Operative technique

X-frame
external fixation system

Modular external fixation system

LOWER LIMB AND PELVIS

citieffe®
Essential moves in Trauma

This operative technique is intended for orthopaedic surgeons and describes the standard procedure suggested by the manufacturer. Surgeons should however decide on the best approach to be followed depending on their clinical judgment and the patient's needs.

Before use please read the instruction booklet enclosed in the packaging.

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SYSTEM DESCRIPTION

X-frame is a modular external fixation system indicated for the treatment of diaphyseal and periarticular fractures of the long bones and pelvis.

The many possible configurations, ease of use and variety of accessories make the **X-frame system suitable for both temporary (Damage Control) and permanent treatment**, in each case ensuring quick and stable application.

The X-frame system clamps feature the **patented double locking system** that allows the bone screws and rods to be moved independently, simplifying corrections of the bone segments on different planes.

The individual clamp components are **colour-coded** to quickly identify the relevant slots for both the rod and the bone screw.

INDICATIONS

The X-frame is indicated for:

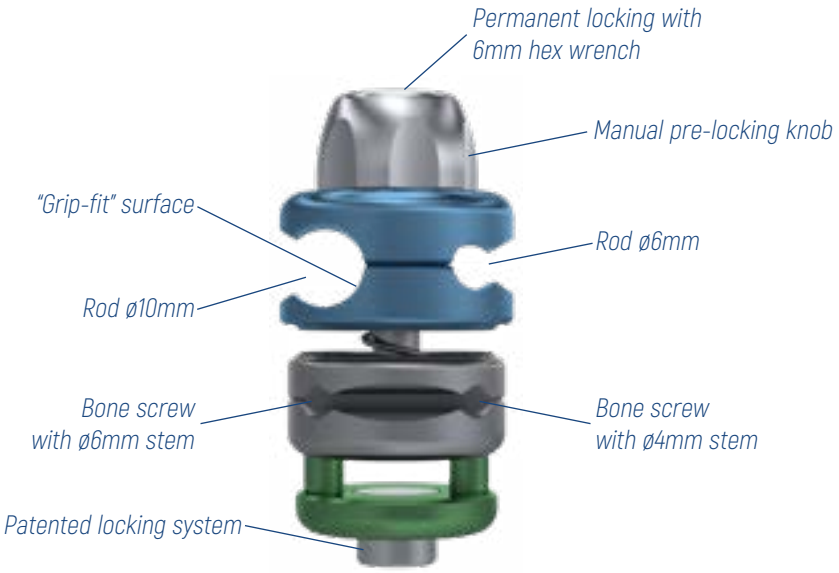
- open or closed long bone fractures
- pelvic fractures
- infected and aseptic non-unions
- arthrodesis

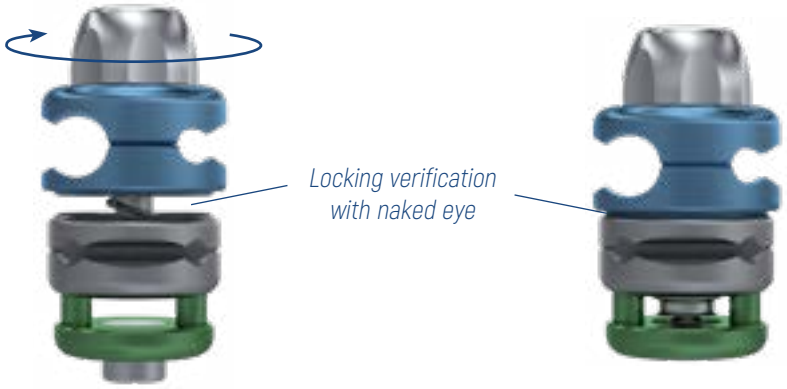
SYSTEM COMPONENTS

Pin-to-rod clamp

The X-frame pin-to-rod clamp provides an easy and stable connection and features the **patented double locking system** that allows the bone screw to be locked to the clamp, resulting in more freedom when positioning the rods.

The "**grip-fit**" coating of the rod slot increases surface roughness to improve rod adhesion.





The X-frame pin-to-rod clamp can be used with both steel and titanium bone screws with ø4mm and ø6mm stem and different types of thread with diameters ranging from 3mm to 6mm.

