

Operative technique



rekrea
LIMB RECONSTRUCTION SYSTEM

**Limb
reconstruction
system**

The purpose of the information provided in this document is intended to describe the product. Surgeons should, however, decide on the best approach to be followed according to their clinical judgement and the patient's needs. Read the instructions for use included in the product pack before use.

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Product description

STERILE

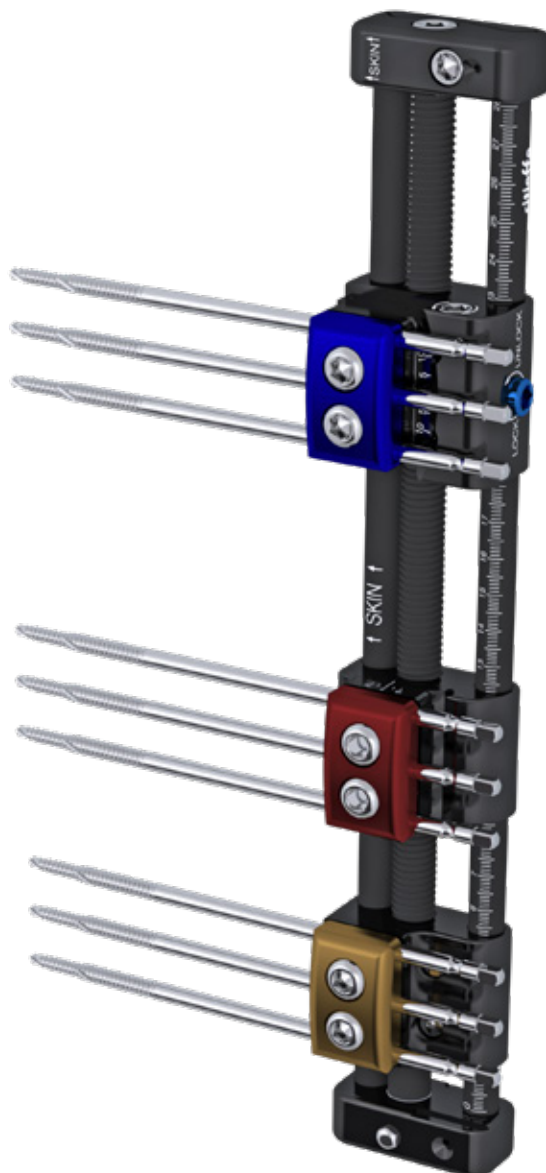
Rekrea is a monolateral limb reconstruction system with a range of fixator body lengths that is also available as Bifocal and Small versions. The Small line (fixator bodies and clamps) is indicated for pediatric use and small bones.

The innovative advantage of the rekrea system over other reconstruction systems is that it affords **individual movement of the clamps** by means of **the transport mechanism built into the fixator body** that makes it easy to use for both patients and surgeons.

The main elements of the rekrea system are:

- fixator body made of three lightweight radiolucent rods, one of which provides compression/distraction;
- bone screw clamps allowing various types of configuration depending on treatment requirements;
- dedicated instrument set for bone screw and Kirschner wire insertion.

All system components are available **sterile packed for single use**.



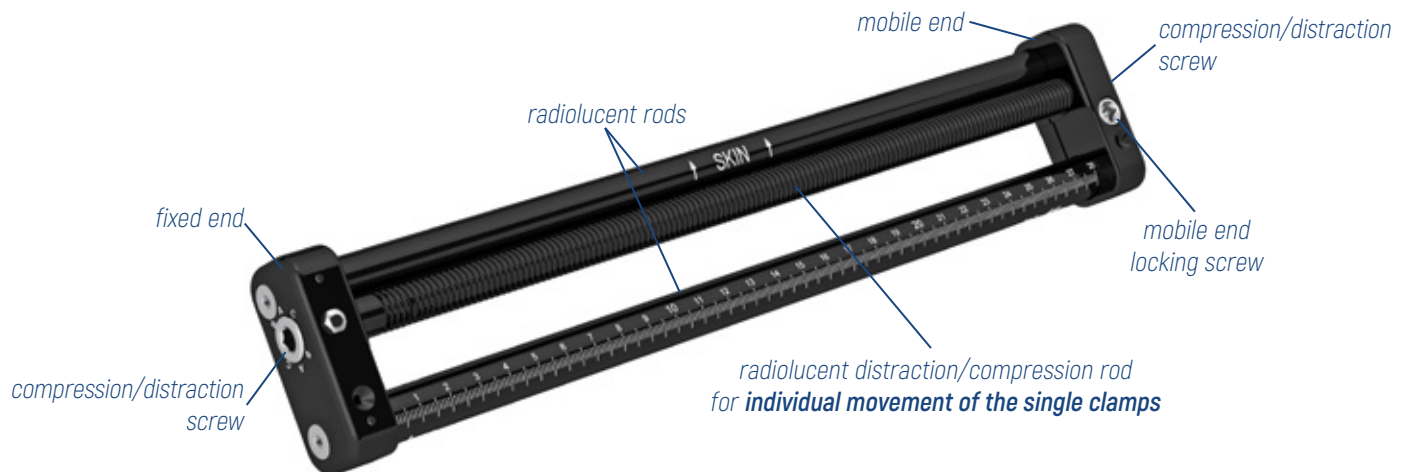
Fixator body

The fixator body comes in different lengths and the following types:

- **rekrea** fixator body;
- **rekrea Bifocal** fixator body for use in treatment involving significant bone transport when it is preferable to move the clamps in opposite directions or at different speeds;
- **rekrea Small** fixator body for small bones.

