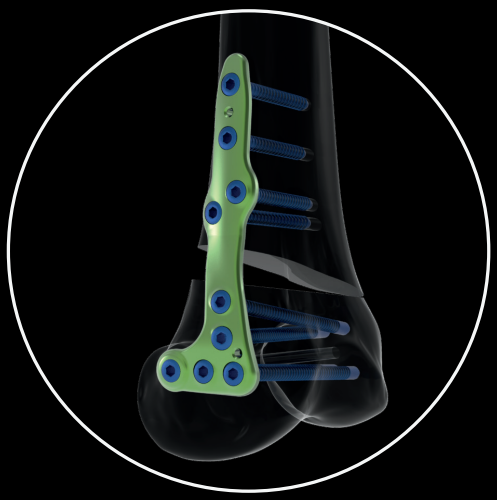
NEWCLIP-TECHNICS

INNOVATION MEANS MOTION



ACTIVMOTION DFO PSI
LATERAL OPENING WEDGE DISTAL FEMORAL OSTEOTOMY USING PATIENT SPECIFIC CUTTING GUIDE

- Internal hinge protection
- Femoral slope controlled
- Accuracy of correction

ACTIVMOTION PSI

Indications: The implants of the ACTIVMOTION range are intended for knee osteotomy in adults.

Contra-indications:
- Serious vascular deterioration, bone devitalization.
- Pregnancy.
- Acute or chronic local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency affecting the concerned area.
- Insufficient bone quality preventing a good fixation of the implants into the bone.
- Muscular deficit, neurological deficiency or behavioral disorders, which could submit the implant to abnormal mechanical strains.
- Allergy to one of the materials used or sensitivity to foreign bodies.
- Serious problems of non-compliance, mental or neurological disorders, failure to follow post-operative care recommendations.
- Unstable physical and/or mental condition.

TECHNICAL FEATURES

DISTAL FEMORAL OSTEOTOMY PLATE

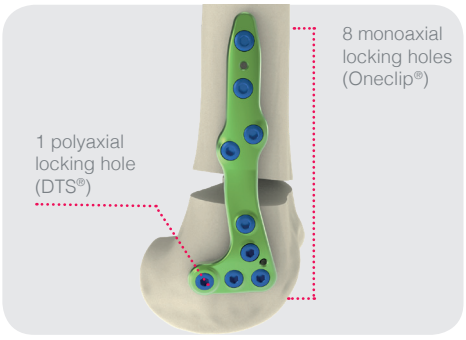
→ TECHNICAL FEATURES

- **Anatomic asymmetrical implant** (green anodized for right plate and blue anodized for left plate),
- 2 offset screw holes above the osteotomy site improving the mechanical features of the assembly and preventing loss of angular correction,
- **8 locking screws** (Oneclip®),
- **1 polyaxial locking screw** (DTS®) allowing to avoid the intercondylar notch, if necessary,
- Possible angulation of the screw before locking (25° locking range) thanks to the DTS® system.

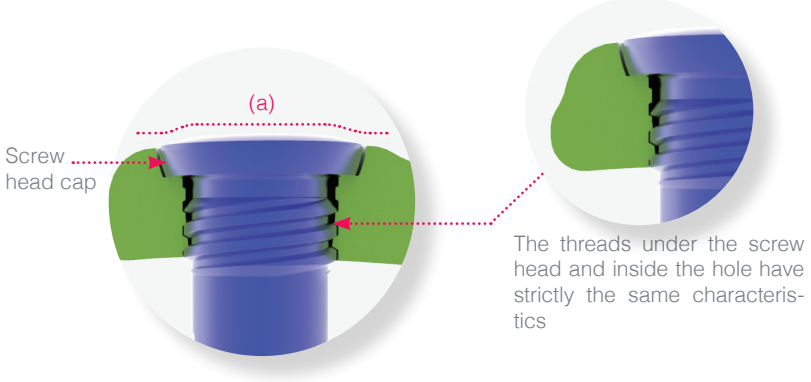
FIXATION

→ TECHNICAL FEATURES

- Ø4.5 mm reinforced core screws for optimal mechanical stability (progressive core diameter Ø3.9 to 4.5 mm),
- Buried screws to minimize risks of soft tissue irritation.



