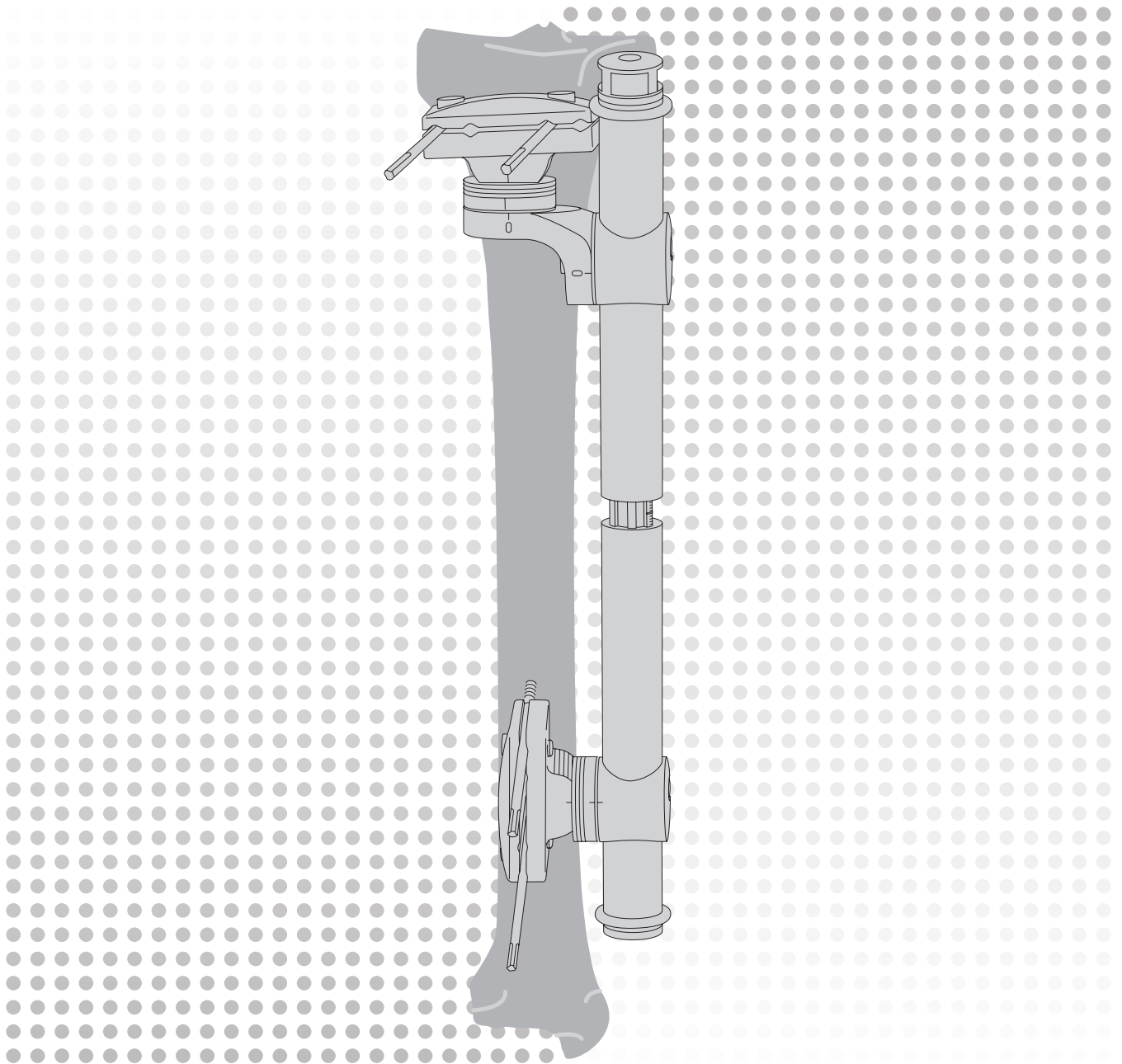


# MEFiSTO

Monolateral External Fixation System for  
Trauma and Orthopaedics

## Surgical Technique



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 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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# MEFiSTO

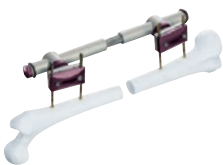
## System Description

It is light in weight, consists of only a few components, and offers compatibility with DePuy Synthes mini, medium, and large external fixators. The clamps have a clip-on, self-holding mechanism.

### Overview of available Fixator systems

	Rod Fixators External Fixation Family (clip-on)	Supplements to the External Fixation Family	Monolateral Systems MEFiSTO Systems
Large rod Ø 11 mm	 Large External Fixator	 Hybrid Ring Fixator	 Carbon fibre tube
Medium rod Ø 8 mm	 Medium External Fixator	 External Distal Radius Fixator (DRF)	
Small rod Ø 4 mm	 Small External Fixator		
Mini rod Ø 3 mm		 External Mini-Fixator	

\* MEFiSTO central body, MEFiSTO angulator, and MEFiSTO segment transport are also available.



MEFiSTO



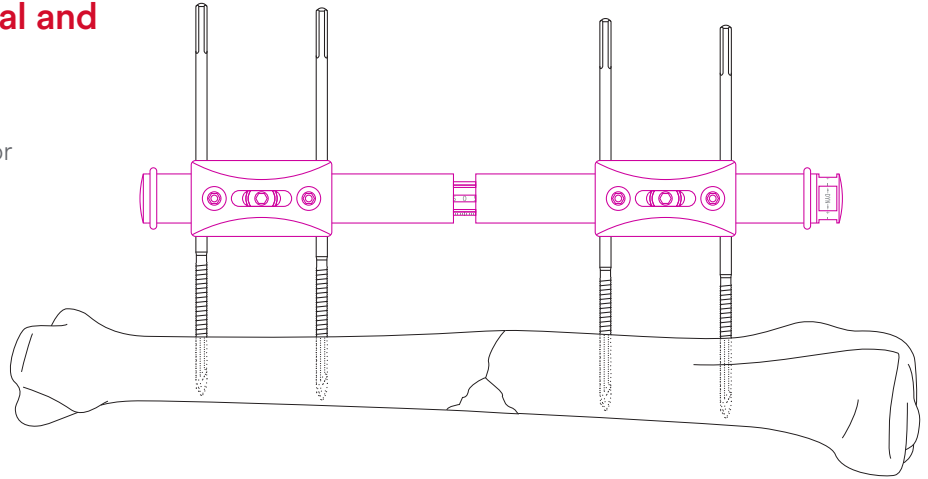
MEFiSTO Segment Transport

# Configurations

## Standard assembly for tibial and femoral fractures

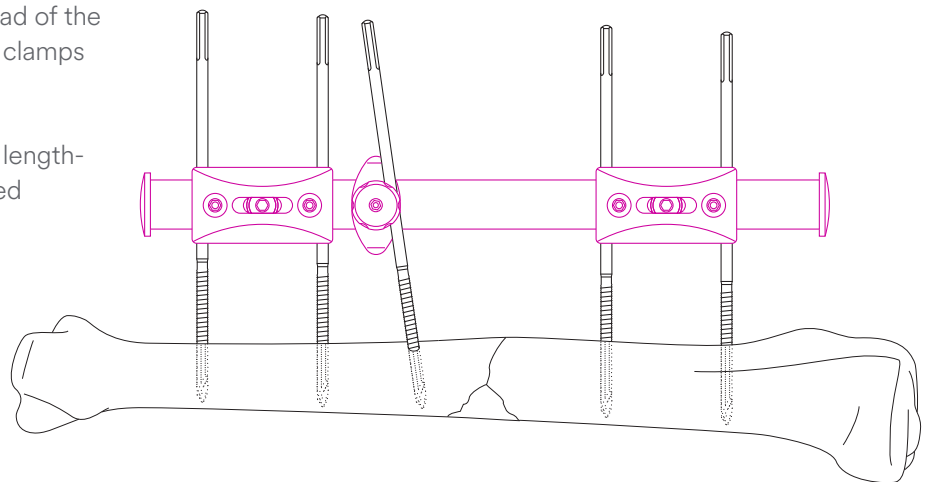
Central Body and Standard Clamps  
(assembly with standard clamps and/or  
single pin clamps)