Rekrea fixator body

Available lengths: 250, 300, 350, 400, 450, 500mm



Rekrea Bifocal fixator body

Available lengths: 250, 300, 350, 400mm



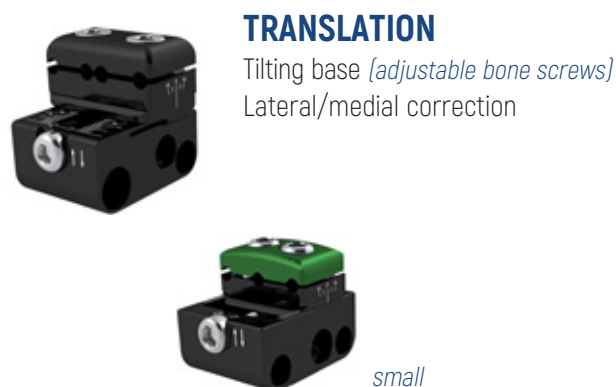
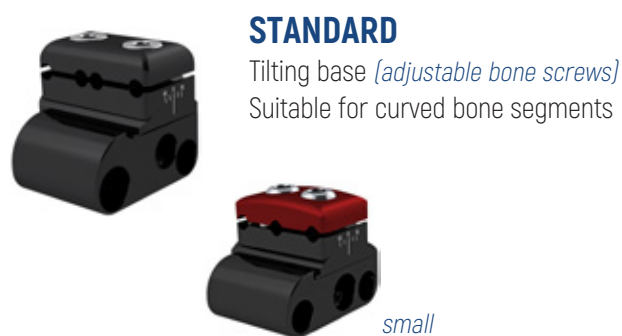
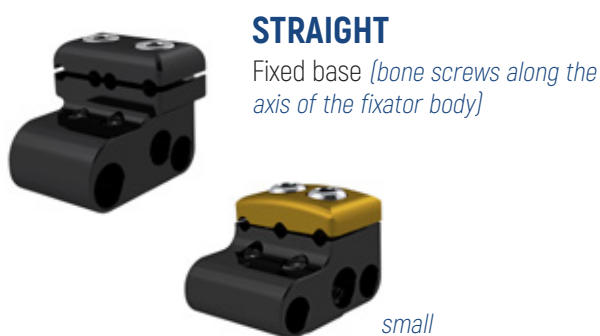
Rekrea Small fixator body

Available lengths: 150, 200, 250, 300, 350mm



Mobile clamps

At the base of all rekrea clamps there are two screws (green "ON" screw and purple "LOCK-UNLOCK" screw) that control the sliding of the clamp along the fixator body rods.



The rekrea and rekrea Bifocal fixator body clamps are used with bone screws with $\varnothing 6\text{mm}$ stem.
The rekrea Small fixator body clamps are used with bone screws with $\varnothing 5$ or 6mm stem.

Accessories

Ring



The rings come in 6 different diameters: 120mm (**F4-5680**), 140mm (**F4-5681**), 160mm (**F4-5682**), 170mm (**F4-5683**), 180mm (**F4-5684**), 200mm (**F4-5685**) and consist of complementary 2/3 and 1/3 portions.

NOTE The values refer to the inner diameter of the rings

Foot ring



Rekrea foot rings come in 2 sizes: 120x260mm (**F4-5672**) and 150x300mm (**F4-5675**).

For improved ease of use, they consist of two complementary portions.

NOTE The values refer to the inner measurements of the rings.

Ring accessories



Bone screw holder

Allows the insertion of screws with $\varnothing 5\text{mm}$ and $\varnothing 6\text{mm}$ stems and can be connected on both sides of the rings. When it is necessary to insert screws on multiple planes, the screw holder can be assembled with the screw and wire spacer.



Wire holder

Allows insertion of wires with a diameter of 1.8mm and can be connected on both sides of the rings. When it is necessary to insert wires on multiple planes, the wire holder can be assembled with the screw and wire spacer.



Pin for clamp

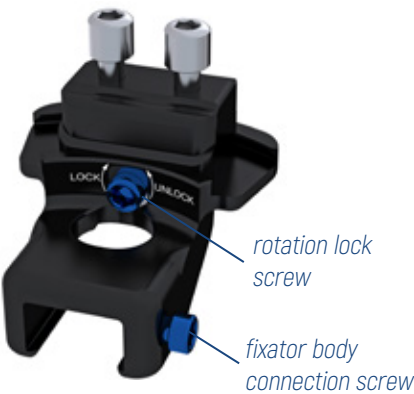
Pins for clamp can be connected on both sides of the rings. When used with F4-5100 clamps, they allow insertion of bone screws of any diameter or use of stabilisation rods available in kits of two rods for the stabilisation of hybrid assemblies.



Screw and wire spacer

The oval section inside the spacer allows the positioning of wire and screw holders at different levels. The spacer can be connected on both sides of the rings.

