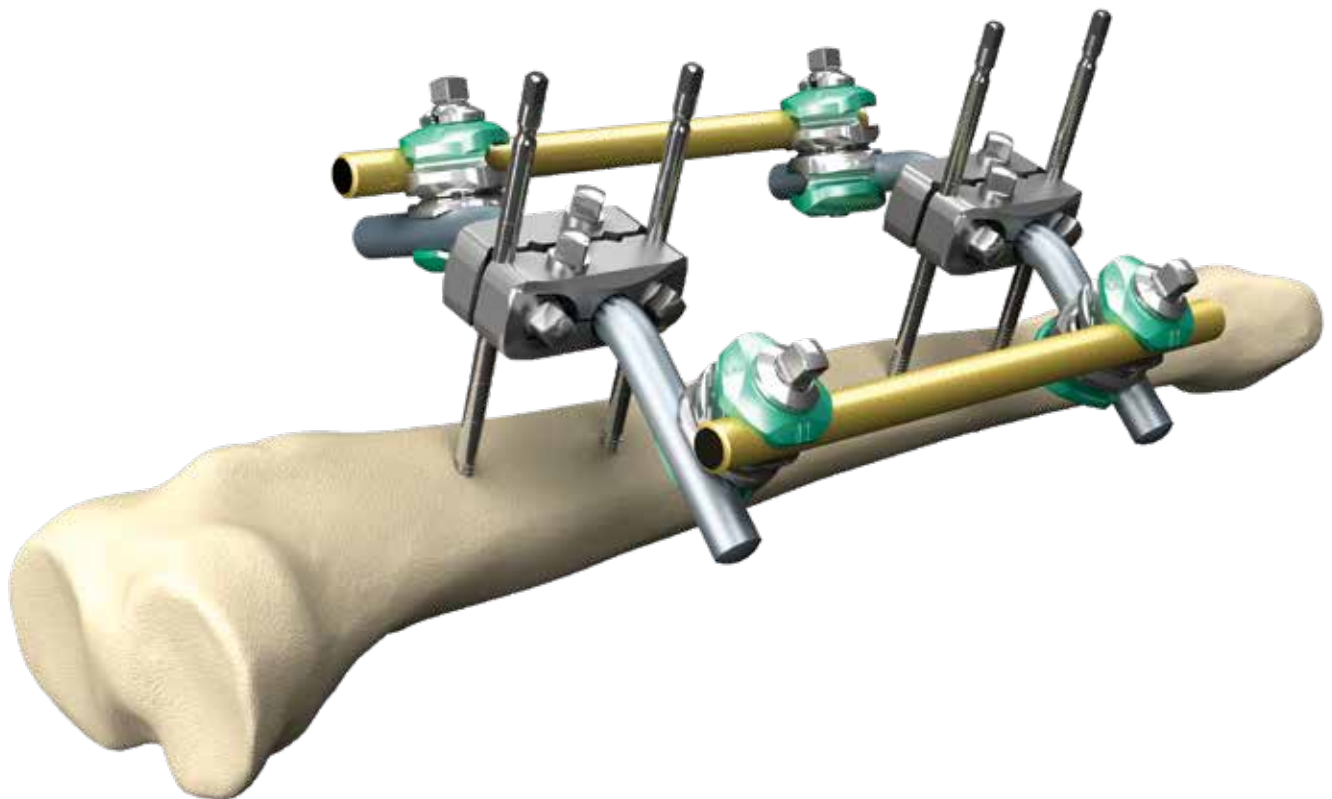


Hoffmann® 3

Modular External Fixation

Operative technique



Hoffmann 3

External fixation

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This publication sets forth detailed recommended procedures for using Stryker osteosynthesis 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

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our cleaning and sterilization guide (OT-RG1).

WARNING

Multi-component 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.

CAUTION

The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Acknowledgments

Stryker acknowledges the following surgeons for their support in the development of this technique guide:

Prof. David Seligson M.D.
 Prof. Andrew R. Burgess M.D.
 Dr. Greg M. Osgood M.D.
 Mr. Christopher T. Andrews, FRCS.

Introduction

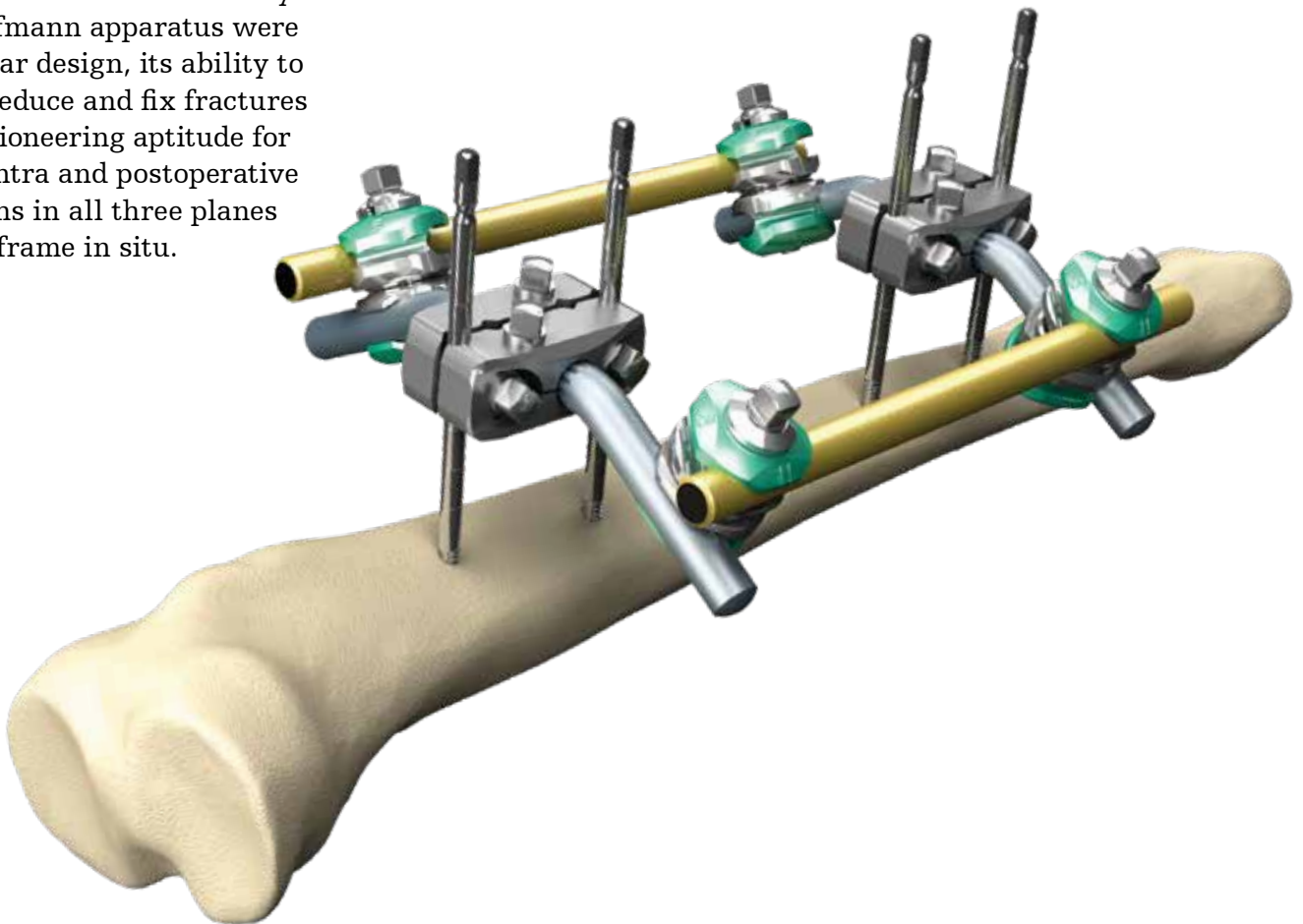
In 1938, Raoul Hoffmann, a German-born surgeon living and working in Geneva, Switzerland, set himself the goal of designing a new way to reduce and fix broken bones. His objective was to devise a system that would utilise an alternative form of fracture treatment, without reliance on open surgery. The result was history's first fully-functional, mainstream external fixation system¹.

The main features of the newly born Hoffmann apparatus were its modular design, its ability to realign, reduce and fix fractures and the pioneering aptitude for making intra and postoperative corrections in all three planes with the frame in situ.

Hoffmann's closed reduction technique helped establish the very doctrine for minimally invasive orthopaedic surgery while laying the foundation for the osteotaxis method, a term that Hoffmann coined himself¹.

Over the years, the Hoffmann System has evolved considerably. Today's completely modular Hoffmann 3 remains faithful to the ingenuity of its inventor.

The Hoffmann 3 is a modular, multiplanar external fixation system with independent pin placement capabilities, rapid assembly snap-fit couplings and MR conditional frame options that are designed to adapt freely to the anatomy to form constructs of high stability for the management of trauma and correction of deformities.



1. Raoul Hoffmann and His External Fixator, Schwechter, E. M., Swan, K. G.; Published in J Bone Joint Surg Am, Vol. 89, Issue 3, Pages 672 - 678.

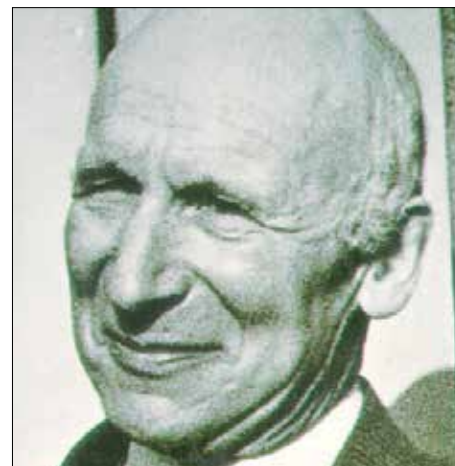
Introduction

It is comprised of a handful of key elements that work in precise agreement to enable surgeons to create a wide variety of frames that allow unhindered access to damaged tissues, permitting rapid and effective treatment of numerous traumatic injuries^{2,3}. The Hoffmann 3 is not just an update to the earlier renditions of this system; it is the result of comprehensive engineering that has successfully built upon and significantly added to the power, utility and rich legacy of the previous generations.

In the Hoffmann 3 you will find not just a new look, but a demonstrably innovative feel to the entire platform of 11mm based components. The new generation of fully articulating delta couplings promote enhanced stability, greater versatility and unrivalled convenience.

The delta couplings feature full compatibility with Hoffmann II MRI and even Hoffmann II Compact MRI. That means you can use any combination of 5, 8 and 11mm connecting rods in any construct you build. You can rotate all of the couplings independently to allow numerous provisional options and the freedom to refine your construct throughout the entire surgical procedure.

These same couplings can be locked securely once definitive reduction and fixation have been achieved. A variety of pin clamps allow you to accurately position each pin while an expanded selection of straight and angled posts extends the reach and utility of your frames.



This versatile resource of components enables you to build entire constructs that meet the requirements set forth in ASTM (American Society for Testing and Materials) standards that govern safe usage of medical devices in MRI environments. Compliance with these standards include all Vectran coated connecting rods, making Stryker both a pioneer and industry leader in MR conditional external fixation technology⁴⁻⁶.

1. Raoul Hoffmann and His External Fixator, Schwlechter, E. M., Swan, K. G.; Published in J Bone Joint Surg Am, Vol. 89, Issue 3, Pages 672 - 678.

2. The Damage control Orthopedic (DCO) Footplate: A New Use of the Hoffmann II External Fixation System. Beck, D.J. Seligson, D. Mereau, T., Published in OsteoTrauma Care 2004, Volume 12, Pages 16 - 19.

3. A Comparison of Two Military Temporary Femoral External Fixators. LTC Paul J. Dougherty, MD; CPT Brian Vickaryous, MD; Edgar Conley, PhD; and Kyle Hickerson, BS; Published in Clinical Orthopaedics and Related Research Number 412, Pages 176 -183

4. Stryker White Paper; Magnetic Resonance Imaging Testing of External Fixation Frames: Stryker Hoffmann II; J. Nyenhuis, PhD.; School of Electrical and Computer Engineering, Purdue University

5. Thermal Response and Torque Resistance of Five Cortical Half Pins Under Simulated Insertion Technique; Wikenheiser, M. A., Market, M. D., Lewallen, D. G., et al., Published in J. Orthop Res 1995; 13; 615 - 619

6. Patents: www.stryker.com/patents

Introduction

The Hoffmann 3 was developed for use in acute trauma, damage control orthopaedics and definitive fixation settings and is endowed with a variety of features that make it simple, fast, precise and adaptable for many types of patients, regardless of their size or build.

You can place pins wherever they are needed and then build the frame around them. You can assemble constructs to suit a variety of fractures, including those close to a joint, while easily accommodating the associated soft tissue envelopes. The single point of tightening snap-fit technology and simple instrumentation are designed to enable you to build stable frames quickly and easily²⁻³. With the frame in place, minimal effort is needed to fine-tune the construct after initial reduction¹. Rods and couplings can be clicked on and off at any time. These important features help contain and rapidly stabilise orthopaedic injuries to allow the patient's overall physiology to improve while providing either temporary or definitive treatment⁴.

The third generation of the Hoffmann system has undergone a rigorous testing protocol to ensure that it continues the venerable tradition of its predecessors. In the following pages, you will find a thorough description of the Hoffmann 3 and a detailed



overview of several commonly utilised frames using this ground-breaking system.

Stryker is committed to the highest level of quality, safety and patient care. The entire Hoffmann 3 External Fixation System (Hoffmann 3) was designed from the ground up for MR conditional placement in MRI environments up to 3.0 Tesla. Hoffmann 3 complies with the American Society for Testing and Materials (ASTM) testing requirements for passive medical devices in the MRI environments.

For more detailed information please refer to the specific section in this operative technique.



1. Raoul Hoffmann and His External Fixator, Schwedter, E. M., Swan, K. G.; Published in J Bone Joint Surg Am, Vol. 89, Issue 3, Pages 672 - 678.
2. The Damage control Orthopedic (DCO) Footplate: A New Use of the Hoffmann II External Fixation System. Beck, D.J. Seligson, D. Mereau, T., Published in OsteoTrauma Care 2004, Volume 12, Pages 16 - 19.
3. A Comparison of Two Military Temporary Femoral External Fixators. LTC Paul J. Dougherty, MD; CPT Brian Vickaryous, MD; Edgar Conley, PhD; and Kyle Hickerson, BS; Published in Clinical Orthopaedics and Related Research Number 412, Pages 176 -183
4. Stryker White Paper; Magnetic Resonance Imaging Testing of External Fixation Frames: Stryker Hoffmann II; J. Nyenhuis, PhD.; School of Electrical and Computer Engineering, Purdue University

Indications and contraindications

Intended use

The Hoffmann 3 Modular External Fixation System is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

Indications for use

The Hoffmann 3 Modular External Fixation System components are external fixation frame components for use with the components of the Hoffmann II MRI and Hoffmann II Compact MRI External Fixation Systems, in conjunction with Apex Pins. It is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

The indications for use of external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

Contraindications

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

Conditions presenting an increased risk of failure include:

1. Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device.
2. Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
3. Previous history of infections.
4. Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing.
5. Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
6. Malignancy in the fracture area.
7. Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen.

See package insert V15267, V15271 for warnings and precautions.

Radiologist guidelines

MR conditional

Stryker is committed to the highest level of quality, safety and patient care. The entire Hoffmann 3 External Fixation System (Hoffmann 3) was designed from the ground up for MR conditional placement in MRI environments.

Hoffmann 3 complies with the American society for testing and materials (ASTM) testing requirements for passive medical devices in the MRI environments.

Stryker utilizes a systems approach to address two key areas of concern in MRI use:

- (1) Frame displacement and
- (2) Frame heating.

To address these concerns, Hoffmann 3 is designed with non-ferromagnetic materials and insulated carbon rods:

- Clamps and couplings are made from aluminum, austenitic steel and titanium
- Posts are made from austenitic steel and aluminum
- Apex Pins are made from austenitic steel and titanium
- Carbon-fiber rods are coated with an electrically insulating Vectran

Since Hoffmann 3 components are non-magnetic, magnetic fields in the MRI environment will not displace the frame nor pose a risk of magnetic injury to patients or damage to the scanner if used under proper conditions.

1. ASTM F2503-08: <http://www.astm.org/Standards/F2503.htm>

Radiologist guidelines

MRI components

The MRI components have been tested according to ASTM standards F2052, F2119, F2182, and F2213.

The Hoffmann 3 MRI system can only be guaranteed for MRI use when using Stryker's Apex Pins to build a frame.

CAUTION

Frame tests have been performed² in areas where the greatest temperature increase is expected with commonly used frames. Due to the versatility of the system, an unlimited number of frames can be built which makes it impossible to test each and every construct.

Based on the test results, the Hoffmann 3 may be used in MRI procedures under the specified conditions. There are factors that can influence these results like the number of pins used in the clamps and the number of open and closed loops in the frame. Therefore, it is recommended that each frame be evaluated by the responsible HCP or MR scientist before the MRI procedure to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Stryker recommends for patient's safety to minimize SAR settings as much as possible.



4922-1-010



4922-1-020



4922-1-030



4922-1-015



4922-1-025



4921-2-060



4921-2-080



4922-2-020



4922-2-320



4922-2-220



4922-2-240



4922-2-340



4922-1-220



4922-8-XXX



4922-7-220



4922-2-160



4922-2-120



4922-2-140

Non-clinical testing has been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 3.0 Tesla or maximum spatial gradients higher than 90.0 mT/cm.

MR image quality may be compromised if the area of interest is in the exact same area as or approx. 10cm under worst case conditions to the position of the frame or its individual components.

² Based upon Biomechanical Lab Reports: BML 11-066, BML 11-270, BML 12-061, BML 12-062, Stryker in Selzach, Switzerland.