- Dynamization up to 5 mm
- Compression/bone lengthening



A carbon fibre tube can be used instead of the  
central body (assembly with standard clamps  
and/or single pin clamps)

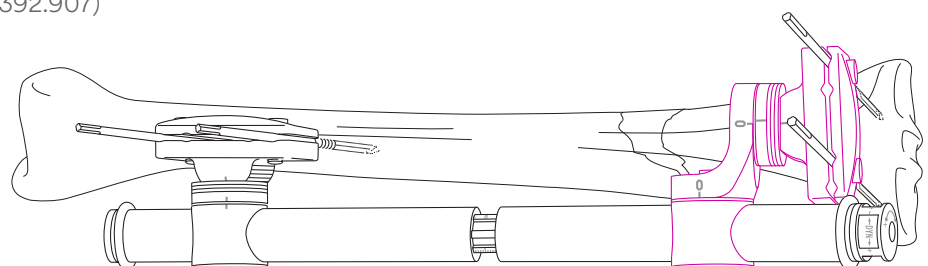
- Radiolucent
- In cases where compression, bone lengthening or dynamization is not required



## T-assembly for metaphyseal tibial fractures

Central body (or carbon fibre tube), standard clamps,  
and in addition:

- Connecting Piece for T-Assembly (392.907)
- To assemble clamps, see section “Assembly of clamps” under “Product information”

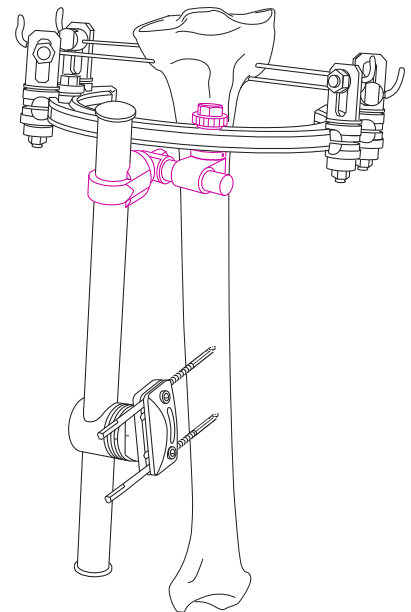


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## Hybrid ring fixation for proximal and distal tibial fractures

Central body, standard clamp, central body to ring clamp, central body to tube clamp, and in addition:

- Central Body to Ring Clamp (392.913)
- Large External Fixator in Vario Case (186.100)
- To assemble clamps, see section “Assembly of clamps” under “Product information”

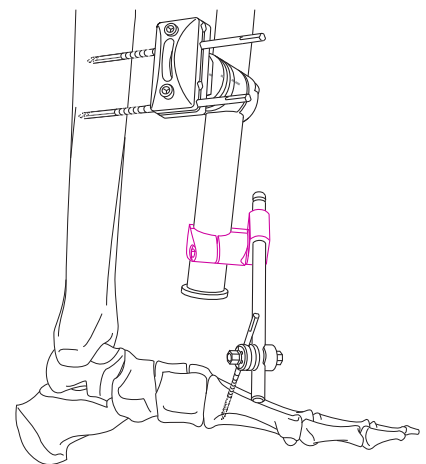


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## MEFiSTO connected to the tubular external fixator for femoral and tibial fractures

Central body (or carbon fibre tube), standard clamps, central body to tube clamp and in addition:

- Central Body to Tube Clamp (392.911)
- Large External Fixator in Vario Case (186.100)
- To assemble clamps, see section “Assembly of clamps” under “Product information”

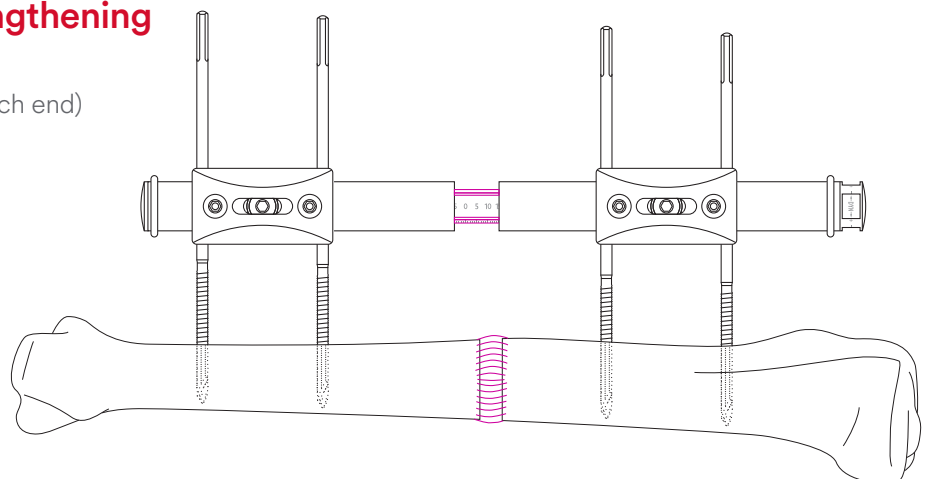


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## Tibial and femoral bone lengthening

Central body and standard clamps

- Distraction up to 15 cm (7.5 cm at each end)



# Warning

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## ▲ 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](http://www.e-ifu.com) and/or [www.depuysynthes.com/ifu](http://www.depuysynthes.com/ifu)

# The AO Principles of Fracture Management

## Mission

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

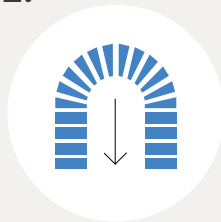
### AO Principles<sup>1,2</sup>

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

<sup>1</sup> Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3<sup>rd</sup> ed. Berlin, Heidelberg New York: Springer 1991.

<sup>2</sup> Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3<sup>rd</sup> ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.



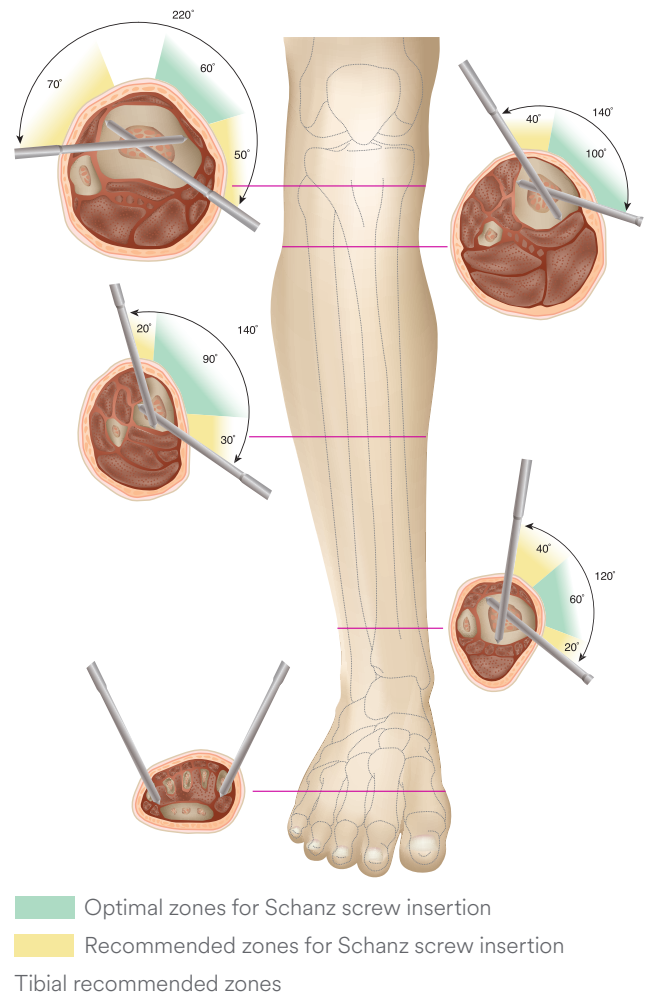
# Preoperative Planning

## Surgical approach to the tibia

The anatomy of the tibia requires particular surgical caution. The soft tissue area where Schanz screws can be inserted without injuring important structures (main vessels, nerves, muscles, and tendons) is anteromedial at the tibia. This “recommended zone” varies between an angle of 220° proximal to the tibial tubercle and 120° above the ankle joint.

