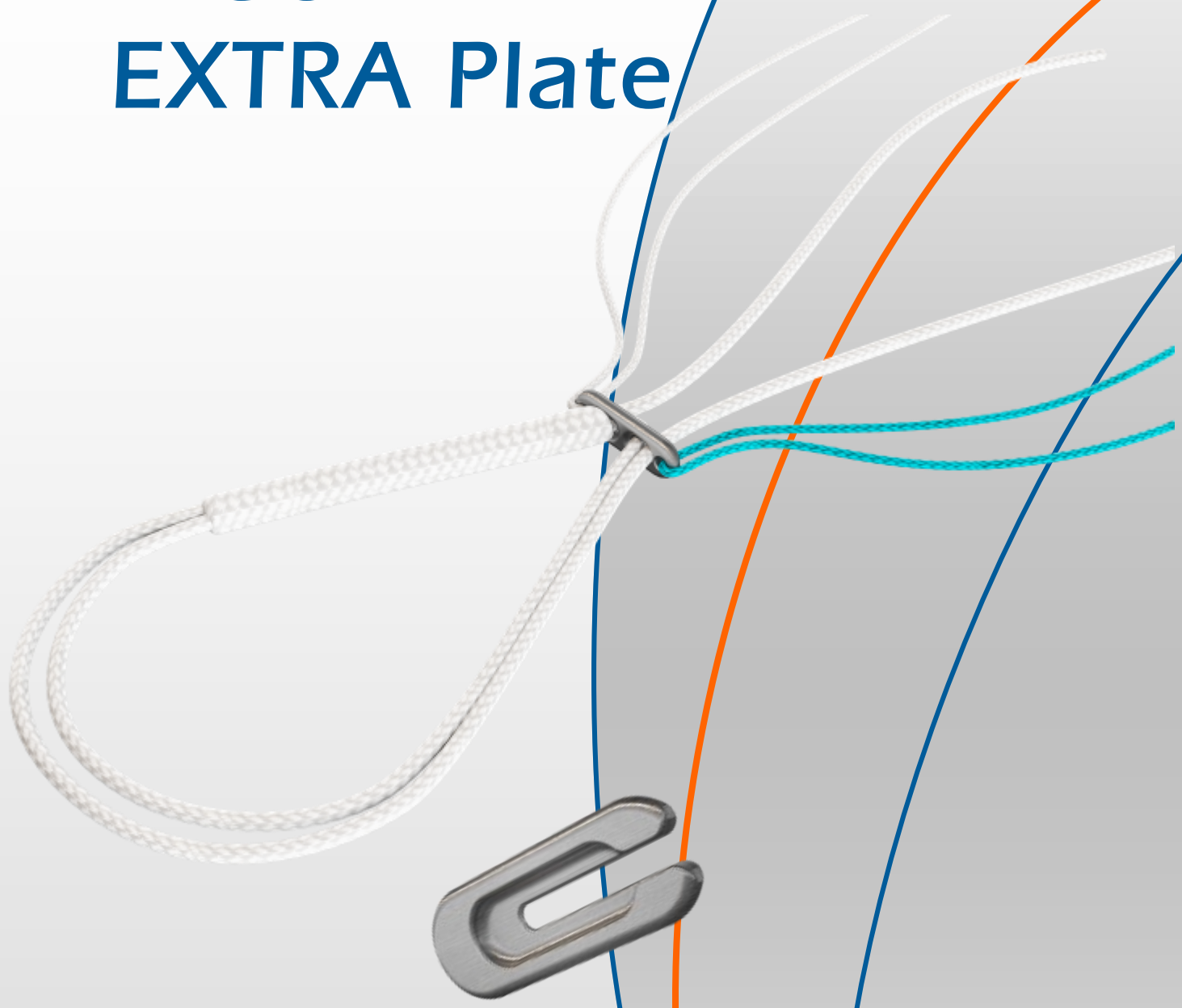


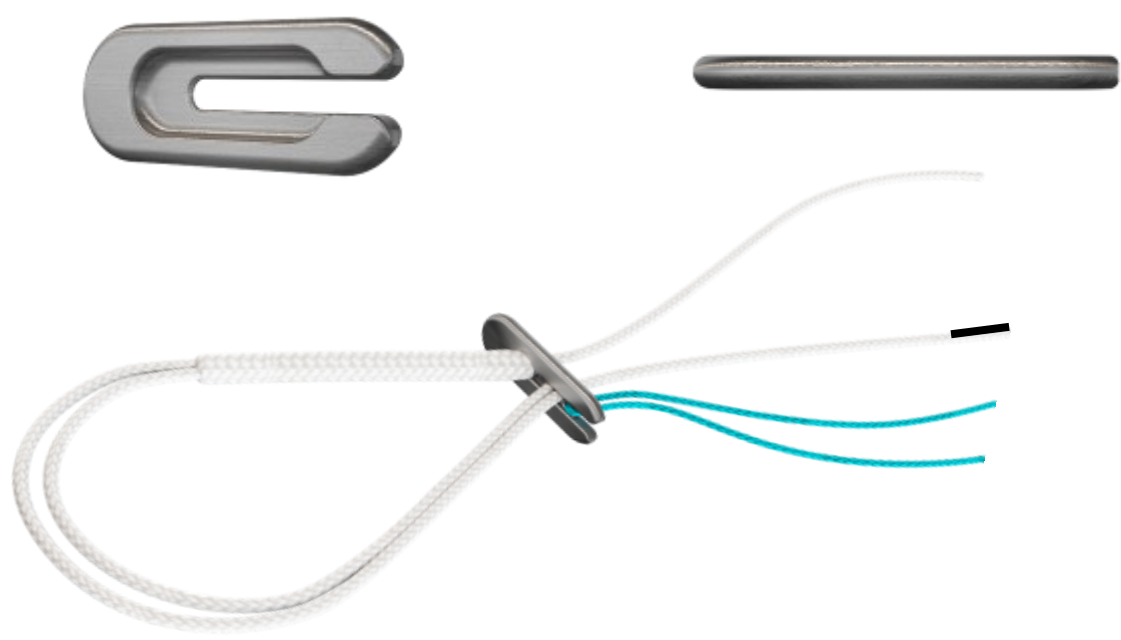
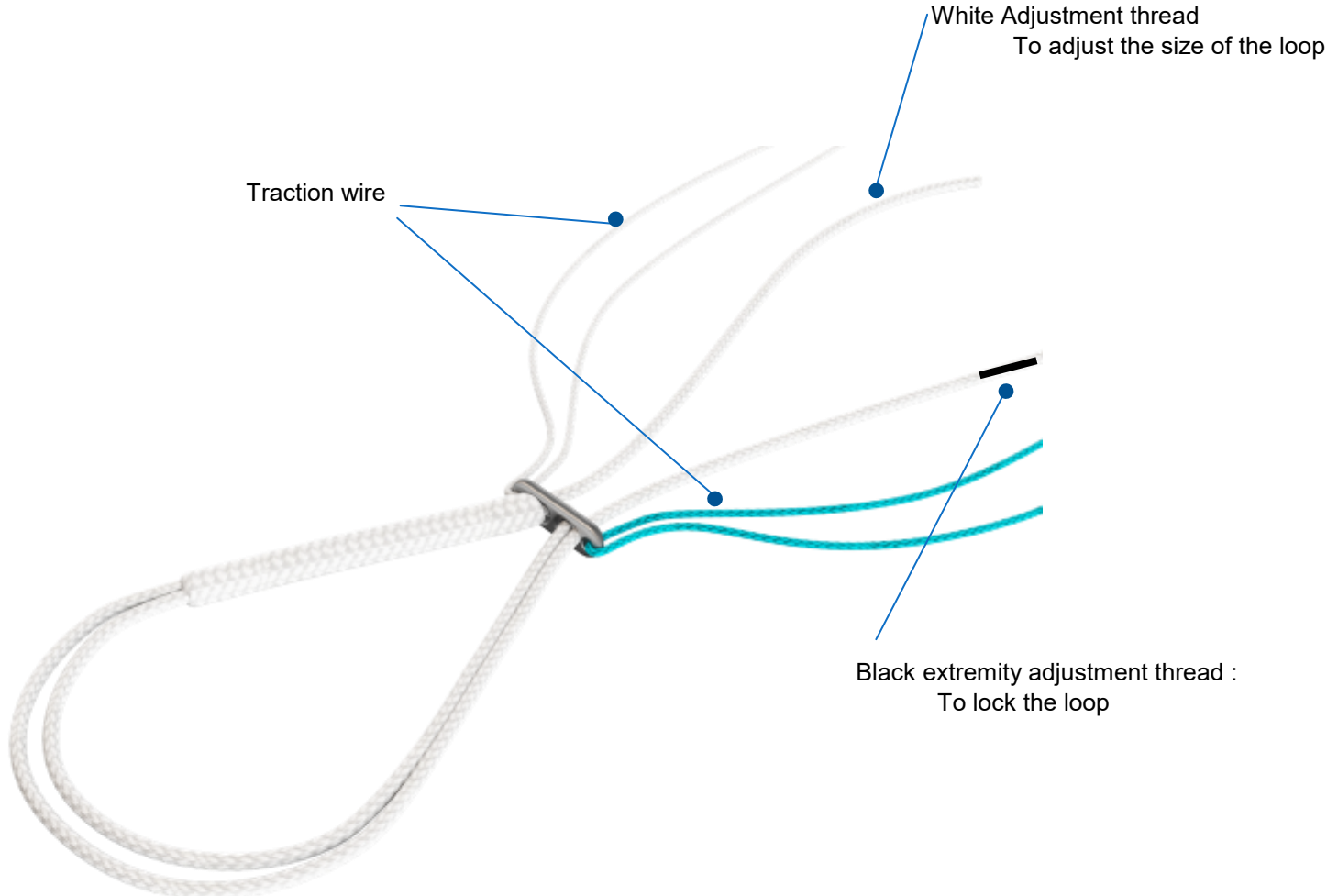
COMETE[®] Control