Radiologist guidelines

It has been shown by specific MRI tests² that the Hoffmann 3 external fixation system may be used for patients undergoing MRI procedures using up to 3.0 Tesla MR systems if certain specific conditions are met. The following frames have been tested in 1.5 Tesla and with 2 exceptions also in 3.0 Tesla MRI environments. All components are safe with respect to displacement in an MRI magnetic field with a maximum spatial gradient of 90 mT/cm.

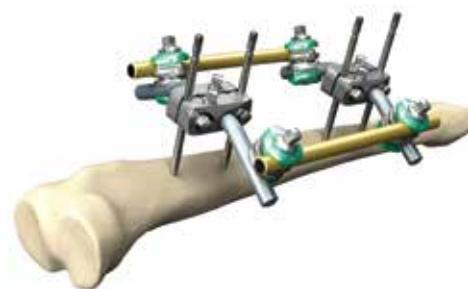
Standard bilateral tibia frame

1.5 Tesla MR system

ΔT_{\max} : 4.45°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR System

ΔT_{\max} : 2.80°C at 0.5W/kg at a whole body average SAR for MR imaging time of 15 minutes



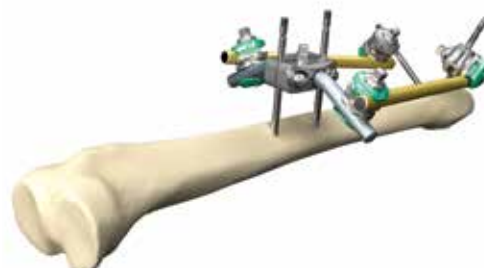
Distal tibia shaft frame with independent pin placement

1.5 Tesla MR system

ΔT_{\max} : 2.55°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR system – *USE OF OUT OF BODY COIL RECOMMENDED

ΔT_{\max} : 6.70°C at 0.5W/kg at a whole body average SAR for MR imaging time of 15 minutes

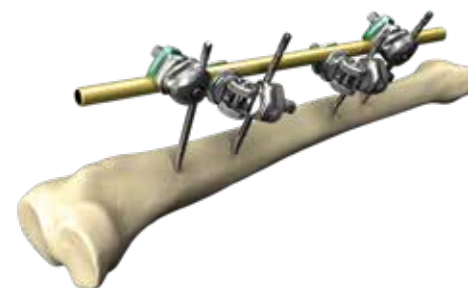


Tibia single rod frame with multiplanar delta coupling

1.5 Tesla MR system

ΔT_{\max} : 2.8°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR system – Not yet tested at 3.0 Tesla



CAUTION

Tests have been performed using a MR system for a max. image time of 15 minutes. Please note that the Specific Absorption Rate (SAR) may be reported differently, e.g. as whole body averaged SAR or as partial SAR by the software depending on the MR system used.

* $\Delta T_{\max} < 2.0^\circ\text{C}$ at 0.5W/kg if frame is more than 25cm away from body coil centre

² Based upon Biomechanical Lab Reports: BML 11-066, BML 11-270, BML 12-061, BML 12-062, Stryker in Selzach, Switzerland.

Radiologist guidelines

Femur emergency frame with independent pin placement

1.5 Tesla MR system

ΔT_{\max} : 2.65°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR system – *USE OF OUT OF BODY COIL RECOMMENDED

ΔT_{\max} : 6.10°C at 0.5W/kg at a whole body average SAR for MR imaging time of 15 minutes

Knee bridging Z-frame, Independent pin placement, with rod coupler

1.5 Tesla MR system

ΔT_{\max} : 1.0°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR system – Not yet tested at 3.0 Tesla

Pelvis osteotaxis frame with multi-Iliac crest pin placement

1.5 Tesla MR system

ΔT_{\max} : 2.65°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR system

ΔT_{\max} : 4.70°C at 0.5W/kg at a whole body average SAR for MR imaging time of 15 minutes

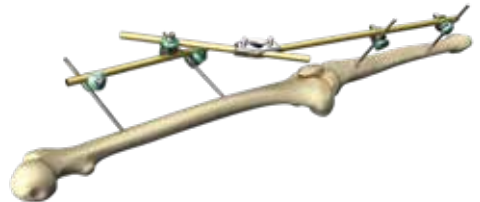
Pelvis osteotaxis frame with independent Iliac crest pin placement

1.5 Tesla MR system

ΔT_{\max} : 1.20°C at 1.0W/kg at a whole body average SAR for MR imaging time of 15 minutes

3.0 Tesla MR system – *USE OF OUT OF BODY COIL RECOMMENDED

ΔT_{\max} : 7.60°C at 0.5W/kg at a whole body average SAR for MR imaging time of 15 minutes



CAUTION

Tests have been performed using a MR system for a max. image time of 15 minutes. Please note that the Specific Absorption Rate

(SAR) may be reported differently, e.g. as whole body averaged SAR or as partial SAR by the software depending on the MR system used.

* $\Delta T_{\max} < 2.0^\circ\text{C}$ at 0.5W/kg if frame is more than 25cm away from body coil centre

² Based upon Biomechanical Lab Reports: BML 11-066, BML 11-270, BML 12-061, BML 12-062, Stryker in Selzach, Switzerland.

Components

Delta couplings

Design features for easy frame assembly:

- Pre-assembled thumbwheel for provisional tightening
- Three dimensional rotation
- Snap-fit technology

Delta coupling, rod-to-rod or pin-to-rod

The rod-to-rod delta couplings can snap onto Ø5, Ø8 or Ø11mm connecting rods and Ø5mm Apex Pins. Rod-to-rod delta couplings are color coded green/green.



Delta coupling, rod-to-rod or pin-to-rod

Delta coupling, pin-to-rod

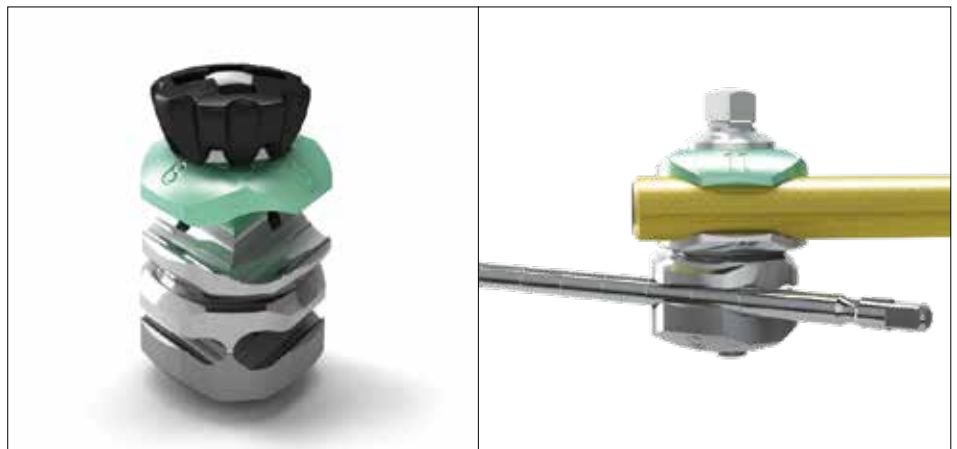
The pin-to-rod delta couplings are designed to fit onto a choice of Ø5, Ø8 or Ø11mm connecting rods and Ø4, Ø5 or Ø6mm Apex Pins. Pin-to-rod delta couplings are color coded grey/green.



Delta coupling, pin-to-rod

Delta coupling, pin-to-rod, inverted

'Inverted' pin-to-rod delta coupling are available with the bolt on opposite side to facilitate easy tightening when required by special frame construct accessibility. 'Inverted' pin-to-rod delta couplings are color coded green / grey.



Delta coupling, pin-to-rod, inverted

NOTICE

Standardization with one coupling may be achieved by utilizing a rod-to-rod delta coupling with Ø8mm or Ø11mm connecting rod and 5mm Apex Pins or 3/5mm, 4/5mm Hybrid Apex Pins.

Components

Delta couplings

Delta coupling, rod-to-rod, multiplanar

The multiplanar rod-to-rod delta coupling is designed to snap onto a choice of Ø5, Ø8 or Ø11mm connecting rods and/or Ø5mm Apex Pins on each side of the joint.

The planar joint allows for 180 degrees of motion and 360 degrees of rotation and with that offers additional flexibility in frame construction.

Multiplanar delta couplings are color coded green/green and include two pre-assembled thumbwheels for provisional tightening.

Delta coupling, pin-to-rod, multiplanar

The multiplanar pin-to-rod delta coupling is designed to snap onto a choice of Ø5, Ø8 or Ø11mm connecting rods and Ø4, Ø5 or Ø6mm Apex Pins on each side of the joint.

The planar joint allows for 180 degrees of motion and 360 degrees of rotation and with that offers additional flexibility in frame construction. multiplanar delta couplings, pin-to-rod are color coded grey/green and include two pre-assembled Thumbwheels for provisional tightening.



Delta coupling, rod-to-rod, multiplanar



Delta coupling, pin-to-rod, multiplanar

For easier reduction of the fracture and flexible adjustment of the frame the multiplanar delta couplings can be tightened on one side while keeping full rotational flexibility and adjustability on the other side.

The distance between the bars or pins can be varied from 0 to 37mm allowing very flexible frame construction and adjustment.

Components

Provisional tightening

Step 1

Snap two rods (or a pin and a rod) into a delta coupling.

Step 2

Provisionally tighten the coupling to the rods using the thumbwheel.



Step 1



Step 2

Step 3

Remove the single-use thumbwheel from the delta coupling before the final tightening.

Should provisional tightening or re-adjustment be necessary, the Thumbwheel can be re-attached.



Step 3



Final tightening

For final tightening use either the T-handle (4920-9-030) or spanner wrench (4920-9-036).



Final tightening



Components

5-Hole pin clamp

5 Hole pin clamps can be used if parallel pin placement is desired. The clamp can hold up to five Apex Pins, accommodating Ø4, Ø5 or Ø6mm pins.

- Pin clamps are secured to the Apex Pins by tightening the 7mm square nuts on the side of the clamp

Posts

Straight, 30° or 90° angled Ø11mm posts are used along with the pin clamps to provide a compact, fracture-specific frame.

- Posts are locked into place by tightening the two 7mm square nuts on the top of the clamp

Fixed post clamps

5 Hole pin clamps with either one or two straight or 30° angled fixed posts are included in the Hoffmann 3 platform for efficient frame construction.

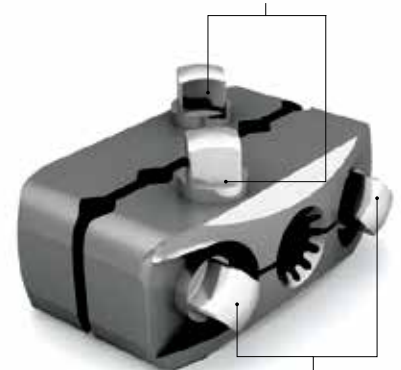
Rod coupler, 30°

The rod couplers are designed to connect two Ø11mm connecting rods in a fixed angle. They are ideal for long spanning frames such as knee bridging frames or pelvic bow creation. The couplers allow also asymmetric fixation of the rods, thus allowing for exact adaptation to the anatomy of the patient. The window in the coupler allows for visual control of the depth of the rods in the clamping area. With that one can ensure stable connection and tight fit.

NOTICE

Tightening of the nuts for locking the posts without any posts in the hole can deform the 5-hole pin clamps and therefore limit its functionality.

Nuts for locking the posts in place



Nuts for securing clamps to the Apex Pins

NOTICE

Alternatively the 5-hole pin clamp with posts can be replaced by a pre-welded 5-hole pin clamp with fixed posts.



Components

5, 8 and 11mm connecting rod options

Carbon fiber Vectran Coated Connecting Rods, 5, 8 and 11mm options

Stryker provides electrically insulated carbon rods for MR conditional use. The Ø11mm Vectran Coated Carbon Connecting Rods are available in lengths from 100mm to 650mm.

The Vectran Coated Semi Circular rods may be used for the fixation of distal femur or proximal and distal tibia fragments (see page 23 and 24).



MR conditional

CAUTION

All Vectran Coated Carbon Connecting rods are intended for single patient use only. Once used on a patient they have to be disposed of.

Unused rods can be reprocessed in the tray according to the cleaning and sterilization instructions mentioned in the package insert. Tests have shown intended performance for 50 reprocessing cycles.*

CAUTION

Frames using one or more MR unsafe components shall not be used in MR Environment.



MR unsafe

* Biomechanical Test Reports:
BML 11-059, BML 12-054

Compatible components

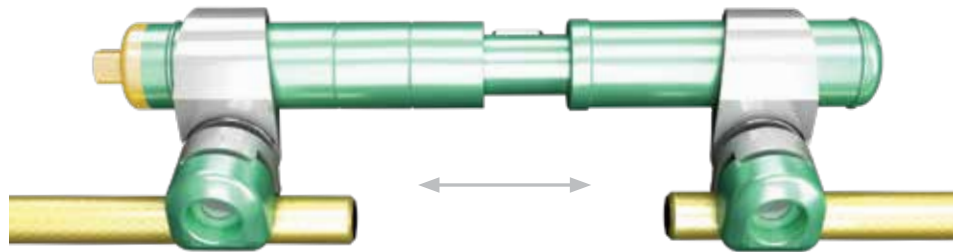
Compression / distraction tube

The compression /distraction (C/D) tube may be incorporated into the frame to allow fine adjustments for fracture reduction. The C/D tube may be distracted to a maximum of 45mm. One complete revolution of the 7mm square head screw equals 1mm displacement. Turn counter-clockwise for distraction and clockwise for compression.

Ø20mm rod-to-tube clamps are used to connect the compression / distraction tube to 8mm connecting rods or multi-pin clamp posts. The rod-to-tube clamps employ the same non-slip, snap-fit mechanism as the pin-to-rod and rod-to-rod delta couplings.

CAUTION

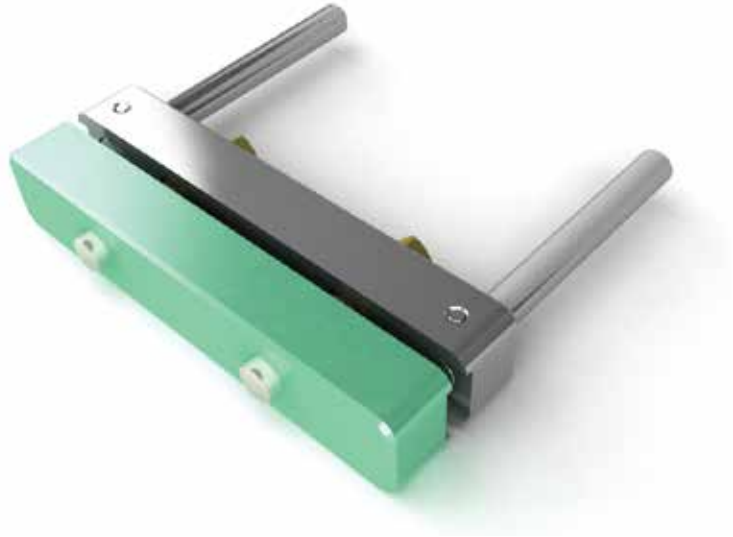
MR conditional information:
compression / distraction Tube
should be used OUT OF BODY
COIL.



Compatible components

Pelvic clamp

The pelvic clamp is specially designed to be used with pins placed in the iliac crest. Since the clamp does not have dedicated pin grooves, it can clamp onto pins that are not fully parallel.



10-hole pin clamp

10-hole pin clamps can hold up to ten 4, 5 or 6mm Apex Pins to build frames tailored to bridging long distances in the femur or tibia by increasing stability due to its wide pin spread.

NOTICE

Tightening of the nuts for locking the posts without any posts in the hole can deform the 10-hole pin clamps and therefore limit its functionality.



CAUTION

All Hoffmann II MRI components are mechanically compatible with the Hoffmann 3 Couplings. However, only the frames shown in this operative technique have been tested for MR environment.

Components

Apex Pin

Four types of half pins are offered in the system: blunt / self-tapping half pins, blunt / cancellous half pins, self-drilling/self-tapping half pins, and self-drilling transfixing pins. Pre-drilling is necessary when using blunt pins. It is optional to pre-drill when using selfdrilling pins.

General guidelines for pre-drilling

- Always pre-drill with a new, sharp drill
- Drill slowly to help prevent thermal injury
- When placed through an exposed bone surface irrigating the interface can reduce heating
- Always use a drill that's smaller in diameter than the Apex Half Pin

Additional options

- Stainless steel and titanium
- HA coating
- Sterile and non sterile packaging
- Hybrid Apex Pins with 3mm thread diameter and 5mm shaft, as well as 4mm thread diameter and 5mm shaft

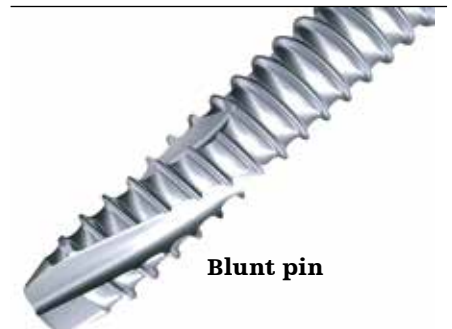
NOTICE

For additional information please refer to the specific Apex Pin Brochure.

Literature number APEX-ST-1.