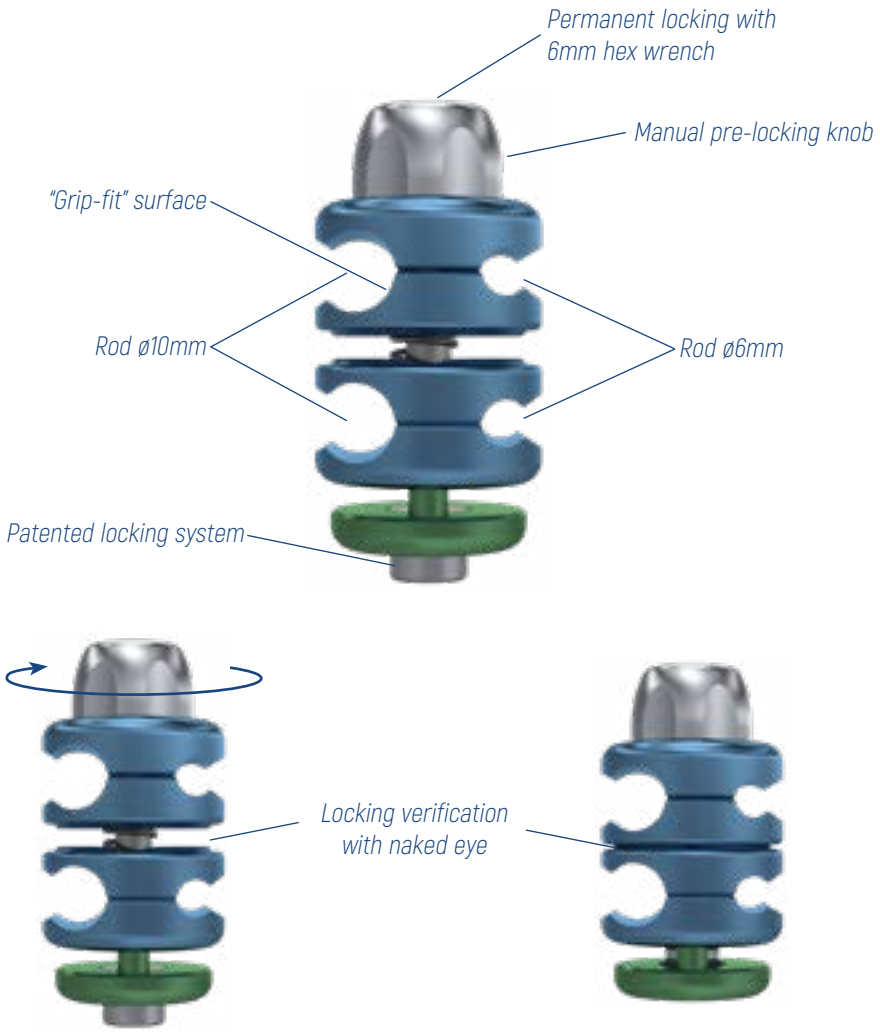
Basic pin-to-rod clamp

The pin-to-rod clamp is also available in a basic version without independent locking mechanism.

Rod-to-rod clamp

The X-frame rod-to-rod clamp provides an easy and stable connection between two or more rods and features the **patented double locking system** that allows the rods slotted in one section of the clamp to be locked while leaving those in the opposite section free.

The "**grip-fit**" coating of the rod slot increases surface roughness to improve rod adhesion.



