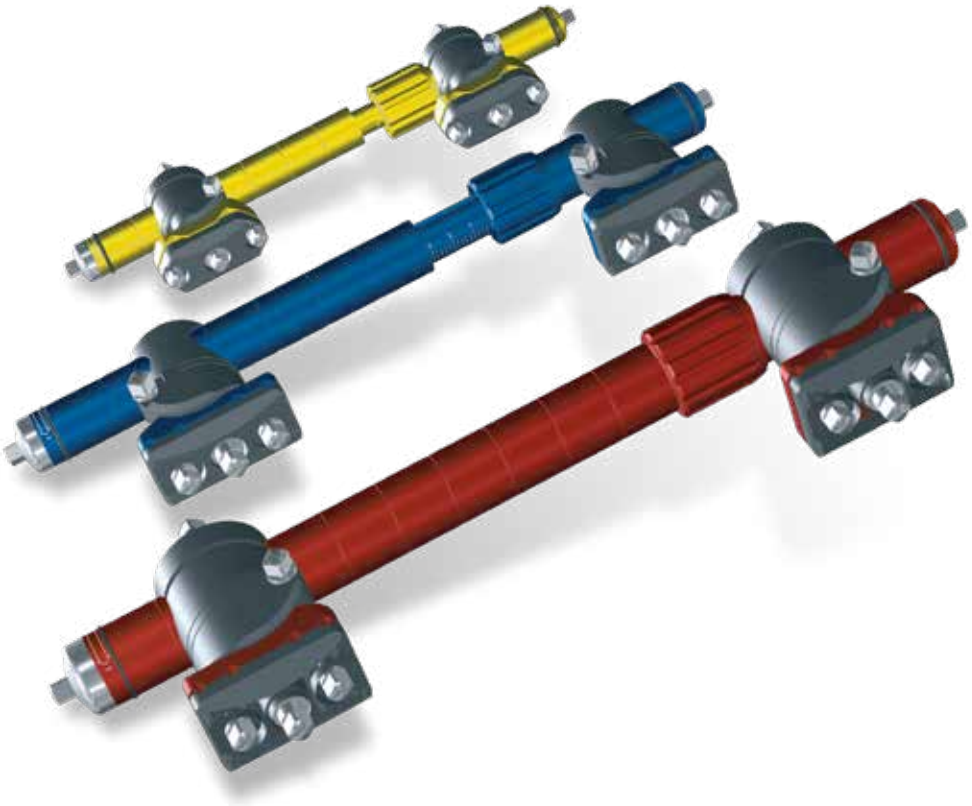
stryker

Monotube® Triax External Fixation System

Operative technique



Monotube Triax
External Fixation System

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to performing your first surgery.

⚠ WARNING

Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1). All non-sterile devices must be cleaned and sterilized before use.

⚠ WARNING

Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects, contraindications,warnings and precautions.

⚠ WARNING

- The surgeon must warn patients of surgical risks, and make them aware of possible adverse effects
- The patient should be warned that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma, malunion or nonunion
- The surgeon must warn the patient that the device has a finite expected service life and may need to be removed at some time in the future

Overview

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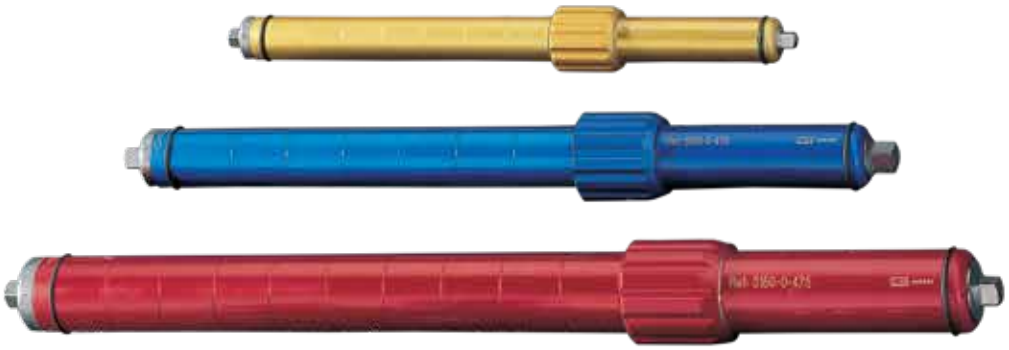
Carbon Tubes



Dynamic Tubes

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Overview

Monotube Triax

Pin Clamps

Triax Single Pin Clamp

Triax Carbon Monotube

The Monotube Triax External Fixation System is a dynamic axial fixator designed to help maintain fracture reduction while allowing the bone to share the load in the axial plane.

It has been designed to handle a wide variety of orthopaedic and trauma applications keeping in mind the need for controlled dynamisation. The built in dynamisation collar allows 0mm-3mm axial compression thus allowing the surgeon to initiate the natural callus formation that is critical to the healing process[1].

Its modularity and multiple repositioning possibilities allow restoration of the correct anatomy in three planes.

The system consists of three basic components: The dynamic tube, the pin clamp, and the single pin clamp. Speciality clamps and accessories are also available.

Key system components include:

- Dynamic Monotubes (Red, Blue, Yellow)
- Carbon Monotubes (Red, Blue, Yellow)
- Standard Pin Clamps
- Single Pin Clamps
- Tube-to-Tube Clamps
- T-Adapters
- Apex Pins (Self-Tapping, Blunt, Cancellous and HA Coated)

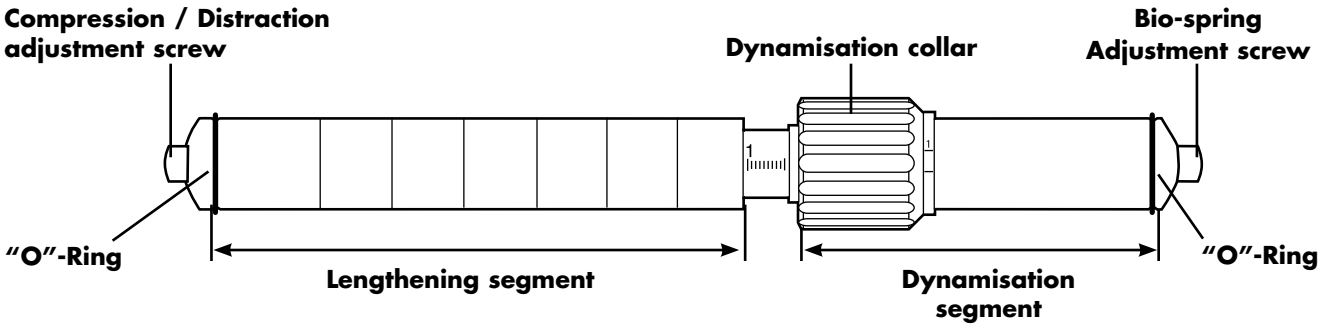
Instruments include:

- T-Handle (for locking the system)
- Torque Wrench (colour-coded)
- Dynamisation Wrench (used to open/shut the dynamisation collar)
- External Compression/Distraction Devices for use with Triax Carbon Tubes
- Fracture Reduction Handles.
- Spanner Wrenches

1. Unilateral External Fixation. (Authors: J. Cañadell, F. Forriol), Published By University of Navarra, Pages 46-54)

Components

Dynamic monotube



Carbon Monotube

Components

Component selection

The chart below can be used to determine proper frame components for the fracture being treated but can of course vary from one clinical situation to another. The type of tube selected is determined by:

- Location/type of fracture
- Length of tube required
- Dynamisation requirements

Dynamic Monotube Triax

Dynamic Tubes include an internal compression/distraction mechanism, which is useful in lengthening procedures and to adjust fracture reductions. The long portion of the tube is referenced as the Lengthening Segment. The shorter portion is called the Dynamisation Segment and includes two adjustable dynamisation features: Biocompression and Adjustable Bio-Spring. These tubes are available in three colour-coded sizes: Yellow, Blue, and Red.

Triax Carbon Tubes

Carbon Tubes should be used when dynamisation is not desired, or when a radiolucent tube is helpful as in the case with distal radius and proximal tibial fractures. This economical option also comes in the same three diameter sizes and a variety of lengths as presented in Chart No 1. The hollow carbon tube comes complete with end caps, which help prevent the pin clamps from sliding off the tube during frame application.

Chart No 1

Monotube Lengths and Pin Options

Tube Colour (Dynamic) End Cap Colour (Carbon)	Dynamic Monotube	Carbon Monotube	Pin Size
Yellow	• 15mm x 180mm Fully Compressed • 15mm x 250mm Fully Distracted	15mm x 150mm 200mm 250mm 300mm	3mm & 4mm
Blue	• 20mm x 250mm Fully Compressed • 20mm x 350mm Fully Distracted	20mm x 200mm 250mm 300mm 350mm	4mm & 5mm
Red	• 25mm x 320mm Fully Compressed • 25mm x 470mm Fully Distracted	25mm x 250mm 300mm 350mm 400mm	5mm 6mm

Indications & Contraindications

Indications / Intended Use

Indications specific to the Dynamic Tube Assemblies, Tube to Tube Clamp, Carbon Tubes

The Monotube Triax External Fixation System is a unilateral external fixator intended to be used for stabilization of open and / or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. The system may be used to address a variety of fracture types in addition to nonunions, arthrodesis, limb lengthening and osteotomies.

Additional indications specific to the Single Pin Clamp: This is used in conjunction with Half Pins or Transfixing Pins of the Hoffmann External Fixation System and the Carbon Mono-Tube or the Mono-Tube is intended to be used for the stabilization of fractures of the tibia, femur, humerus or radius. This clamp may be used alone in this Mono-tube frame configuration (pins, clamps, Carbon Mono-tube or Mono-Tube) or in conjunction with the Mono-Tube pin holder.

Additional indications specific to the T-Adaptor: This device is intended for the stabilization of very proximal or distal fractures of long bones (i.e. tibia, femur, humerus, ulna or radius) where pin placement perpendicular to the long axis of the bone is desired. In addition, the Monotube T-Connector may be used following an osteotomy to correct varus or valgus deformities of the tibia or femur.

Contraindications

See instructions for use (www.ifu.stryker.com) for warnings, precautions and contraindications.

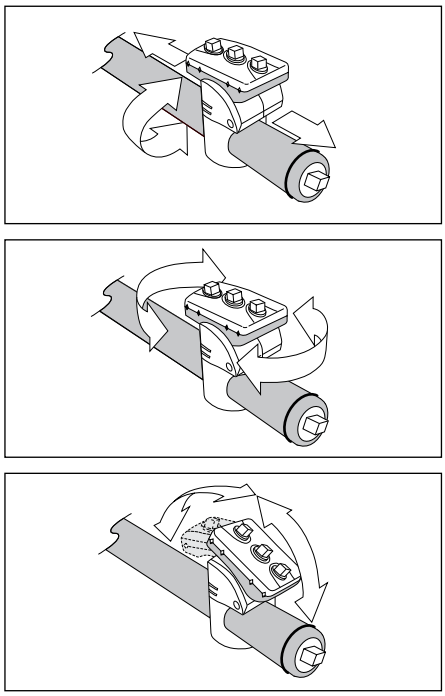
⚠ WARNING

The Stryker Monotube Triax external fixation system has not been evaluated for safety and use in MR environment and has not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

Technical Details

Triax Standard Pin Clamp

Monotube Triax Pin Clamp Screws



Monotube Triax Pin Clamp Degrees of freedom

The Monotube Triax Pin Clamp allows independent control of the fracture reduction in three planes. Clamps may be placed anywhere along the length of the tube at virtually any angle, wherever the best bone purchase may be available.

A unique compression sleeve allows for adequate mobility in rotation preventing deviation of the pin clamp.

The two outer square head screws "A" when tightened hold the pins in the clamp. Each screw can independently lock up to two pins in place. The red and blue Triax Clamps have four pin positions, and the yellow Triax Clamp has two pin positions.

The centre square head screw "B" allows for +/- 20° degrees of angulation in the sagittal plane.

The side square head screw "C" allows for 360° of rotation in the coronal plane.

The square head screw "D" at the bottom of the clamp allows for translation along the length of the tube and for 360° rotation around the axis of the tube.

NOTICE

All square head screws need to be tightened to the appropriate torque to maintain adequate stability using the torque wrench.

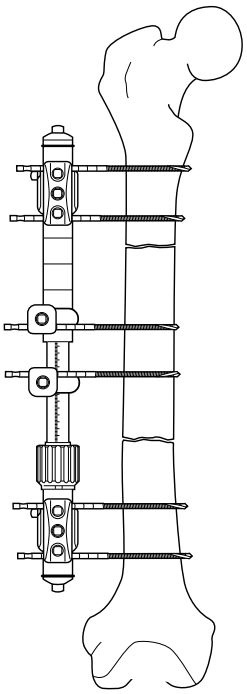
Also identified by three colour-coded sizes, the Monotube Triax Clamps each accept a minimum of two half pin diameters as also indicated in Chart No 1.

NOTICE

Blue and Red components have 7mm square head screws and Yellow components have 5mm square head screws.