Adjustable T clamp for ring or foot ring



The adjustable T clamp for ring (or foot ring) is to be connected to one of the fixator body ends and allows to use a rekrea system ring enabling it to tilt ($\pm 11^\circ$); once the desired position has been achieved, the position is locked by tightening the two screws.

NOTE The adjustable T clamp for ring allows a medio-lateral correction of $\pm 13^\circ$, or of $\pm 10^\circ$ for the Small version.



SF26160 - SF26182 small
Adjustable T clamp for ring

Ring

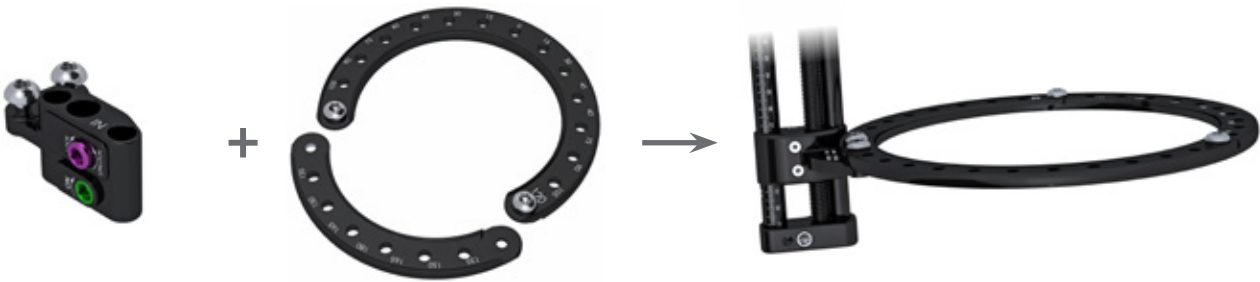
Configuration with
fixed ring

Mobile ring clamp



At the base of the ring clamp there are two screws (green “ON” screw and purple “LOCK-UNLOCK” screw) that control the sliding movement of the clamp along the fixator body rods.

A mobile clamp may be connected to any rekrea ring.

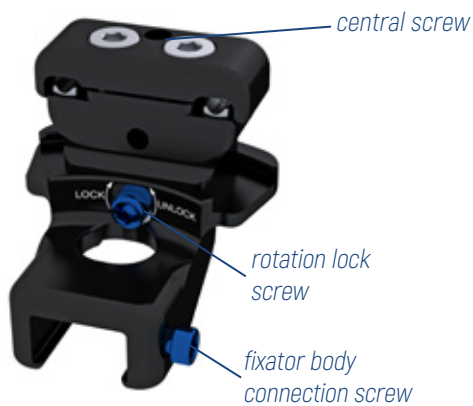


SF26200 - SF26190 small
Ring clamp

Ring

Configuration with
mobile ring

Adjustable T clamp



Once connected to one of the fixator body ends, the adjustable T clamp allows to position two bone screws (ø5mm or ø6mm stem) on the same plane with a parallel or convergent orientation. A third bone screw (ø5mm or ø6mm stem), at an angle of 9° to the others, guarantees better stump stability.

The two screws of the upper block lock the lateral bone screws and the tilting ($\pm 11^\circ$) of the clamp. The central screw locks the tilted third bone screw.

NOTE The T clamp must be positioned so that the "SKIN" marking faces towards the patient's skin.

It is important to lock the coplanar screws in the clamp before locking the central third bone screw by turning the corresponding screw.

NOTE The adjustable T clamp allows a medio-lateral correction of $\pm 13^\circ$, or of $\pm 10^\circ$ for the Small version.

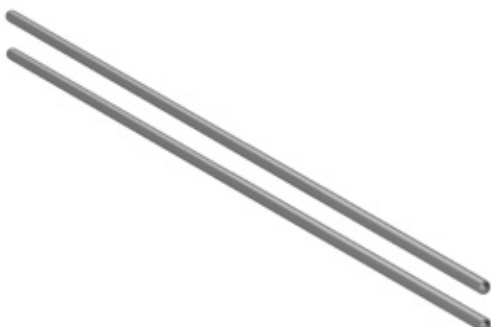


Rod support kit



When connected to one of the fixator body ends, the rod support kit allows to connect a stabilization rod kit to a ring in order to consolidate the hybrid assembly.

Rod kit



The rod kit consists of 2 pieces and comes in 3 sizes:

Rod kit 400mm [SF26340]

Rod kit 450mm [SF26345]

Rod kit 500mm [SF26350]

Dynarek



The Dynarek accessory with its silicone buffer allows controlled dynamisation whilst preventing the collapse of the lengthened segment.

The clamp in direct contact with the Dynarek must be free to slide (green "ON" screw and purple "LOCK-UNLOCK" screw loose).

It can be mounted only on rekrea and rekrea Bifocal fixator bodies.

Sandwich



The Sandwich clamp allows to increase the distance between the bone screws of a long segment, in order to improve the stability of the system.

It can only be mounted on rekrea and rekrea Bifocal fixator bodies, on the base of the Standard clamp SF26105 or Translation clamp SF26110.

Trock



The Trock accessory allows the insertion of two parallel bone screws at an angle of 130° to the fixator body, with an anteversion of 10°.

It can **only** be mounted **on the base of the Swiveling clamp SF26115**, that allows to increase or decrease the offset between the bone screws and the fixator body.