COMETE[®] EXTRA Plate



Surgical technique





COMETE® CONTROL and COMETE® Extra plate are a class IIb medical devices manufactured by COUSIN BIOTECH S.A.S. The CE conformity has been carried out by the notified body SGS Belgium NV (CE1639). The management system of COUSIN BIOTECH S.A.S is certified for compliance with ISO 13485 standard. Please read carefully the instructions for use before using the device.

Non contractual pictures and texts. Specifications likely to be modified without notice.
Cousin Biotech S.A.S capital : 340 656 € - 398 460 261 RCS Lille – N°TVA FR 34 398 460 261

COMETE® Control and Extra Plate

COMETE® Control

- COMETE® Control is made of a green and a white traction wire.

To pass the COMETE® CONTROL plate through the tunnel, tract the white or the green traction wire . Pull the other traction wire and adjustment threads without applying tension.

- COMETE® Control two adjustment threads.
White Adjustable thread to adjust the loop
Black Adjustable thread to lock the loop.

- To adjust the loop : start pulling the white adjustment thread and pull the same length with the black thread. Reproduce the movement until adjust the loop to the desired length.

- Do not force on the locking thread during the loop adjustment time

- Lock the COMETE® CONTROL : Hold a tension on the white adjustable thread and pull tightly the black adjustment thread to lock the loop.

COMETE® Extra plate

- Dimension
 - Length 20 mm
 - Width 7 mm
 - Thikness 1.50 mm

COMETE® Control with COMETE® Extra plate

- Remove one of the two traction wire. Slide the extended plate under the button. Make sure that the remaining traction wire is on the slot side to avoid hindering the interlocking.

Note :

This document is aimed to have a correct use of instrumentation set. Anatomical acces and surgical technique are under responsibility of surgeon.

COMETE® Control and Extra Plate



1

COMETE® Control positioning

- Pull the white COMETE® Control traction wires to orientate the COMETE® Control titanium plate in the tunnel. (Pull the other traction wire and adjustment threads without applying tension). Pass the COMETE® Control and the graft through the tibial and femoral tunnels. Stop towing when the titanium plate pass the lateral femoral cortex.
- To lock the plate on the cortex, pull the green traction wire. To make sure the titanium plate is perpendicular to the femoral cortex. Pull back the graft.



2

COMETE Control adjustment

- Start pulling the white adjustment thread and pull the same length with the black thread. Reproduce de mouvement until adjuste the loop to the desired length.

Do not force on the locking thread during the loop adjustment time

- Maintain a tension on the white adjustment thread and pull tightly the black adjustment thread to lock the loop.



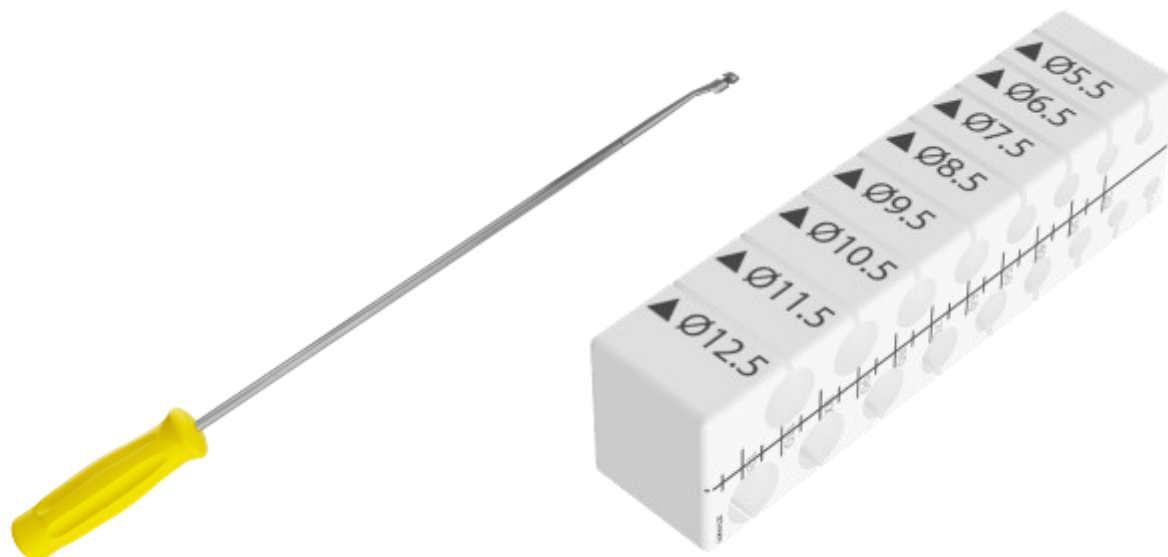
3

Tibial fixation

- Place the COMETE® Extra Plate on the COMETE® Control to increase the cortical contact surface. Remove one of the two pulling wire. Slide the extended plate under the button. Ensure that the remaining thread is on the slot side to avoid hindering the interlocking.
- Begin to pull the white adjustment thread and pull the same length with the black thread. =Reproduce the movement until adjust the loop to the required tension.
Do not force on the locking thread during the loop adjustment time
- Use the black adjustment thread to lock the loop at the applied tension.
- Control the graft tensioning
- Cut the adjustment threads on the femur and tibia at a minimum distance of 10mm from the cortical button