Technical Details

Triax Single Pin Clamp



The Monotube Triax Single Pin Clamps are designed for independent pin placement. They are designed to allow for capture and stabilisation of fracture fragments. They are also intended for use in pathologies that require non parallel pin position for additional stability of the frame.

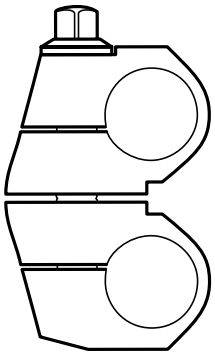
The Single Pin Clamp has a snap-fit fixation mechanism to attach to the pins. A serrated interlocking mechanism between the jaws of the pin clamp allows for rotational locking. A 7mm square head screw allows easy access.

Pins can be placed parallel or convergent to achieve stability.

- The Monotube Triax Single Pin Clamps comes in three sizes and accepts the following Apex pins:
    - Yellow 3/4mm
    - Blue 4/5mm
    - Red 5/6mm
- Top locking for adjustable control of the pin placement
- The Single Pin Clamp allows 360° of medio lateral rotation
- The square head screw positioned at the bottom of the pin clamp allows for translation along the length of the tube and 360° rotation around the axis of the tube.

Technical Details

Triax Tube-to-Tube



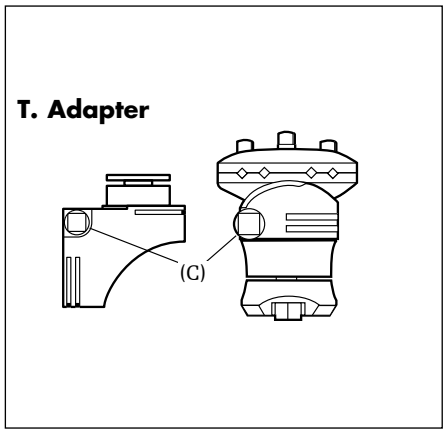
Triax Tube-to-Tube Clamps

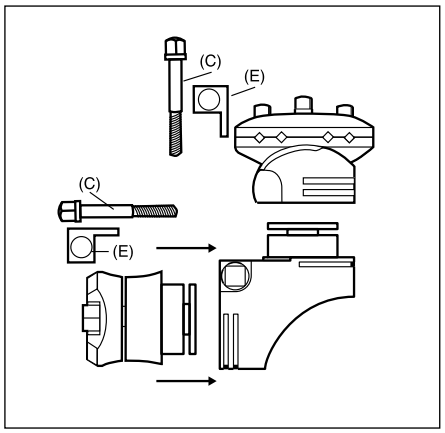
These clamps allow connection of Yellow, Blue and Red tubes together to treat complex trauma or pelvic fractures. The clamps are suitable for both Dynamic and Carbon Tubes. Clamps are available in the following configurations:

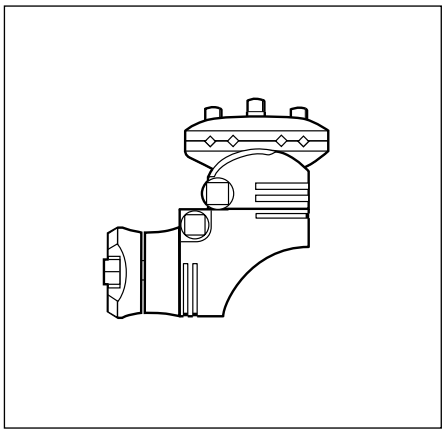
- RED TO RED
- RED TO BLUE
- BLUE TO BLUE
- BLUE TO YELLOW
- YELLOW TO YELLOW

Technical Details

Triax T-Adapter







T-Clamps

T-Clamps are beneficial when treating proximal and distal fractures or fractures that pass across a joint. The T-Clamp allows for perpendicular placement of pins.

Monotube T-Adapter Assembly

Standard Monotube Triax Clamps can be converted to T-Clamps using the T-Adapter.

Be sure you select the appropriate adapter for the size of clamp to be modified.

Assembly Instructions

1. Select the appropriate T-Adapter and matching Standard Pin Clamp using the chart below.
2. Remove body screw (C) and compression sleeve (E) from T-Adapter with the appropriate Monotube Triax Torque wrench.
3. Remove body screw (C) and compression sleeve (E) from Standard Pin Clamp. Separate pin connector from the tube coupling.
4. Insert T-Adapter into the tube coupling and replace compression sleeve (E). Body screw (C) should be introduced through the recessed portion of the clamp until fully seated and finger tight.
5. Insert pin connector onto T-Adapter and replace compression sleeve (E). Body screw (C) should be introduced through the recessed portion of the clamp until fully seated and finger tight.

NOTICE

Body screws and compression sleeves are exactly alike and will fit in either position. However, if body screws are not started from the recessed side of the clamp, they will not fully seat. In addition, the T-adapter should always be connected to the tube coupling before the pin connector.

T-Adapter	Ref #	Required Standard Pin Clamp	Ref #
Yellow (15mm) Blue (20mm) Red (25mm)	5150-4-065 5150-4-070 5150-4-075	Yellow (15mm) Blue (20mm) Red (25mm)	5150-3-065 5150-3-070 5150-3-075