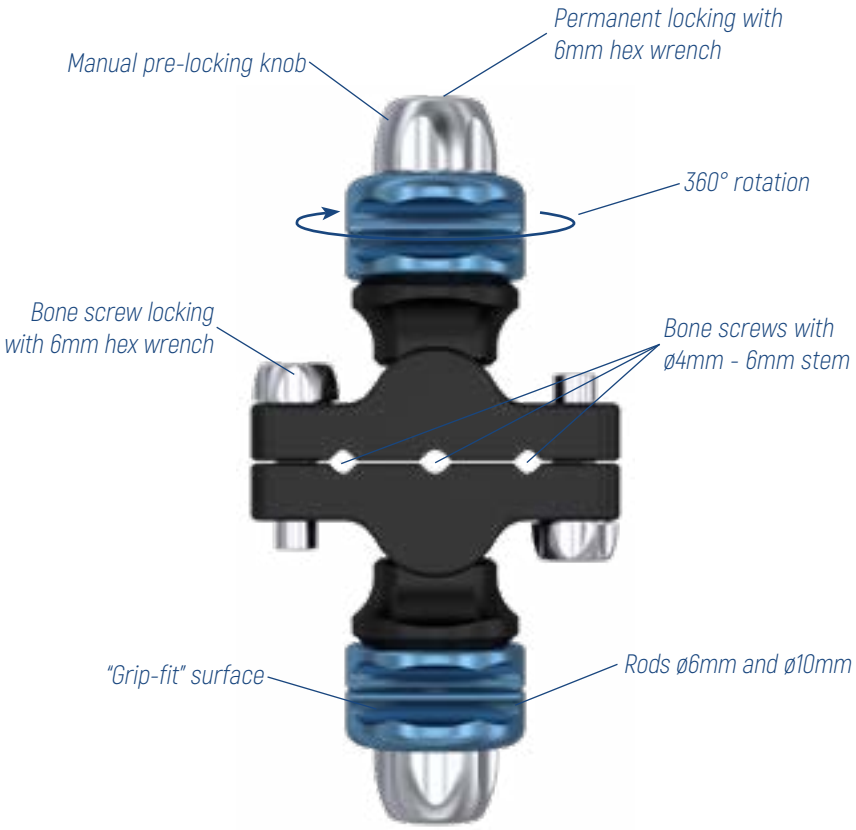
Basic rod-to-rod clamp

The rod-to-rod clamp is also available in a basic version without independent locking mechanism.

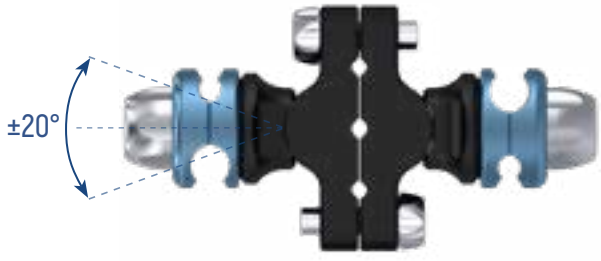
Multi-pin clamp

The X-frame multi-pin clamp enables 3 to 5 bone screws to be positioned and provides an easy and stable connection between two or more ø6mm and ø10mm rods.

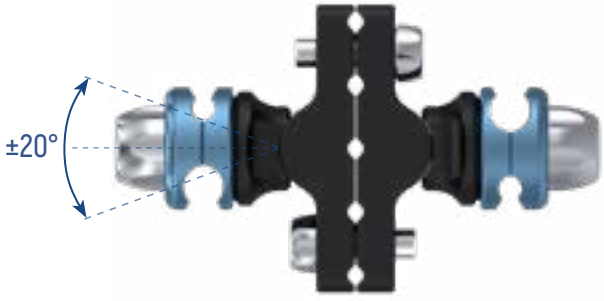
The "**grip-fit**" coating of the rod slot increases surface roughness to improve rod adhesion.



3- and 5-pin clamps have the same interaxle spacing between the bone screw slots and the rod slots.
The rod connection section can move by ±20°.