Schanz screws should not be inserted in the lateral surface of the distal third of the tibia in order to avoid injury of the anterior tibial artery.

The assembly must not hinder access for initial debridement or secondary procedures such as skin transplants, sequestrectomies, bone grafts or internal fixation at a later date.



## Surgical approach to the femur

A lateral approach to the femur (within a range of about 30°) is recommended. Careful preoperative planning and care in placing the Schanz screws is also necessary.

### ▲ 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.
- Select the appropriate Schanz screw for the patient’s bony anatomy.

# Surgical and Assembly Technique

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The following technique describes only one of many assembly variations. Preoperative planning is essential for postoperative bone lengthening and/or dynamization, ensuring that the central body is aligned parallel to the longitudinal axis of the bone.

In addition to the recommended technique, there are alternatives to each step which are described in more detail under Alternative “Assembly Technique”.

## ■ Note:

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

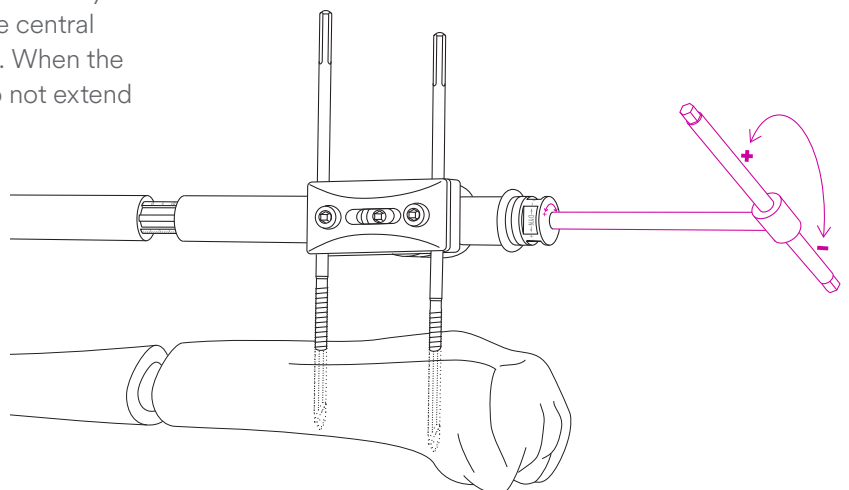
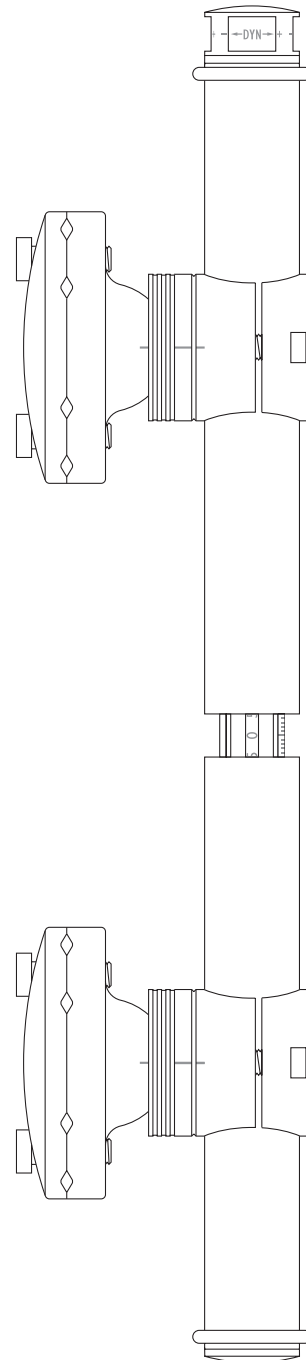
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## 1. Preassembly and adjustment of central body

Preassemble the Central Body (392.901) and two Standard Clamps (392.903) and push an O-Ring (392.925) onto each end of the central body. Make sure that the central screws for the saddle joint and the screws for the main body on the standard clamps are loose enough.

Before or after attaching the clamps, the central body is extended by at least 10 mm (5 mm at each end) to the required total length, enabling – if necessary – compression for the definitive reduction.

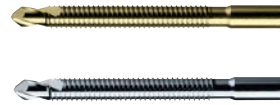
The central body is extended using the Allen Key which is inserted in the opening at the ends of the central body and turned in the direction of the + arrow. The central body can be extended by 7.5 cm at each end. When the STOP sign is reached on the splined shaft, do not extend or turn the Allen key any further.



---

## Seldrill Schanz Screws

Titanium	Stainless Steel	Diameter (mm)	Length (mm)
494.782–788	294.782–788	5.0	100–250
494.792–798	294.792–798	6.0	100–250



---

## 2. Choose Schanz screws

Choose between Seldrill Schanz screws in pure titanium (TiCP) (494.7XX) or stainless steel (294.7XX) and self-tapping Schanz screws in titanium alloy or stainless steel.

The Seldrill Schanz screw is a self-drilling screw with radial preload. Predrilling is necessary for the self-tapping Schanz screw.

As a rule, 5.0 mm Schanz screws are used for the tibia and 6.0 mm Schanz screws for the femur. The MEFiSTO clamps accept all Schanz screws with diameters from 4.0 mm to 6.0 mm.

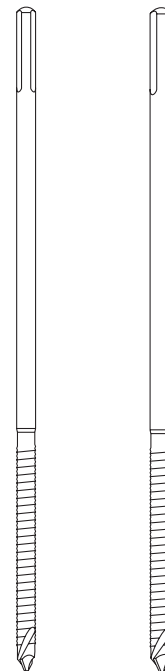
### ▲ Precautions:

- The Seldrill Schanz screw has been developed to minimise heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the Seldrill Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.

### ■ Notes:

- Less experienced users are advised to use a hand drill when placing the Seldrill Schanz screw in the far cortex.
- In anatomically uncritical regions of osteoporotic bone, the Seldrill Schanz screw may penetrate the far cortex to aid in stability.

Ø 5.0 mm      Ø 6.0 mm



### 3. Insertion of Schanz screws in the proximal fragment

The first Seldrill Schanz screw can be inserted freely in the proximal fragment considering the condition of the soft tissue. To insert the second Seldrill Schanz screw parallel to the first, the Parallel Drill Sleeve Holder (392.915) is used.

The hole configuration corresponds to that of the standard clamp. The holder can be equipped with 6.0/5.0 mm and 7.0/6.0 mm drill sleeves.