Operative Technique

Frame Application with Dynamic Monotube Triax

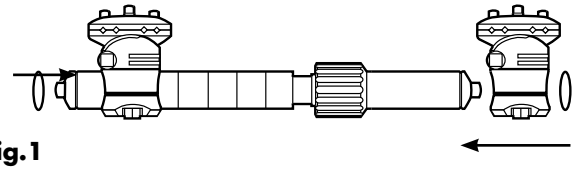


Fig.1

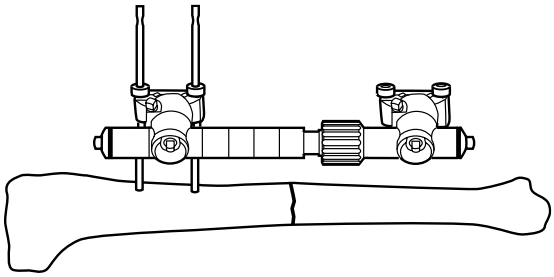


Fig.2

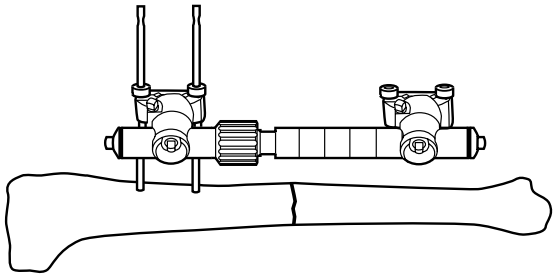


Fig.3

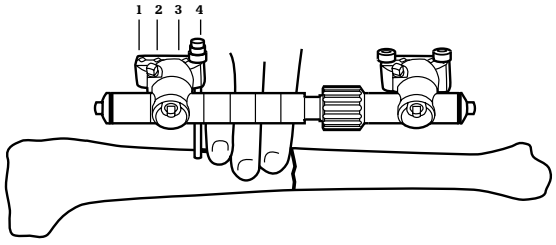


Fig.4

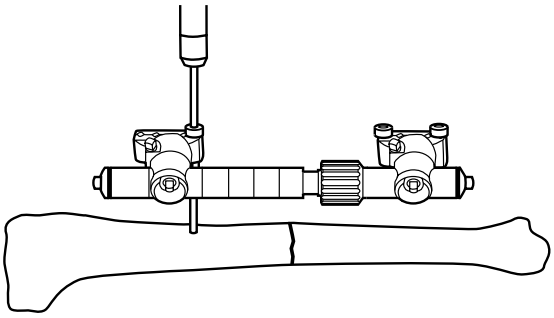


Fig.5

Preparation

To prepare for application of the frame, remove "O"-Rings, and place selected clamps on the tube. Once the clamps are in place, replace the "O"-Rings to prevent the clamps from sliding off the frame during the procedure (Fig.1).

Positioning of the Dynamic Tube

The Dynamic Tube may be placed with the dynamisation segment positioned either proximally or distally to accommodate any fracture pattern and provide a variety of pin placement options (Fig.2 and Fig.3).

The tube should be distracted to 1cm before use. The dynamisation collar should be locked before placement (See figures 12 and 13).

Pin Placement

Once a gross reduction is achieved, the first self-drilling Apex Pin*, usually considered the most critical, is placed approximately three finger breadths proximal or distal to the fracture, depending on surgeon preference. Care should be taken to see that the first pin is placed properly in the best quality bone. Insert the Apex Assembly through the clamp and into hole No 4 (Fig.4). (The holes in the clamp are referred to as holes No 1-No 4; the hole closest to the fracture is always hole No 4). After making a small incision, split the soft tissue with forceps. Insert the Predrill Assembly through the incision and push down until sleeve is perpendicular to and touches the bone. Holding the sleeve in this position, insert the self-drilling, self-tapping Apex Pin (Fig.5).

***If non-self-drilling self-tapping Apex Pins are preferred, see page 21 of this technique for the pre-drilling protocol.**

Operative Technique

Frame Application with Dynamic Monotube Triax

Turn the drill brace counterclockwise four to five turns. The Apex pin tip will mark the cortex and prevent slipping of the pin. Turn the drill brace clockwise, driving the Apex Pin through the first cortex*. Resistance will be felt as the tip of the pin begins to penetrate the second cortex. The pin should be advanced until both cortices are fully engaged. Remove the drill brace from the pin.

Place second pin in hole No 1, utilising the same technique (Fig.6).

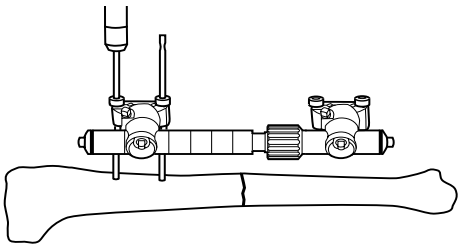


Fig.6

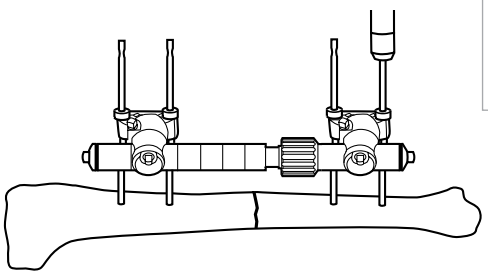


Fig.7

NOTICE

It is important that all square head screws be positioned outward and within easy reach to facilitate adjustment, tightening and final locking of the fixator. It is also important that the Tube be distracted at least one 1cm prior to application to allow for compression / distraction and finetuning of the reduction postoperatively. Care should be taken to ensure that the collar is closed prior to dynamisation application.

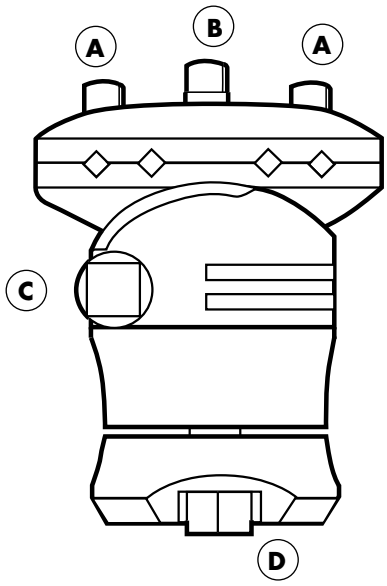
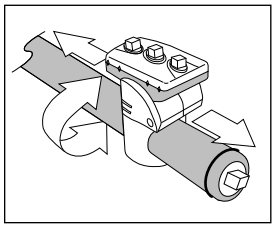
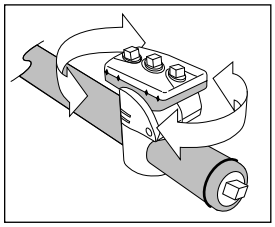
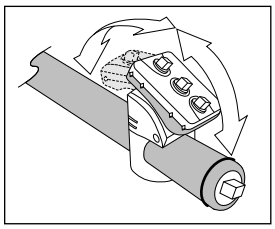


Fig.8







Using the same technique for the opposite side of the fracture, place the third pin at least three finger breadths from the fracture, again taking care to see that the pin is placed properly in the best quality bone. A third incision is made and an additional Predrill Assembly is inserted through hole No 1 in the second Pin Clamp. The procedure is repeated for the final hole closest to the fracture is always hole No 4 (Fig.7). Although pins are typically placed in holes No 1 and No 4, when using multiple pin clamps, holes No 2 and No 3 can be used, if necessary.

NOTICE

Always use Apex Pins with the Monotube Triax system.

Pin Clamp Function

It is important to review the function of the Pin Clamps. The two outer screws (A) on the clamp face, when tightened, hold the clamp to the pins. The centre screw (B) locks +/– 20° of angulation. The side screw (C) locks the 360° rotation of the clamp. The nut on the bottom of the clamp (D) locks the clamp-to-tube connection (Fig.8).

Final Reduction

All Predrilling Assemblies are now removed and the proximal pin group is locked into the clamp, which is left loose on the tube. The tube will now slide freely with the clamps, allowing for final reduction.