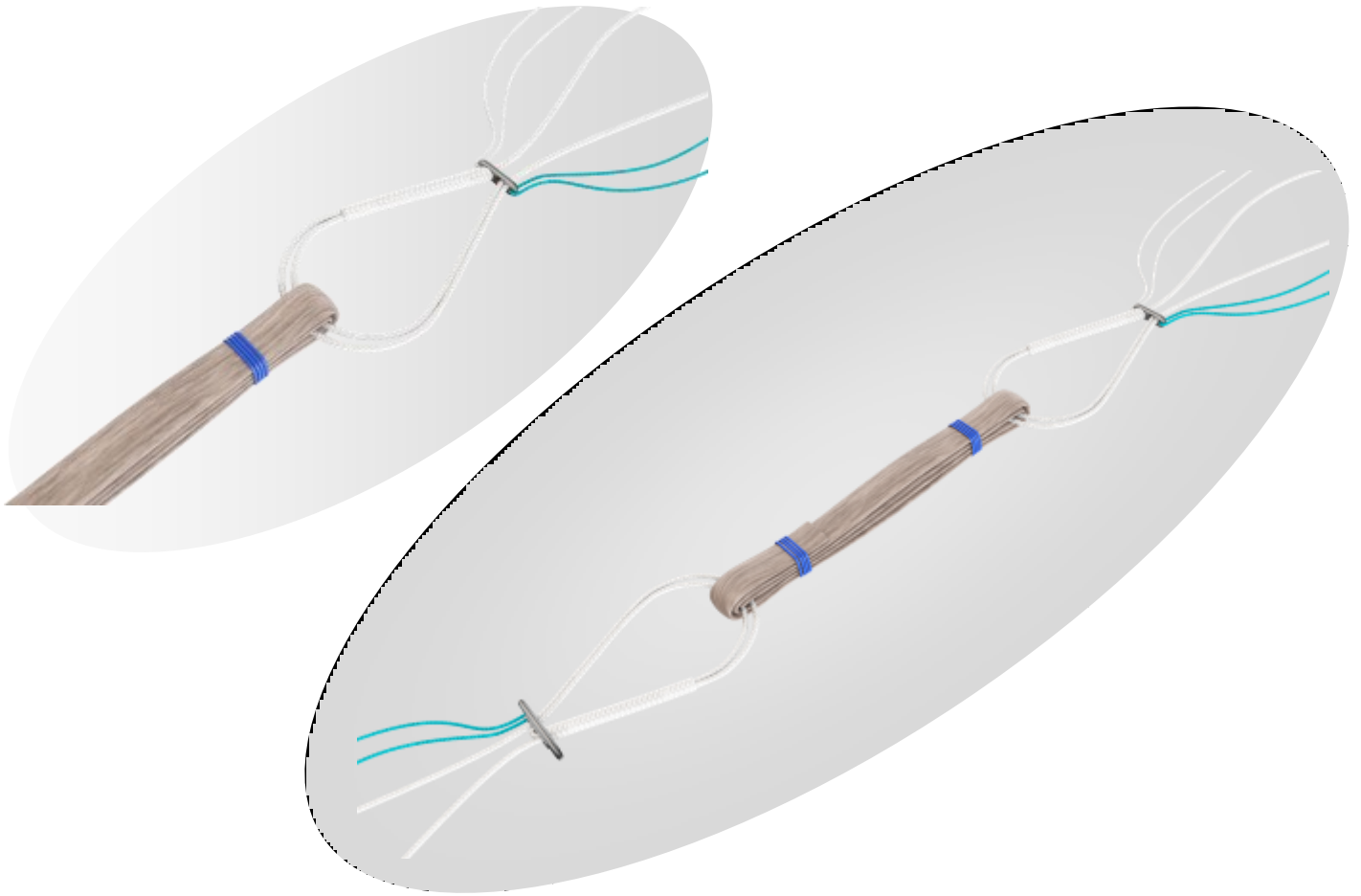
COMETE® Control and Extra Plate

HARVESTING



- Harvest the semi tendinosus with the open stripper.

GRAFT PREPARATION

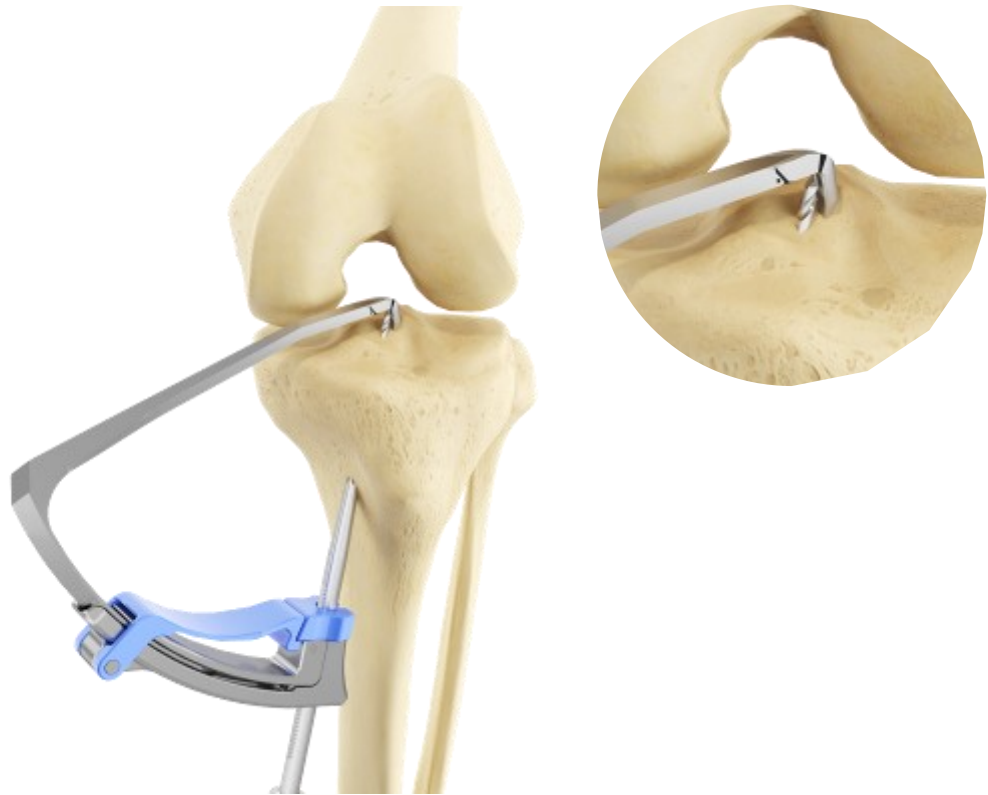


- Pass the semi tendinosus through the femoral and tibial adjusted loops.
- Obtain a four-bundle graft of sufficient length.

Perform a distal and proximal suture combining the 4 strands of the graft

Calibrate the graft (diameter and length) using graft sizer.

TIBIAL PLACEMENT



- Assemble the tibial guide and select the angulation.
- Place the tip of the tibial guide in the tibial ACL Footprint.
- Use the laser marking to estimate the exit of the wire pin guide.
- Insert the tibial guide sleeve, flat surface facing upware. Just apply a single « clic » after the contact with the cortex.
- Drill the wire pin guide throught the tibial guide sleeve.
- Control the wire pin guide positioning.

TIBIAL DRILLING



- Select the reamer that matches the graft diameter.
- Advance the reamer over the wire pin guide and drill the tibial tunnel.

FEMORAL PLACEMENT



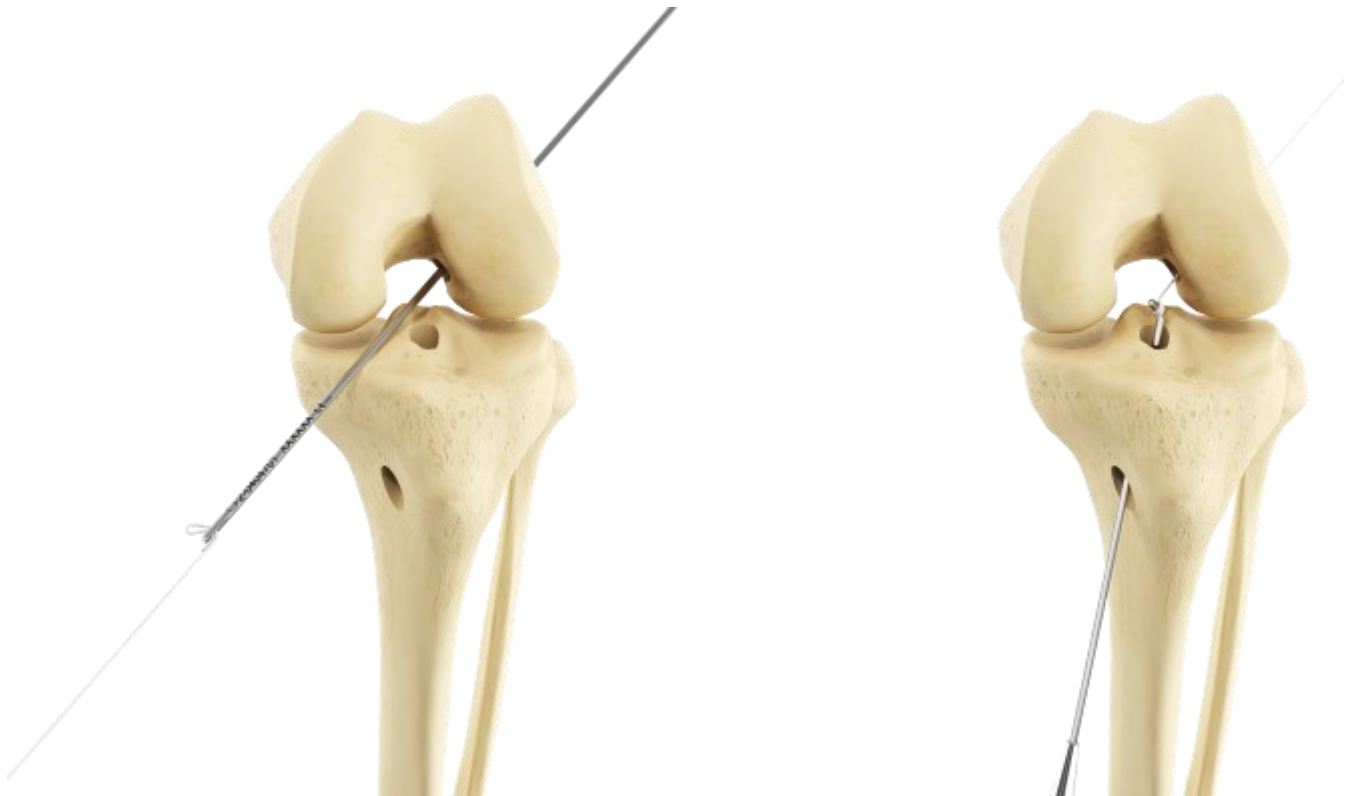
- Select the appropriate offset : 1 mm more than the graft radius.
- Place the hook of the femoral guide in the over the top position.
- Place the eylet pin through the femoral guide untill pass the lateral cortex and skin.
- Control the eylet pin position.