3-pin clamp



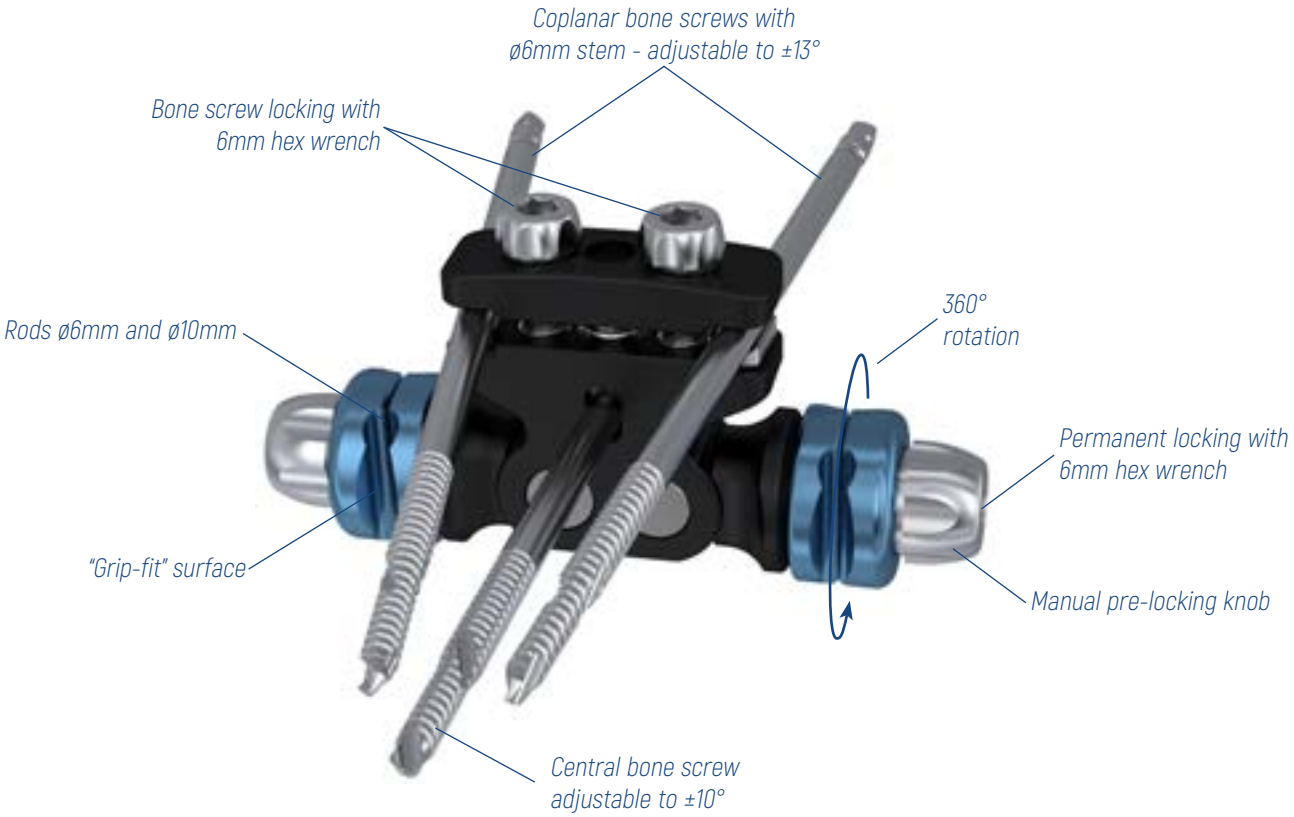
5-pin clamp

Periarticular clamp

The X-frame periarticular clamp is indicated in the treatment of periarticular fractures and can be used for configurations combined with all X-frame clamps.

The clamp enables tripod bone screws to be positioned in the metaphyseal zone using two coplanar screws that can be adjusted to a ±13° angle and a third central bone screw that can be adjusted to a ±10° angle.

The "**grip-fit**" coating of the rod slot increases surface roughness to improve rod adhesion.



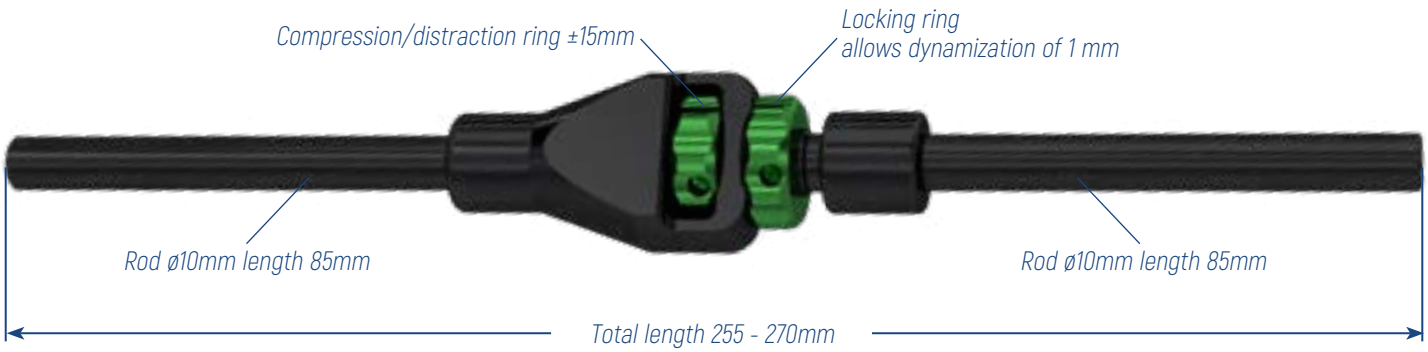
The periarticular clamp has the same interaxle spacing between the 3- and 5-pin clamp rod slots.
The rod connection section can move by ±20°.