Operative Technique

Frame Application with Dynamic Monotube Triax

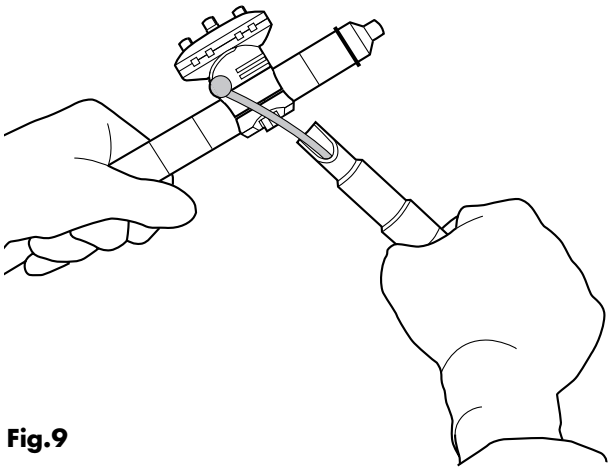


Fig.9

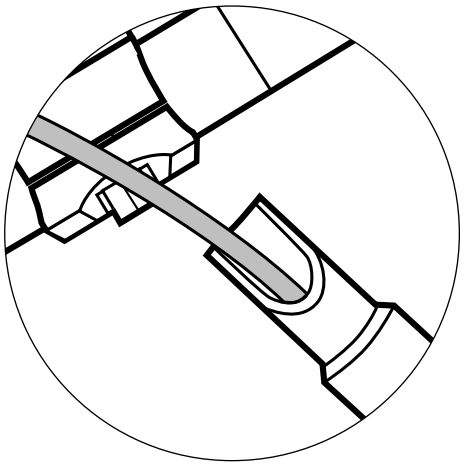


Fig.10

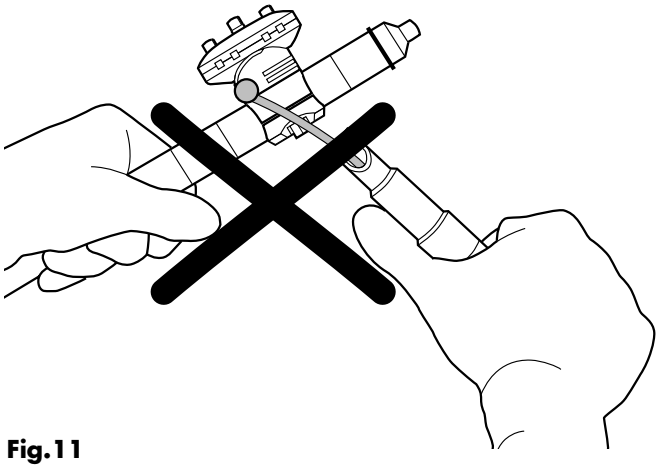


Fig.11

Locking the Fixator

Once an anatomical reduction is achieved, lock the fixator in all planes. The torque wrench should be used after initial tightening to assure all clamps are locked properly. For the Red system, this helps ensure the components are tightened to 11Nm; for the Blue system 9Nm; and for the Yellow 5Nm.

Use of Monotube Torque Wrench

Proper use of the torque wrench is important. Make sure the torque wrench head is fully seated over the clamp screw.

Grip the end of the wrench handle, keeping the thumb in a "fist" position (Fig.9). Tighten the clamp screw only until the silver torque wrench bar contacts the colour-coded handle. When the bar and the wrench handle come in contact, the clamp screw has been tightened to the recommended maximum torque (Fig.10).

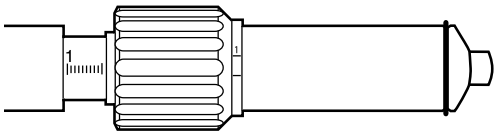
Improper placement of the thumb can change the torque level achieved by the wrench. This may result in undertightening of the screws on the clamp (Fig.11).

NOTICE

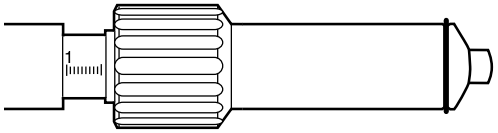
Do not overtighten as this may damage the clamp or torque wrench.

Operative Technique

Frame Application with Dynamic Monotube Triax



Open Dynamization Collar



Closed Dynamization Collar

Fig.12

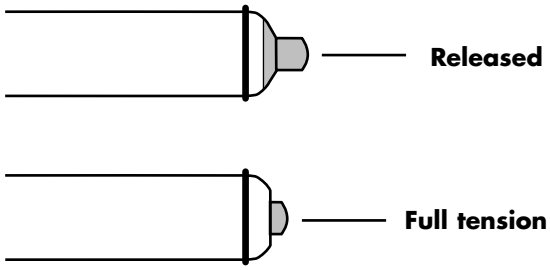


Fig.13

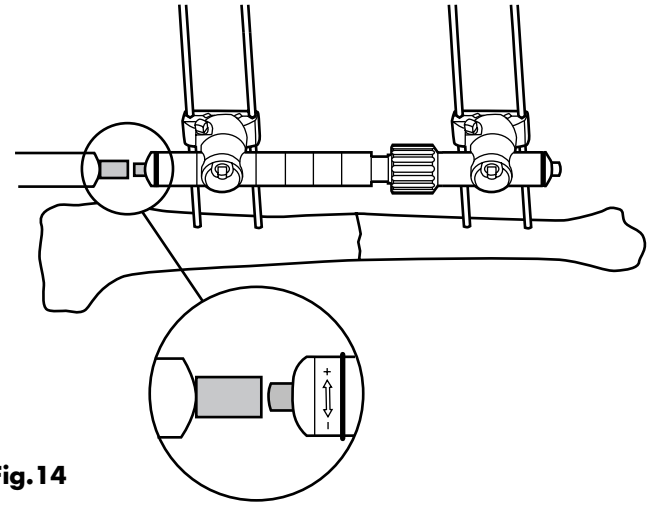


Fig.14

Locking the Dynamisation Features

Finally, and most importantly, be sure that the dynamisation collar is fully closed and that the frame is static before application (Fig.12).

Bio-Spring tension should also be fully released. The Bio-Spring tension adjustment screw is located on the end of the dynamisation segment of the tube. Upon frame application, the spring should be in released position, i.e., turned until silver disc is flush with the end of the tube (Fig.13).

Compression/Distraction

If compression/distraction of the reduction is required after frame application, this can be accomplished by using the internal compression/ distraction mechanism.

The compression/distraction adjustment screw is located on the end of the lengthening segment of the tube, (+)= distraction and (–)= compression. One complete revolution of the screw provides 1mm of compression or distraction (Fig.14). The end of the tube is marked with a visual reference each 1/4 turn.