Available drill sleeves

For Seldrill Schanz screws  $\varnothing$  5.0 mm:

393.830 long

393.840 short

For Seldrill Schanz screws  $\varnothing$  6 mm:

392.917 long

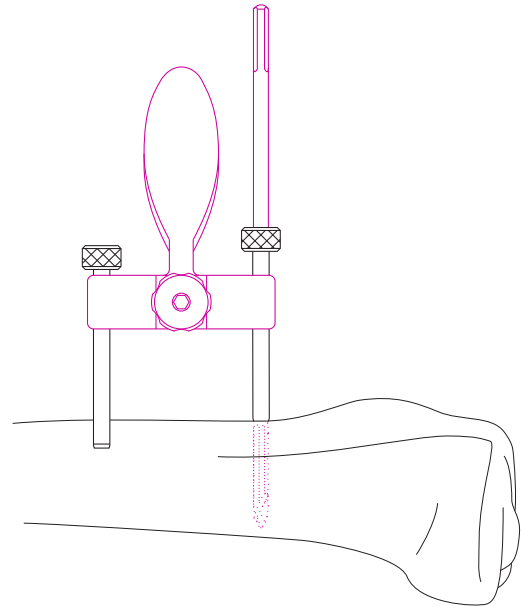
392.916 short

#### ■ Note:

To insert the drill sleeve through the soft tissue use the corresponding complete drill sleeve assembly (trocar included).

The corresponding drill sleeve must be used for predrilling for the standard Schanz screws.

For alternative Schanz screw insertion procedures, under section 3. Insertion of Schanz screws: alternatives.

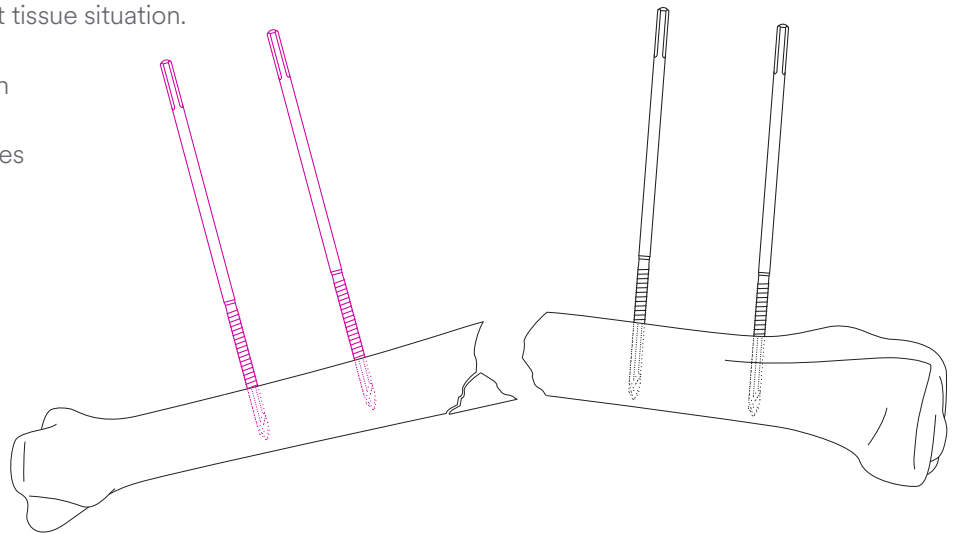


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## 4. Insertion of Schanz screws in the distal fragment

- ① The Schanz screws are inserted in the distal fragment in the same way as for the proximal fragment. The first Schanz screw can be inserted freely due to the large swivelling range of the standard clamp, and considering the nature of the fracture and the soft tissue situation.

For alternative Schanz screw insertion procedures, see under section 3:  
Insertion of Schanz screws: alternatives



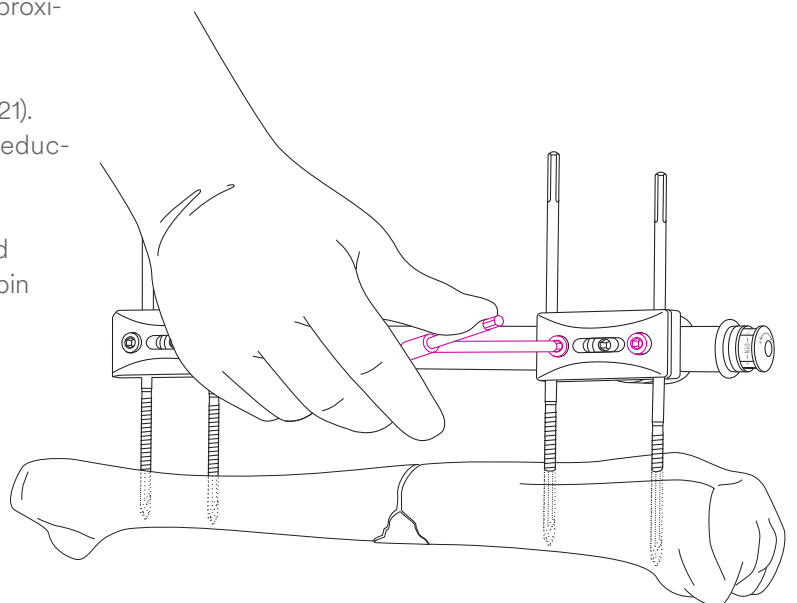
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## 5. Mounting the preassembled device on the Schanz screws

Loosen the outer screws of the standard clamps and slide the clamps on the Schanz screws in the distal and proximal fragments.

Tighten the fixing screws with the Allen key (392.921). Tightening the clamping plate does not restrict reduction or the swiveling range of the clamp.

For alternative methods of assembling the standard clamps or the system, see section 2 under “Single pin clamps instead of standard clamps”.

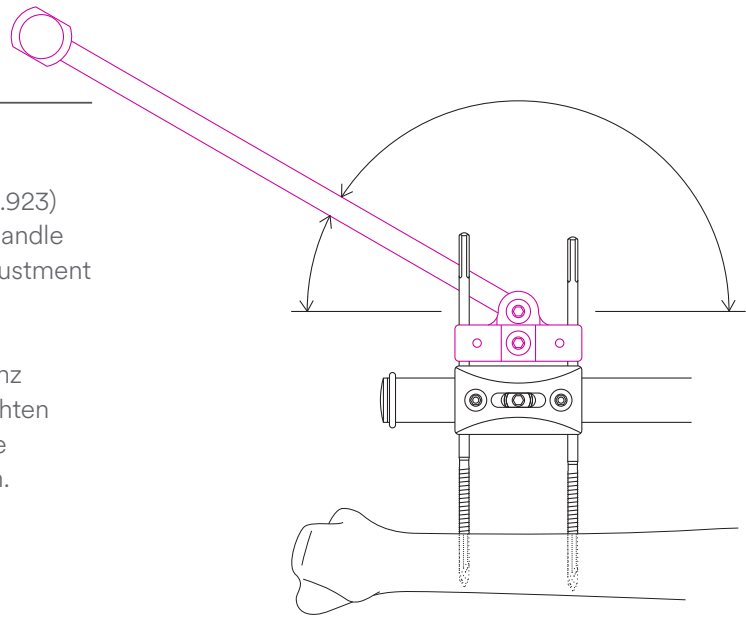


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## 6. Assembly of reduction grips

The hole configuration of the Reduction Grip (392.923) corresponds to that of the standard clamps. The handle of the reduction grip can be swivelled to allow adjustment at any angle.