Remove the upper cover and the screws before assembling the Trock clamp



SF26115
Swiveling clamp

+



SF26310
Trock clamp



Bone screws

The steel double-diameter thread bone screws are self-drilling and self-tapping and are designed to afford optimum capture with minimal damage to the bone tissue.

The double-diameter profile and intrinsic stiffness of the fixator guarantee the stability of the system.

Principles of function of the double-diameter bone screw:

- the self-drilling tip creates a hole the size of the smaller diameter;
- the smaller diameter inserts into the bone with ease;
- the first self-tapping portion performs the tapping of the bone;
- the second self-tapping portion facilitates the transition to the larger diameter;
- the larger diameter penetrates while correcting any ovalisation of the first hole.

The bone screws available are: cortical bone screws, nickel-free cortical bone screws (for patients who have inflammatory or allergic reactions to the element) and hydroxyapatite (HA)-coated cortical bone screws (increase bone capture in situations in which the screws remain in place for lengthy periods).

All types come in a range of thread diameters and lengths.



Indications

Rekrea external fixators are indicated in adult or pediatric patients in reconstructive procedures for the treatment of shortening of upper and lower limb, bone loss and deformity correction.

The surgeon's judgement must guide the choice of the most appropriate implant type and size and the treatment technique to be adopted.

For specific product applications, consult medical literature and operative techniques.

SHORTENING

Indication: SMALL shortening
Treatment: MONOFOCAL controlled distraction

Indication: LARGE shortening
Treatment: BIFOCAI controlled distraction

BONE LOSS

Indication: SMALL bone defect
Treatment: compression-distraction

Indication: MEDIUM bone defect
Treatment: MONOFOCAL bone transport

Indication: LARGE bone defect
Treatment: bone transport with partial acute shortening
Treatment: MULTIFOCAI bone transport

BONE DEFORMITY

Indication: DIAPHYSEAL deformity
Treatment: osteotomy and acute or gradual correction

Indication: METAPHYSEAL deformity
Treatment: osteotomy and acute or gradual correction

Indication: deformity with SHORTENING
Treatment: apical osteotomy and lengthening

Operative technique

The following instructions/descriptions apply to the whole rekrea system

Clamp assembly



Remove the mobile end by loosening the locking screw.

Make sure that the **"ON"** and **"LOCK-UNLOCK"** screws are loose.

Insert the clamps from the side marked **"IN"** sliding them along the rods of the fixator body to the desired position.

Replace the mobile end and tighten the locking screw.

The rekrea fixator body must be positioned so that the **"SKIN"** marking is facing towards the limb to be treated.

Bone screw insertion



Open the clamp using the T-wrench (**SF1011**) and insert 2 protection sleeves (**SF1220**) together with the trocars (**SF1240**) until they touch the cortical bone.

Tighten the screws again using the T-wrench.

Insert the two cannulated trocar for $\varnothing 2\text{mm}$ wires (**SF1250**) inside the cannula and then two Kirschner wires $\varnothing 2 \times 270\text{mm}$ (**66220**) inside the trocars to examine the direction of the screws.

Remove the trocars and wires, leaving the protection sleeves inside the clamp.

INSTRUMENTS REQUIRED



SF1011
T-wrench



SF1220
Protection sleeve L. 120mm



SF1240
Trocar for protection sleeve



SF1250
Cannulated trocar for $\varnothing 2\text{mm}$ wires



Select the drill bit with the right diameter for the bone screws to be used (**SF1330** ø3mm - **SF1340** ø 4.8mm).

Perform pre-drilling through the protection sleeve.



Insert the first bone screw through the protection sleeve.

Perform pre-drilling through the second protection sleeve.



Remove the drill bit and insert the second bone screw.

Loosen the two screws of the clamp using the T-wrench (**SF1011**) to remove the two protection sleeves (**SF1220**).

Tighten the clamp using the T-wrench (**SF1011**).

NOTE: for setups with only two bone screws, there must always be a free hole between the screws.

INSTRUMENTS REQUIRED



SF1330 Drill bit ø3mm
SF1340 Drill bit ø4.8mm



SF1220
Protection sleeve L. 120mm



SF1011
T-wrench

Clamp activation

At the base of all rekrea clamps there are two screws (green "ON" screw and purple "LOCK-UNLOCK" screw) that control the sliding of the clamp along the fixator body rods.



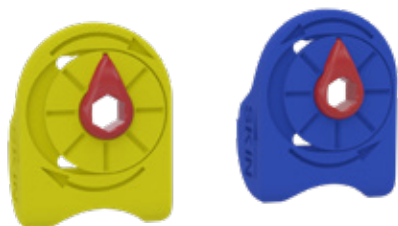
During the treatment the green "ON" and purple "LOCK-UNLOCK" screws at the base of the clamps **must never be in the same position**; when the green screw is tightened, the purple screw must be completely loose and vice versa.

Use the L-wrench on the compression/distraction screw that is on the terminals to enable the individual movement of the clamps.

Clockwise rotation brings the activated clamp closer to the L-wrench, counterclockwise rotation moves the activated clamp away from the key.

1/8 of a turn corresponds to a movement of the clamp of 0.25mm, half a turn of the key to 1mm.