→ EFFICIENT LOCKING



Features:
- The screw head is stopped in the hole by its cap, ensuring the locking,
- The screw head is buried in the plate (a),
- Plate and screws are all made of titanium.

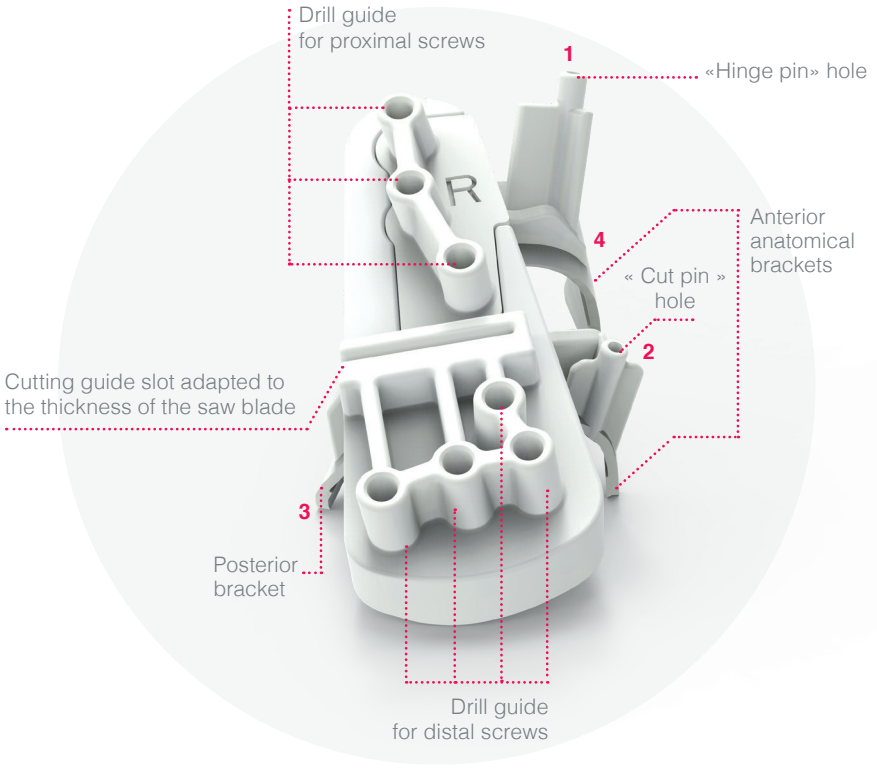
Construct limiting cold welding risks for improved removal properties. Optimized coaptation of both profiles during locking.

TECHNICAL FEATURES

PATIENT SPECIFIC CUTTING GUIDE - STEP BY STEP

The patient specific guide for DFO based on patient's CT scan, offers a correction into the frontal and sagittal planes.

→ TECHNICAL FEATURES



1. The «**Hinge Pin**» going through this hole serves as:
- a **mechanical stop** for the cut,
- an indication of the **hinge position** (hinge: 12 mm from the medial cortex).

2. The «**Cut Pin**» going through this hole allows to check:
- The **direction of the osteotomy cut,**
- The **PSI position** (compliance of the real position with the planned position).

3. 2 Anterior brackets helping for the **PSI positioning.**

4. Posterior anatomical bracket congruent with the femoral surface for accurate positioning.

→ PROCESS

Day 1...