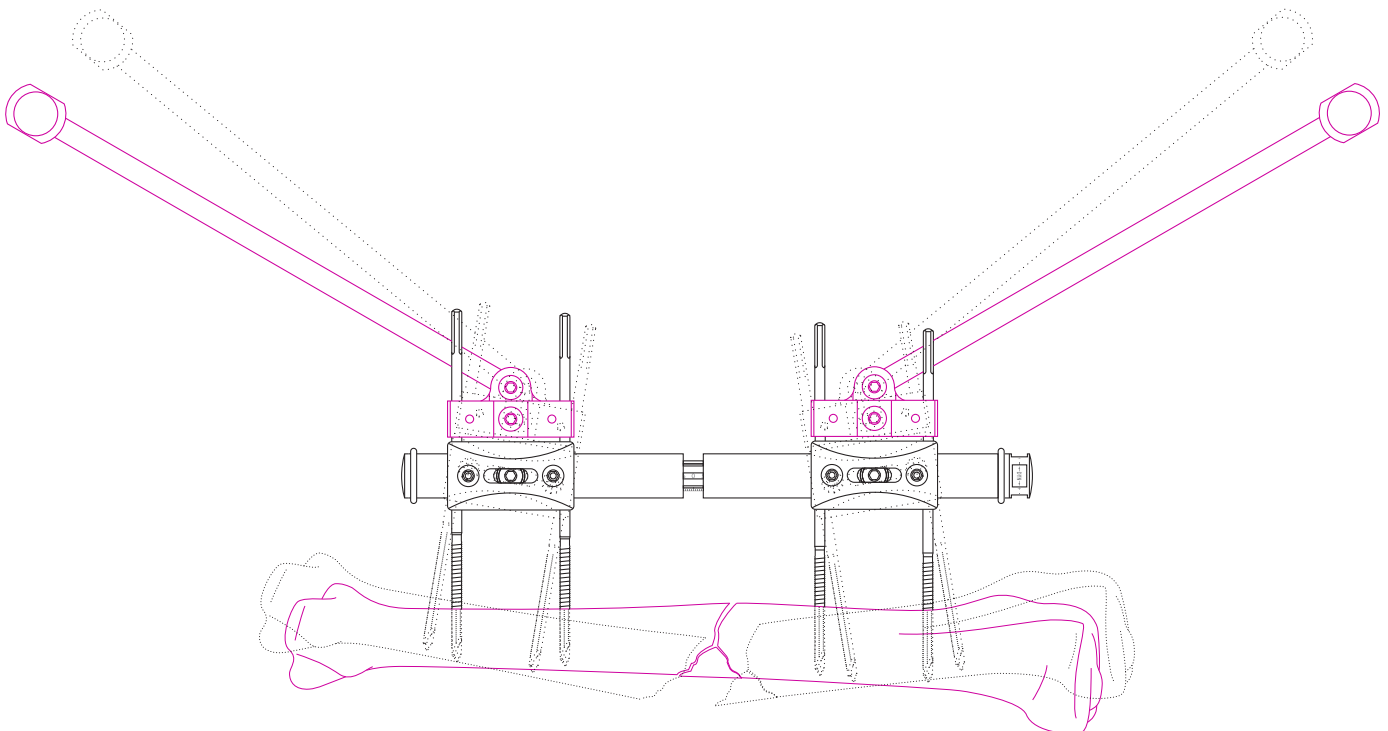
Place the clamp of the reduction grip on the Schanz screws, push it toward the standard clamp and tighten the clamp with the Allen key. Swivel the grip to the desired position and tighten the swivel connection.



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## 7. Final reduction

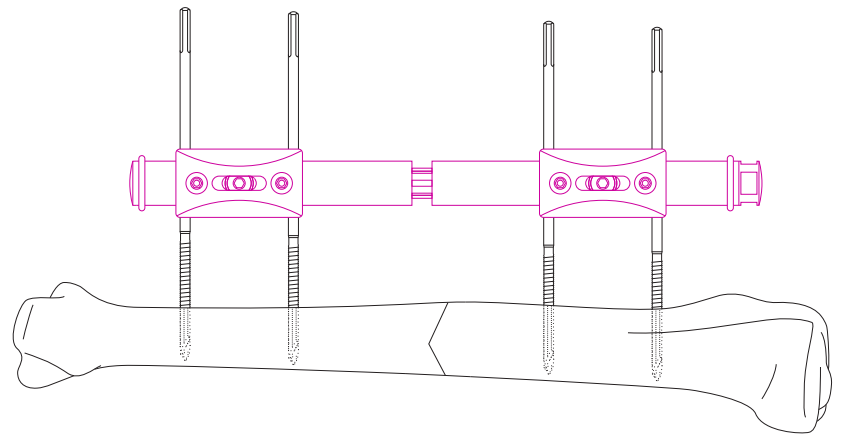
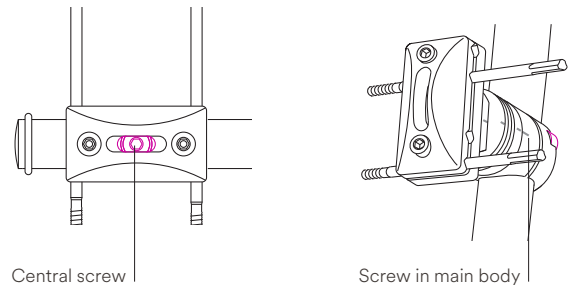
- 1 Carry out the final reduction and check using an image intensifier.



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## 8. Final fixation

Holding the reduction, fix the position of the standard clamps with the central screw in the saddle joint (opening in the clamping plate). Then tighten the screw in the main body of both clamps for final fixation to the central body.



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## 9. Dynamization

Dynamization from 0 to 5 mm can be achieved by turning the cap marked DYN on the central body.

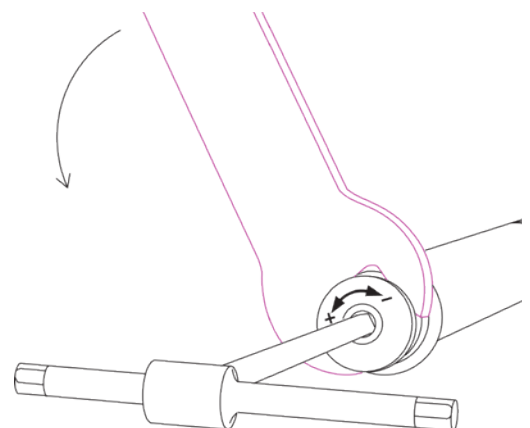
Hold the Allen Key  $\varnothing$  5.0 mm with T-Handle (392.921) in the opening at the end of the central body, which is marked DYN. Use the Dynamization Wrench (392.922) to turn the cap. By doing this, white marks become visible on the bolt. Each mark corresponds to 1 mm. A complete rotation of the cap results in a 1 mm dynamization.

In cases where dynamization to stimulate callus formation is required, parallel alignment of the central body to the longitudinal axis of the bone is essential.

### ■ Note:

Only carry out dynamization when the first callus formation is visible on X-ray.

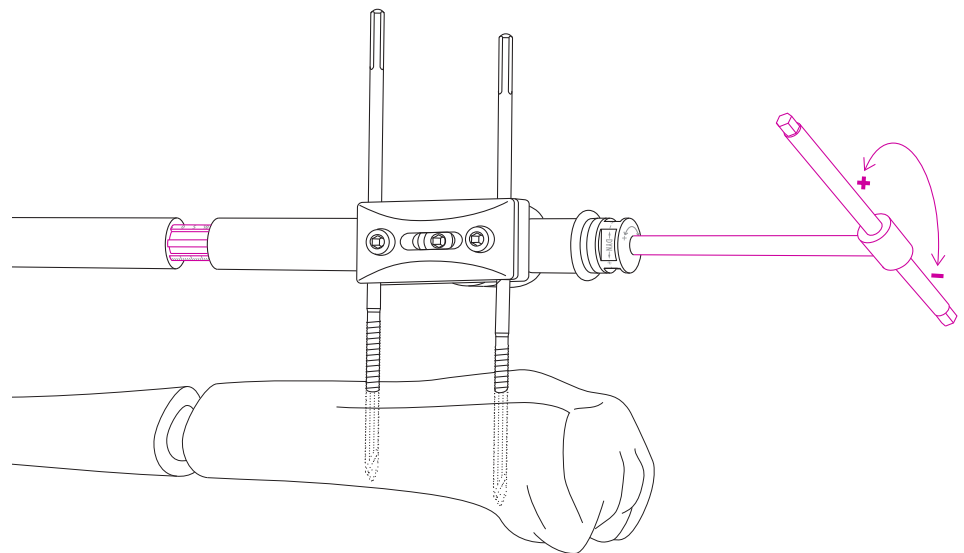
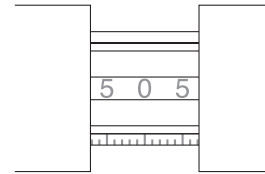
The central body must be extended by at least 6 mm before dynamization.