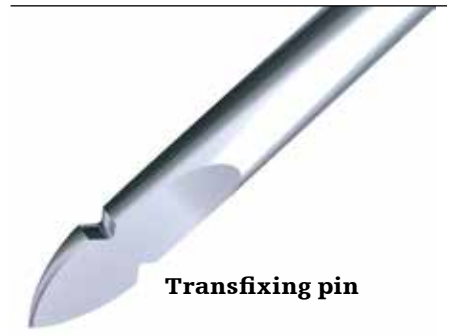
Self-drilling pin



Blunt pin



Cancellous pin



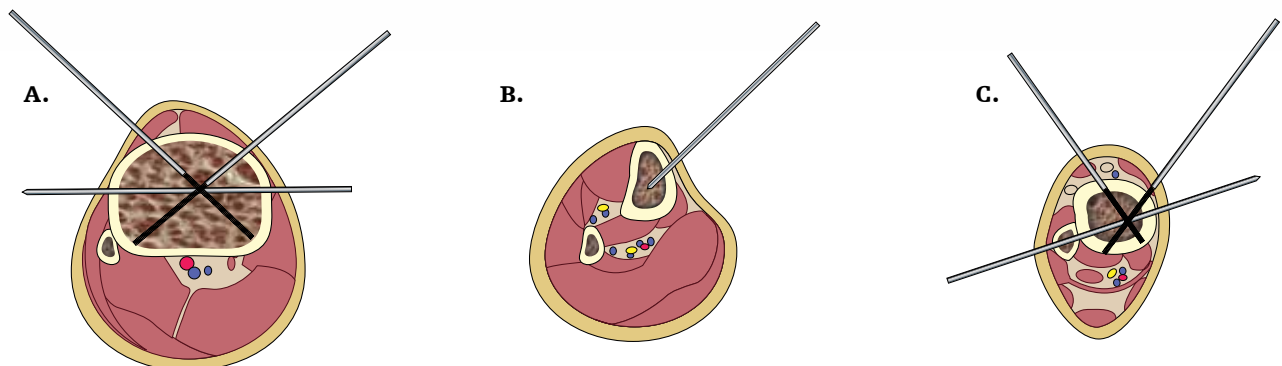
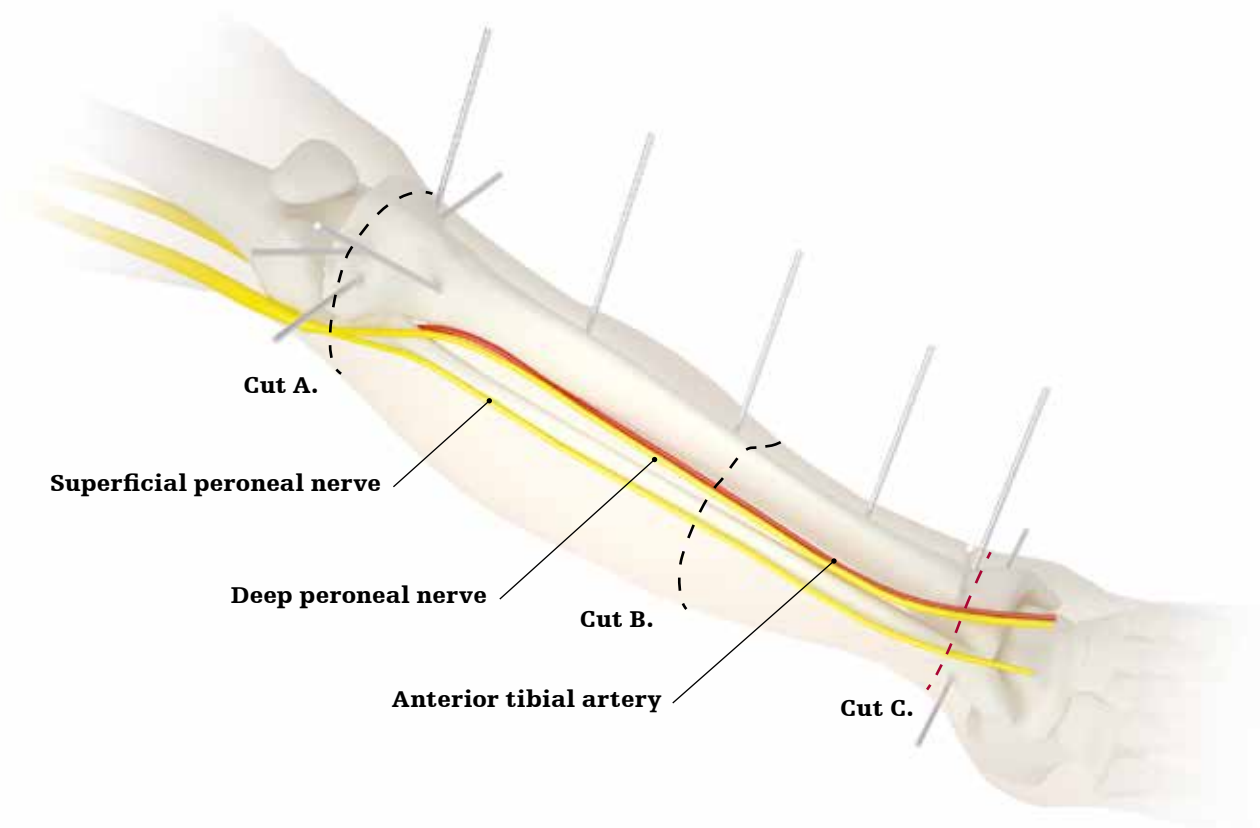
Transfixing pin

Pin thread diameter	Drill bit	Location
3mm	2.2mm	Ulna, radius, wrist, metacarpal
4mm	3.2 – 3.5mm	Radius, ulna, humerus, tibia, metatarsal
5mm	4.0 – 4.5mm	Tibia, femur, calcaneus, pelvis
6mm	4.5 – 5.0mm	Adult tibia, femur, pelvis

Tibial frames

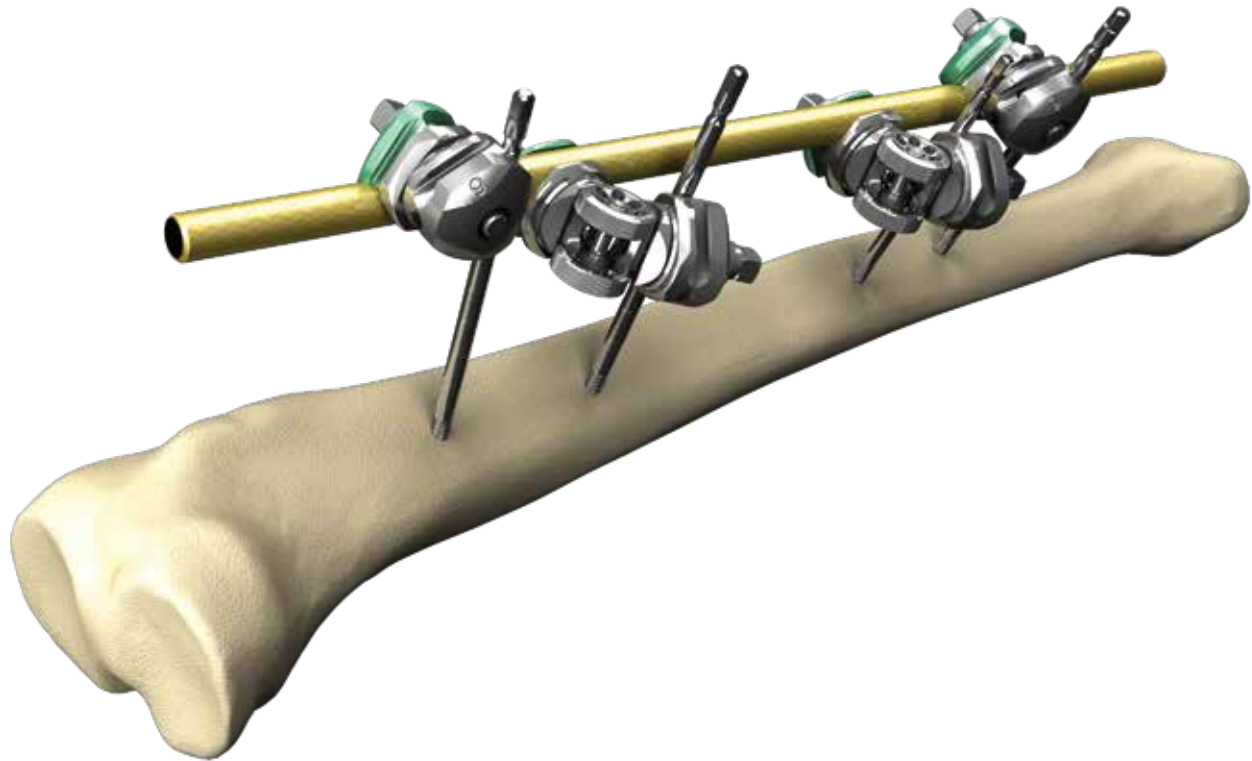
Pin technique / safe zones

- Knowledge of the cross-sectional anatomy of the tibia helps to ensure safe pin placement
- Apex Pins can be placed in the medial face of the tibia from plateau to pilon
- Transfixing pins can be safely placed except in the distal third of the tibia proximal to the metaphysis and distal to the fibula head near the peroneal nerve
- Before insertion of anterior Apex Pins near the ankle joint, perform blunt dissection to bone to ensure safety of neurovascular bundle



Tibial single rod frame

**Independent pin placement,
with multiplanar delta couplings**

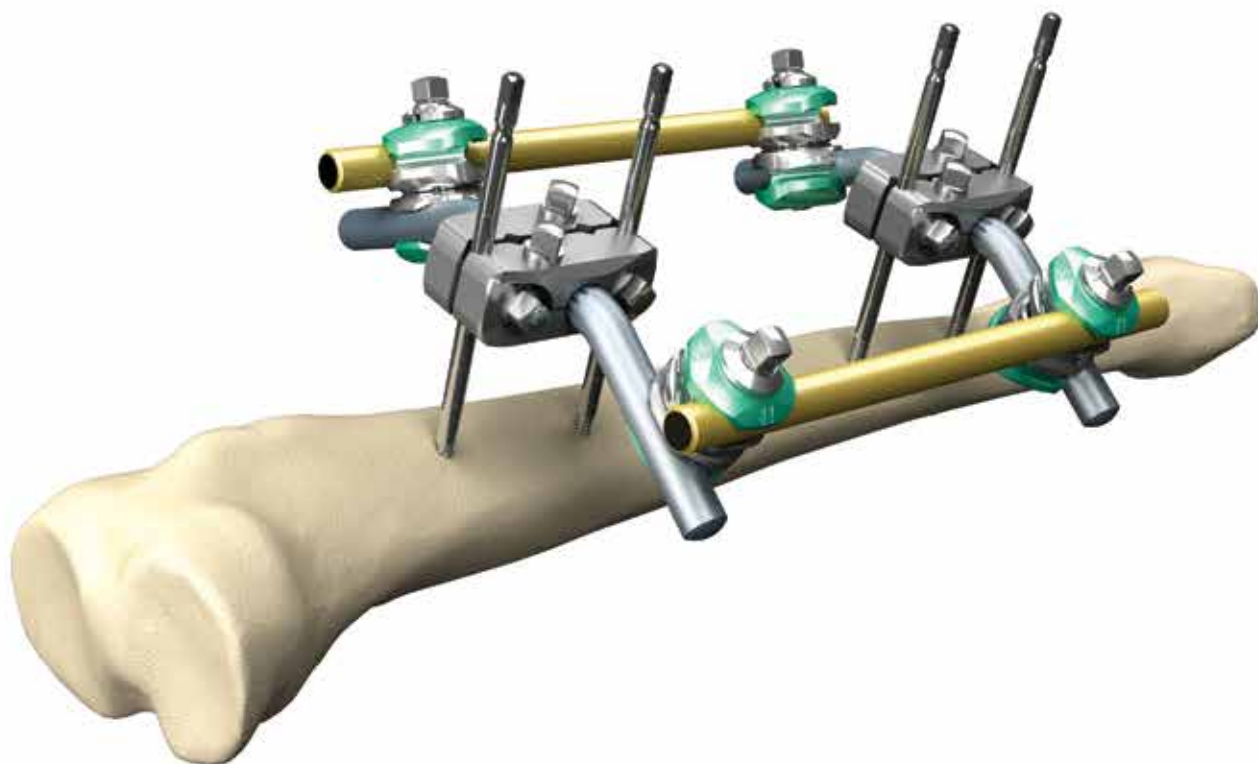


Components list

Ref	Description	Quantity
4922-1-025	Pin-to-rod delta coupling, multiplanar	2
4922-1-020	Pin-to-rod delta coupling	2
5018-5-150	Apex Pin Ø5 x 150mm	4
4922-8-300	Connecting rods Ø11 x 300mm	1

Tibial standard bi-lateral frame

Parallel pin placement



Components list

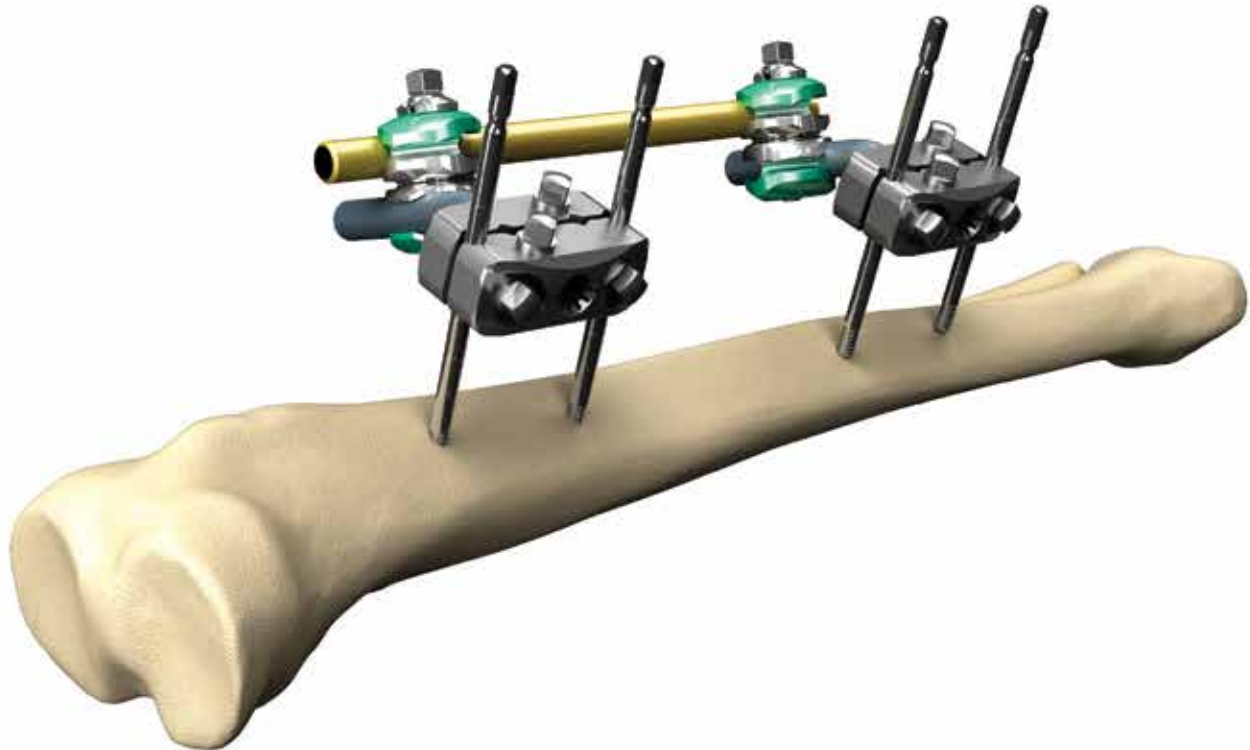
Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	2
4922-2-140	30° Angled post Ø11mm	4
4922-1-010	Rod-to-rod delta coupling	4
5018-5-150	Apex Pin Ø5 x 150mm	4
4922-8-300	Connecting rods Ø11 x 300mm	2

NOTICE

Alternatively the pin-to-rod delta couplings can be replaced by multiplanar pin-to-rod delta couplings, thus offering more flexibility and freedom when placing the Apex Pins and when reducing the fracture before final tightening.