Clip for fixator ends



Two colored clips and a L-shaped operating key are supplied together with the fixator body (excluding bifocal bodies) to facilitate the movement of the clamps. The clips are to be applied to the fixator terminals.

The notches on the clips correspond to a movement of the 0.25mm clamp.

The red hand follows and indicates the progression of the clamp.



YELLOW clip: **clockwise** rotation.
The released clamp moves towards the wrench.

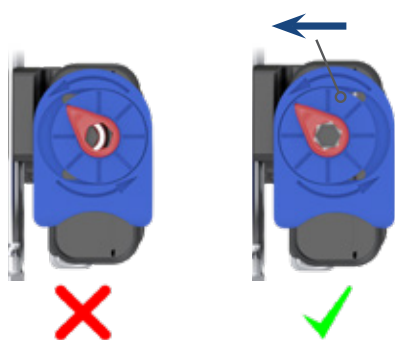


BLUE clip: **counter-clockwise** rotation.
The released clamp moves away from the wrench.



Select the corresponding clip according to the desired movement of the clamp.

Insert the clip on the end of the fixator with the "SKIN" arrow in the direction of the patient's skin.



Only for rekrea and rekrea Bifocal fixator bodies

Ensure that the clip hole aligns with the compression/distraction screw hole.

In the event of misalignment, move the selector sideways until it clicks.



Once the correct activation of the terminal has been verified (see page 15) proceed by turning the L-shaped operating key in the direction indicated by clip.

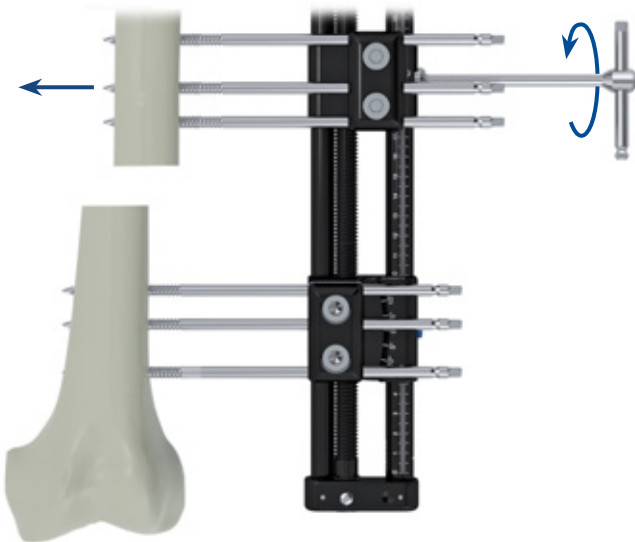
1/8 of a turn corresponds to a movement of the clamp of 0.25mm, half a turn of the key to 1mm.

Alignment of the bone docking site

Towards the end of the treatment, an x-ray may show sub-optimum alignment between the advancing segment and the area of contact with the opposite segment (**docking site**).

If you want to perform a lateral/medial correction or a varus/valgus deviation, it is recommended to use the translation clamp and/or the swiveling clamp.

Lateral/medial correction - TRANSLATION clamp



If a translation clamp is used for the transported stump, it will be possible to correct its medial or lateral translation.

Correction can be achieved by applying the T-wrench (**SF1011**) on the central correction screw of the Translation clamp.



*Translation clamp
SF26110 - SF26174 small*

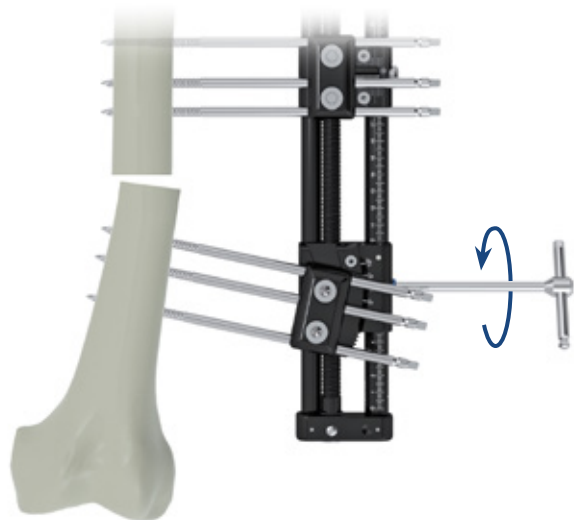
central correction screw



Turn the T-wrench (**SF1011**) on the central correction screw to achieve the desired alignment.

Remove the T-wrench and complete the treatment.

Correction of varus-valgus deviation - SWIVELING clamp



The swiveling clamp allows micrometric varus-valgus correction using the angular correction screw.

Before starting angular correction, turn the locking screw (blue) anti-clockwise to the **"UNLOCK"** position using the T-wrench (SF1011).



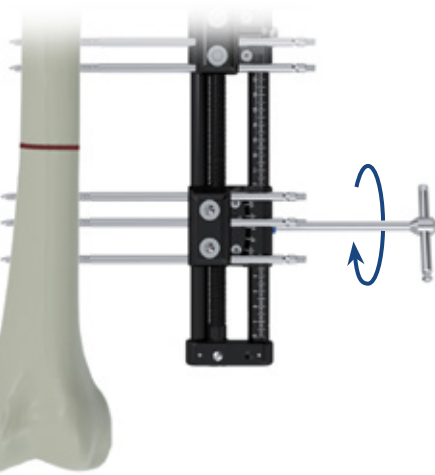
Swiveling clamp
SF26115 - SF26176 small

angular correction
screw

central locking screw

Turn the angular correction screw with the T-wrench (SF1011) to restore varus-valgus alignment.