FEMORAL DRILLING



- Select the reamer that matches the graft diameter.
- Drill the femoral tunnel over the eyelet pin at the desired depth.
- Select the 5 mm canulated reamer.
- Drill the intraosseous tunnel and note the length when the femoral distal cortex is felt to get the intraosseous tunnel depth.

SUTURE LOOP POSITIONNING



- Pass a suture loop through the eylet pin and pull the eylet pin while holding the loop to the antero medial arthroscopic portal.
- Pass the loop on the joint.
- Retrieve the loop through the tibial tunnel.

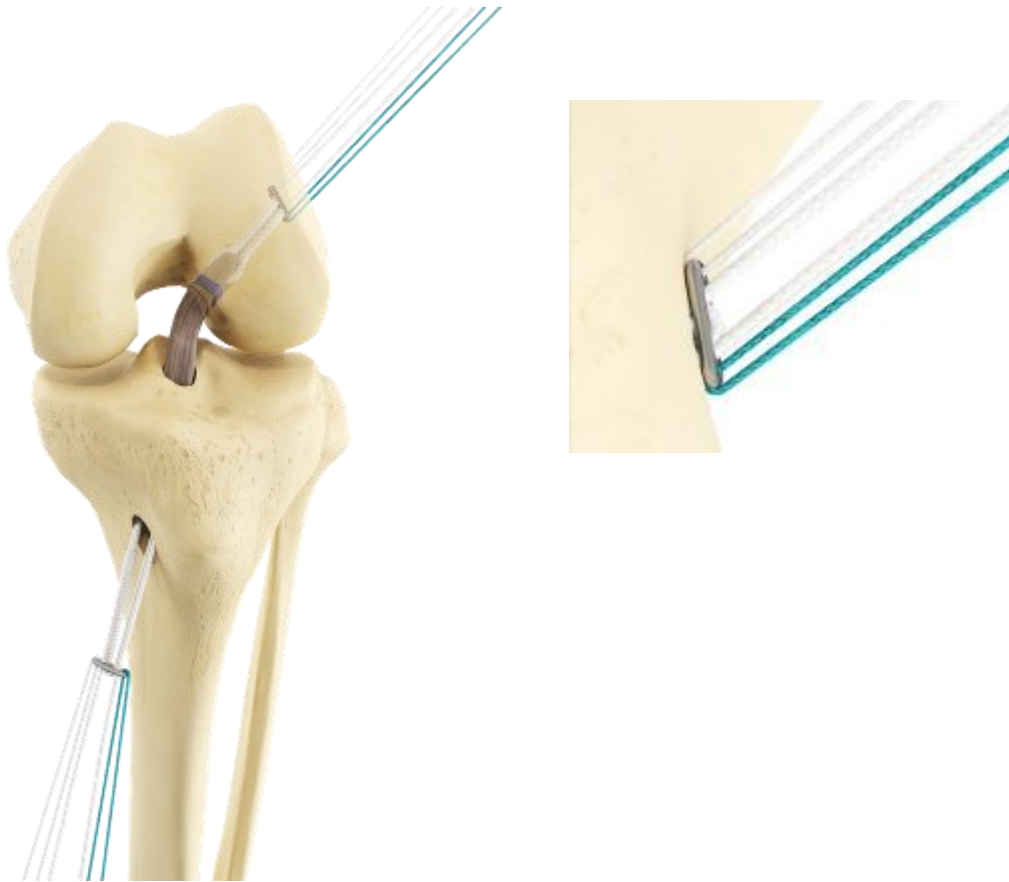
COMETE® CONTROL POSITIONNING ON FEMORAL SIDE



- Pass the COMETE® traction wires and the adjustable threads through the suture loop and tract it until the COMETE® Control wires and threads emerge from the skin surface.
- Pull the white COMETE® Control traction wire to orientate the COMETE® titanium plate in the tunnel. Pass the COMETE® control and the graft through the tibial and femoral tunnels. Stop pulling when the titanium plate pass the femoral cortex.
- To lock the plate on the cortex, pull the green traction wire. To make sure the titanium plate is perpendicular to the femoral cortex, pull back the graft to control the fixation.

COMETE® Control and Extra Plate

FEMORAL FIXATION BY COMETE® CONTROL AND EXTRA PLATE



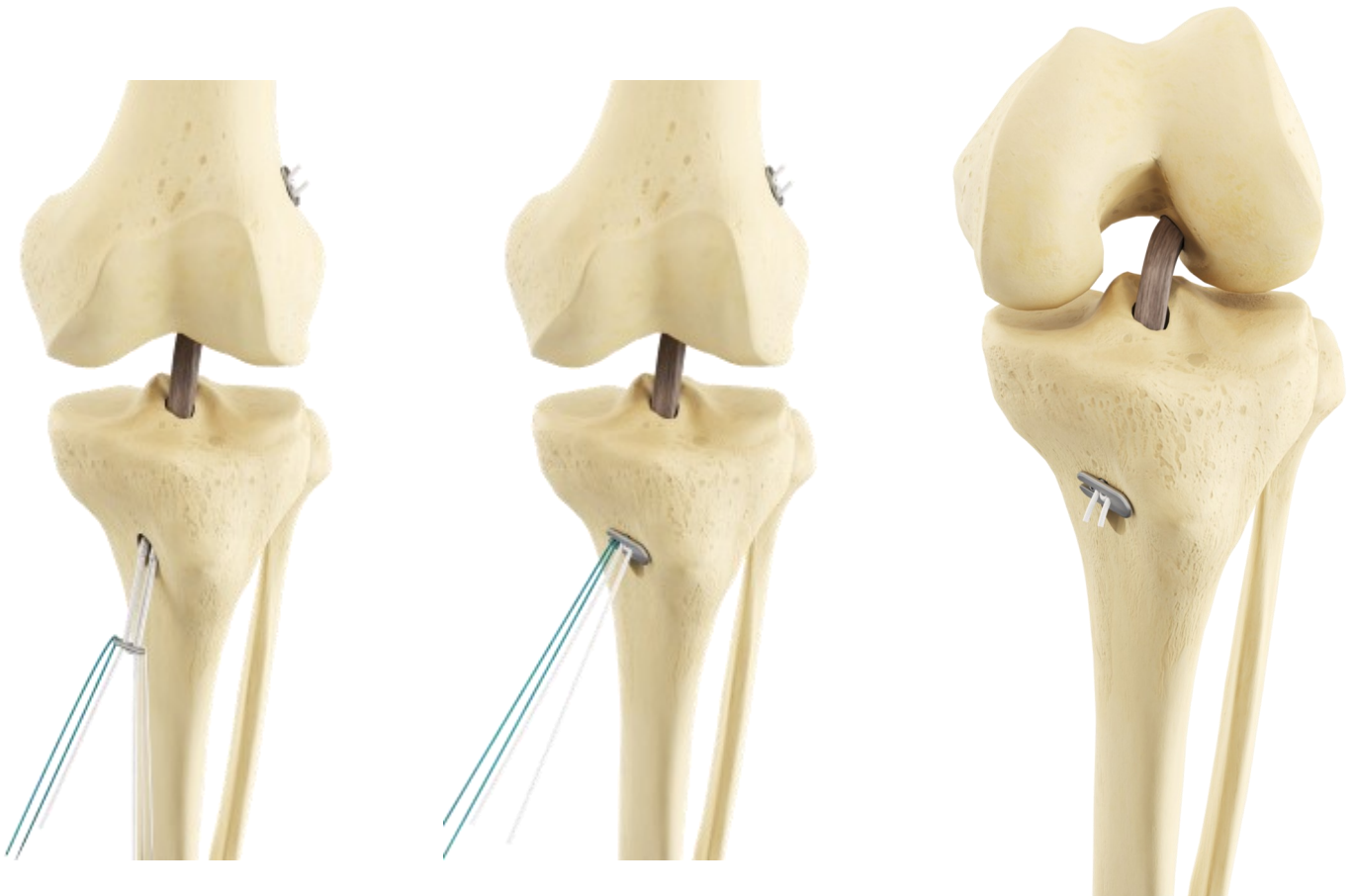
○ Start pulling the white adjustment thread and pull the same length with the black adjustment thread. Reproduce the movement until adjust the loop to the desired length.

Do not apply a tension on the locking thread (black extremity thread) during the loop adjustment time.

○ Lock the loop. hold a tension on the white adjustment thread and pull tightly the black adjustment thread.