Tibial standard osteotaxis half frame

Parallel pin placement

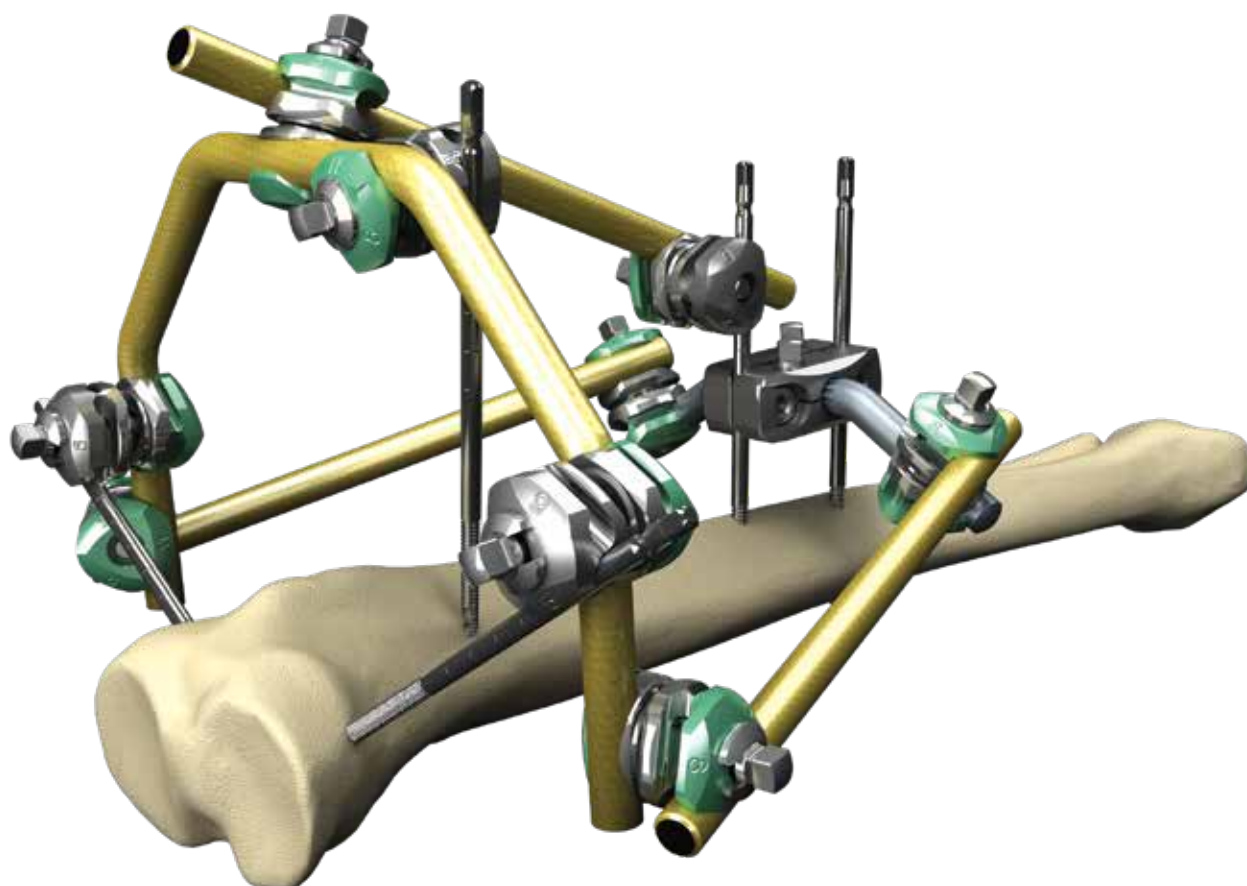


Components list

Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	2
4922-2-140	30° Angled post Ø11mm	2
4922-1-010	Rod-to-rod delta coupling	2
5018-5-150	Apex Pin Ø5 x 150mm	4
4922-8-300	Connecting rods Ø11 x 300mm	1

Tibial plateau semi-circular frame

Parallel / independent pin placement

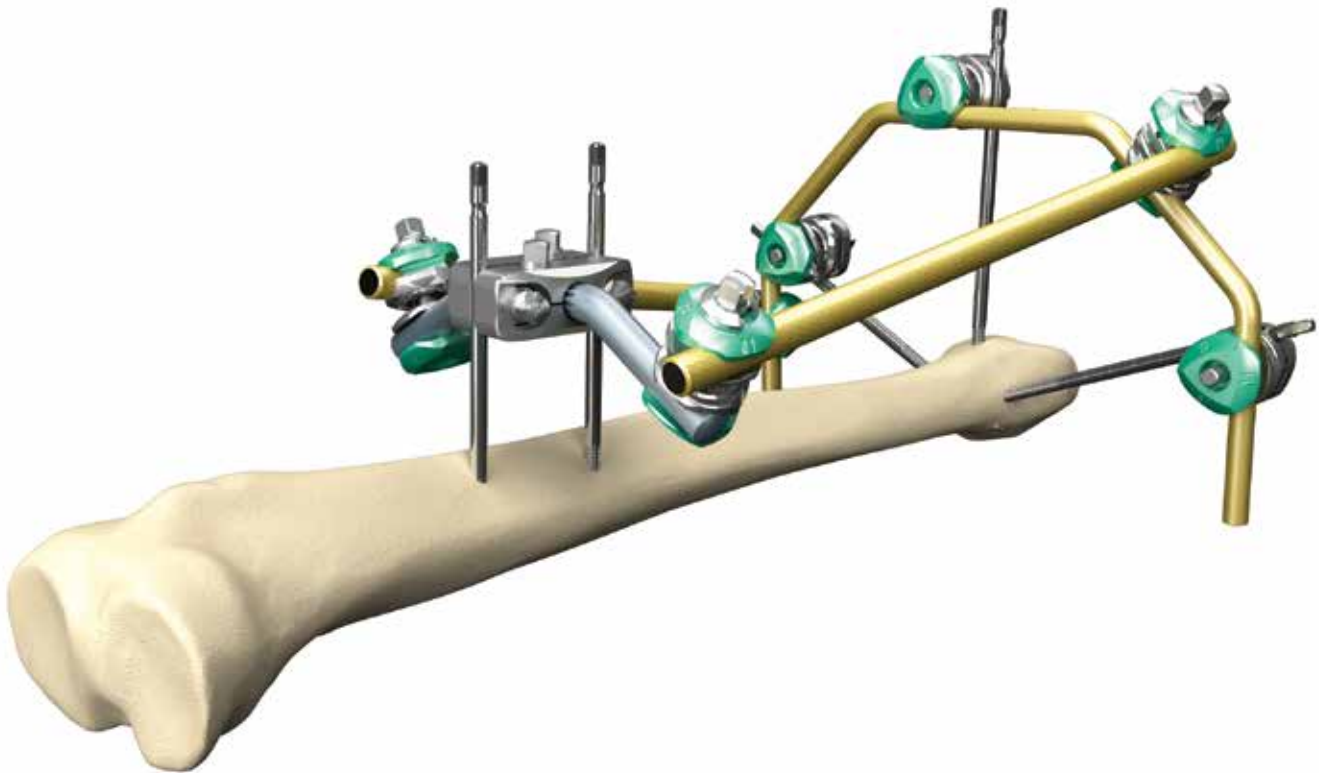


Components list

Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	1
4922-2-140	30° Angled post Ø11mm	2
4922-1-010	Rod-to-rod delta coupling	5
4922-1-020	Pin-to-rod delta coupling	2
4922-1-030	Pin-to-rod delta coupling, inverted	2
5018-5-150	Apex Pin Ø5 x 150mm	5
4922-7-220	Semi circular rod Ø11 x 220mm	1
4922-8-300	Connecting rods Ø11 x 300mm	3

Distal tibia semi-circular frame

Parallel / independent pin placement

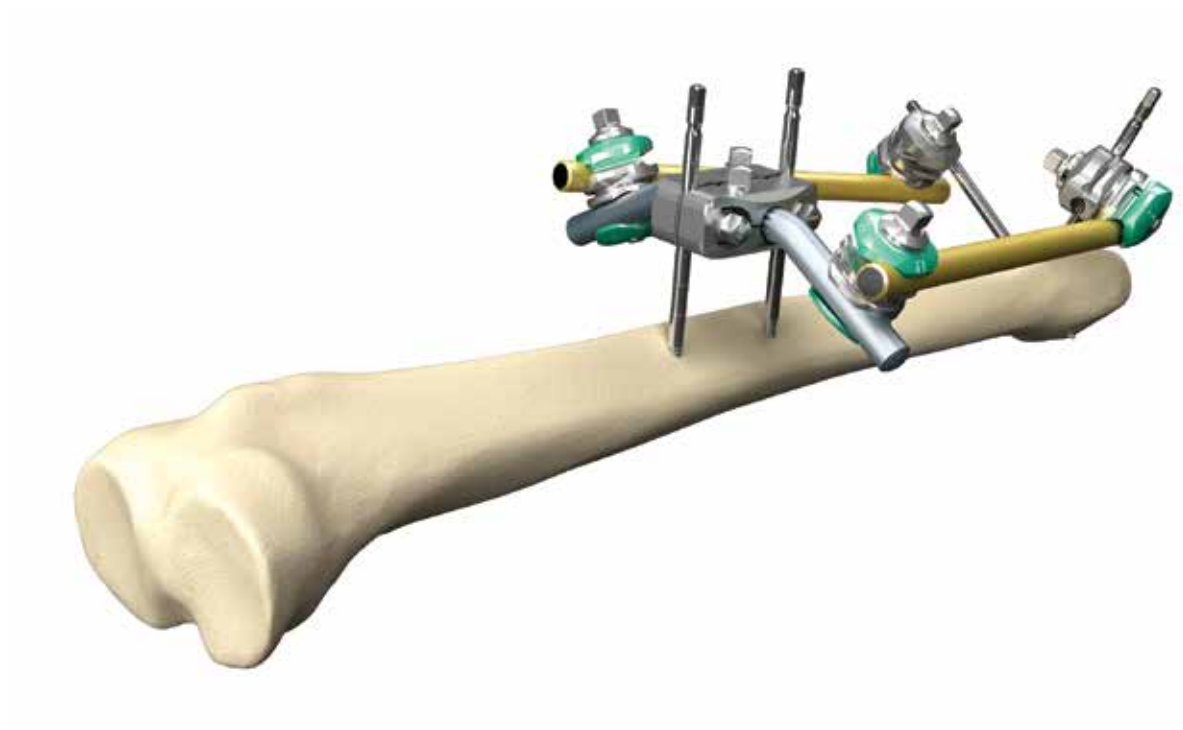


Components list

Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	1
4922-2-140	30° Angled post Ø11mm	2
4922-1-010	Rod-to-rod delta coupling	4
4922-1-020	Pin-to-rod delta coupling	3
4922-1-030	Pin-to-rod delta coupling inverted (alternatively 1)	
5018-5-150	Apex Pin Ø5 x 150mm	5
5028-7-030	Semi-circular rod Ø8mm	1
4922-8-300	Connecting rods Ø11 x 300mm	2

Distal tibia shaft frame

Parallel / independent pin placement



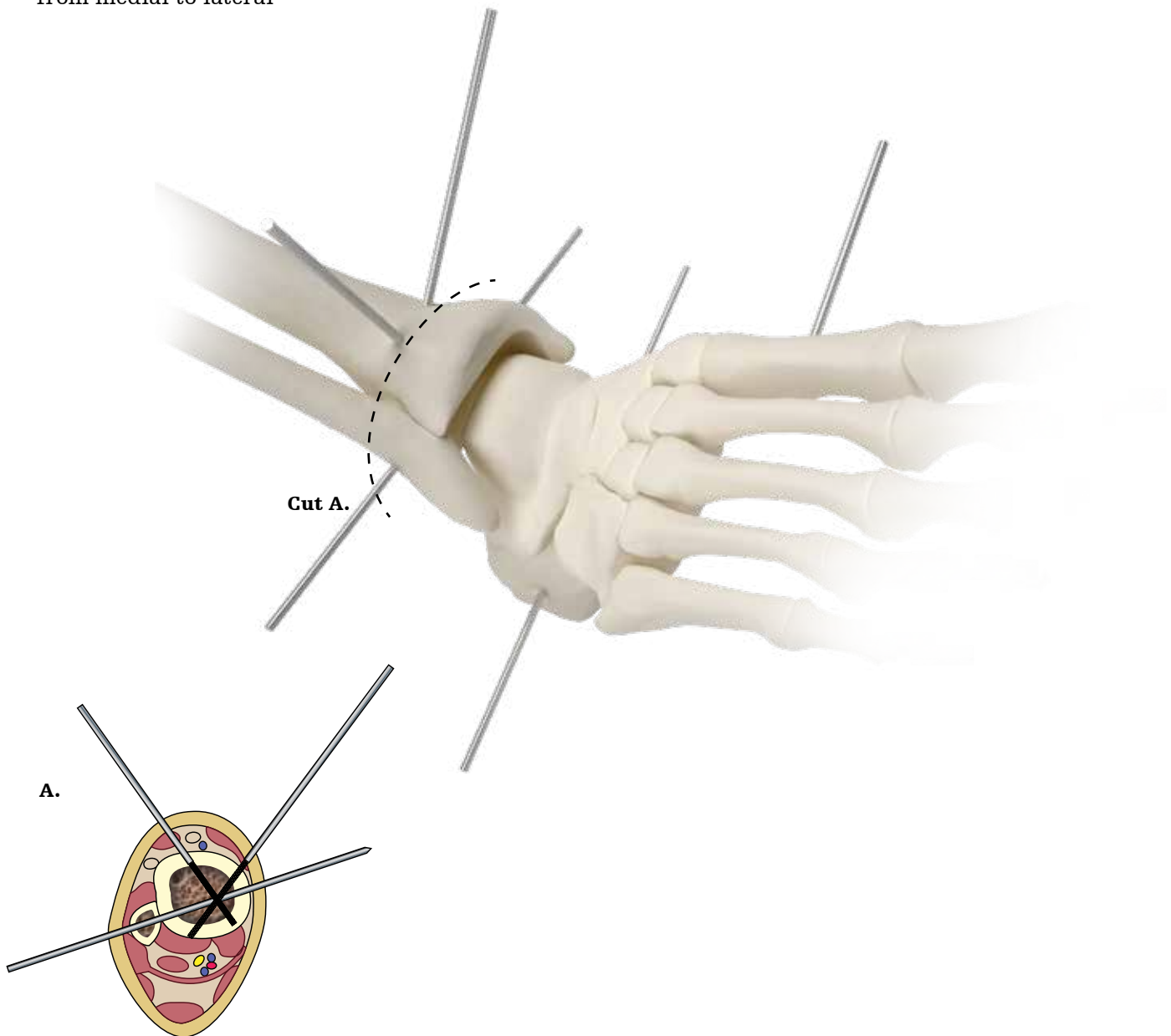
Components list

Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	1
4922-2-140	30° Angled post Ø11mm	2
4922-1-010	Rod-to-rod delta coupling	2
4922-1-020	Pin-to-rod delta coupling	2
5018-5-150	Apex pin Ø5 x 150mm	4
4922-8-250	Connecting rods Ø11 x 250mm	2

Ankle frames

Pin technique / safe zones

- Proximal to the ankle half-pins can be placed from the medial to lateral in the anteromedial face of the tibia
- Distal to the crossing of the anterior tibial vessels just proximal to the ankle transfixing pins are also safe
- Before insertion of anterior Apex Half Pins near ankle joint, perform blunt dissection to bone to ensure safety of neurovascular bundle
- Transfixation pins are placed through the calcaneus from medial to lateral



Ankle cross brace frame

Independent pin placement



Components list

Ref	Description	Quantity
5018-5-150	Apex Pin Ø5 x 150mm	1
5018-3-180	Apex Pin Ø5 x 180mm	1
5023-3-090	Apex Pin Ø4 x 90mm	1
5030-5-200	Transfixing pin Ø5/4 x 200mm	1
4922-1-010	Rod-to-rod delta coupling	5
4922-1-020	Pin-to-rod delta coupling	3
4922-1-030	Pin-to-rod delta coupling inverted	2
4922-8-350	Connecting rods Ø11 x 350mm	2
4922-8-200	Connecting rods Ø11 x 200mm	3

NOTICE

Alternatively to the Ø4mm transfixing pin with Ø5mm thread (5030-5-200) we recommend the Ø5mm transfixing pin 300mm x 40mm with Ø6mm thread (5050-4-300).

Ankle bridging frame

Parallel pin placement



Components list

Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	3
4922-2-140	30° Angled post Ø11mm	2
4922-2-120	Straight post Ø11mm	2
4922-1-010	Rod-to-rod delta coupling	4
5018-5-150	Apex Pin Ø5 x 150mm	2
5030-5-200	Transfixing pin Ø5/4 x 200mm	2
4922-8-250	Connecting rods Ø11 x 250mm	2

NOTICE

Alternatively to the Ø4mm transfixing pin with Ø5mm thread (5030-5-200) we recommend the Ø5mm transfixing pin 300mm x 40mm with Ø6mm thread (5050-4-300).

Ankle bridging half frame

Parallel / independent pin placement



Components list

Ref	Description	Quantity
5018-5-150	Apex Pin Ø5 x 150mm	3
5023-3-090	Apex Pin Ø4 x 90mm	1
4922-1-010	Rod-to-rod delta coupling	3
4922-1-020	Pin-to-rod delta coupling	4
4922-8-300	Connecting rods Ø11 x 300mm	1
4922-8-150	Connecting rods Ø11 x 150mm	2

NOTICE

Alternatively, a second pin can be placed in the calcaneus.