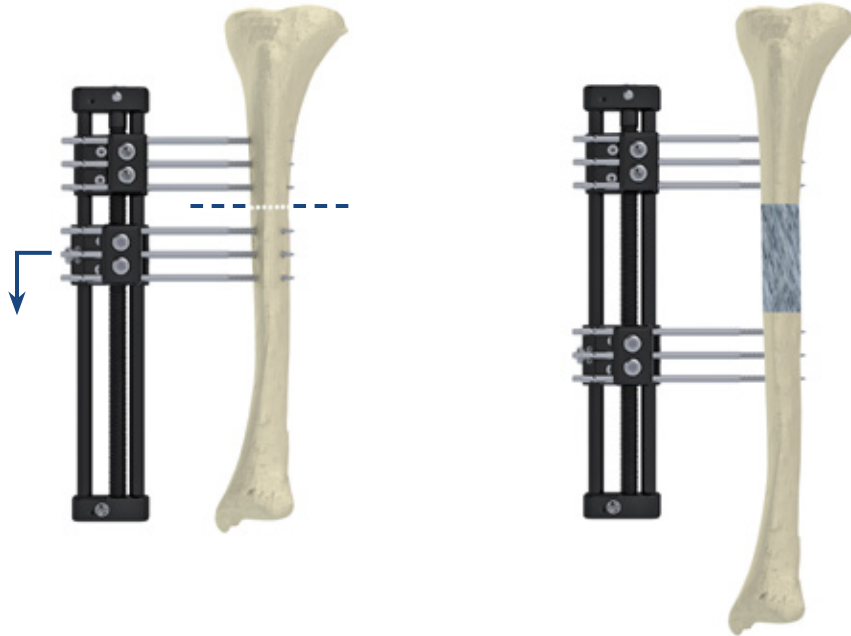
The graduated scale indicates the entity of the angular correction.



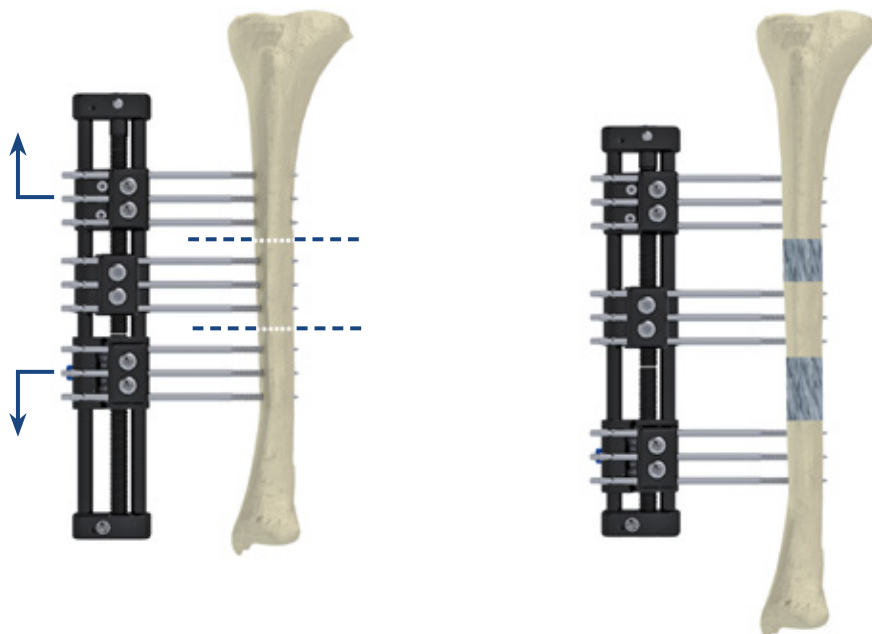
Once the desired correction has been achieved, turn the locking screw (blue) clockwise to the **"LOCK"** position to stabilise the clamp, using the T-wrench (SF1011).