Dynamization device

The X-frame dynamization device provides controlled dynamization of the site and compression/distraction of the fracture. Controlled dynamization, i.e. allowing controlled micro-movements to the fracture site, stimulates callogenesis while protecting the bone callus from excessive crushing.

When the locking ring is fully closed, dynamization is limited, i.e. relying solely on the elasticity of the implant.
If the locking ring is turned, controlled dynamization on the bone callus of 1mm is possible.

On the other hand, compression or distraction of the fracture is achieved by turning the compression/distraction ring either manually or using the bolt: one full turn equals a movement of 2mm.



OPERATIVE TECHNIQUE

Bone screw insertion

The position and length of the bone screws and the type of clamps to be used must be planned according to the fracture site and type.

Bone screws must be positioned so as to achieve maximum mechanical stability with bicortical grip of the threaded section of the screw; incorrect positioning could weaken the bone and the seal of the fixator.

Both titanium and steel self-drilling and self-tapping screws do not require pre-drilling and the double thread diameter design allows the screw to be retracted without losing stability.

Make a deep incision where the bone screw is to be inserted and dissect down to the cortex.

Slide the trocar into the cannula (same diameter as the screw to be implanted) and insert into the incision until it touches the cortex.

NOTE If a cannulated trocar is used, a ø2mm K. wire can be inserted to assess the correct position of the bone screw prior to its insertion.

Keep the cannula in contact with the cortex, remove the trocar (and wire if fitted) and insert the bone screw.

Insert the bone screw through the cannula with a low-speed electric drill brace or T-handle.

Make sure the screw thread passes through both cortices and protrudes from the second cortex by at least 2mm.

If pre-drilling is required (only necessary for constant diameter titanium screws and HA-coated screws), a ø3mm or ø4.8mm drill bit can be used based on the thread diameter used.