Ankle stabilization frame

Independent pin placement



Components list

Ref	Description	Quantity
5018-5-150	Apex Pin Ø5 x 150mm	2
5023-3-090	Apex Pin Ø4 x 90mm	1
4922-1-010	Rod-to-rod delta coupling	3
4922-1-020	Pin-to-rod delta coupling	3
4922-8-250	Connecting rods Ø11 x 250mm	2
4922-8-100	Connecting rods Ø11 x 100mm	1

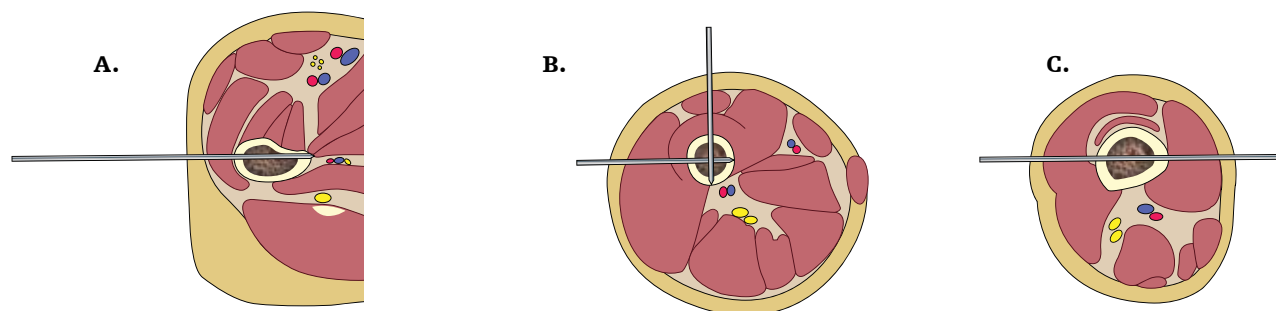
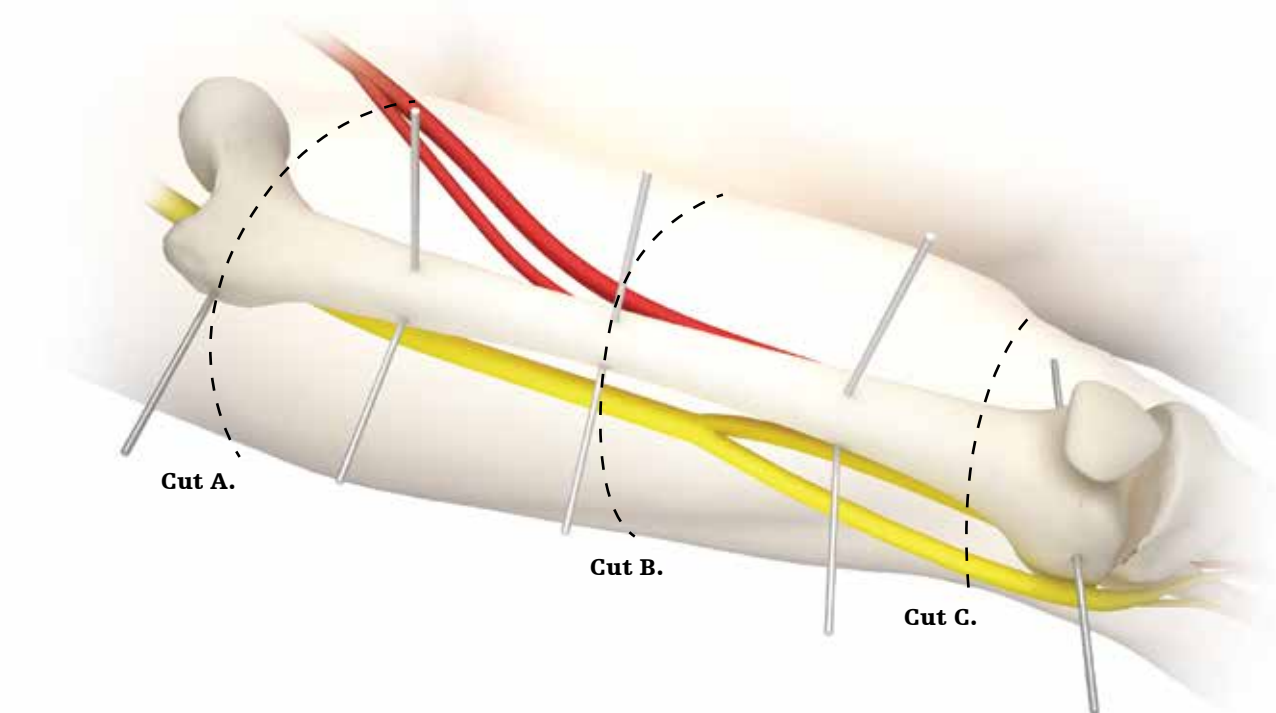
NOTICE

Alternatively, a second pin can be placed in the calcaneus.

Femur frames

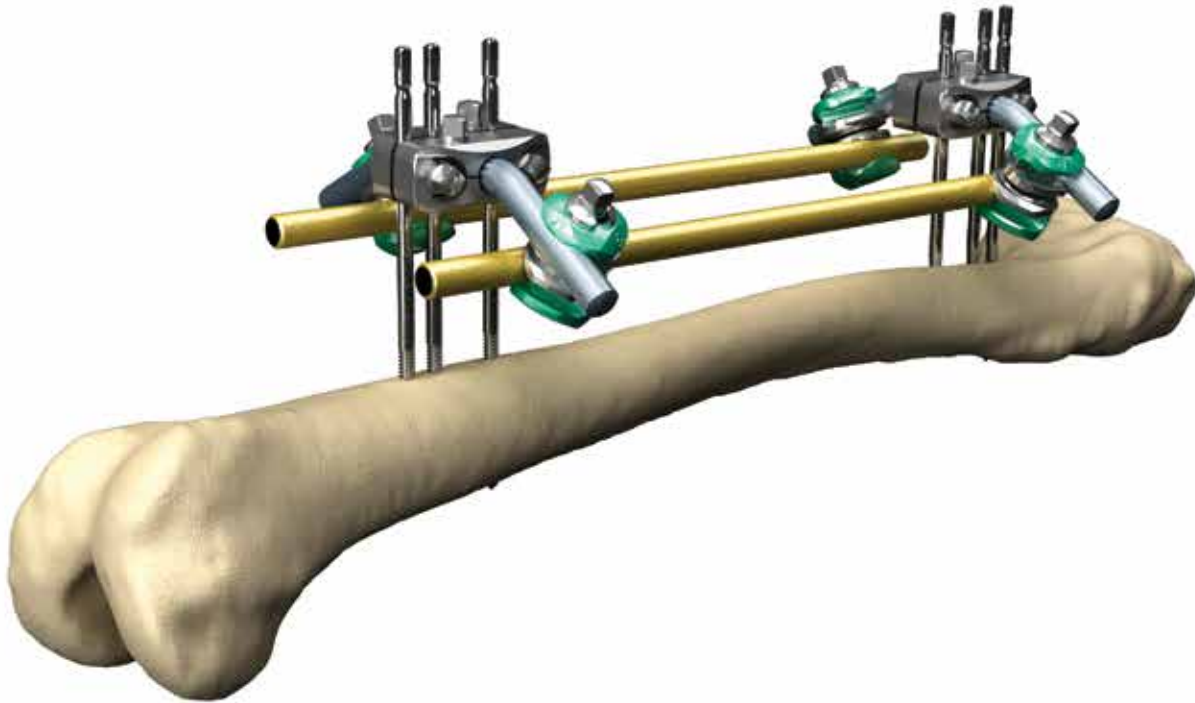
Pin technique / safe zones

- In the femur half-pins placed from lateral to medial are safe the entire length of the bone
- Transfixing pins can be placed in the distal quarter of the femur distal to the passage of the femoral artery posteriorly



Femur bi-lateral frame (double half frame)

Parallel pin placement

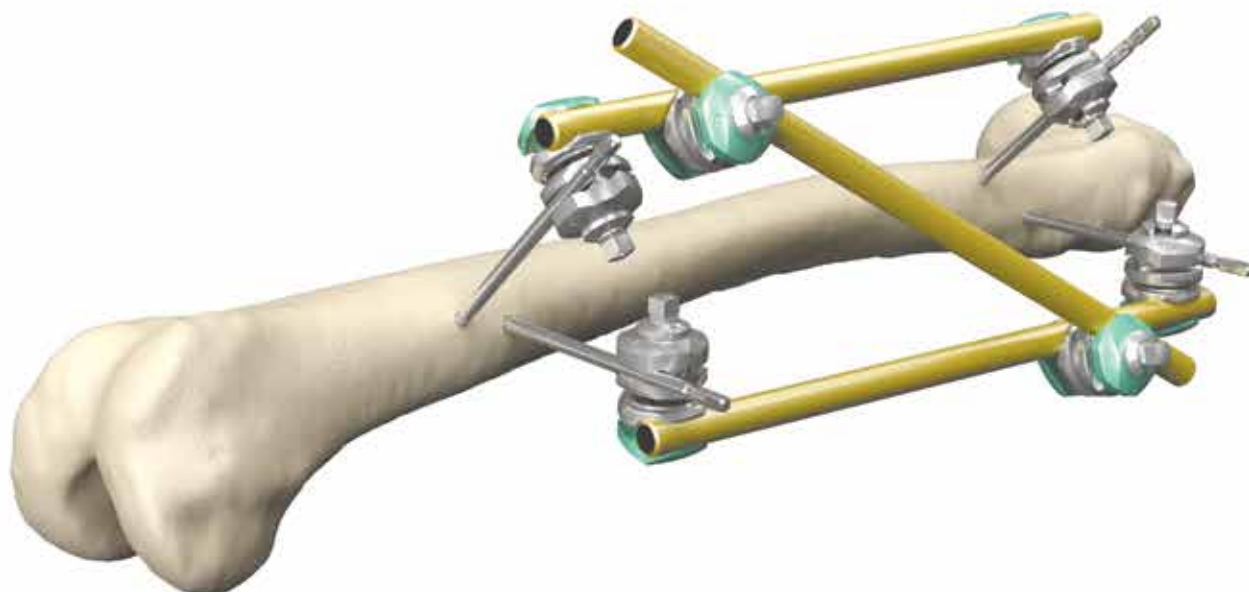


Components list

Ref	Description	Quantity
4922-2-020	5-Hole pin clamp	2
4922-2-140	30° Angled post Ø11mm	4
4922-1-010	Rod-to-rod delta coupling	4
5021-6-180	Apex Pin Ø6 x 180mm	6
4922-8-350	Connecting rods Ø11 x 350mm	2

Femur emergency frame

Independent pin placement



Components list

Ref	Description	Quantity
4922-1-020	Pin-to-rod delta coupling	4
4922-1-010	Rod-to-rod delta coupling	2
5021-6-180	Apex pin Ø6 x 180mm	4
4922-8-350	Connecting rods Ø11 x 350mm	3

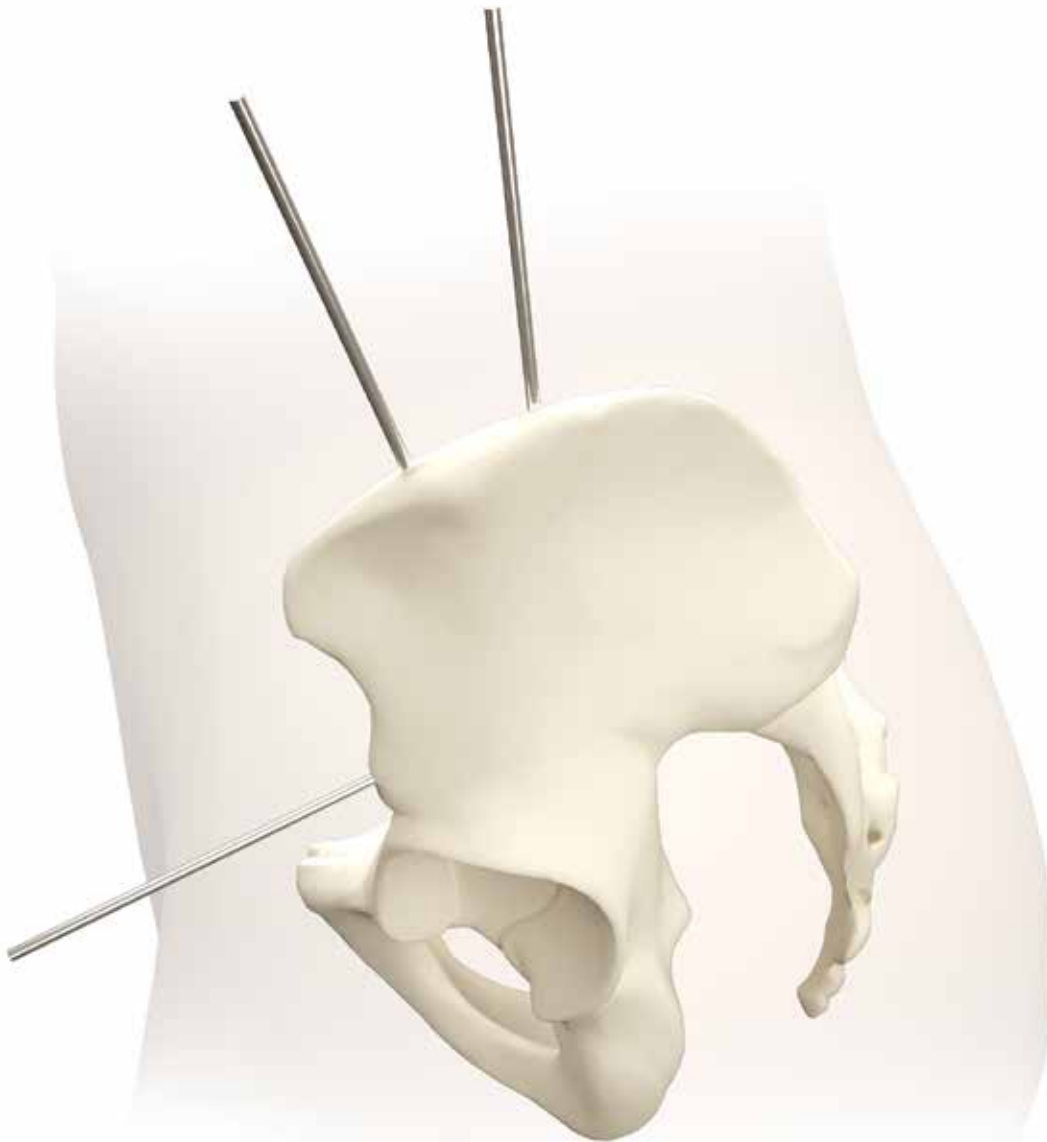
NOTICE

Apply additional pins and rods before patient transportation.

Pelvic frames

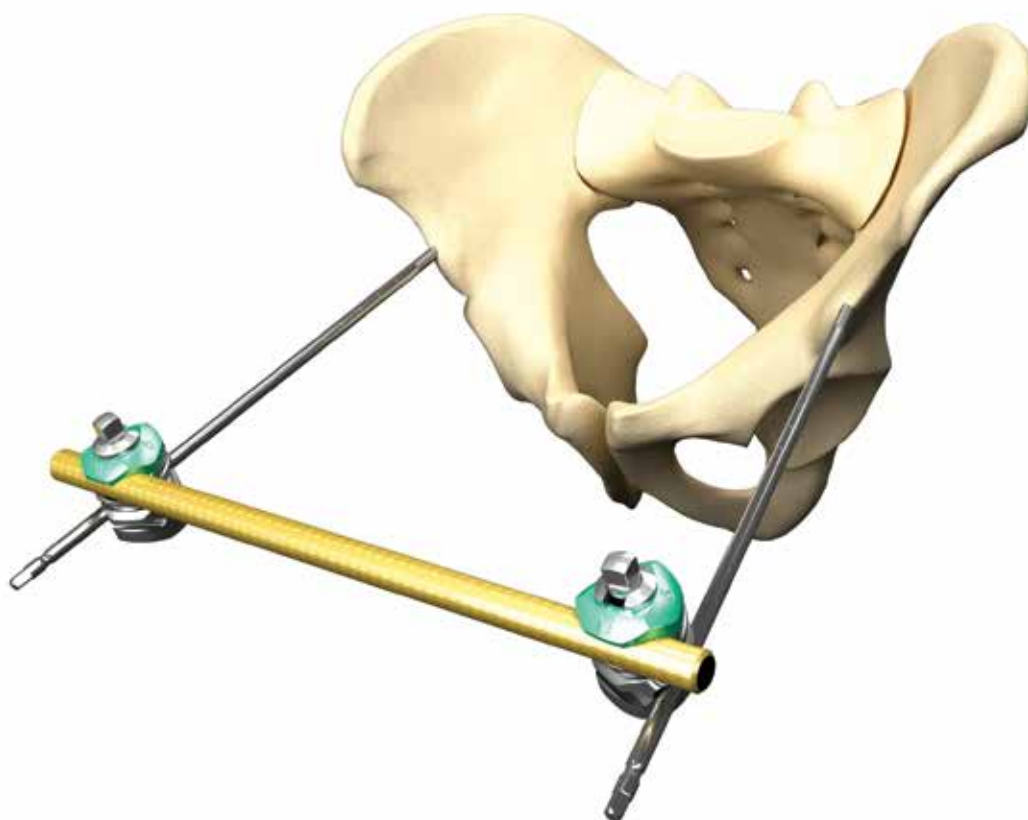
Pin technique / safe zones

- Pins can be placed percutaneously in the iliac wings
- Pins can be placed in the pelvis in the crest between the anterior-superior and anterior inferior iliac spines



Pelvic emergency frame

Single supra-acetabular pin placement

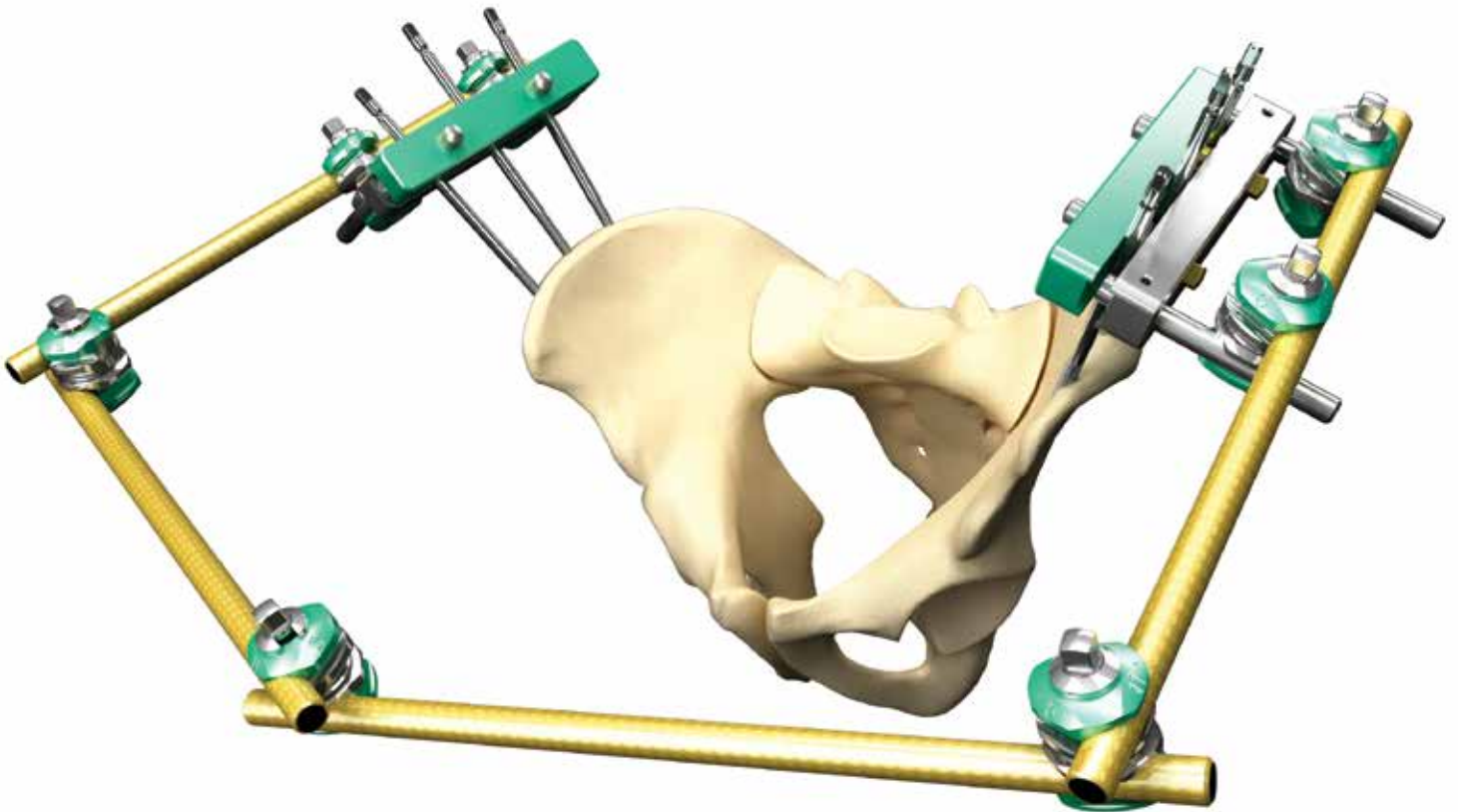


Components list

Ref	Description	Quantity
4922-1-020	Pin-to-rod delta coupling	2
5021-8-200	Apex Pin Ø6 x 200mm	2
4922-8-400	Connecting rods Ø11 x 400mm	1