1 Patient case identification, **decision to go for DFO with PSI**

2 Newclip Technics protocol **validated** using patient CT scan

3 **Fill in of the order form** for 3D design of the PSI for DFO

4 **Preplanification**'s validation by the surgeon and Newclip Technics

5 **Manufacturing** and control of the PSI for DFO

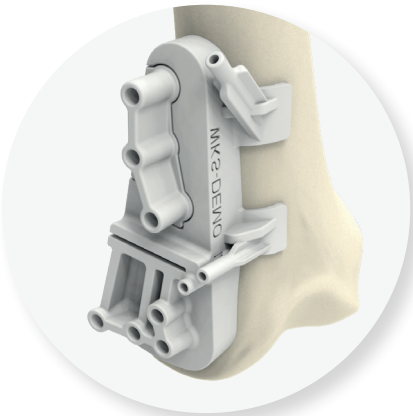
6 Implants and instruments set **supplied** for surgery

7 **Final preoperative** planning file provided

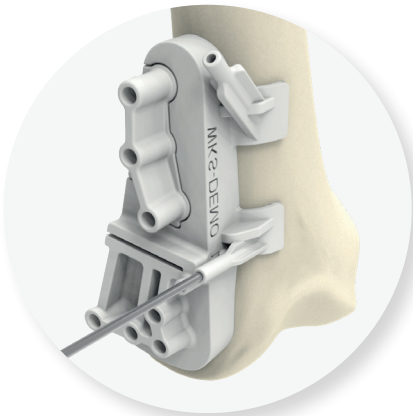
8 **Surgery**

SURGICAL TECHNIQUE

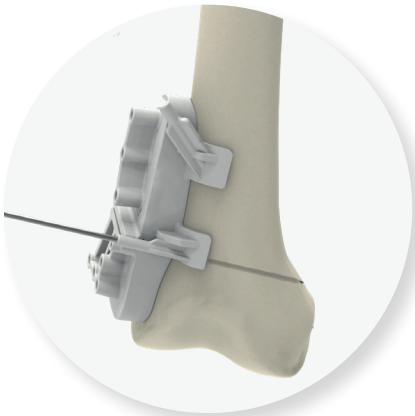
FIXATION AND POSITIONNING VALIDATION



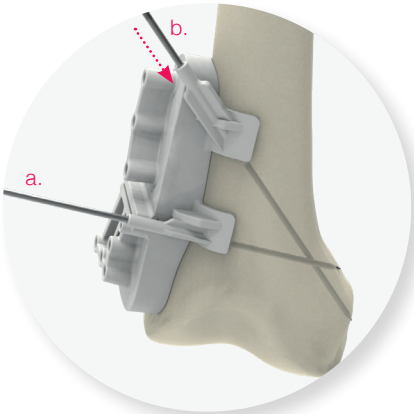
1. Position the anatomical cutting guide on the femur lateral face using the anterior brackets and the congruent shape of the PSI. To guarantee the positioning, push the anatomical cutting guide the most distally as possible until a buttress is felt thanks to the posterior bracket and the mentioned value posted on the 2nd page of the planification file.



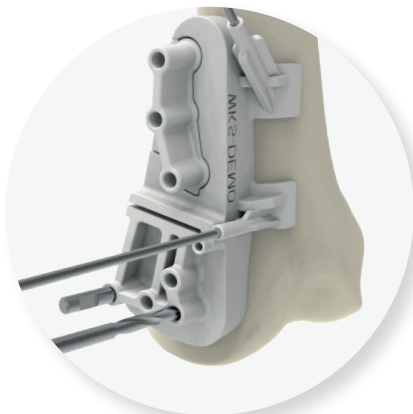
2. Hold the PSI against the bone by keeping pressure on it. Insert the Ø2.2 mm cut pin (33.0222.150) through the cut pin hole positioned on the anterior distal bracket. To check the insertion depth, measure the part of the pin remaining out of the pin hole. Compare the value with the one mentioned in the planning file.



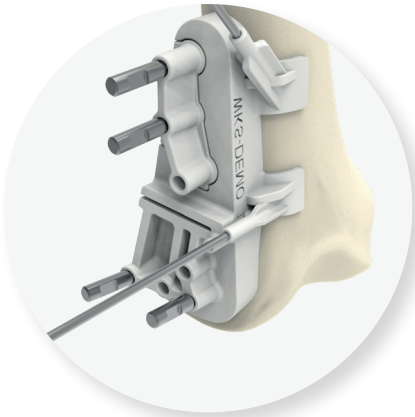
3. The cut pin is descendant and targets the medial condyle. Its insertion is located 1 mm above the cut and is computed for each patient individually to obtain the accurate cut position.
The cut pin determines the orientation and the position of the cut.