4 dots 3 dots

2 dots 1 dot

NOTICE

When you reduce a fracture with the internal compression / distraction mechanism, keep the dynamisation collar closed.

Operative Technique

Dynamisation Protocol

Dynamic Monotube Triax allows the surgeon to control the dynamisation process with two adjustments:

- The Biocompression Collar allows the user to set the amount of micromotion at the fracture site. Although the collar opens to 3mm, it is not recommended to open it more than 1mm (Fig.15)
- The Adjustable Bio-Spring allows the surgeon to vary the amount of weight or force required to make the frame move the distance set on the Biocompression Collar. Chart No 2 highlights the amount of load required to move each size Monotube based on spring tension (1kg=2.2lb)

Dynamising the Frame

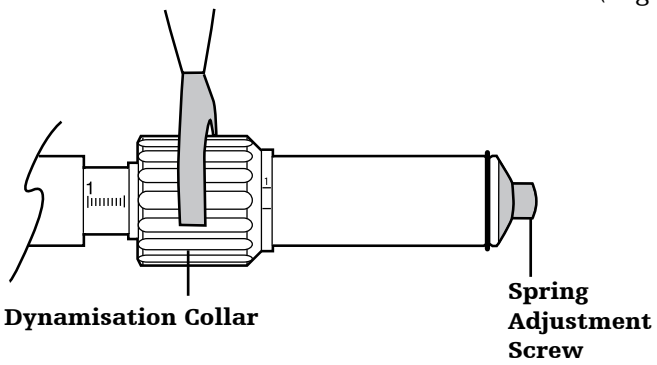


Fig.15

Stable Fracture patterns

Biocompression is recommended for stable fracture patterns. The frame may be dynamised anytime after application. The following steps should be followed:

1. Open the dynamisation collar to 1mm (one complete revolution of the dynamisation collar equates to 1mm). Use the dynamisation wrench if necessary.

Unstable Fracture patterns

The adjustable Bio-Spring is recommended for unstable fracture patterns and leg lengthening. The frame may be dynamised once callus is evident on the X-Ray, approximately 21 to 28 days postoperatively. To dynamise the frame, the following sequence should be followed:

1. Advance Adjustable Bio-Spring tension screw clockwise until fully compressed, about 71/2 full turns. The screw will recede into the tube as it compresses the spring.
2. Open the dynamisation collar to one millimetre. Use the dynamisation wrench if necessary.
3. Reduce Bio-Spring tension one full turn anti-clockwise each week. Be sure to check that the biocompression collar is still set at 1mm after each spring adjustment. The force required to dynamise the frame will be progressively reduced.

⚠CAUTION

X-Ray visualization is required to determine callus formation.

Chart No 2

Reducing Spring Tension

(Approximate Force Required to Dynamise)

Turns	7 1/2	7	6	5	4	3	2	1	None
Amount of Force (Kilograms)									
Yellow	20	17	15	12	9	7	4	1	0
Blue	30	26	22	18	14	10	6	2	0
Red	45	39	33	27	21	15	9	3	0

Operative Technique

Triax Carbon Tubes

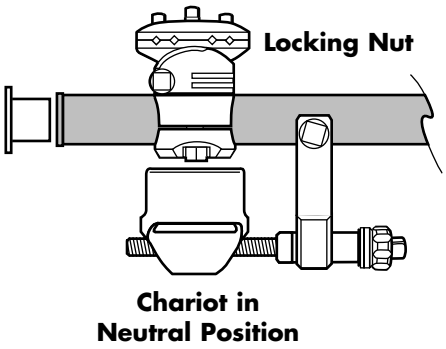


Fig.16

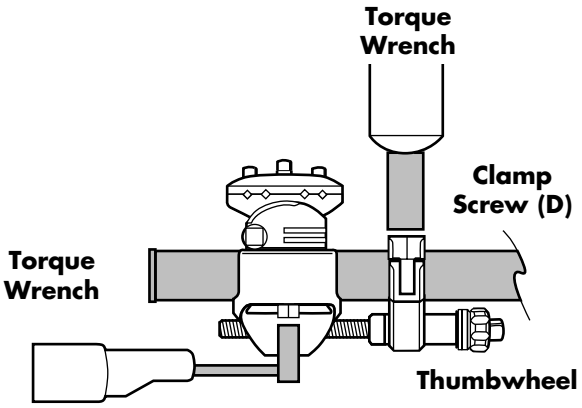


Fig.17

Carbon Tubes

Carbon tubes are available in 3 diameters; Yellow 15, Blue 20, Red 25 and in lengths from 150 – 400mm. If the fracture does not require dynamisation or if a radiolucent frame is desired, carbon tubes can be substituted for the dynamic tube. Surgical protocol does not vary except for placement of clamps on the tube. To place clamps on the tube, remove coloured end cap. Simply slide clamps onto the tube and replace end caps (Fig.16).

Compression or distraction can now be achieved – maximum distraction/compression is as follows:

Yellow 20mm

Blue 30mm

Red 30mm

Compression Distraction Device

The Triax Carbon Tube requires an external compression/ distraction device. To use the device, position the "chariot" over the back of the pin clamp and wrap the locking mechanism around the tube. Tighten the locking screw, utilising the wrench. Loosen pin clamp screw (D), utilising torque wrench (Fig.17). Compression or distraction can be useful when finetuning the reduction. One revolution of the Thumbwheel provides for 1mm of compression or distraction. The external compression/distraction device can then be removed or left on. In either case, retighten the pin clamp screws to proper torque once finished with adjustment.