Pelvic osteotaxis frame

Multi-Iliac crest pin placement

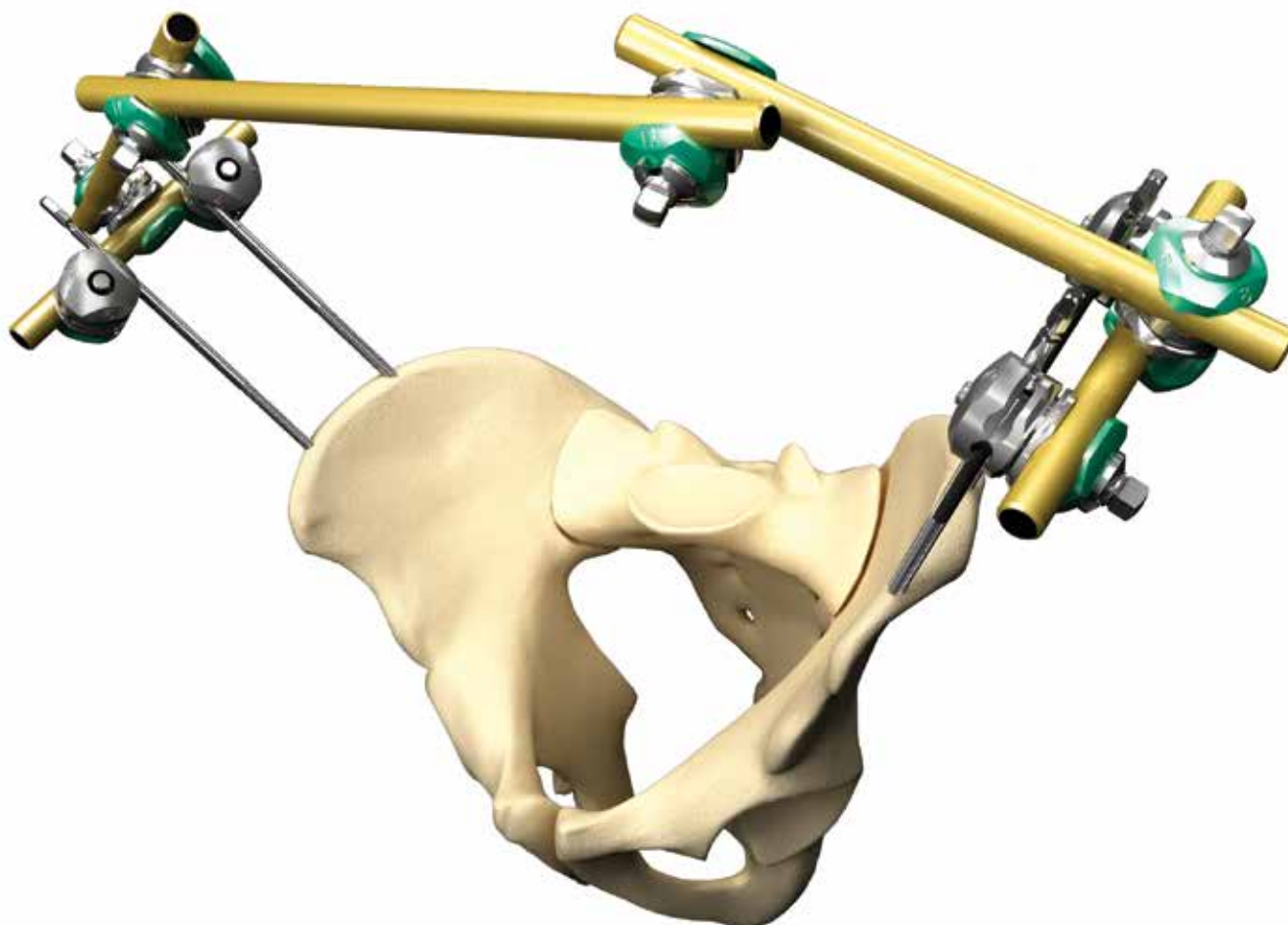


Components list

Ref	Description	Quantity
4921-2-080	Pelvic pin clamp	2
4922-1-010	Rod-to-rod delta coupling	7
5018-6-200	Apex Pin Ø5 x 200mm	6
4922-8-350	Connecting rods Ø11 x 350mm	2
4922-8-400	Connecting rods Ø11 x 400mm	2

Pelvic osteotaxis frame

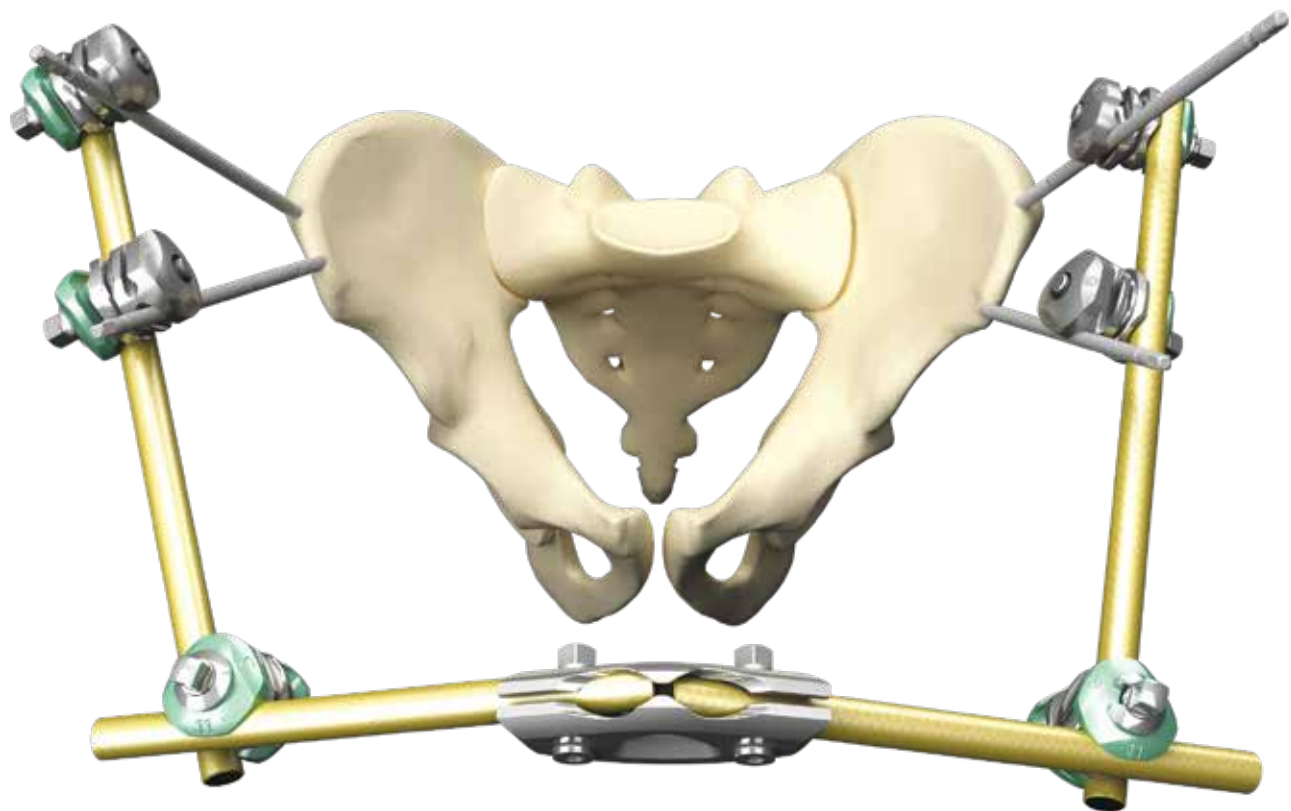
Independent iliac crest pin placement



Components list

Ref	Description	Quantity
4922-1-030	Pin-to-rod delta coupling, inverted	4
4922-1-010	Rod-to-rod delta coupling	4
5018-6-200	Apex pin Ø5 x 200mm	4
4922-8-350	Connecting rods Ø11 x 350mm	3
4922-8-150	Connecting rods Ø11 x 150mm	2

Pelvic osteotaxis frame
Independent iliac crest pin placement,
with rod coupler

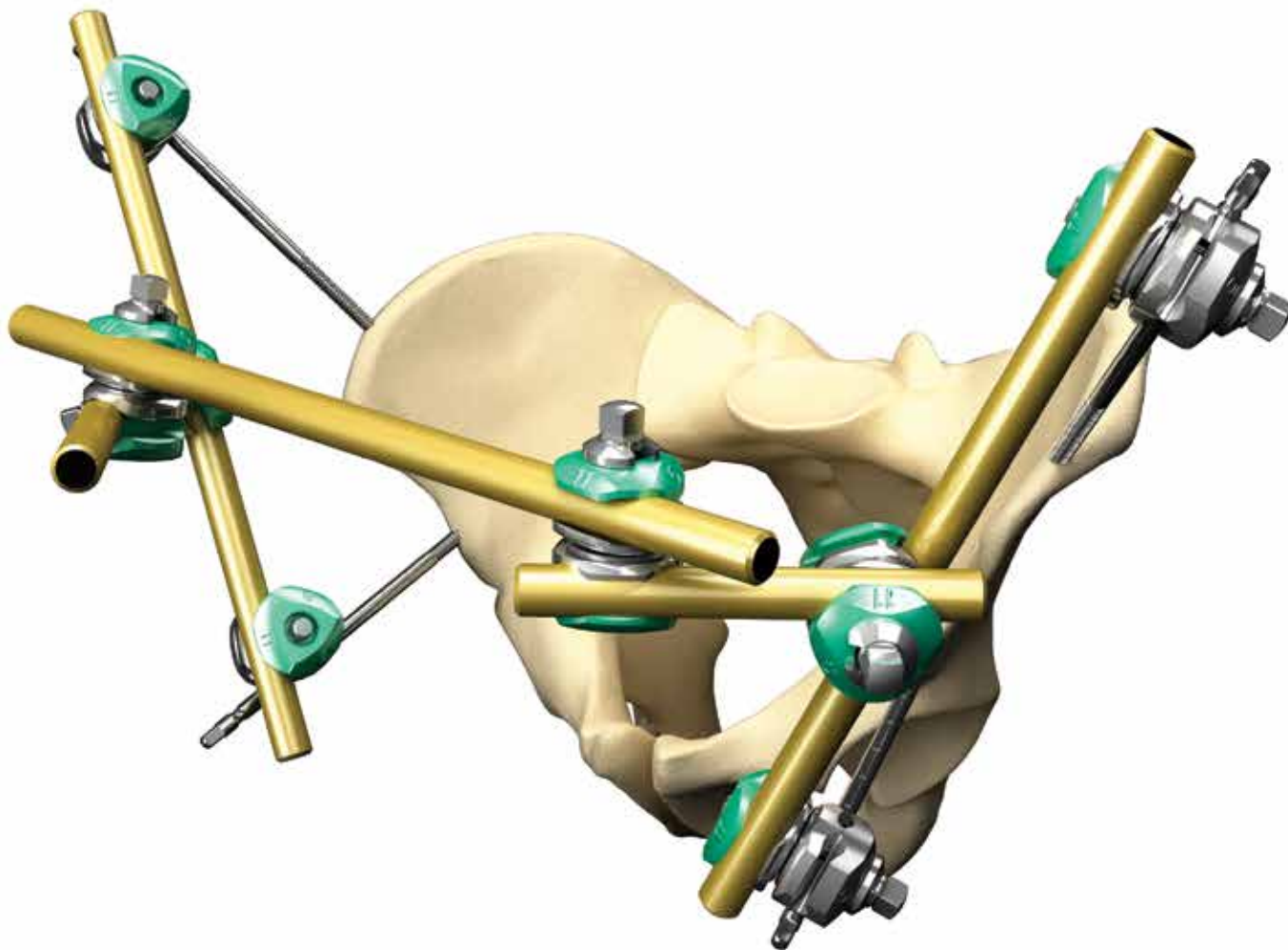


Components list

Ref	Description	Quantity
4922-1-030	Pin-to-rod delta coupling, inverted	4
4922-1-010	Rod-to-rod delta coupling	2
4922-1-220	Rod coupler, 30°	1
4922-8-150	Connecting rod Ø11 x 150mm	2
4922-8-250	Connecting rod Ø11 x 250mm	2
5018-6-180	Apex Pin Ø5 x 180mm	4

Pelvic orthogonal frame construct

Perpendicular iliac crest / Supra-acetabular pin placement



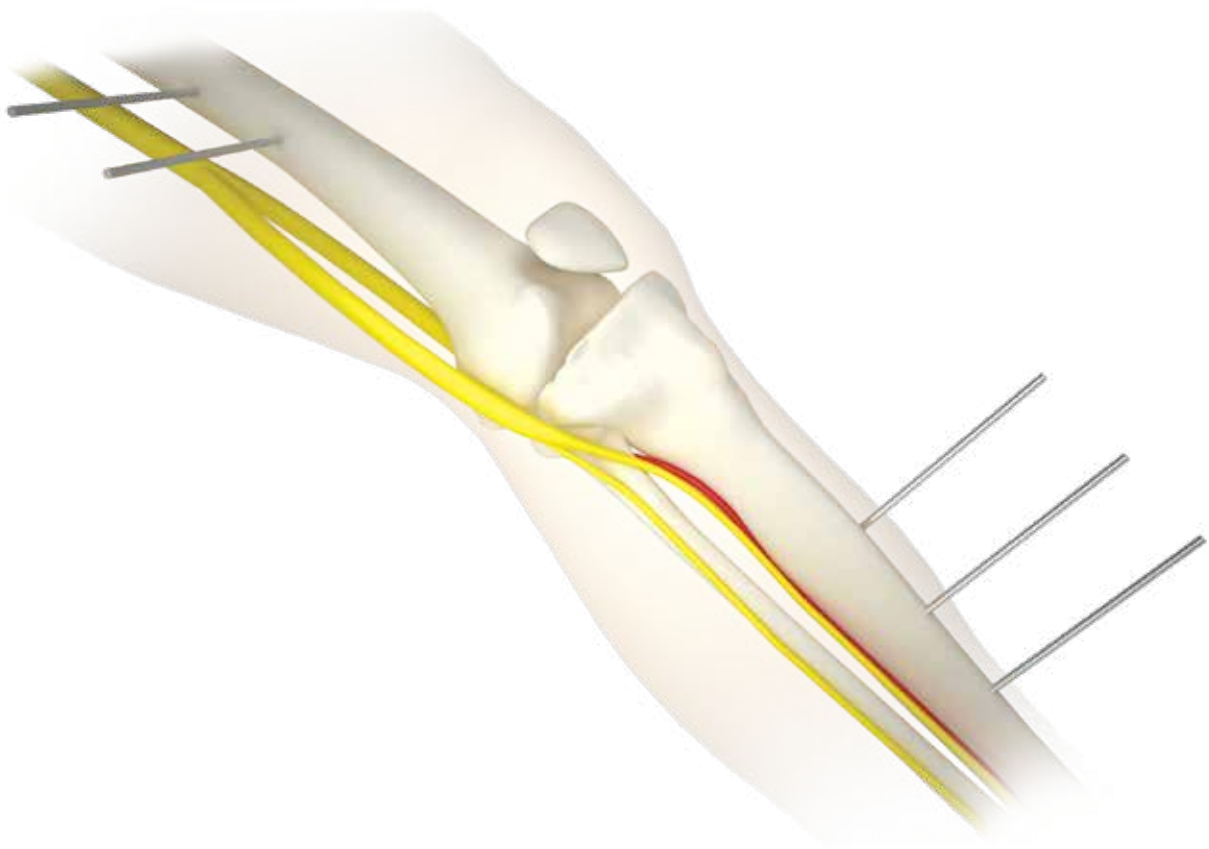
Components list

Ref	Description	Quantity
4922-1-020	Pin-to-rod coupling	4
4922-1-010	Rod-to-rod coupling	3
5018-6-200	Apex pin Ø5 x 200mm	4
4922-8-350	Connecting rods Ø11 x 350mm	2
4922-8-150	Connecting rods Ø11 x 150mm	2
4922-8-400	Connecting rods Ø11 x 400mm	1