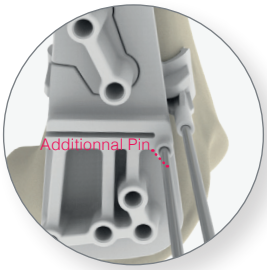
4. Insert the Ø2.2 mm hinge pin (33.0222.150) in the hole positioned on the anterior proximal bracket. To control the insertion depth, measure the part of the Ø2.2 mm hinge pin (33.0222.150) remaining out the pin hole. Compare the value with the one mentioned in the planning file.
a) The Cut pin and the Hinge pin give the good positioning of the guide on the femur.
b) The crossing point between both pins gives the hinge thickness and location.

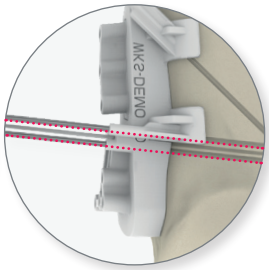


5. Now that the PSI is confirmed to be well positioned, drill using the Ø4.0 mm drill bit (ANC212) through the 7 pin holes.
Insert at least two Ø3.9 mm monocortical pins for cutting guide (ANC657) in the distal part of the guide and two Ø3.9 mm bicortical pins for cutting guide (ANC657) in the proximal part of the guide.
Insert at least 4 pins, adding up to 6 will avoid vibrations during the cut.



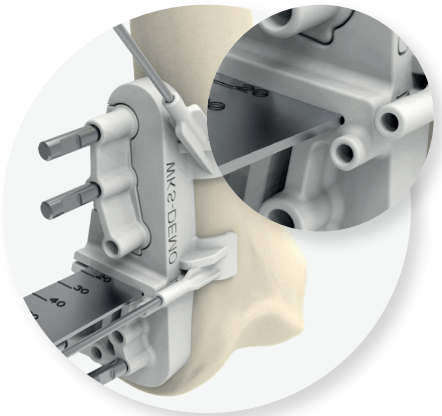
6. Using a hammer, insert the pins (ANC657) all the way in.



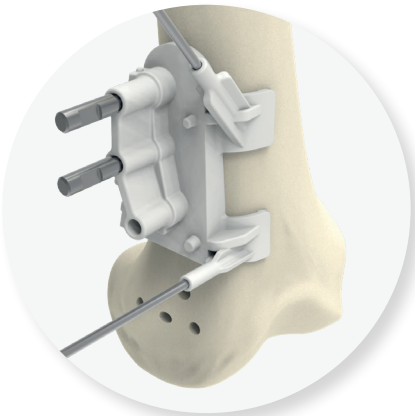


Optionnal step :
An additional pin placed below the window of the PSI upper part can be used to secure the trajectory of the saw blade during the cut.

CUTTING

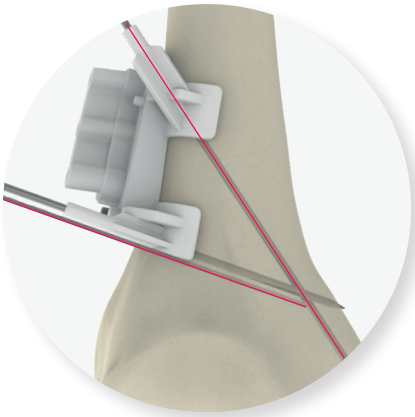


7. Place the saw blade in the window of the PSI.
The anterior part of the window is closed to stop the extension of the cut on the anterior face of the femur. Once the cut is finalized on the posterolateral area of the femur, remove the saw blade.