○ Cycling the graft and COMETE® Control. Hold the COMETE® Control at the tibia. Perform several flexion-extension movements.

TIBIAL FIXATION BY COMETE® CONTROL AND EXTRA PLATE



● Use COMETE® Extra Plate to increase the cortical contact surface. Remove one of the two traction wire. Slide the extended plate under the button. Make sure that the remaining wire is on the slot side to allow a fully interlocking button on the Extra plate plate.

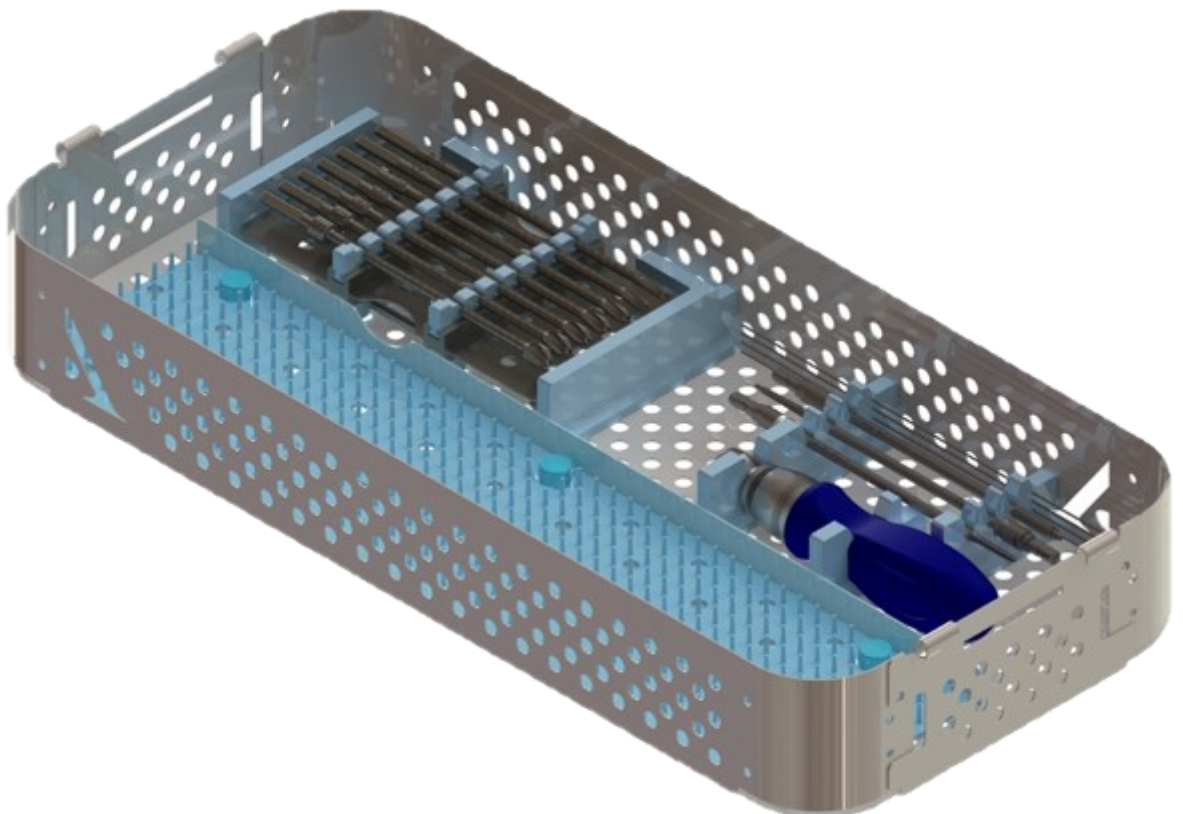
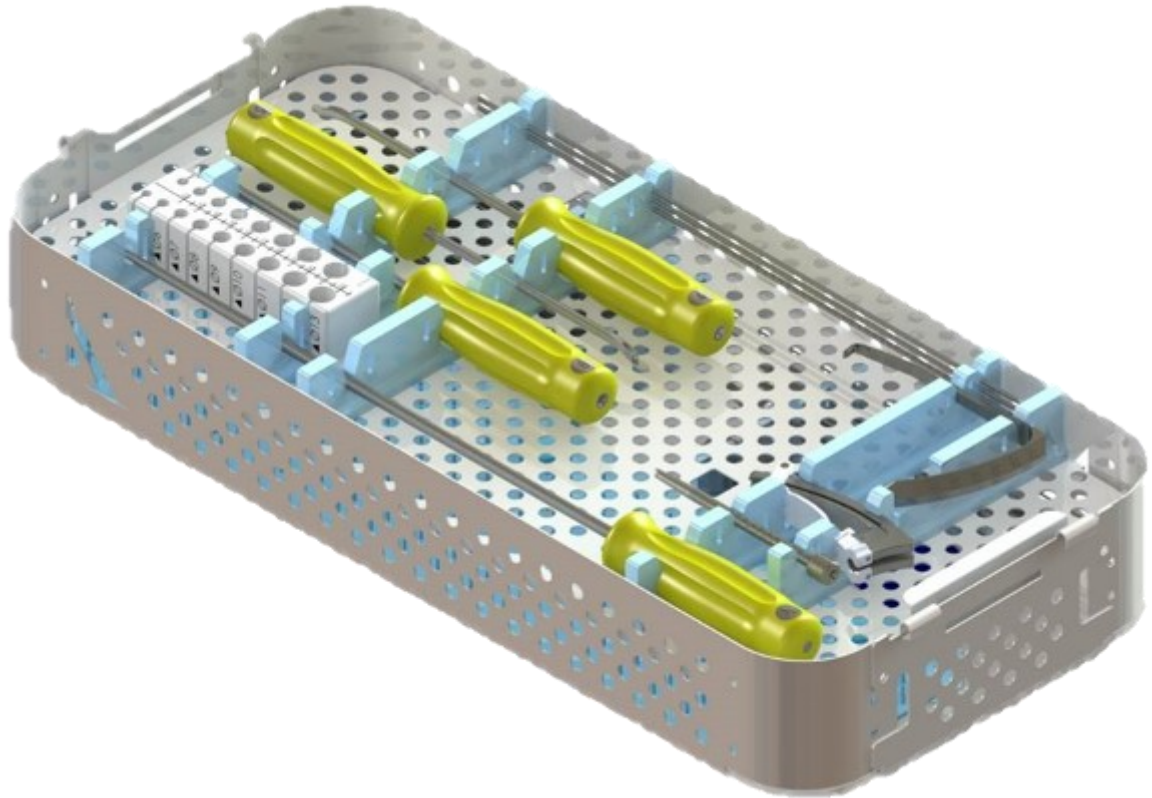
● Begin to pull the white adjustment thread and pull the same length with the black thread. Reproduce the movement until adjust the graft to the desired tension.

Do not apply a tension on the black adjustment thread during the loop adjustment time.

- Control the graft tensioning.
- Lock the loop. hold a tension on the white adjustment thread and pull tightly the black adjustment thread.
- Control the graft tensioning.
- Cut the adjustment threads on the femur and tibia at a minimum distance of 10mm from the cortical button.

INSTRUMENTATION SET - DESCRIPTION

*INSIDE-OUT MODULAR INSTRUMENTATION SET
2-0299940*



INSTRUMENTATION SET - DESCRIPTION

INSIDE-OUT MODULAR INSTRUMENTATION SET

2-0299940

Designation	Référence
5mm IN/OUT femoral guide.....	2-0405305
6mm IN/OUT femoral guide.....	2-0405306
7mm IN/OUT femoral guide.....	2-0405307
Graft sizer.....	2-0401800
Open Stripper Ø5mm.....	2-0405505
Modular guide body / handle.....	2-0404800
Modular tibial guide sleeve.....	2-0404900
Modular tibial aimer.....	2-0405000
Threaded graduated Eyelet pin Ø2,4mm Lg300m.....	2-0404700
Trocard eyelet pin Ø2.4mm Lg350mm.....	2-0405400
Wire pin guide Ø2,4mm Lg300mm.....	2-0405600

Designation	Référence
Reamer Ø5mm.....	2-0405210
Reamer Ø5,5mm.....	2-0405215
Reamer Ø6mm.....	2-0405220
Reamer Ø6,5mm.....	2-0405225
Reamer Ø7mm.....	2-0405230
Reamer Ø7,5mm.....	2-0405235
Reamer Ø8mm.....	2-0405240
Reamer Ø8,5mm.....	2-0405245
Reamer Ø9mm.....	2-0405250
Reamer Ø9,5mm.....	2-0405255
Reamer Ø10mm.....	2-0405260
Reamer Ø11mm.....	2-0405270
Ratcheting handle.....	2-0406400
Screw guidewire Ø 1.1mm length 240mm.....	2-0405700
Wire Nitinol Ø 1.1mm length 300mm.....	15INBR001F10
Shank screwdriver ECLIPSE® BCP / Profil.....	2-0406200
Shank starter Ø 7mm.....	2-0406300