Possible configurations

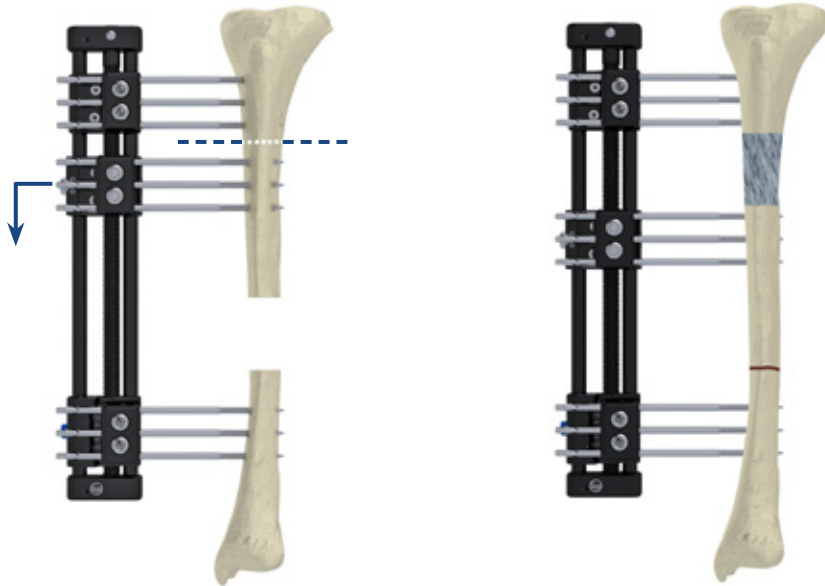
MONOFOCAL controlled distraction



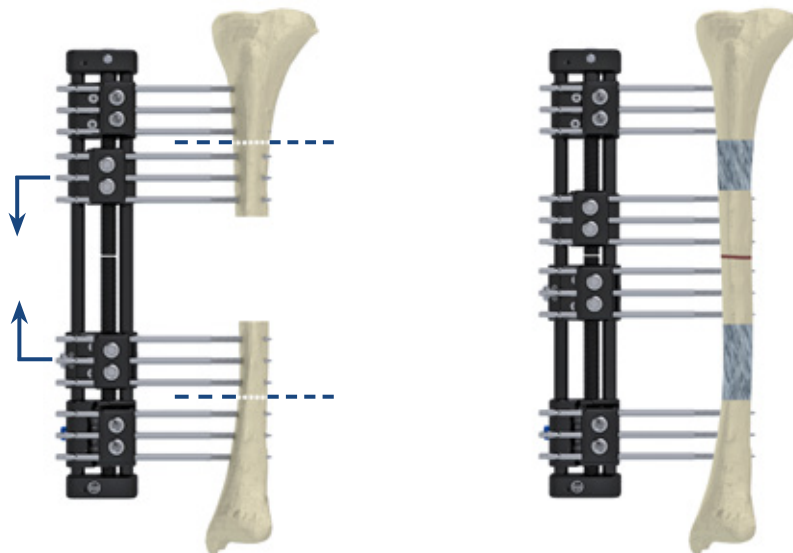
BIFOCAL controlled distraction



MONOFOCAL bone transport



BIFOCAL bone transport



Possible configurations with accessories



Ordering information - rekrea

STERILE

rekrea fixator body



Code	L. (mm)
SF26005	250
SF26010	300
SF26015	350
SF26020	400
SF26025	450
SF26030	500

All the fixator bodies are supplied with a T-wrench, 2 rekrea clips and 15 locking caps

rekrea bifocal fixator body



Code	L. (mm)
SF26055	250
SF26060	300
SF26065	350
SF26070	400

All the fixator bodies are supplied with a T-wrench, 2 rekrea clips and 15 locking caps



SF26100

Straight clamp



SF26105

Standard clamp



SF26110

Translation clamp



SF26115

Swiveling clamp

on request

STERILE


SF26150 Adjustable T clamp



SF26160 Adjustable T clamp for ring



SF26200 Mobile ring clamp



SF26300 Dynarek



SF26301 Dynarek Small



SF26305 Sandwich



SF26310 Trock

Ordering information - rekrea small

STERILE

rekrea small fixator body



All the rekrea small fixator bodies are supplied with a T-wrench, 2 rekrea small clips and 15 locking caps

Code	L. (mm)
SF26080	150
SF26082	200
SF26084	250
SF26086	300
SF26088	350



SF26170

Straight clamp small



SF26172

Standard clamp small



SF26174

Translation clamp small



SF26176

Swiveling clamp small



SF26180

Adjustable T clamp small



SF26182

Adjustable T clamp small for ring



SF26190

Mobile clamp small for ring

Ordering information - rekrea and rekrea small

STERILE


Aluminium ring



Code	ø (mm)
F4-5680	120
F4-5681	140
F4-5682	160
F4-5683	170
F4-5684	180
F4-5685	200

Aluminium foot ring



Code	Size (mm)
F4-5672	120x260
F4-5675	150x300



F4-5610 Bone screw holder



F4-5612 Wire holder



SF26290 Pin for clamp



SF26292 Screw and wire spacer

Rod support kit



- SF26320 Rod support kit
- SF26370 Rod support small kit

Rod kit for hybrid assembly



Code	L. (mm)
SF26340	400
SF26345	450
SF26350	500

- F4-5100 Clamp

- F4-5200 Bone screw holder

Kirschner wire trocar tip



Code	Size (mm)	Packaging (pcs.)
643718310	ø1.8x310	3
643718400	ø1.8x400	3

Kirschner wire trocar tip with ball



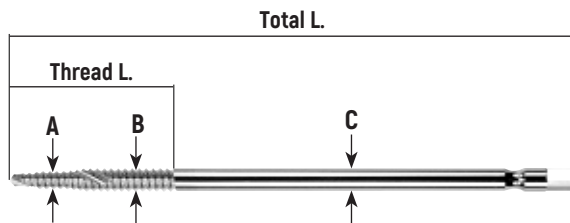
Code	Size (mm)	Packaging (pcs.)
643518400	ø1.8x400	5
643418400	ø1.8x400	1