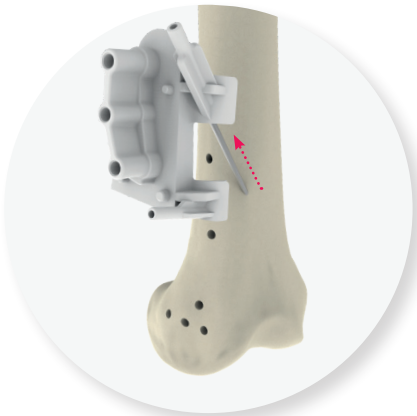
8. Remove the Ø3.9 mm distal pins for cutting guide (ANC657) and the distal part of the PSI.

9. Re-insert the saw blade and finalize the cut toward the anterior area of the femur.

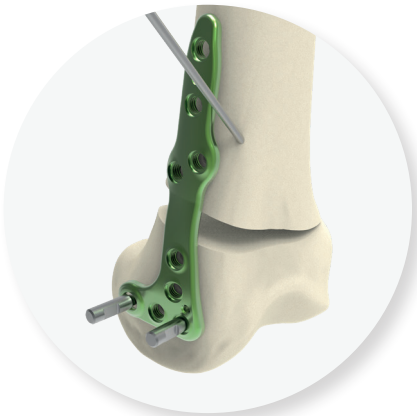


10. Once the saw blade gets in contact with the Ø2.2 mm hinge pin (33.0222.150), stop the cut. The point reached is at the limit of the internal hinge and is located at 12 mm from the medial cortical.

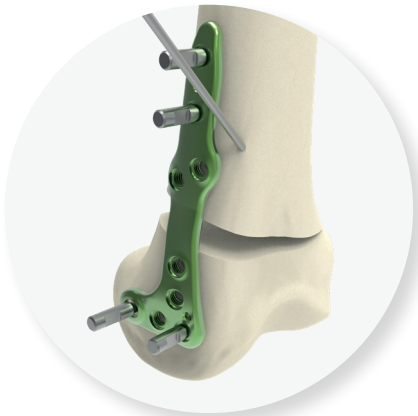
OPENING AND PLATE FIXATION



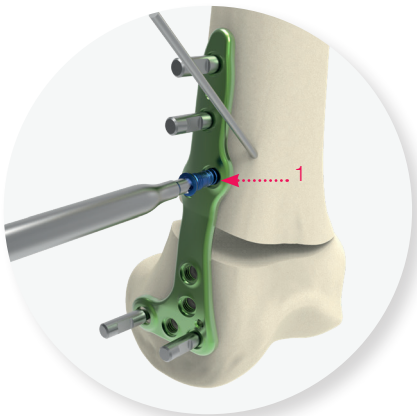
11. Remove the Ø3.9 mm pins for cutting guide (ANC657) and the Ø2.2 mm cut pin (33.0222.150).
Then, remove the proximal part of the PSI by sliding it along the Ø2.2 mm hinge pin (33.0222.150) and perform the opening.

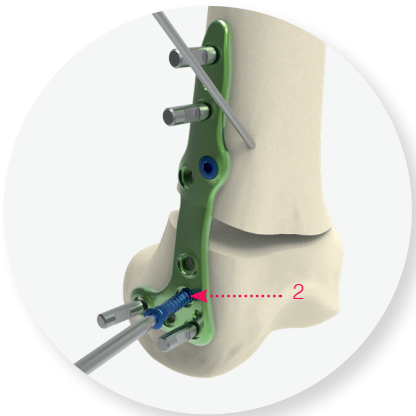


12. Position the plate by inserting two Ø3.9 mm distal pins for cutting guide (ANC657).

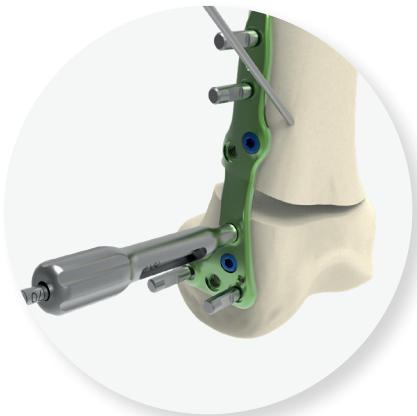


13. The planned opening is reached in both frontal and sagittal planes when the proximal holes previously drilled and the plate holes are facing each other.
Then, insert two Ø3.9 mm proximal pins for cutting guide (ANC774) in order to fix the plate and hold the opening.