## 10. Bone lengthening (+) / Compression (-)

Bone lengthening and compression can be achieved by extending or shortening the central body, i.e. by inserting and turning the Allen key in either end of the central body. The central body can be extended at each end by 7.5 cm independently (15 cm in total).

See under “Bone Lengthening”.

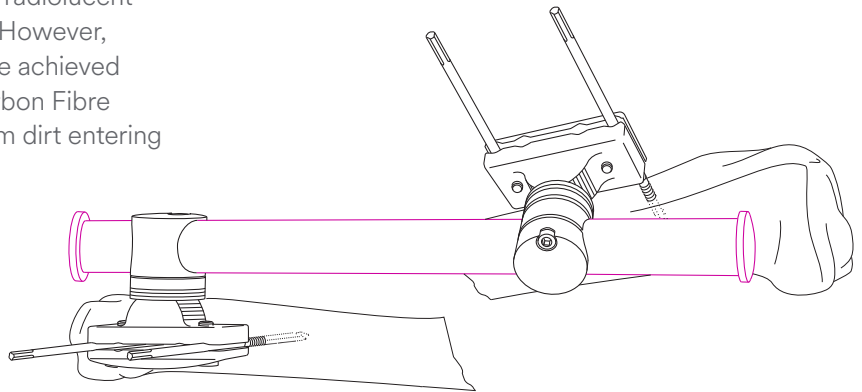




# Alternative Assembly Techniques

## 1. Carbon fibre tube instead of central body

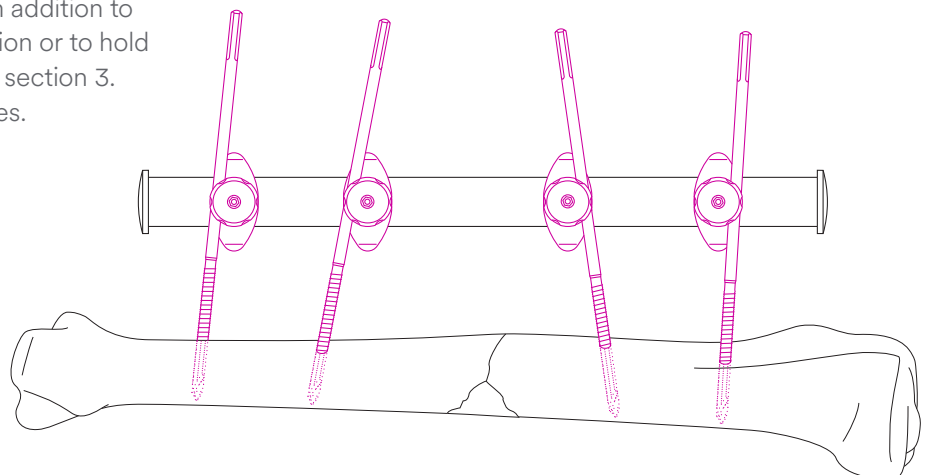
A carbon fibre tube can be used instead of the central body to connect the standard or single pin clamps. Carbon Fibre Tubes (392.930/392.934) are radiolucent and lighter in weight than the central body. However, bone lengthening or compression cannot be achieved with carbon fibre tubes. Place Caps for Carbon Fibre Tube (392.929) on both ends to protect from dirt entering the tube.



## 2. Single pin clamps instead of standard clamps

Single Pin Clamps (392.905) can also be mounted on the central body or carbon fibre tube. The Schanz screws can thus be inserted singly and do not have to be inserted parallel to one another as with the standard clamps. It is possible to use two single pin clamps per fragment or a standard clamp in one and two single pin clamps in the other fragment.

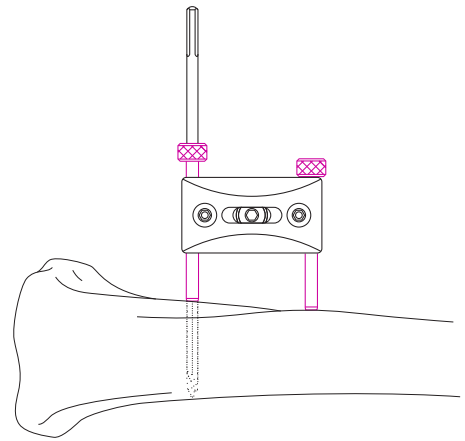
A single pin clamp can also be used in addition to standard clamps to reinforce the fixation or to hold another fragment. See step 3c, under section 3. Insertion of Schanz screws: alternatives.



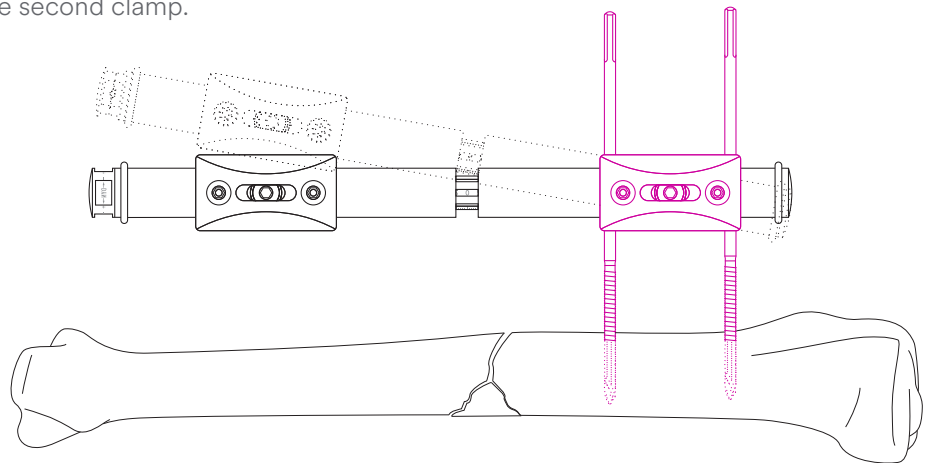
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### 3. Insertion of Schanz screws: alternatives

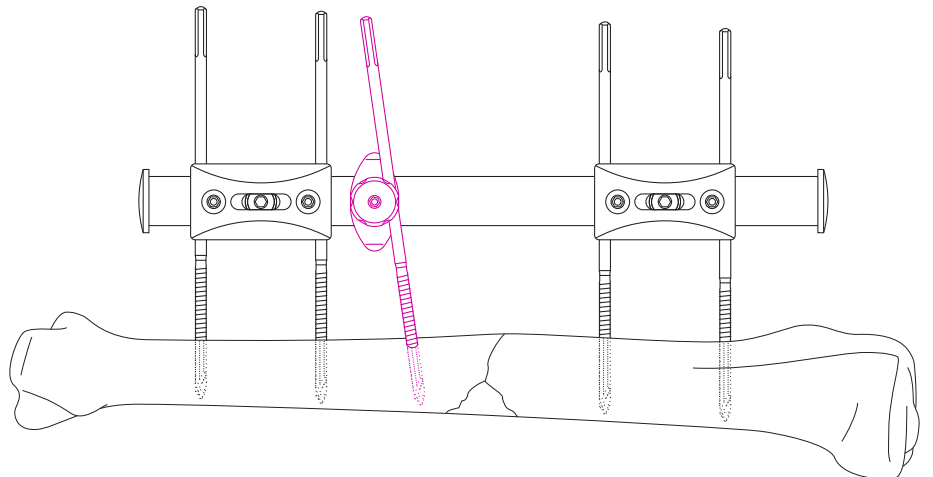
a The protection sleeves can be placed through the openings of the standard clamps. By this, the Schanz screws can be inserted directly through the clamps.



b Two Schanz screws can be first inserted in the proximal fragment and then mounted with the preassembly of central body and clamps. Two additional Schanz screws are then inserted in the distal fragment directly through the second clamp.