INSTRUMENTS REQUIRED

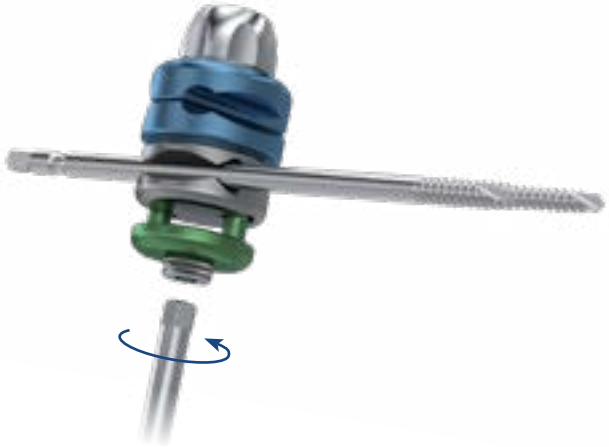
SF1240
Trocar for ø6mm cannula

SF1220
Cannula ø6mm L. 120mm with handle

F4-0220
T-handle for chucks

SF1070-SF1090
Chuck for ø4mm-ø6mm bone screws

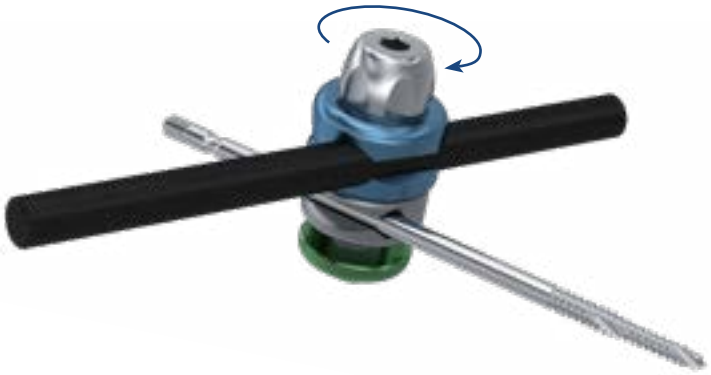
Pin-to-rod clamp connection



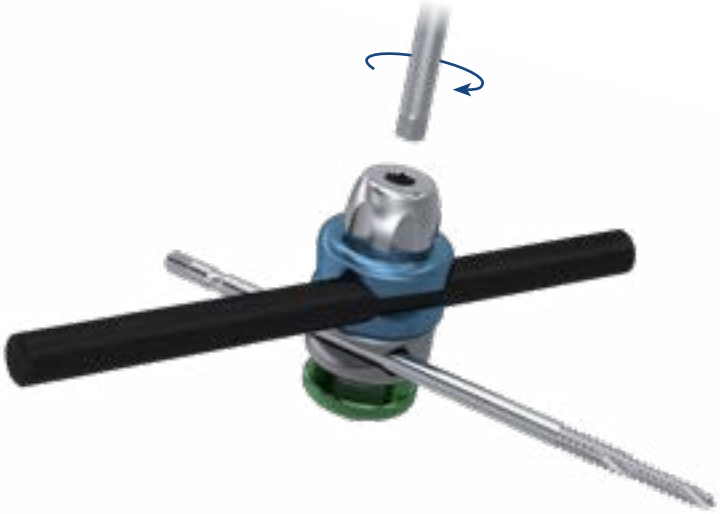
Connect the bone screw to the clamp, and check the distance to the skin surface.

The clamp can be pre-locked by turning the locking mechanism with the 6mm hex wrench.

This ensures that the clamp remains integral with the bone screw, leaving the construct free to facilitate reduction.



Connect the rod of the desired diameter and length to the clamp and, once it is in the correct position, turn the manual pre-locking knob clockwise.



Once the reduction maneuvers have been completed, permanently lock the clamp with the 6mm hex wrench.

Rod-to-rod clamp connection

Connect the first rod of the chosen diameter and length to the clamp.

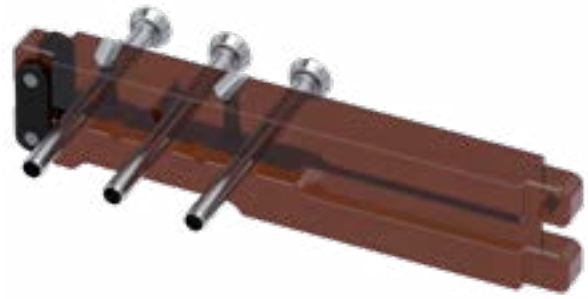
The clamp can be pre-locked by turning the locking mechanism with the 6mm hex wrench.

This ensures that the clamp remains integral with the rod, leaving the construct free to facilitate reduction.

Connect the second rod and, once it is in the correct position, turn the manual pre-locking knob clockwise.

Once the reduction maneuvers have been completed, permanently lock the clamp with the 6mm hex wrench.

Insertion of bone screws for 3- and 5-pin clamps



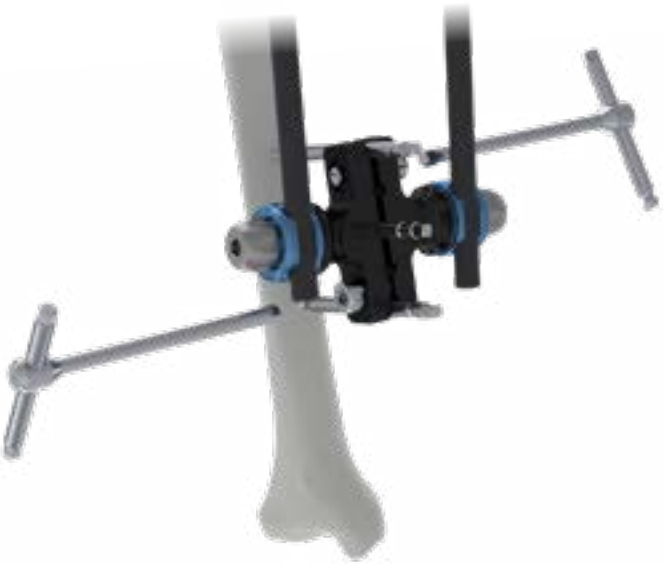
Bone screws can be inserted into the multi-pin clamps using a drill guide. Set the drill guide on the multi-pin clamp side.

Insert the trocar into the cannula of the diameter of the scew to be implanted and proceed with insertion through the holes in the guide until contact is made with the cortical bone.

NOTE When using the cannulated trocar, a ø2mm wire can be introduced to assess the correct position of the bone screw before its insertion.

Insert the first bone screw into one of the holes in the guide and then insert the other screws.

It is advisable to place the outermost screws first and then the middle ones, if necessary.