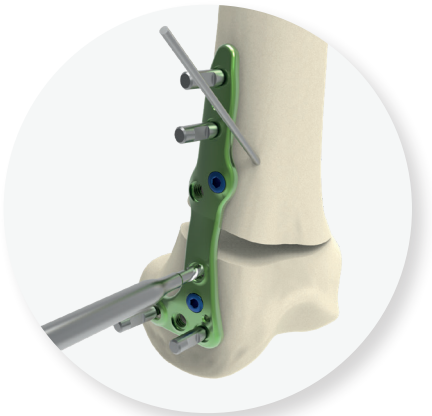




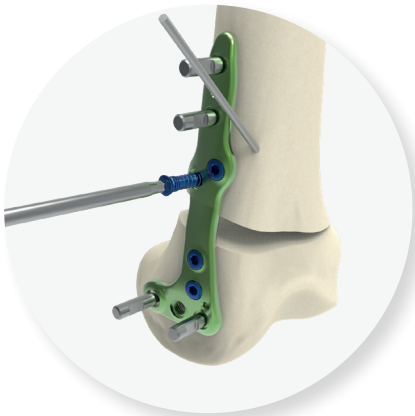
14. In the 2 holes previously drilled (step 5) and close to the opening, countersink (ANC120-US) to prepare the first cortex.
The length screw is defined in the planification file but it is possible to verify it by using the length gauge (ANC210).
Then, insert the two Ø4.5 mm DTS self-tapping screws (ST4.5Lxx-ST) using the screwdriver (ANC312)



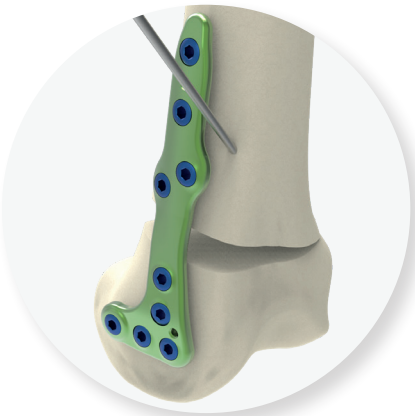
15. In the undrilled hole situated under the osteotomy cut, lock the Ø4.0 mm drill guide (ANC212)
Then, start drilling using the Ø4.0 mm drill bit (ANC211).
The length screw is defined in the planification file but it is possible to verify it by using the drill guide (ANC212) and the drill bit (ANC211).



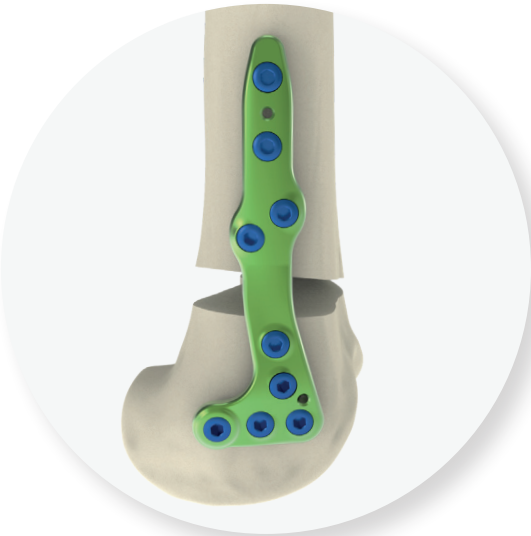
16. To ease the insertion of the Ø4.5 mm DTS self-tapping screws (ST4.5Lxx-ST), use the countersink (ANC120-US) to widen the first cortex previously drilled.
Then, insert the Ø4.5 mm DTS self-tapping screw (ST4.5Lxx-ST) using the screwdriver (ANC119-SK).