INSTRUMENTATION SET - DESCRIPTION

INSIDE-OUT MODULAR INSTRUMENTATION SET

2-0299940

Option Designation	Référence
Screwdriver for Screws – Diameter 7 to 12 mm.....	16INTO001
Starter tap for Screws.....	11INTA001
Short reamer Ø5mm.....	2-0406710
Short reamer Ø5,5mm.....	2-0406715
Short reamer Ø6mm.....	2-0406720
Short reamer Ø6,5mm.....	2-0406725
Short reamer Ø7mm.....	2-0406730
Short reamer Ø7,5mm.....	2-0406735
Short reamer Ø8mm.....	2-0406740
Short reamer Ø8,5mm.....	2-0406745
Short reamer Ø9mm.....	2-0406750
Short reamer Ø9,5mm.....	2-0406755
Short reamer Ø10mm.....	2-0406760
Short reamer Ø11mm.....	2-0406770

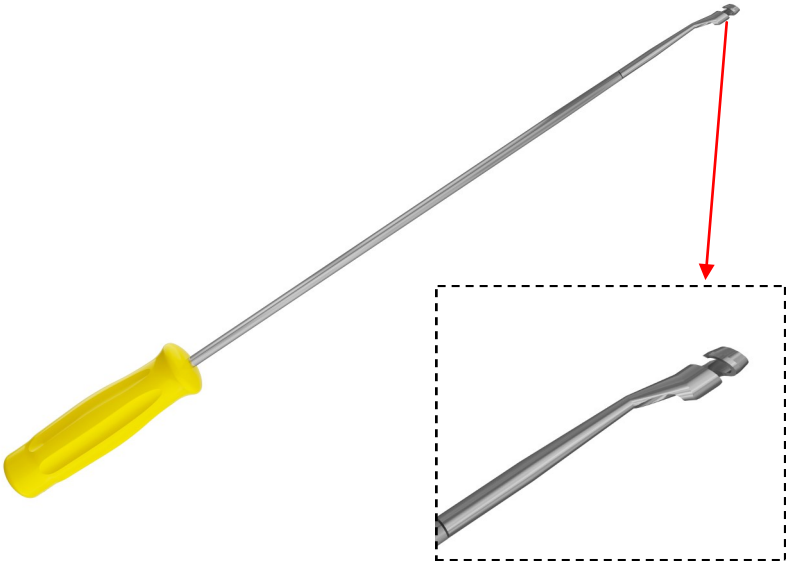


EXPLANATORY NOTES

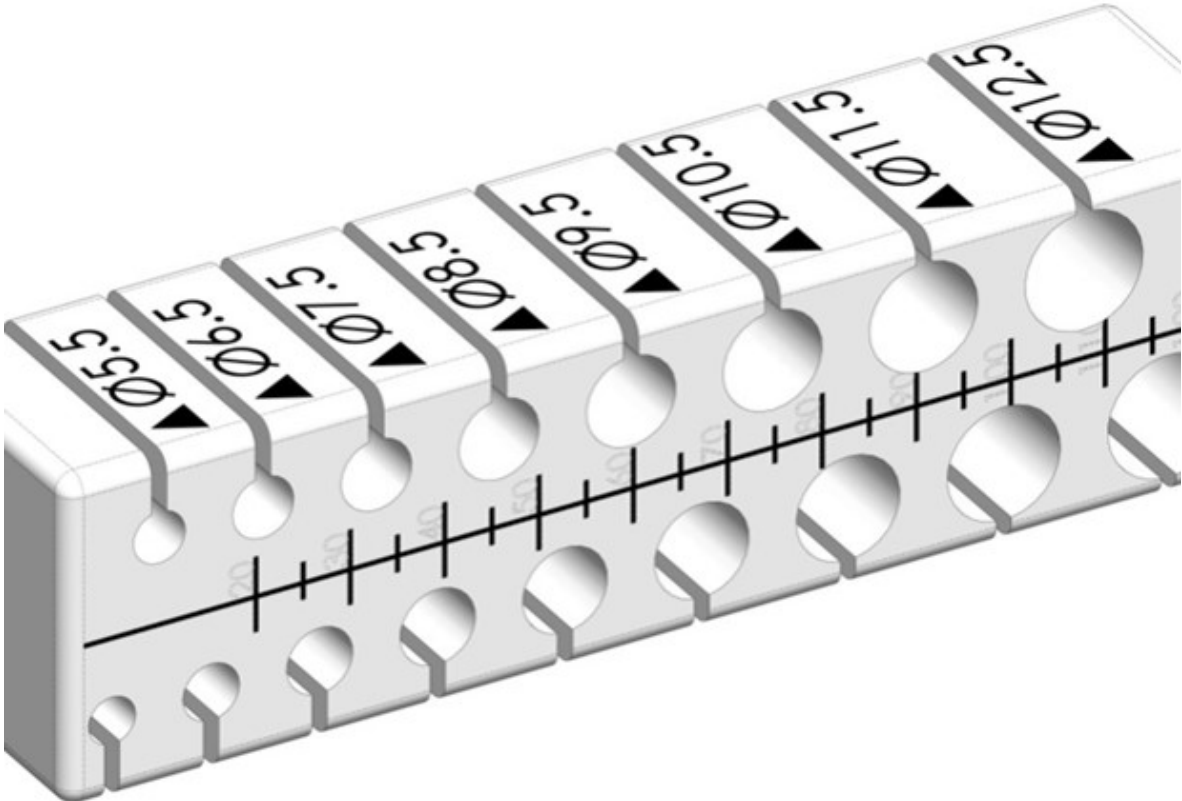
INSTRUMENTATION SET - DESCRIPTION

HARVESTING

Open Stripper Ø 5mm: length 350 mm



Graft sizer: diameter and length



INSTRUMENTATION SET - DESCRIPTION

FIXATION

- Ratcheting handle



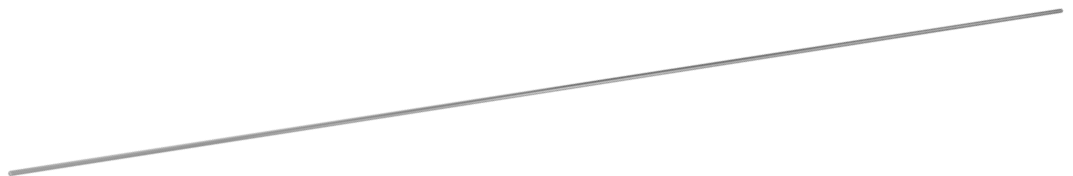
- Shank starter Ø 7mm



- Shank screwdriver ECLIPSE® BCP / Profil



- Wire Nitinol Ø 1.1mm length 300mm and Screw guidewire Ø 1.1mm length 240mm



- Screwdriver for Screws – Diameter 7 to 12 mm



- Starter tap for Screws

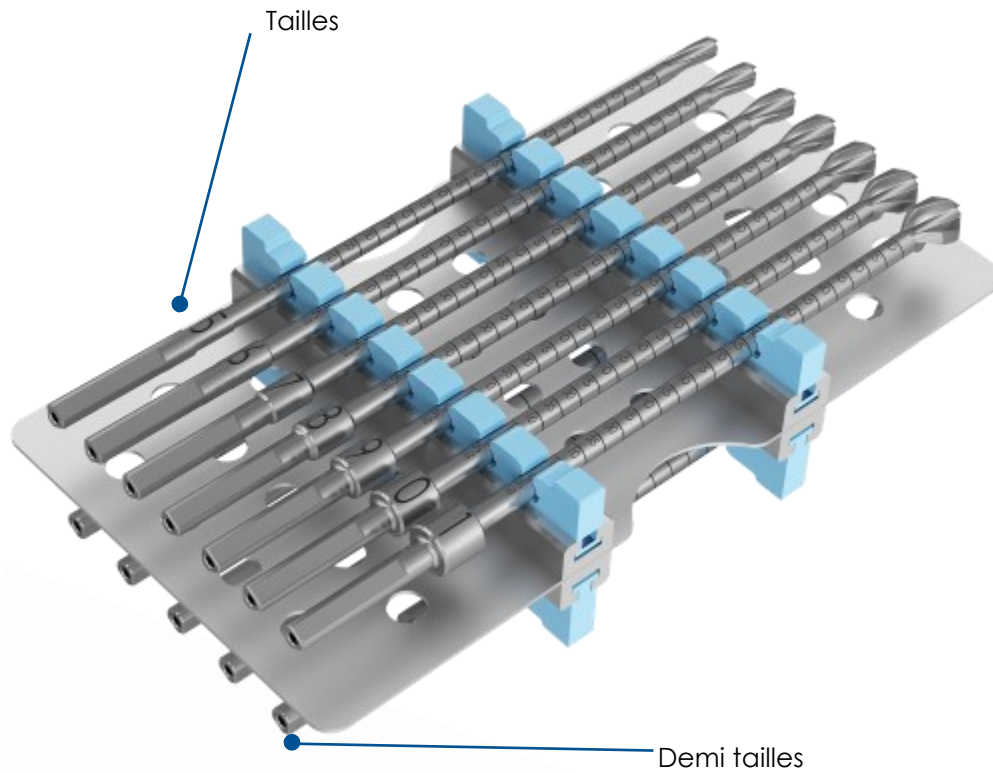


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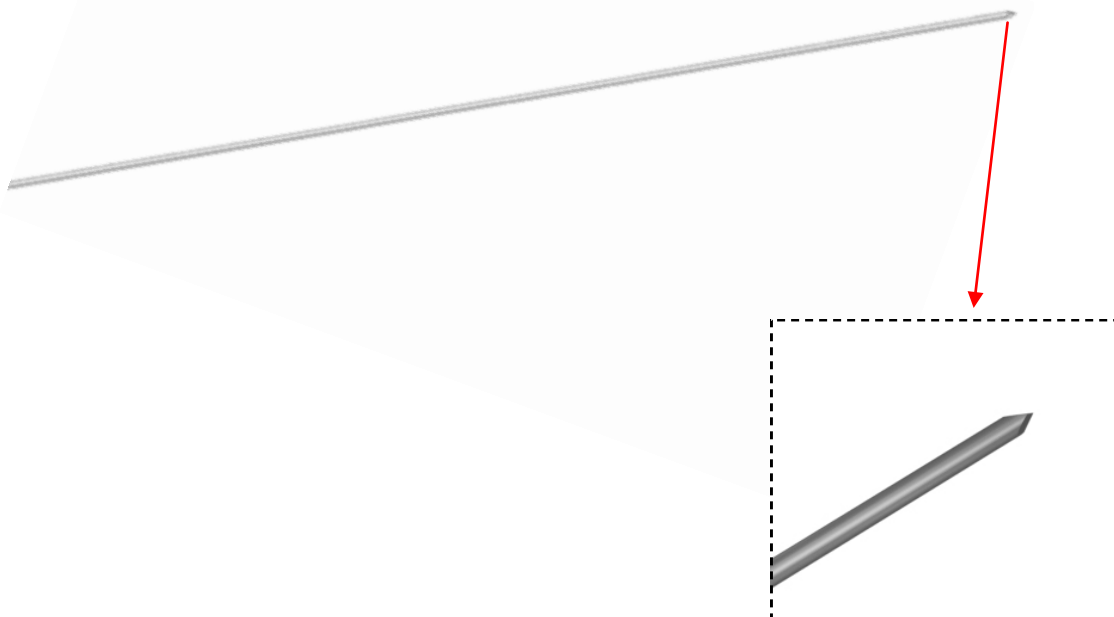
DRILLING

- Reamer and short reamer

- Diameters: 5 / 5.5 / 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9 / 9.5 / 10 and 11 mm.