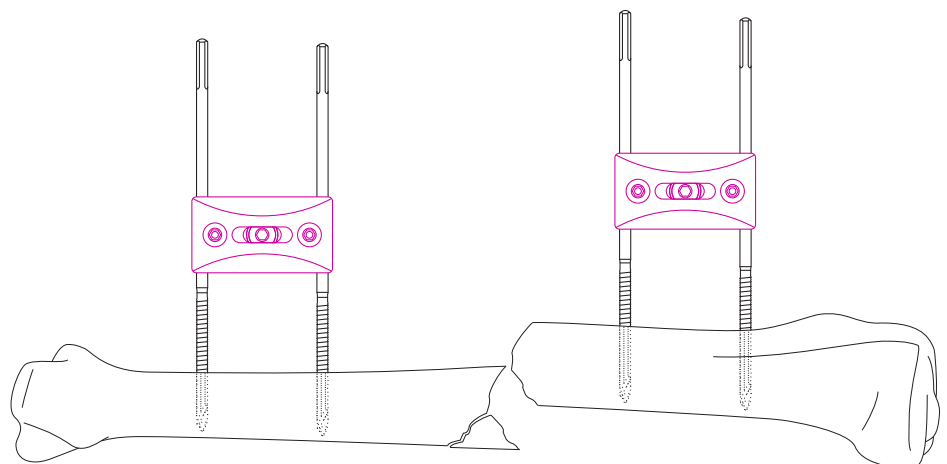
c It is possible to insert more than two Schanz screws per main fragment. Additional Schanz screws can be inserted for additional stability or to hold other fragments. The open single pin clamps can be attached to the central body subsequently for this purpose.



# Bone Lengthening

## Assembly

- Place the Schanz screws in the proximal fragment using the parallel drill sleeve holder.
- Mount a standard clamp on the inserted Schanz screws.
- Push the central body with the preassembled second standard clamp through the clamp on the Schanz screws and align it parallel to the longitudinal axis of the bone.
- Insert the Schanz screws in the proximal fragment directly through the drill sleeve secured in the second clamp or, after making marks on the skin, using the parallel drill sleeve holder.
- Secure the second standard clamp on the Schanz screws.
- Remove the central body.
- Perform a corticotomy using a drill and/or chisel and/or saw.
- Push the central body through the clamps again. Adjust or correct the fragments. Hold the reduction, if necessary using the reduction grips.
- Tighten the screw on the main bodies of the clamps and the central screw in the saddle joints.

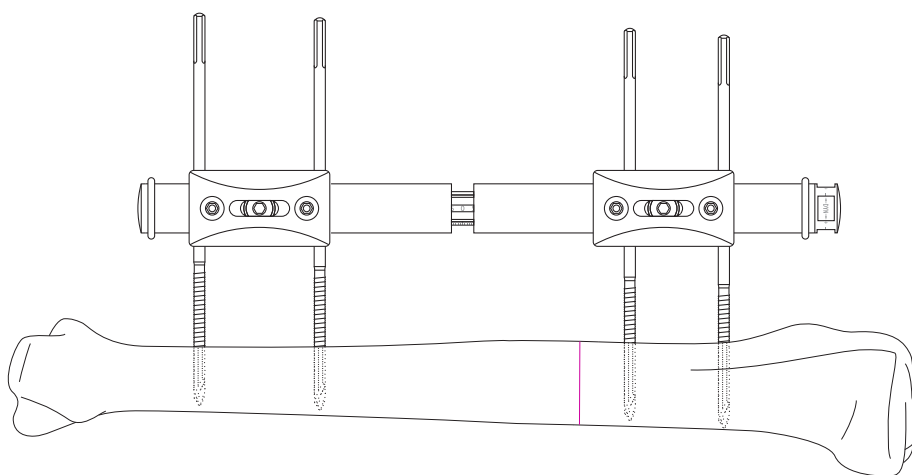


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■ **Note:**

Due to the large swivelling range of the standard clamps, the Schanz screws – as opposed to the central body – do not necessarily have to be placed on the longitudinal axis of the bone.

The use of single pin clamps allows the individual placement of Schanz screws. Alignment of the central body parallel to the longitudinal axis of the bone is essential.

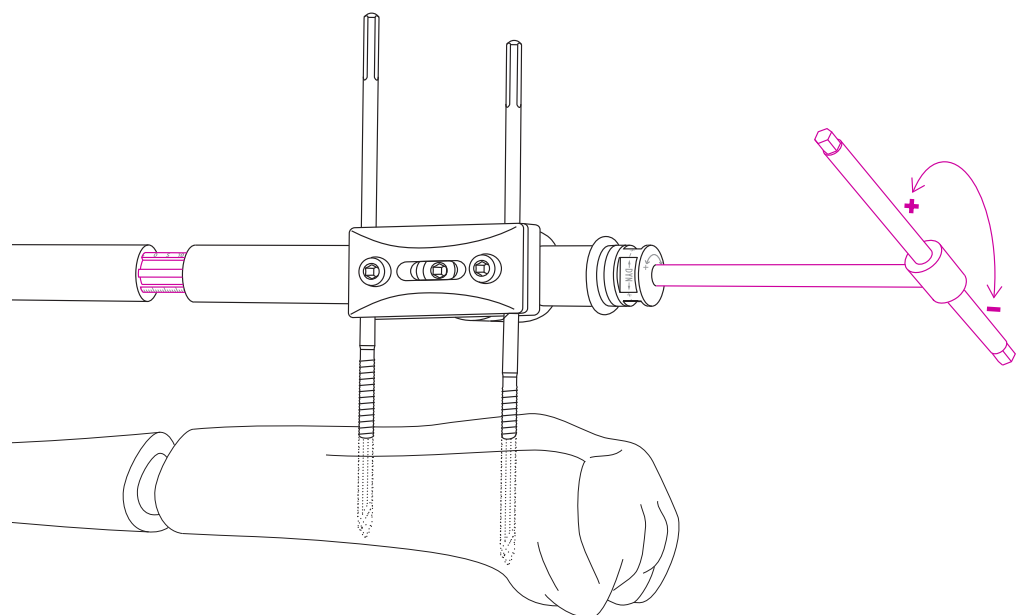


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## Bone lengthening procedure

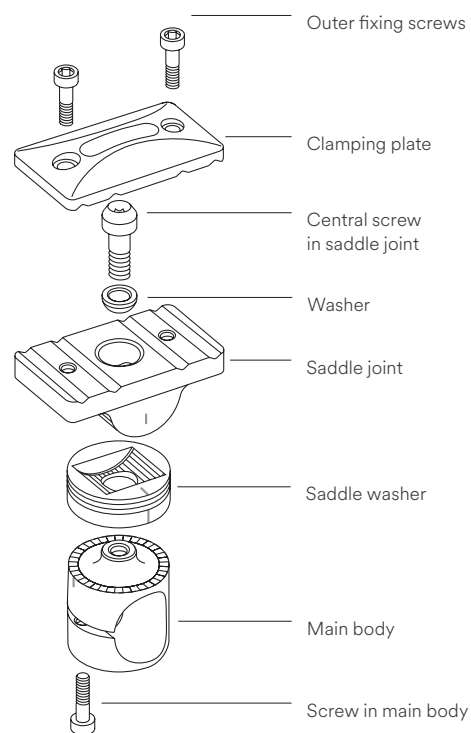
- Bone lengthening can begin seven to ten days after corticotomy.
- Extension is usually 1 mm per day. 1 mm on the central body corresponds to a full rotation with the Allen key. It is advisable to extend in steps of 0.25 mm. A quarter-turn should be made about every six hours.
- X-ray control one week after beginning bone lengthening to confirm separation of bone.
- After three to four weeks, callus formation is checked by X-ray. If callus formation is inadequate, the bone lengthening should be reduced at the doctor's discretion to two or three quarter-turns daily.
- The maximum extension distance for the central body is 15 cm, that is 7.5 cm at each end. First one side and then the other can be extended depending on the specific situation. In order to obtain uniform loading, it is advisable to change sides after an extension of 1 to 3 cm.