17. Repeat the previous step with the undrilled hole situated above the oteotomy cut.



18. Finalize the assembly by inserting the 5 remaining Ø4.5 mm DTS self-tapping screws (ST4.5Lxx-ST).
Proceed by inserting alternatively distal and proximal screws, getting further and further away from the osteotomy site.
Each pin must only be removed right before inserting a screw in its place. Finally, remove the Ø2.2 mm hinge pin (33.0222.150) from the hinge.



Final Result

IMPLANT REFERENCES

MEDIAL OPENING WEDGE TIBIAL PLATES*

Ref.	Description
JATDL1-ST	Lateral opening wedge DFO plate - Right - Size 1 - STERILE
JATGL1-ST	Lateral opening wedge DFO plate - Left - Size 1 - STERILE

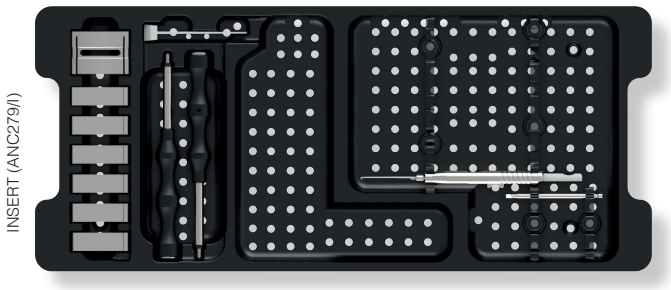
Ø4.5 MM DTS® SELF TAPPING SCREW

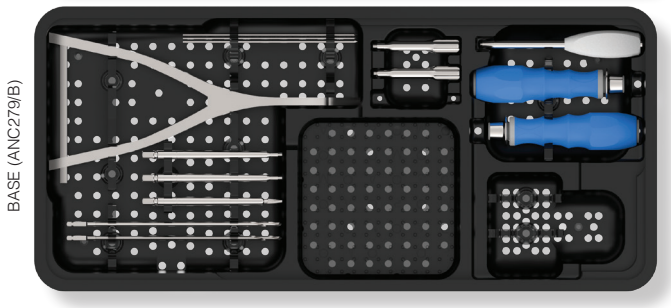
Ref.	Description
ST4.5Lxx-ST	DTS® self-tapping screw - Ø4.5 mm - STERILE From L30 mm to L90 mm (5 mm increments)
CT4.5Lxx-ST	Standard cortical screw - Ø4.5 mm - STERILE From L 20 mm to 60 mm (2 mm increments)

INSTRUMENTS REFERENCES

ACTIVMOTION INSTRUMENTS

Ref.	Description	Qty
ANC024	Handle for metallic wedge and cutting guide	2
ANC119-SK	3.0 mm quick coupling hexagonal non prehensor screwdriver	2
ANC120-US	Ø4.2 mm countersink with US quick coupling system	1
ANC210	Length gauge for Ø4.5 mm screws	1
ANC211	Ø4.0 mm quick coupling drill bit	2
ANC212	Ø4.0 mm DTS Trauma drill guide	2
ANC235	DFO Meary pliers	1
ANC240	Pliers for bending ACTIV plates	2
ANC312	3.0 mm quick coupling hexagonal screwdriver	1
ANC352	Ø6 mm US quick coupling handle	2
ANC785	Ø2.2 pin guide	1
33.0222.150	Pin Ø2.2 L150 mm	3





METALLIC WEDGE FOR KNEE OSTEOTOMY

ANC019	Metallic wedge for knee osteotomy - 6 mm high	1
ANC020	Metallic wedge for knee osteotomy - 8 mm high	1
ANC021	Metallic wedge for knee osteotomy - 10 mm high	1
ANC022	Metallic wedge for knee osteotomy - 12 mm high	1
ANC023	Metallic wedge for knee osteotomy - 14 mm high	1
ANC025	Metallic wedge for knee osteotomy - 16 mm high	1
ANC860	Metallic wedge for knee osteotomy - 18 mm high	1

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Brochure EN - Activmotion PSI - Ed1 - 02/2018 - Medical device EC: class IIb - CE 0120 SGS UK - US Class: II - Read labeling and instructions before use.