M	Steam	Normal	121
15 M	Steam	Normal	132
10 M	Steam	Pre vacuum	132

Label signs information

Sign	information
	Manufacturing Date
	Cautions Information
	Attention to the instruction
	LOT Number
	Manufacturer info
	Non-Sterile
	Reference Number
MAT	Materials
	Single Use