Remove the drill guide and insert the permanent multi-pin clamp.

Tighten the two side locking screws with the a 6mm Allen or T-wrench.

INSTRUMENTS REQUIRED

SF1200
Drill guide for multi-pin clamps

SF1230
Cannula ø6mm L. 90mm

SF1240
Trocar for ø6mm cannula

SF1011
6mm T-wrench

Insertion of bone screws for periarticular clamp

Bone screws can be inserted into the periarticular clamp using a drill guide.

Set the drill guide on the periarticular clamp side.

Insert the trocars into the ø6mm cannulas (the use of cannulated trocar is recommended) position them on the mobile slides and adjust them to the required angle.

Under ampliscope control, two ø2mm K-wires can be inserted to assess correct positioning.

Proceed with the insertion of the two bone screws through the cannula using the low-speed motor drill, the turnbuckle or the T-handle.

Under ampliscopic control, a ø2mm K. wire can be inserted through the central hole to assess the insertion of the third screw.

Remove the drill guide and insert the periarticular clamp, then tighten the two side locking screws with the 6mm Allen or T-wrench.

Remove the K. wire and, under ampliscopic control, insert the third bone screw.

Tighten the locking screw in the centre of the clamp with the wrench.

INSTRUMENTS REQUIRED

SF1200
Drill guide for multi-pin clamps

SF1230
Cannula ø6mm L. 90mm

SF1240
Trocar for ø6mm cannula

SF1011
6mm T-wrench

FRAME ASSEMBLY EXAMPLES

Periarticular fracture - Tibia

Code	Description	Q.ty
XF241600	Periarticular clamp	1
XF231605	5-pin clamp	1
XF310450	Rod ø10x450mm	2
F4-156150	Bone screw ø6mm - L. 150x40mm	3
F4-156180	Bone screw ø6mm - L. 180x50mm	3

Tibial pilon - Delta frame

Code	Description	Q.ty
XF221600	Pin-to-rod clamp	3
XF211600	Rod-to-rod clamp	1
XF231603	3-pin clamp	1
XF310300	Rod ø10x300mm	2
XF310200	Rod ø10x200mm	1
DF424120	Damage Control bone screw ø4mm - L. 120x30mm	1
DF406160	Damage Control bone screw ø6mm - L. 160x40mm	2
DF415220	Transfixing bone screw ø5mm - L. 220mm	1

Knee bridge

Code	Description	Q.ty
XF231605	5-pin clamp	2
XF211601	Basic rod-to-rod clamp	2
XF310400	Rod ø10x400mm	2
XF310200	Rod ø10x200mm	1
F4-156150	Bone screw ø6mm - L. 150x40mm	6

ORDERING INFORMATION

STERILE

XF211600 Rod-to-rod clamp

XF211601 Basic rod-to-rod clamp

XF221600 Pin-to-rod clamp

XF221601 Basic pin-to-rod clamp

XF231603 3-pin clamp

XF231605 3-pin clamp

XF241600 Periarticular clamp

STERILE

Dynamization device - XF712000

Straight rod ø6mm - radiolucent

Code	L. mm
XF306050	50
XF306075	75
XF306100	100
XF306125	125
XF306150	150
XF306175	175
XF306200	200

Straight rod ø10mm - radiolucent

Code	L. mm
XF310050	50
XF310075	75
XF310100	100
XF310150	150
XF310200	200
XF310250	250
XF310300	300

Code	L. mm
XF310350	350
XF310400	400
XF310450	450
XF310500	500
XF310550	550
XF310600	600
XF310650	650

Semi-circular rod ø10mm - aluminium

Code	L. mm
XF510180	180
XF510220	220

STERILE

Cortical bone screw - stainless steel

Code	Thread ø mm	Stem ø mm	Thread L. mm	Total L. mm
F4-125360	2.5 - 3	4	20	60
F4-125380	2.5 - 3	4	20	80
F4-125390	2.5 - 3	4	20	100
F4-134080	3 - 4	4	20	80
F4-134095	3 - 4	4	34	95
F4-134120	3 - 4	4	34	120
F4-134150	3 - 4	4	40	150
F4-140118	3 - 4	4	25	120
F4-150120	4 - 5	6	30	120
F4-150150	4 - 5	6	30	150
F4-150178	4 - 5	6	30	180
F4-150180	4 - 5	6	40	180
F4-156118	5 - 6	6	30	120
F4-156120	5 - 6	6	40	120
F4-156148	5 - 6	6	30	150
F4-156150	5 - 6	6	40	150
F4-156178	5 - 6	6	35	180
F4-156180	5 - 6	6	50	180
F4-156198	5 - 6	6	40	200
F4-156200	5 - 6	6	60	200
F4-156240	5 - 6	6	60	240