Knee frames

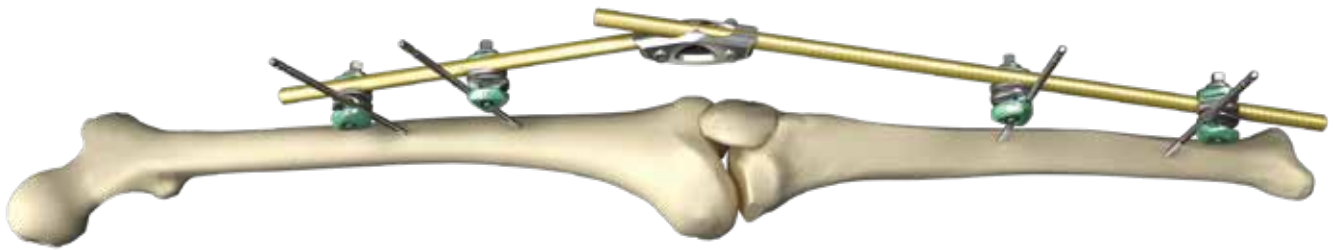
Pin technique / safe zones

- Half-pins are placed in the femur anterolaterally in the shaft
- These are connected to half-pins placed in the anterior-medial face of the tibia



Knee bridging frame

Independent pin placement, with rod coupler



Components list

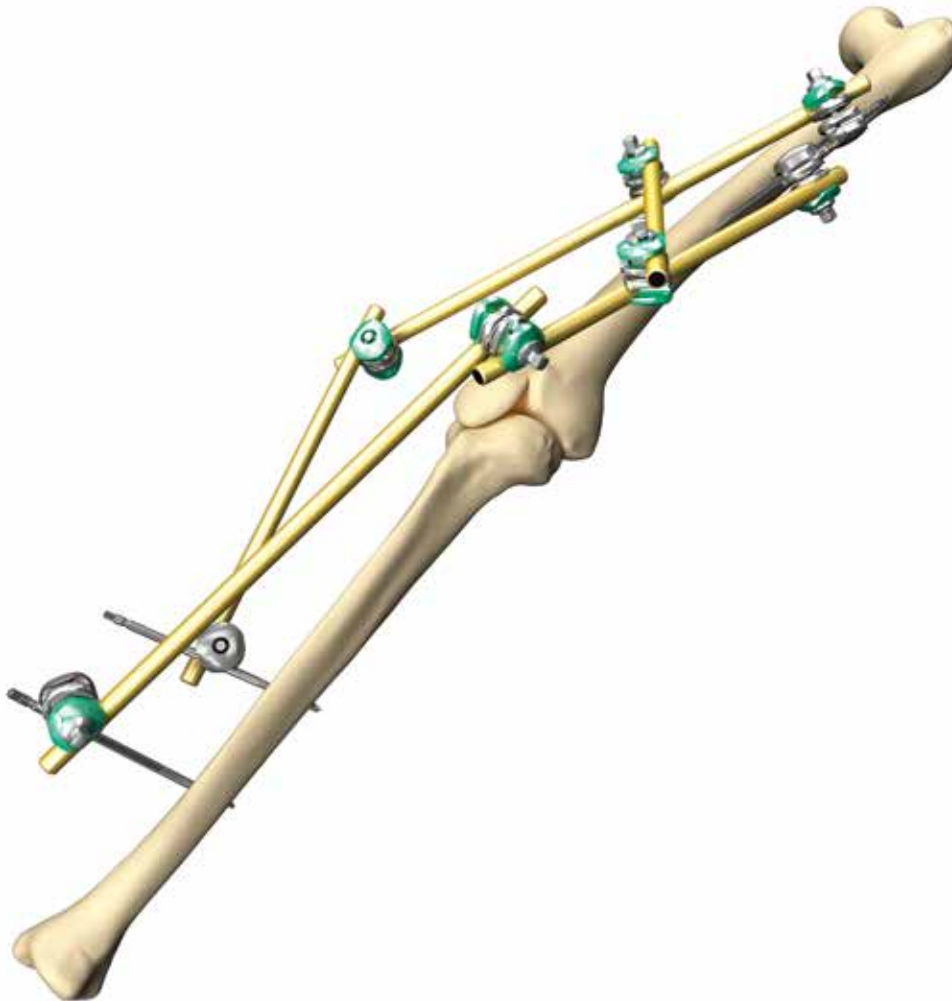
Ref	Description	Quantity
4922-1-020	Pin-to-rod delta coupling	4
5018-6-180	Apex pin Ø5 x 180mm	4
4922-1-220	Rod coupler, 30°	1
4922-8-450	Connecting rod Ø11 x 450mm	1
4922-8-350	Connecting rod Ø11 x 350mm	1

NOTICE

Alternatively the pin-to-rod delta couplings can be replaced by mulitplanar pin-to-rod delta couplings, thus offering more flexibility and freedom when placing the Apex Pins and when reducing the fracture before final tightening or, instead of the rod coupler a rod-to-rod delta coupling could be used.

Knee bridging frame

Independent pin placement

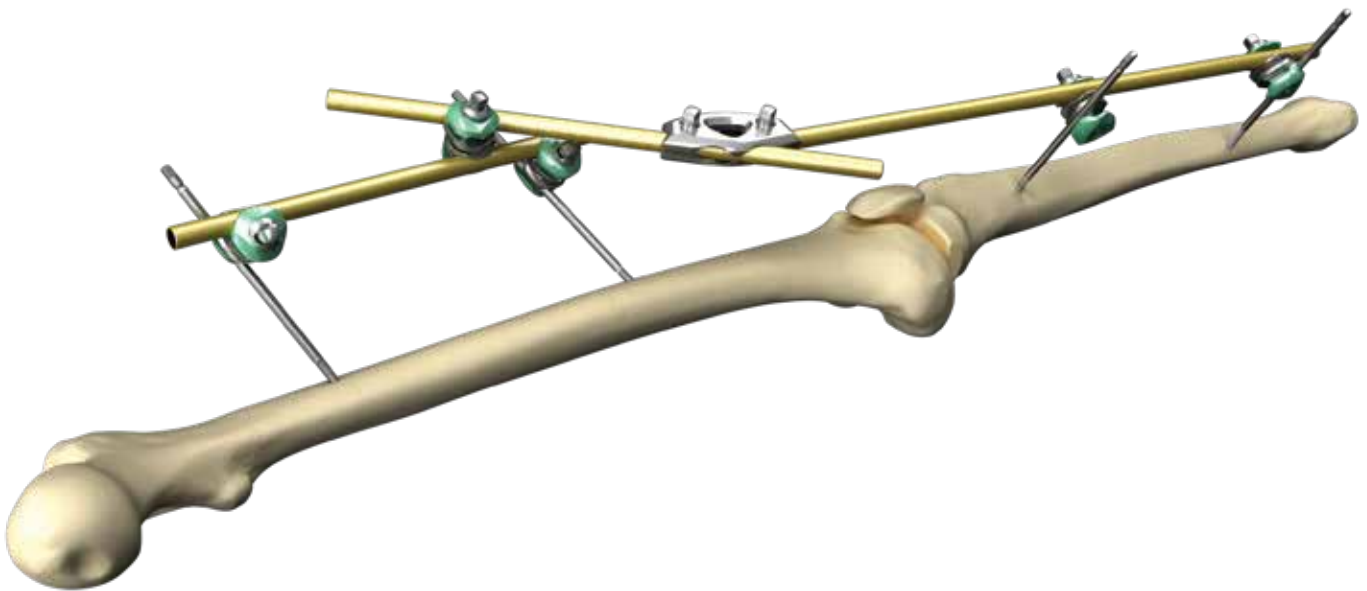


Components list

Ref	Description	Quantity
4922-1-020	Pin-to-rod delta coupling	4
4922-1-010	Rod-to-rod delta coupling	4
5021-6-180	Apex pin Ø6 x 180mm	2
5018-6-180	Apex pin Ø5 x 180mm	2
4922-8-350	Connecting rods Ø11 x 350mm	4
4922-8-200	Connecting rods Ø11 x 200mm	1

Knee bridging Z-frame

Independent pin placement, with rod coupler



Components list

Ref	Description	Quantity
4922-1-020	Pin-to-rod delta coupling	4
4922-1-010	Rod-to-rod delta coupling	1
5018-6-180	Apex pin Ø5 x 180mm	4
4922-1-220	Rod coupler 30°	1
4922-8-400	Connecting rod Ø11 x 400mm	2
4922-8-250	Connecting rod Ø11 x 250mm	1

NOTICE

Alternatively the pin-to-rod delta couplings can be replaced by mulitplanar pin-to-rod delta couplings, thus offering more flexibility and freedom when placing the Apex Pins and when reducing the fracture before final tightening. Or, instead of the rod coupler a rod-to-rod delta coupling could be used.

Military or disaster recovery kits

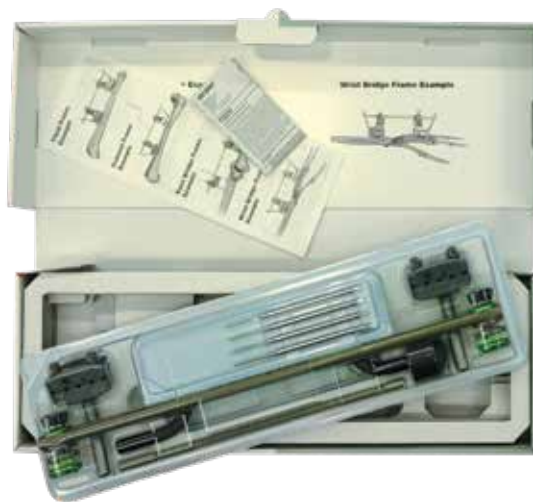
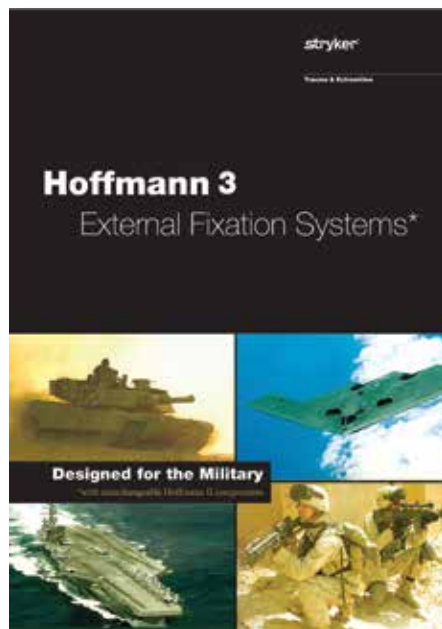
Hoffmann 3 for military or disaster recovery use

Hoffmann External Fixation Systems have a long tradition providing solutions not only for patient care in the established environment of trauma center infrastructures but also in extreme situations such as military operations or disaster recovery management around the world. The Hoffmann brand has been the pioneer brand offering sterile packaged external fixation kits and user friendly set configurations that allow fracture treatment or fracture stabilization either with forward deployed field kits, level 3/4/5 military trays in military actions or in natural disasters such as earthquakes, volcanic eruptions, avalanches, cyclic storms or tsunamis. In these situations the Hoffmann key features offering a stable, smart and simple* way to treat injured patients are crucial.

Universal vision, global engineering, Swiss manufacturing

The third generation of the Hoffmann System has undergone a rigorous design and testing protocol to ensure that it continues the venerable tradition of its predecessors.

In close collaboration with leadership members of armed forces and disaster recovery professionals the Hoffmann 3 Field Kit A and B were designed to allow Stryker to offer tailored solutions for those special situations.



The Hoffmann 3 Sterile Field Kits A and B contain scalpels, mosquito clamps, self-drilling Apex Pins, a manual drill-brace for pin insertion and frame tightening, Hoffmann 3 Delta Couplings and Vectran Coated Carbon Fibre Connecting Rods for the temporary stabilization of diverse fracture patterns.

* White paper: Comparison between the Hoffmann II MRI and the Hoffmann 3 systems: the mechanical behavior of the connecting rods and a monoplanar bilateral frame. E. Wobmann, MSc; M. A. Behrens, MSc; S. Brianza, PhD; T. Matsushita, MD, DMSc; D. Seligson, MD; NL11-NA-TR-2465

Based upon biomechanical test reports from Stryker Trauma AG, Selzach, Switzerland; BML 11-072 and BML 11-059.

Sterile field kit A

Components of the Hoffmann 3 Sterile Field Kit A (ref. 4922-9-940S):



2 x Delta coupling, rod-to-rod, ref. 4922-1-010



2 x 5-hole pin clamp with one Ø11mm 30° angled post, ref. 4922-2-340



1 x Vectran coated connecting rod Ø8 x 250mm, ref. 5028-8-250



1 x Vectran coated connecting rod Ø11 x 400mm, ref. 4922-8-400



4 x Apex Pin Ø5mm, 180 x 50mm, self-drilling, ref. 5018-6-180



4 x Apex Pin Ø3/5mm, 120 x 20mm, self-drilling, ref. 5026-8-120



1 x Drill brace for Apex Pins and couplings/clamps, ref. vim-0°

The brace accepts pins on one end and fits over the clamp/delta coupling nuts, on the other end, to function as a wrench.



1 x No.10 scalpel, ref. sw a-s10°



1 x Mosquito hemostat clamp, ref. 32-01241°



For intended use, indications and contraindications as well as for warnings and precautions see section on page 6 and the following pages of this operative technique and package inserts.

***Not available as a single item. Components are sterile packed in the Hoffmann 3 Sterile Field Kit A.**

Sterile field kit A

Femoral safe zone

Between anterolateral and lateral sites.

Antero-Lateral

Distal from the greater trochanter to 3-4 fingers proximal to patella.

Lateral

Distal from the greater trochanter to 1-2 fingers proximal to knee joint.

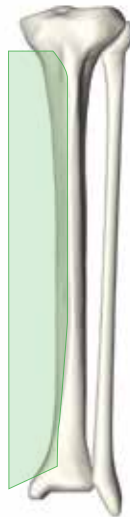


Tibial safe zone

Medial

1-2 fingers distal to knee joint avoiding patella tendon and tibial tubercle.

1 finger proximal to ankle.



Sterile field kit A

Hoffmann 3 Sterile Field Kit A application technique:

Step 1:

Provisionally reduce and align the limb. Apply self drilling, self tapping Apex Pins through 1cm linear incision of the soft tissue made down to the bone with the scalpel. The included hemostat clamp may be used to spread soft tissues before pin insertion.

Step 2:

Pins are placed through both cortices using the black brace, "pin end," as shown.

Step 3:

Insert the first pin 2-3 finger breadth proximal to the fracture/bone defect (fig. 1).

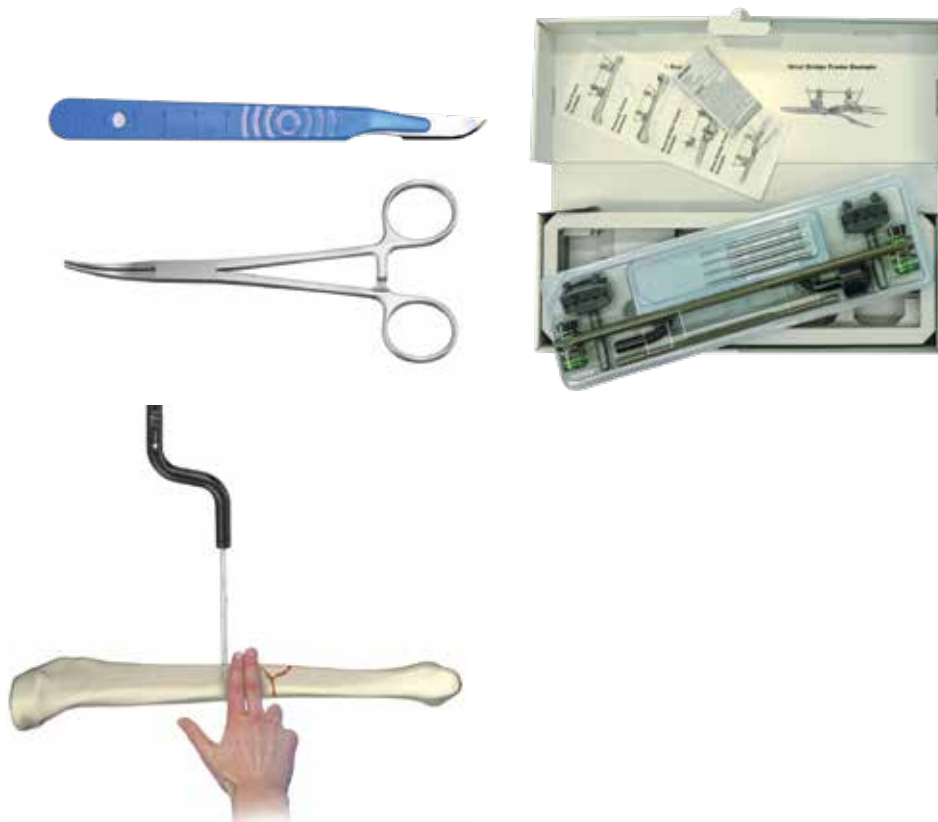


Fig 1.

NOTICE

In emergency situations often there is no X-ray (fluoroscopy) available. Under such circumstances it is not possible to localize the fracture site accurately.

Therefore, it is recommended to place the Apex Pins in an area which is in a safe distance proximally and distally from the fracture site.

Step 4:

The insertion point of the Apex Pin in the first cortex should be positioned exactly in the center of the cross-section of the bone to avoid excentric or tangential positioning (fig. 2).