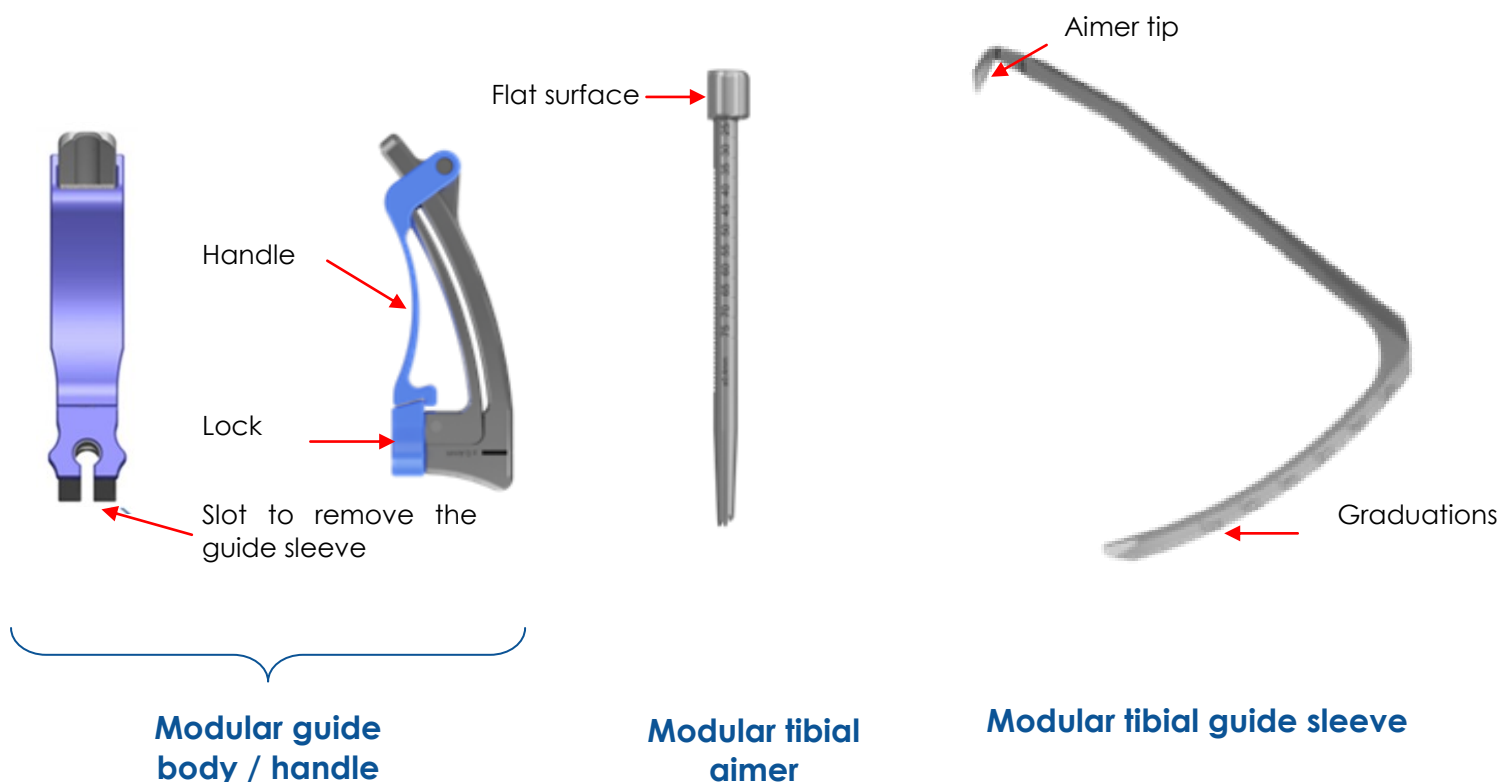
- Wire pin guide Ø2,4mm Lg300mm



INSTRUMENTATION SET - DESCRIPTION

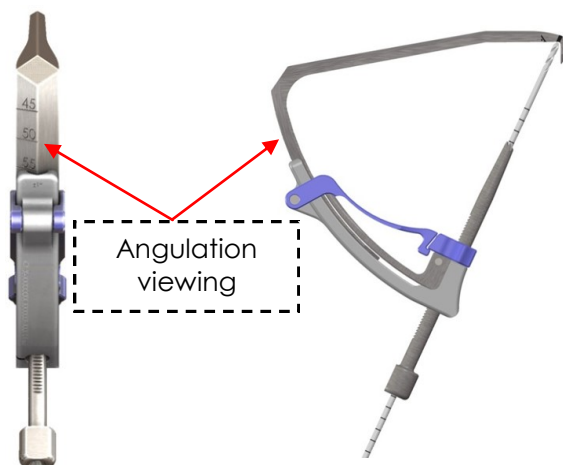
MODULAR TIBIAL GUIDE

○ Description

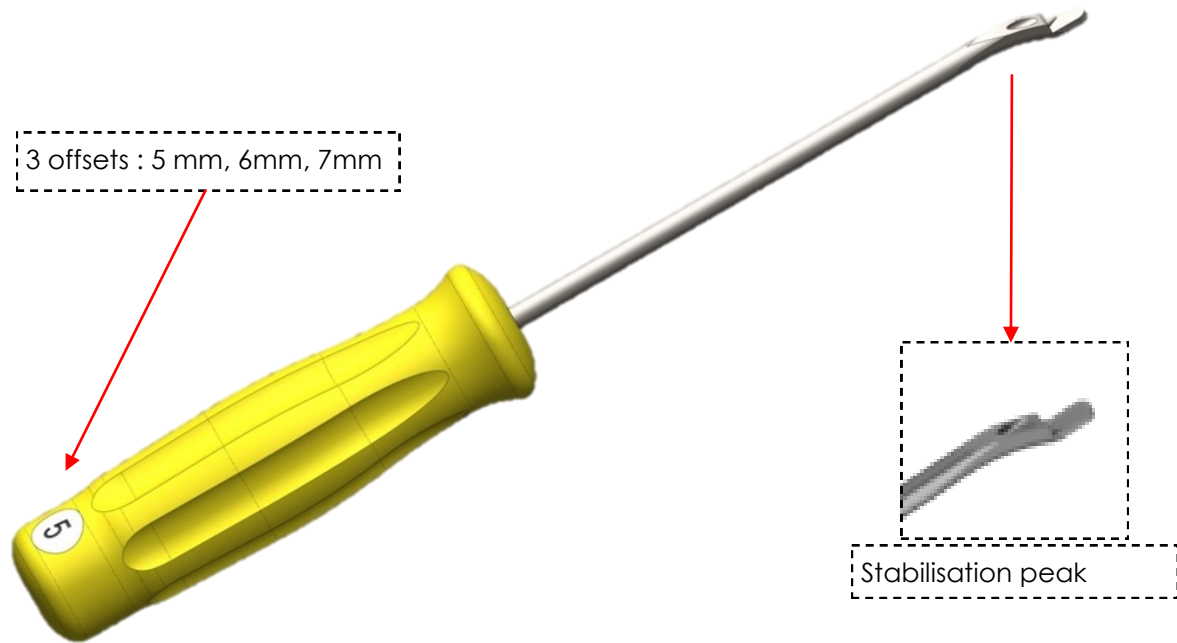


MODULAR TIBIAL GUIDE

- Angulation 45° to 70°
- The pin will emerge in the bend of the guide



INSIDE-OUT FEMORAL GUIDE



THREADED GRADUATED EYELET PIN

- Diameter 2.4 mm, length 350 mm

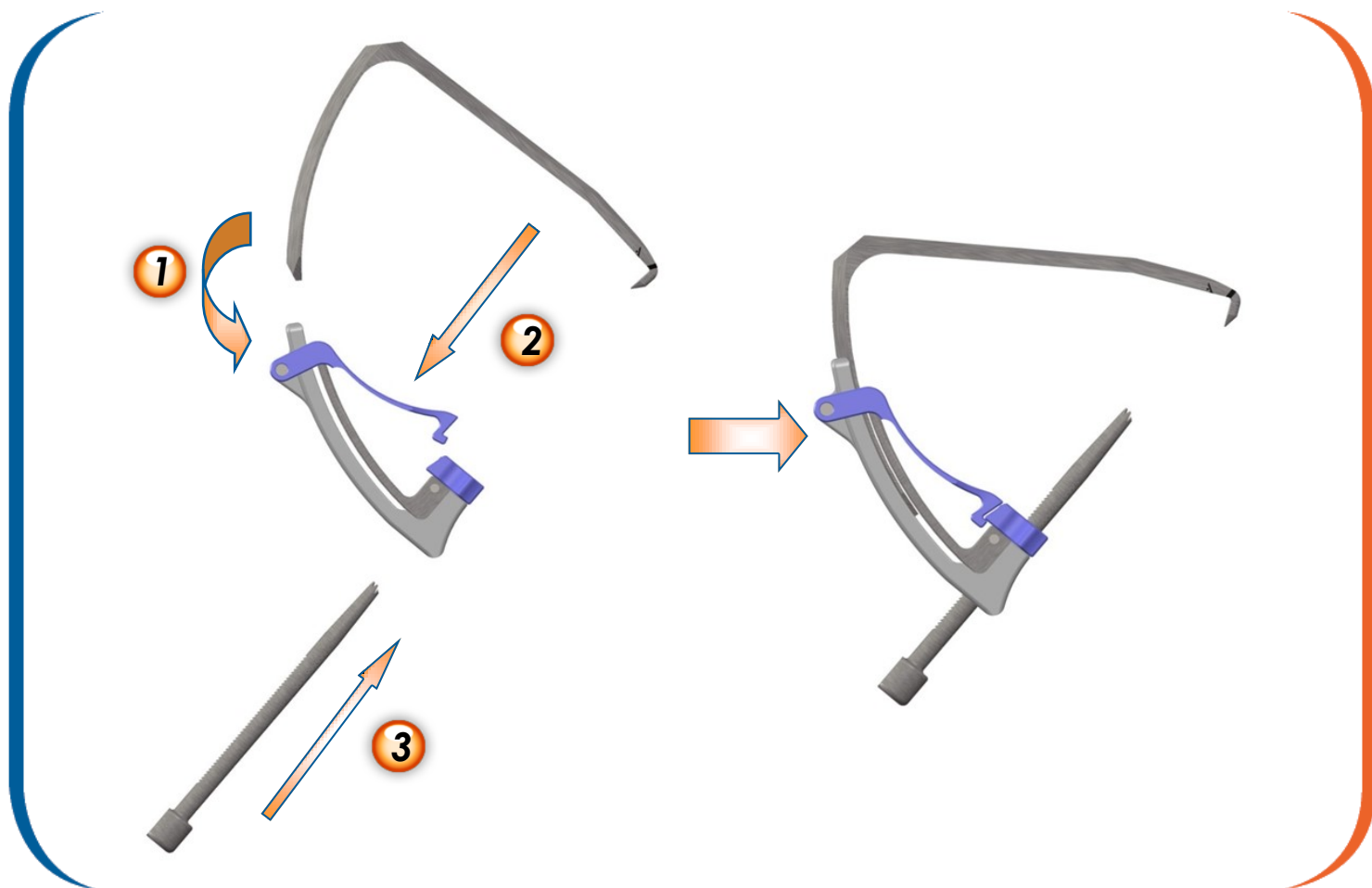


TROCAR EYELET PIN

- Diameter 2.4 mm, length 350 mm



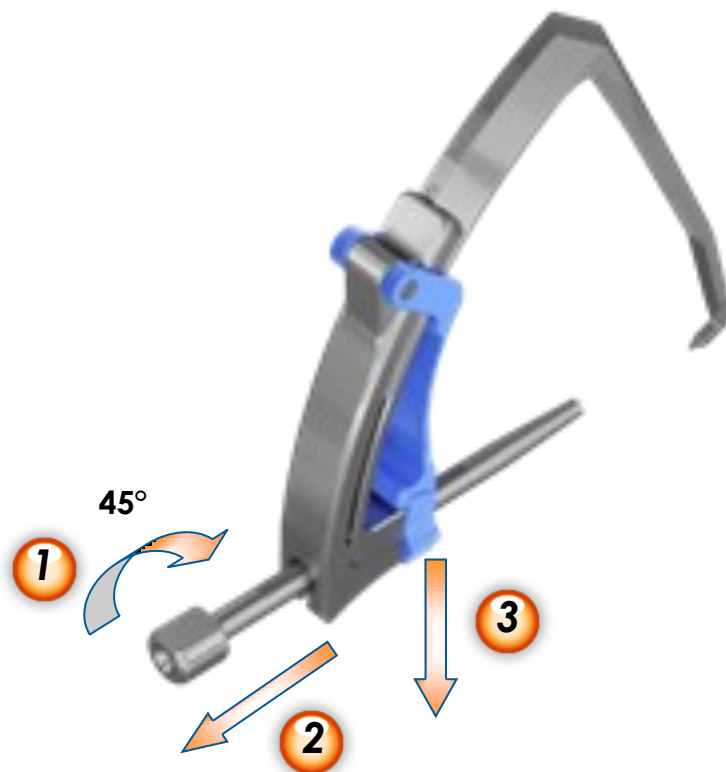
TIBIAL GUIDE ASSEMBLY



- 1 Insert the modular aimer into the modular guide handle to select angulation.
- 2 lock the guide (Modular tibial aimer + Modular guide handle) by pulling the blue handle towards the guide handle.
- 3 Insert the modular tibial guide sleeve into the Modular Guide Handle, flat surface facing upware.

The modular tibial guide sleeve cannot be inserted if the modular guide handle and aimer are not locked correctly. If this occurs, remove the aimer from the guide handle. Reassemble the handle and aimer, then reinsert the guide sleeve.

MODIFICATION OF THE ANGULATION



- Turn the guide sleeve a quarter turn.(1)
- Remove the Modular tibial guide sleeve.(2)
- Unlock the tibial guide by pulling the lock downwards. This action releases the lock and the tibial guide sleeve.(3)
- Change the angulation of the guide.
- Lock the guide.

1

2

3

NOTES



AMPLITUDE®

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