Nickel-free cortical bone screw - stainless steel

Code	A - B ø filetto (mm)	C ø stelo (mm)	L. filetto (mm)	L. totale (mm)
F4-434080	3 - 4	4	20	80
F4-434120	3 - 4	4	34	120
F4-434150	3 - 4	4	40	150
F4-456150	5 - 6	6	40	150
F4-456180	5 - 6	6	50	180
F4-456200	5 - 6	6	60	200

STERILE

HA-coated cortical bone screw - stainless steel

Code	Thread ø mm	Stem ø mm	Thread L. mm	Total L. mm
ST340100HA	3 - 4	4	30	100
ST340120HA	3 - 4	4	40	120
ST256150HA	5 - 6	6	40	150
ST256180HA	5 - 6	6	50	180
ST256200HA	5 - 6	6	60	200
ST360120HA	5 - 6	6	30	120
ST360148HA	5 - 6	6	30	150
ST360150HA	5 - 6	6	40	150
ST360178HA	5 - 6	6	35	180
ST360180HA	5 - 6	6	50	180
ST360198HA	5 - 6	6	40	200
ST360200HA	5 - 6	6	60	200
ST360240HA	5 - 6	6	60	240

Steel hydroxyapatite (HA)-coated cortical bone screws

Code	Thread ø mm	Stem ø mm	Thread L. mm	Total L. mm
ST134060HA	3 - 4	4	20	60
ST134080HA	3 - 4	4	20	80
ST134120HA	3 - 4	4	34	120
ST134150HA	3 - 4	4	40	150
ST156150HA	5 - 6	6	40	150
ST156180HA	5 - 6	6	50	180
ST156200HA	5 - 6	6	60	200
ST156240HA	5 - 6	6	60	240

Bone screw - titanium

Titanium bone screws in combination with X-Frame components are indicated for the temporary stabilisation of fractures where there is no load due to the patient's weight.

Code	Thread ø mm	Stem ø mm	Thread L. mm	Total L. mm
DF424120	4	6	30	120
DF425180	5	6	40	180
DF426200	6	6	45	200
DF406160	4 - 5 - 6	6	45	160
DF406200	4 - 5 - 6	6	45	200
DF415220 *	5	6	50	220
DF417260 *	7	6	60	260

* *Transfixing bone screw*

ORDERING INFORMATION - INSTRUMENTATION

Code	Description	Quantity
66220	Kirschner wire ø2x270mm - **STERILE**	2
F4-0220	T-handle for chucks	1
SF1011	6mm T-wrench	1
EBA-0050	Allen wrench, 6mm	1
SF1070	Chuck for ø4mm bone screws	1
SF1090	Chuck for ø6mm bone screws	1
SF1200	Drill guide for multi-pin clamps	1
SF1220	Cannula ø6mm L. 120mm with handle	2
SF1230	Cannula ø6mm L. 90mm	2
SF1240	Trocar for ø6mm cannula	2
SF1250	Cannulated trocar ø6mm for ø2mm K. wire	2
SF1271	Cannula ø4mm L. 60mm	2
SF1281	Cannulated trocar ø4mm L. 60mm for ø2mm K. wire	2
SF1330	Drill bit ø3mm for ø6mm cannula	1
SF1340	Drill bit ø4.8mm for ø6mm cannula	1
SF1291	X-frame instrument box, empty	1

OPTIONAL ITEMS

Code	Description	Quantity
F4-0205	Torque wrench	1
SF1050	Drill brace	1
SF1304	Quick-connect adapter for screws (ø4mm stem) - **STERILE**	1
SF1306	Quick-connect adapter for screws (ø6mm stem) - **STERILE**	1
SF1270	Cannula ø4mm L. 35mm	1
SF1280	Cannulated trocar ø4mm L. 35mm for ø2mm K. wire	1

X-frame
external fixation system

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LOWER LIMB AND PELVIS

citieffe®
Essential moves in Trauma

INSPIRED BY PEOPLE
MOVED BY INNOVATION

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