During bone lengthening, it is important to note the STOP on the splined shaft. As soon as the STOP shows, the central body must not be extended any further on that end. The consolidation time after bone lengthening is normally the same as the period of time required to lengthen the bone.

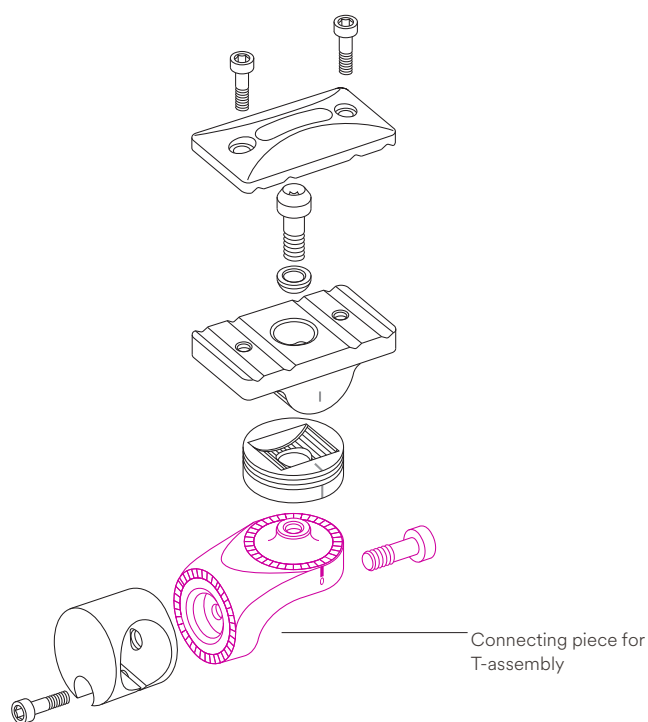


## Assembly of Clamps

### Assembly of Standard Clamp (392.903)



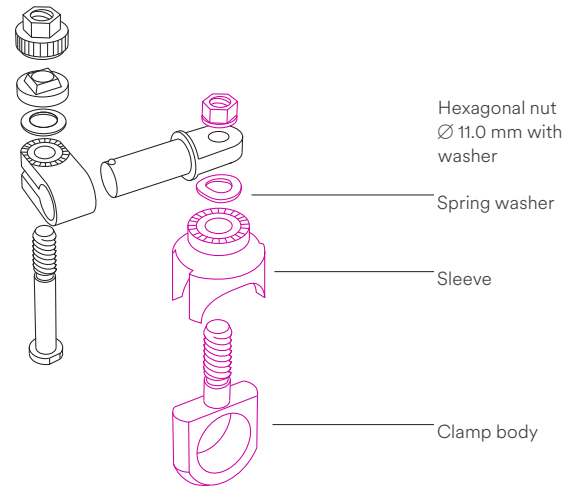
### Assembly of Standard Clamp (392.903) with Connecting Piece for T-Assembly (392.907)



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## Assembly of Central Body to Ring Clamp (392.913)

Combination with the Ring to Rod Clamp (393.436) of the hybrid ring fixator.



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## Assembly of Central Body to Tube Clamp (392.911)

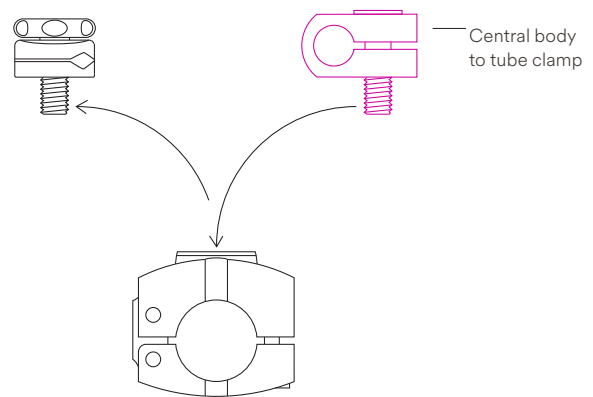
Combination with the MEFiSTO Single Pin Clamp (392.905)

### ■ Note:

For a detailed product information of the Schanz screw, refer to the Surgical Technique Schanz Screws and Steinmann Pins.

### ▲ 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:
  - Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries).
  - Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis.
  - Release of skin tension at soft tissue entry point of implant.

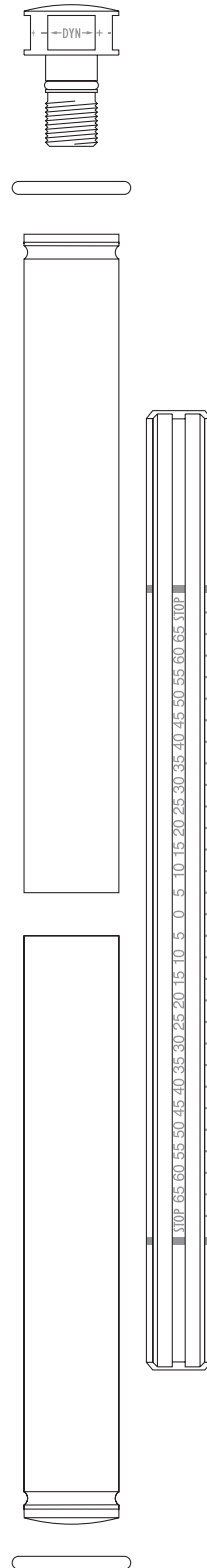


# Cleaning and Maintenance

## Checking function

After cleaning and assembling MEFiSTO, the following must be checked:

- Unhindered sliding of the clamps on the central body.
- Full swivelling range of the saddle joints.
- The screws of the clamps must tighten and loosen easily.
- Smooth turning of the Allen key in the openings of the central body and unimpeded extension to the STOP.
- Correct fit of the Allen key.
- Unhindered turning of the dynamization cap in the sleeve.
- Exact fit of the spanner on the cap.
- Easy assembly of the single pin clamps and the connecting piece for T-assembly.





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## Checking for wear

Visual inspection for wear of the fixation parts after every use is essential. In particular, the rills in the saddle joint and saddle washer of the standard clamps must be inspected for wear. If there are any visible signs of wear, the component in question should not be used any longer. The decision to reuse it rests with the surgeon. The parts of the standard clamps (excluding the screws), the sleeves and the splined shaft of the central body cannot be ordered as spare parts.

# MRI Information

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The “MEFiSTO” is MR unsafe. Do not use this device in any MR environment. This device is known to pose hazards in all MR environments.



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](http://www.e-ifu.com) and/or [www.depuysynthes.com/ifu](http://www.depuysynthes.com/ifu)

Not all products are currently available in all markets.  
This publication is not intended for distribution in the USA.



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