Ordering information - bone screws

STERILE

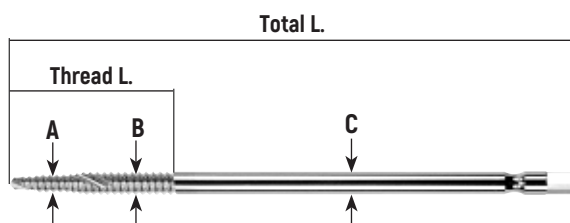


Cortical bone screw



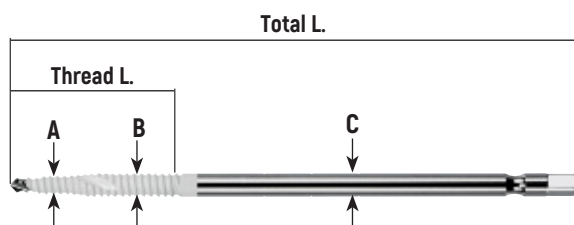
Code	A - B thread $\varnothing$ (mm)	C stem $\varnothing$ (mm)	Thread L. (mm)	Total L. (mm)	rekrea	rekrea Small
F4-130118	2.5 - 3	5	15	120		●
F4-130120	2.5 - 3	5	25	120		●
F4-140118	3 - 4	5	25	120		●
F4-145118	4 - 5	5	25	120		●
F4-145120	4 - 5	5	34	120		●
F4-145148	4 - 5	5	25	150		●
F4-145150	4 - 5	5	40	150		●
F4-145180	4 - 5	5	50	180		●
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	●	●
F4-156148	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	●	●

Nichel free cortical bone screw



Code	A - B thread $\varnothing$ (mm)	C stem $\varnothing$ (mm)	Thread L. (mm)	Total L. (mm)	rekrea	rekrea Small
F4-445120	4 - 5	5	34	120		●
F4-445150	4 - 5	5	40	150		●
F4-445180	4 - 5	5	50	180		●
F4-456150	5 - 6	6	40	150	●	●
F4-456180	5 - 6	6	50	180	●	●
F4-456200	5 - 6	6	60	200	●	●

Hydroxyapatite coated cortical bone screw



Code	A - B thread ø (mm)	C stem ø (mm)	Thread L. (mm)	Total L. (mm)	rekrea	rekrea Small
ST230118HA	2.5 - 3	5	15	120		●
ST230120HA	2.5 - 3	5	25	120		●
ST240118HA	3 - 4	5	25	120		●
ST245118HA	4 - 5	5	25	120		●
ST245120HA	4 - 5	5	34	120		●
ST245148HA	4 - 5	5	25	150		●
ST245150HA	4 - 5	5	40	150		●
ST245180HA	4 - 5	5	50	180		●
ST350120HA	4 - 5	6	30	120	●	●
ST350150HA	4 - 5	6	30	150	●	●
ST350178HA	4 - 5	6	30	180	●	●
ST350180HA	4 - 5	6	40	180	●	●
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	●	●

Ordering information - instrument set



Code	Description	Q.ty	rekrea	rekrea Small
66220	Kirschner wire $\varnothing 2 \times 270 \text{mm}$ - STERILE	1	●	●
F4-0220	T-handle for chuck	1	●	●
SF1011	T-wrench, hexagon 6mm	1	●	●
SF1080	Chuck for $\varnothing 5 \text{mm}$ bone screw	1		●
SF1090	Chuck for $\varnothing 6 \text{mm}$ bone screw	1	●	●
SF1220	Protection sleeve $\varnothing 6 \text{mm}$ L. 120mm with handle	2	●	●
SF1230	Protection sleeve $\varnothing 6 \text{mm}$ L. 90mm	4	●	●
SF1235	Protection sleeve $\varnothing 5 \text{mm}$ L. 90mm	4		●
SF1240	Trocar for protection sleeve $\varnothing 6 \text{mm}$	1	●	●
SF1245	Trocar for protection sleeve $\varnothing 5 \text{mm}$	1		●
SF1250	Cannulated trocar $\varnothing 6 \text{mm}$ for $\varnothing 2 \text{mm}$ wire	2	●	●
SF1255	Cannulated trocar $\varnothing 5 \text{mm}$ for $\varnothing 2 \text{mm}$ wire	2		●
SF1260	Protection sleeve $\varnothing 6 \text{mm}$ L. 60mm	4	●	●
SF1265	Protection sleeve $\varnothing 5 \text{mm}$ L. 60mm	4		●
SF1290	Limb Reconstruction instrument set box, empty	1	●	●
SF1330	Drill bit $\varnothing 3 \text{mm}$ for protection sleeve $\varnothing 6 \text{mm}$	2	●	●
SF1333	Drill bit $\varnothing 3 \text{mm}$ for protection sleeve $\varnothing 5 \text{mm}$	2		●
SF1340	Drill bit $\varnothing 4.8 \text{mm}$ for protection sleeve $\varnothing 6 \text{mm}$	2	●	●

Accessory instrumentation

Code	Description	rekrea	rekrea Small
F4-0205	Dynamometric wrench	●	●
SF1050	Drill brace	●	●
SF1305	Quick-connect adapter for bone screw ($\varnothing 5 \text{mm}$ stem) - STERILE		●
SF1306	Quick-connect adapter for bone screw ($\varnothing 6 \text{mm}$ stem) - STERILE	●	●
SF1011	T-wrench, hexagon 6mm	●	●
SF1380	rekrea template - STERILE	●	
SF6470RK	Wire tensioner	●	●

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