After penetration of the first cortex, a drop in resistance will be detected. Using light pressure, insertion of the pin is continued. Once firm resistance of the second cortex is felt, six complete revolutions of the drill brace will put the pin tip through the second cortex (fig. 2).

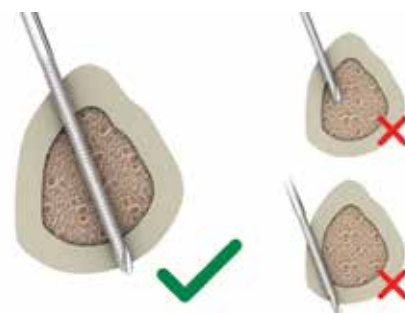


Fig 2.

Sterile field kit A

Step 5:

Place 5-hole pin clamp over first Apex Pin, using the widest placement possible. Keep the clamp nuts facing up and out (medial), as shown (fig. 3). As mentioned above: Keep safe distance from the fracture site.

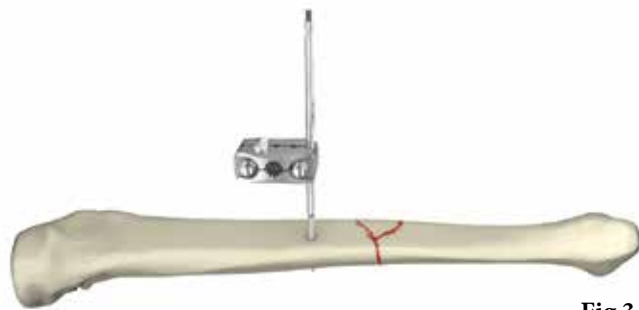


Fig 3.

Step 6:

Insert second proximal pin maintaining parallel alignment with the first pin, using the clamp as a guide (fig. 4).

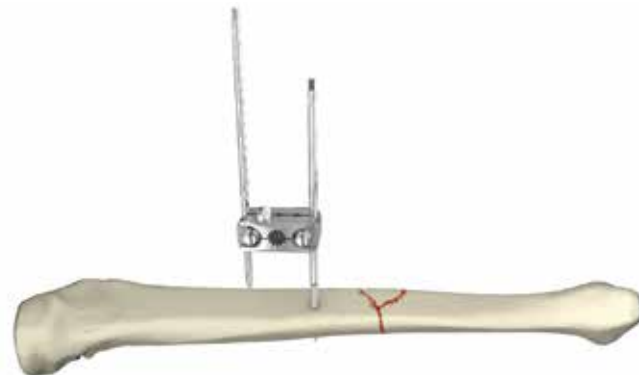


Fig 4.

Step 7:

Repeat the process for the two distal pins, keeping the pins parallel and at least two finger breadth away from the fracture /bone defect (fig. 5).

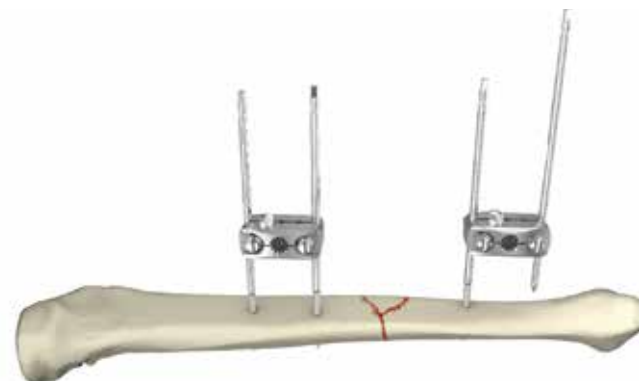


Fig 5.

Step 8:

In the next step attach the rod-to-rod delta couplings with the connecting rod. With frame in place and fracture reduced, fully tighten all nuts, using the drill brace end marked "clamp".

In case the frame is not used in the pre-assembled manner, use the following instructions to assemble the frame.

Sterile field kit A

Step 9:

Attach the delta rod-to-rod couplings as shown. Use care to avoid the 30° bend area when tightening the couplings onto the posts (fig. 6).



Fig 6.

Step 10:

Snap a connecting rod to the coupling. Provisionally tighten using the thumbwheel (fig. 7).



Fig 7.

Step 11:

Remove the thumbwheel from the Rod-to-Rod Coupling to prepare for final tightening (fig. 8).



Fig 8.

Step 12:

Use the "clamp" end of the brace for final tightening while maintaining reduction and alignment of the limb. Repeat for all clamps and couplings (fig. 9).



Fig 9.

Sterile field kit A

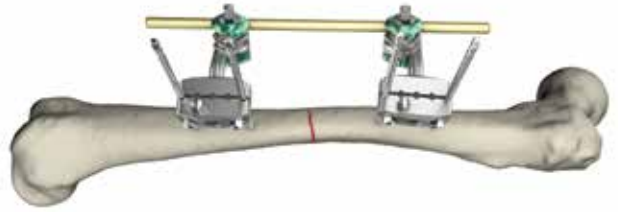
Tibial frame example

(with Ø11mm connecting rod,
Ø5mm Apex Pins).



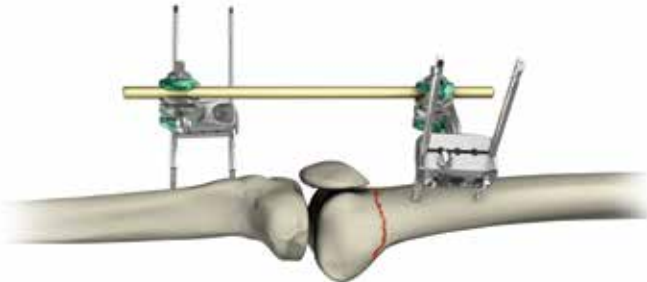
Femoral frame example

(with Ø11mm connecting rod,
Ø5mm Apex Pins).



Knee bridge frame example

(with Ø11mm connecting rod,
Ø5mm Apex Pins).



Wrist bridge frame example

(with Ø8mm connecting rod,
Ø3/5mm Apex Pins).



Sterile field kit B



6 x delta coupling, rod-to-rod, ref. 4922-1-010



3 x Vectran coated connecting rod Ø11 x 400mm, ref 4922-8-400



4 x Apex Pin Ø5mm, 180 x 50mm, self-drilling, ref. 5018-6-180



1 x Drill brace for Apex Pins and couplings/clamps, ref. VIM-0*

The brace accepts pins on one end and fits over the clamp/delta coupling nuts, on the other end, to function as a wrench.



1 x No.10 scalpel, ref. SW A-S10*



1 x Mosquito hemostat clamp, ref 32-01241*



For intended use, indications and contraindications as well as for warnings and precautions see section on page 6 and the following pages of this operative technique and package inserts.

Not available as a single item. Components are sterile packed in the Hoffmann 3 Sterile Field Kit B.

Sterile field kit B

Femoral safe zone

Between anterolateral and lateral sites.

Antero-lateral

Distal from the greater trochanter to 3-4 fingers proximal to patella.

Lateral

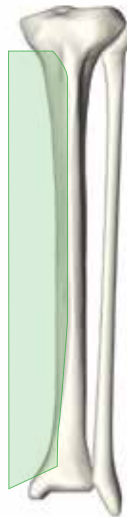
Distal from the greater trochanter to 1-2 fingers proximal to knee joint.



Tibial safe zone

Medial

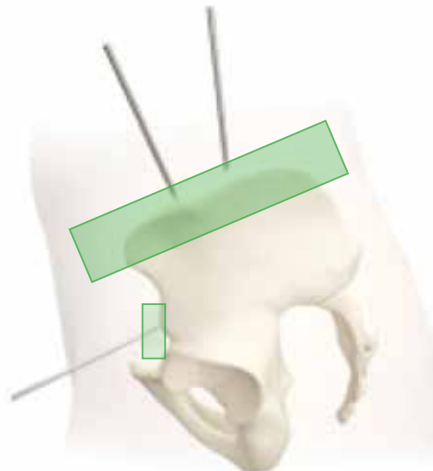
1-2 Fingers distal to knee joint avoiding patella tendon and tibial tubercle.



1 Finger proximal to ankle

Pin placement for pelvic emergency frame; pin technique / safe zones

Pins can be placed percutaneously in the iliac wings or in the crest between the anterior-superior and anterior-inferior iliac spines.



Sterile field kit B

Hoffmann 3 Sterile Field Kit B application technique:

Step 1:

Provisionally reduce and align the limbs. Apply self drilling, self tapping Apex Pins by inserting through 1cm linear incision of the soft tissue made down to the bone with the scalpel. The included hemostat clamp may be used to spread soft tissue before pin insertion.

Step 2:

Pins are placed through both cortices using the black brace, "Pin end," as shown.

Step 3:

Insert the first Pin 2-3 finger breadth away from the fracture / bone defect (fig 1).

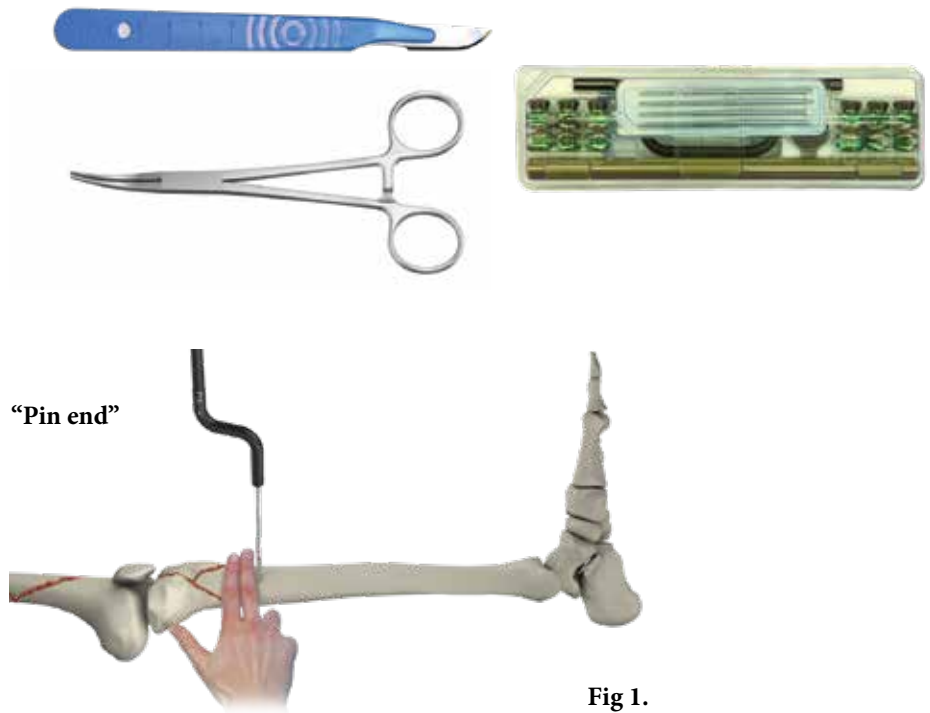


Fig 1.

NOTICE

In emergency situations often there is no X-ray (fluoroscopy) available. Under such circumstances it is not possible to localize the fracture site accurately. Therefore, it is recommended to place the Apex Pins in an area which is in a safe distance from the fracture site.

Step 4:

The insertion point of the Apex Pin in the first cortex should be positioned exactly in the center of the cross-section of the bone to avoid excentric or tangential positioning (fig. 2).

After penetration of the first cortex, a drop in resistance will be detected. Using light pressure, insertion of the pin is continued. Once firm resistance of the second cortex is felt, six complete revolutions of the drill brace will put the pin tip through the second cortex (fig 2).

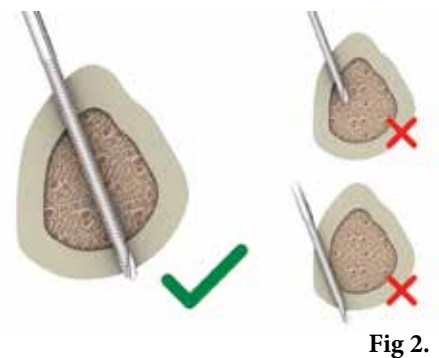


Fig 2.

Sterile field kit B

Step 5:

Place second pin in the same limb/fragment. (fig 3).

NOTICE

The larger the distance between these two pins the more stable the construct will be*

NOTICE

For increased stability follow the «rule of thumb»: «In» – «Up», meaning the delta couplings shall be «in» between the pins, the black thumbwheels looking «up» so that one has access to them for easy tightening.

Step 6:

Attach one delta coupling to each pin.

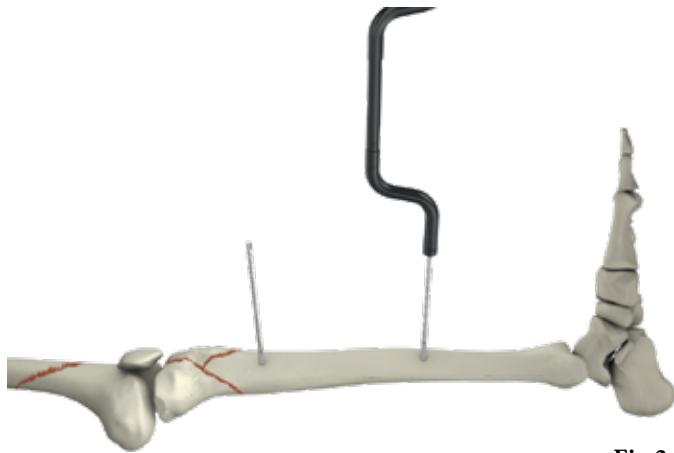


Fig 3.

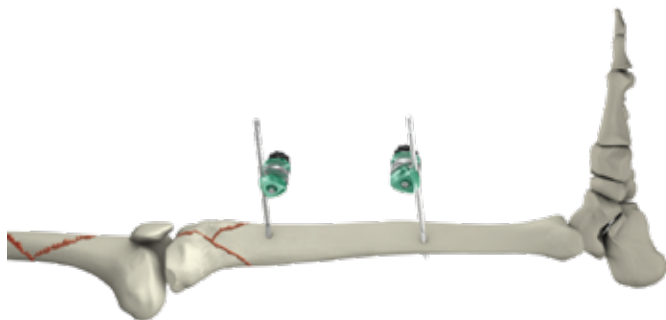


Fig 4.

* Gernot Asche, Wolfgang Roth, Ludwig Schroeder (eds.): The external fixator - standard indications, operating instructions and examples of frame configurations; Markus Behrens: The mechanics and stability of fixator components. Page 32 ff.

Sterile field kit B

Step 7:

Attach a connecting bar to the delta couplings (fig 5). Provisionally tighten the delta couplings using the built-in black thumbwheels by hand (fig. 6).

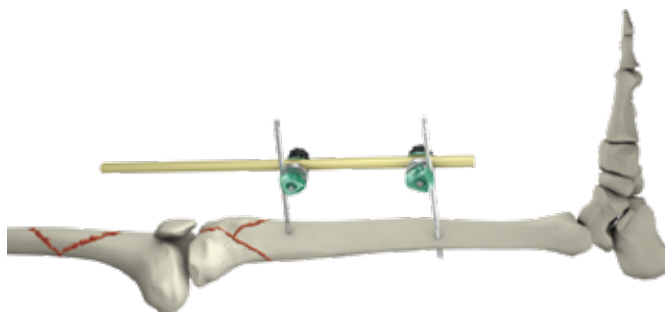


Fig 5.



Fig 6.

Step 8:

Repeat this in the other limb and connect the two frames with 2 more couplings and a third bar to achieve a Z-frame - here shown as a knee-bridging frame (fig. 7). Before final tightening reduce and align the limbs as shown (fig. 7).

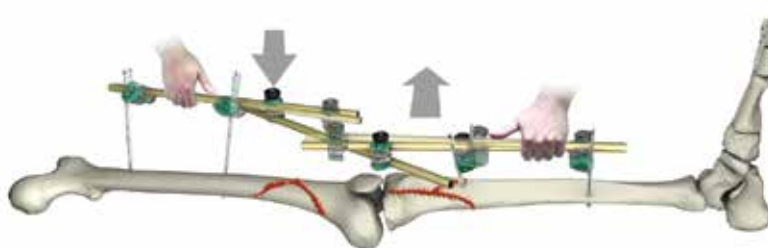


Fig 7.

Step 9:

For final tightening remove the black thumbwheel from the coupling (fig. 8).



Fig 8.

Step 10:

Use the "clamp" end of the brace for final tightening while maintaining reduction and alignment of the limbs. Repeat for all delta couplings (fig. 9).

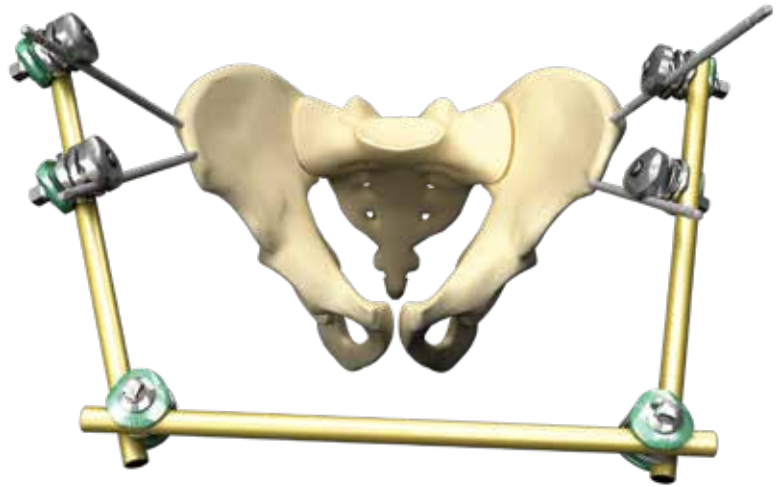


Fig 9.

**Knee bridging
frame example**



**Pelvic emergency
frame example**



Notes

Notes

Notes

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