Operative Technique

Blunt, Self-tapping Pin Protocol

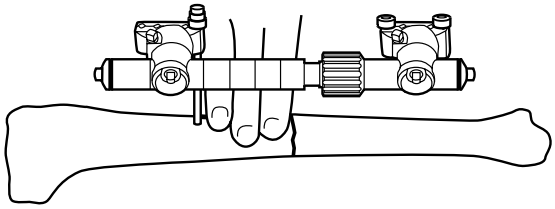


Fig.18

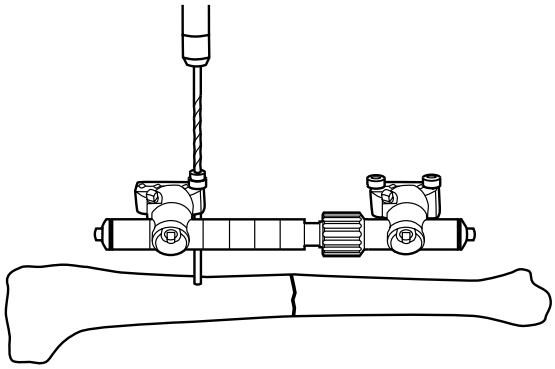


Fig.19

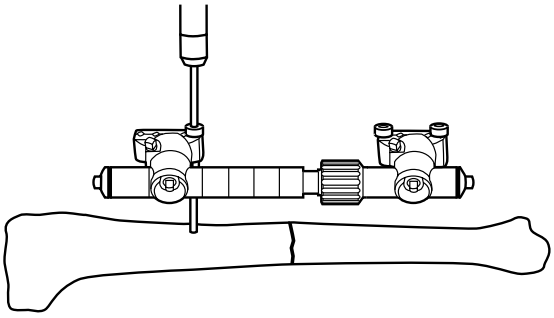


Fig.20

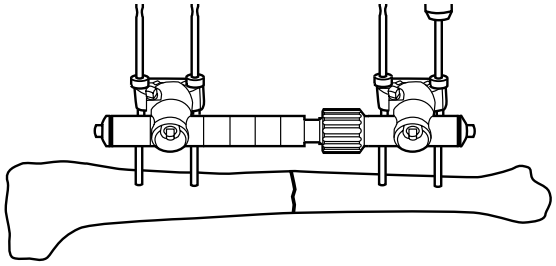


Fig.21

If the surgeon would like to use blunt, self-tapping pins, pin placement can be facilitated using a the appropriate Apex Predrilling Assembly and the appropriate drill for the pins being used (please refer to Chart No. 3 below).

To place the pins, insert the appropriate Predrilling Assembly into the pin clamp. The first pin should be placed three fingerbreadths from the fracture. A 1cm longitudinal incision is made with a blunt dissection through the tissue to bone. Insert the Predrill Assembly mechanism through the hole closest to the fracture is always hole No 4 of the proximal clamp (Fig.18). Insert the Predrill Assembly mechanism down to bone, holding it perpendicular to the bone. Lightly tap the trocar, which is designed to prevent skidding of the drill bit. The trocar is removed leaving the drill guide in the tissue protection sleeve. Introduce the drill bit, and drill through both cortices of the bone (Figure 19). Remove the drill bit and the drill guide sleeve, and insert selected blunt Apex Pin through the tissue sleeve, utilising a Drill Brace or a T-inserter (Fig.20).

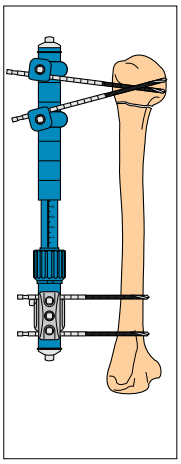
Advance pin until both cortices are fully engaged. After placing the first pin, repeat the procedure for the second pin in the hole closest to the fracture is always hole No 4 of the clamp. Use same technique for second pin clamp and continue with frame application (Fig.21).

Chart No. 3

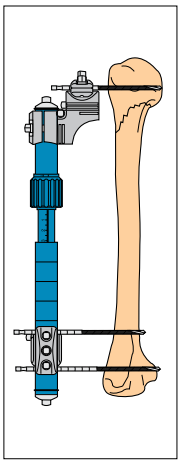
Apex Pin Size	Required Drill Size	Ref #
3mm	2.2mm	5085-1-222
4mm	3.2mm	5085-2-032
5mm	4.0mm	5085-2-040
6mm	4.5mm	5085-2-045

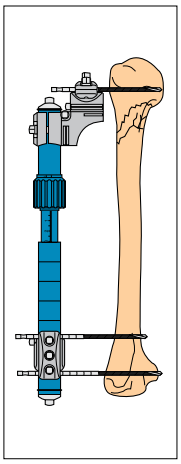
Operative Technique

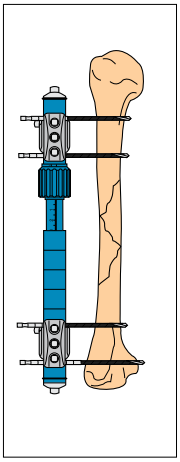
Humeral

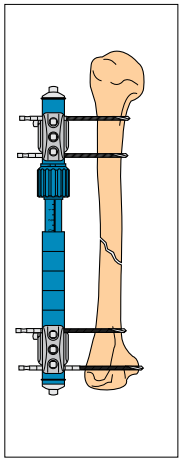


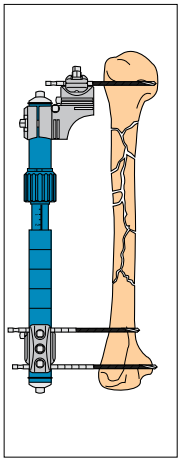
Proximal Humerus



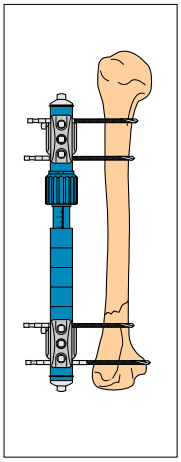






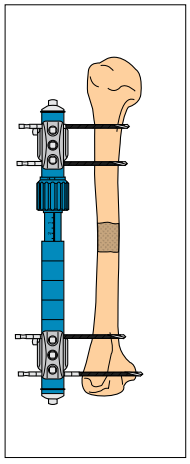


Diaphyseal Humerus

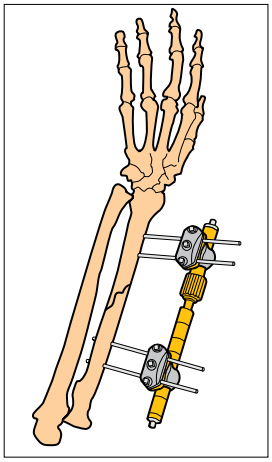


Distal Humerus

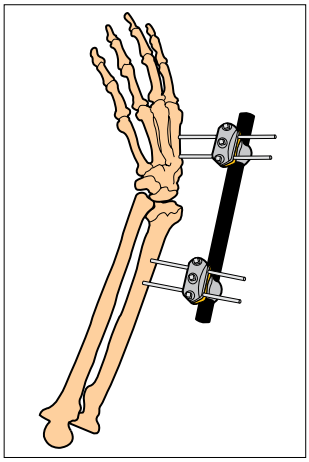
Forearm and Wrist



Humeral Lengthening

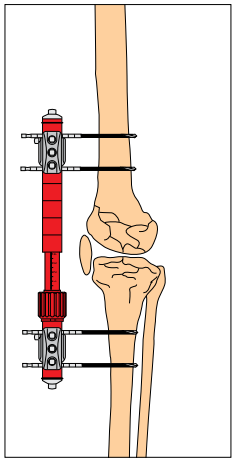


Radial Shaft

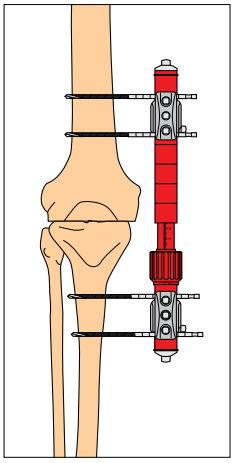


Bridging

Knee Joint

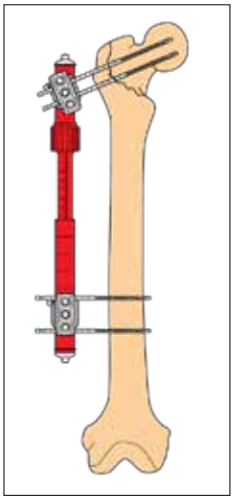


Floating Knee

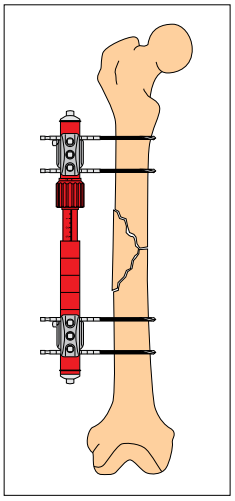


Knee Arthrodesis

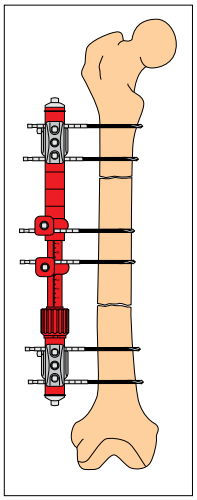
Femur



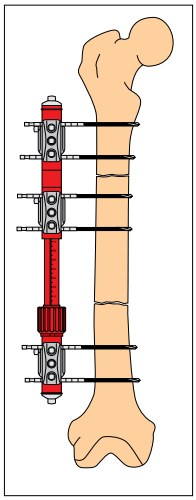
Proximal Femur

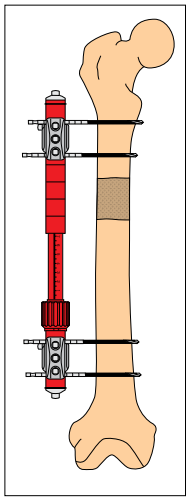


Femoral Shaft



Segmental Femur

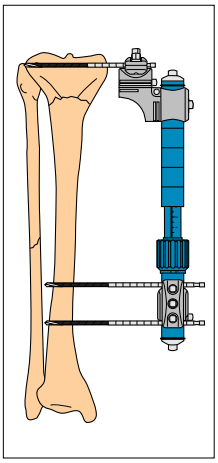




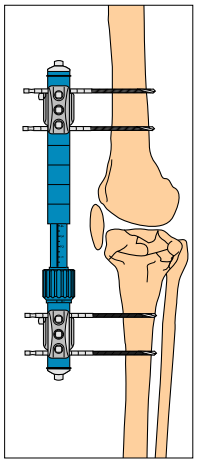
Femoral Lengthening

Operative Technique

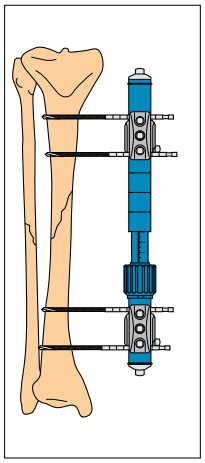
Tibial



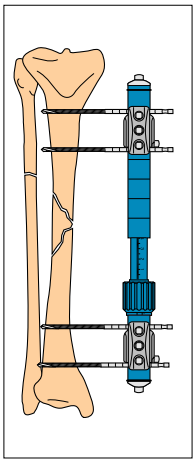
Proximal Tibia



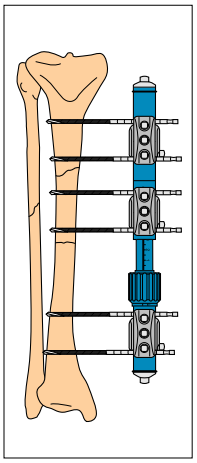
Tibial Plateau



Diaphyseal Tibia*

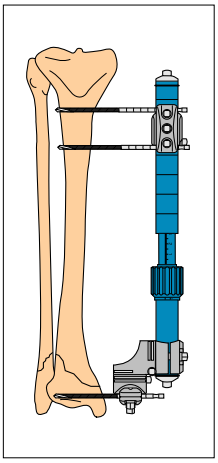


Butterfly mid shaft Tibia*

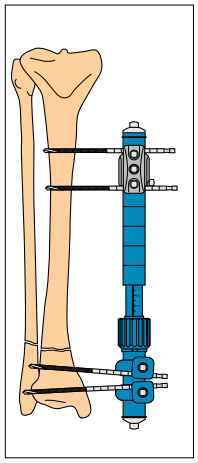


Segmental Tibia

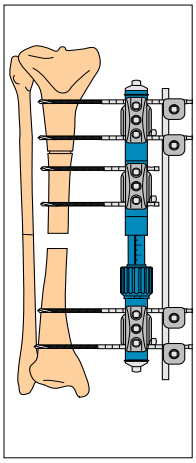
Hybrid



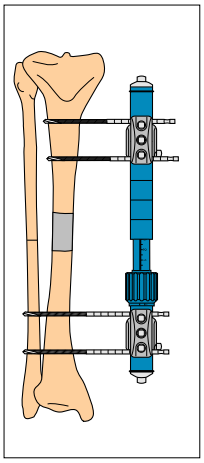
Distal Tibia



Distal Tibia



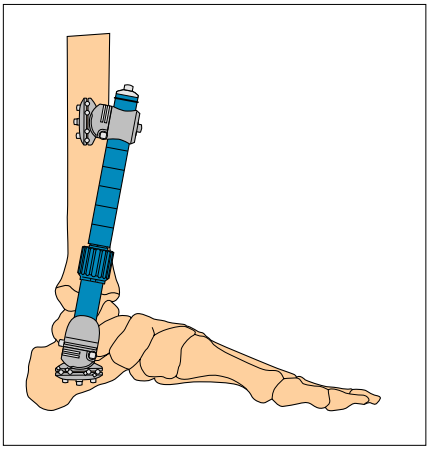
Tibial Bone Transport



Tibia Lengthening

Proximal Tibia

Ankle



Ankle Fracture

*May also be placed antero-medial

Notes:

Notes:

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Manufacturer:
Stryker GmbH
Bohnackerweg 1
2545 Selzach, Switzerland
www.stryker.com