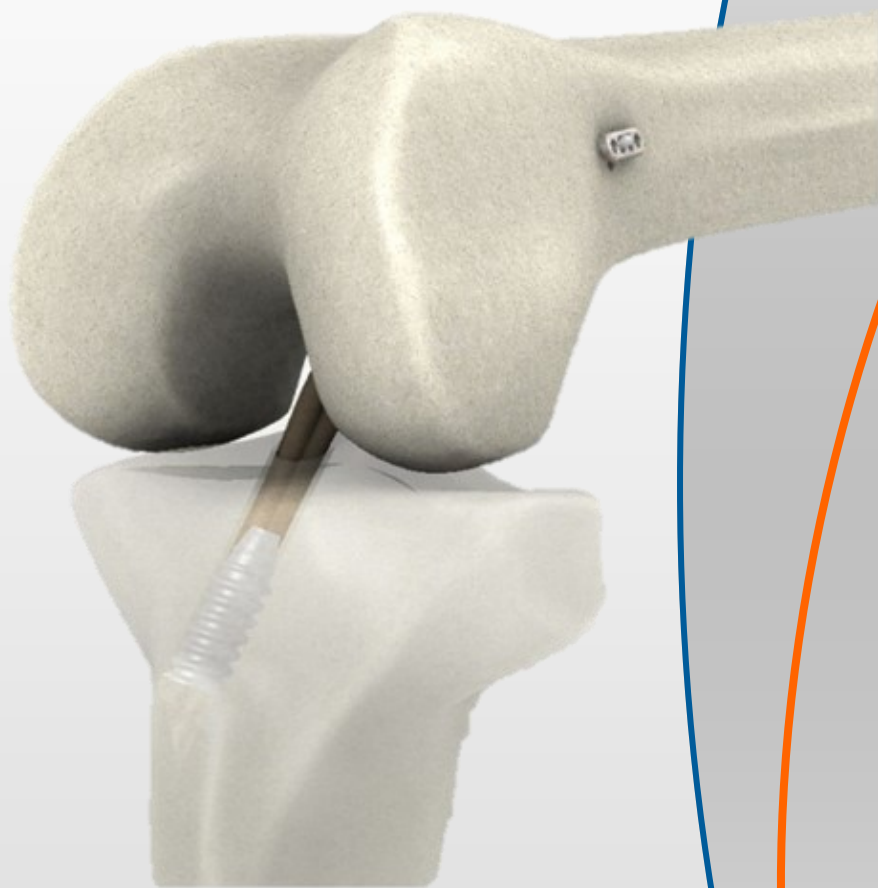


MODULAR INSIDE-OUT



SURGICAL TECHNIQUE
MECHANICAL
INSTRUMENTATION

Note:

The purpose of this surgical technique description is to provide instruction on how to use the instrumentation properly. The surgeon is fully responsible for choosing and performing the approach and surgical technique

SURGERY TECHNIQUE SUMMARY

1

Tibial tunnel location

Place the aimer tip onto the ACL foot print. Drill the wire pin guide through the sleeve guide and check the positioning



2

Tibial drilling

Drill the tibial tunnel onto the wire pin guide. use a reamer that matches the graft diameter



3

Femoral tunnel location

Select the appropriate offset: 1 mm more than the graft radius.
The guide is inserted in the joint, the tip is placed in the "over the top" position.
Placed the eylet pin through the sleeve



4

Femoral drilling

Drill the femoral tunnel over the eylet pin using the reamer that matches the graft diameter.

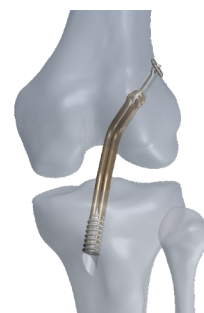
Drill the total femoral tunnel with the 5 mm reamer untill the lateral cortex and note the intaosseous tunnel depth to select the appropriate COMETE Length



5

Fixation

Femoral fixation: Pass the COMETE through the distal femoral cortex.
Tibial fixation : screw an ECLIPSE BCP or Profil

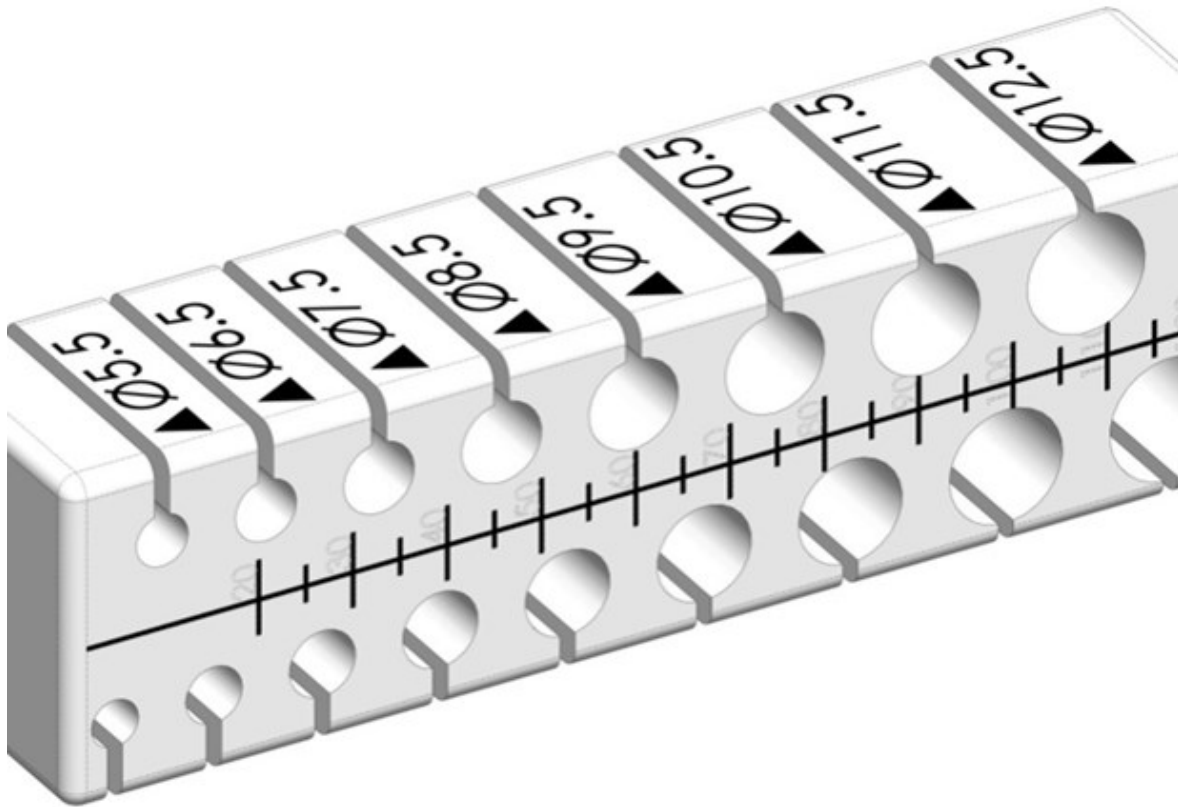


HARVESTING



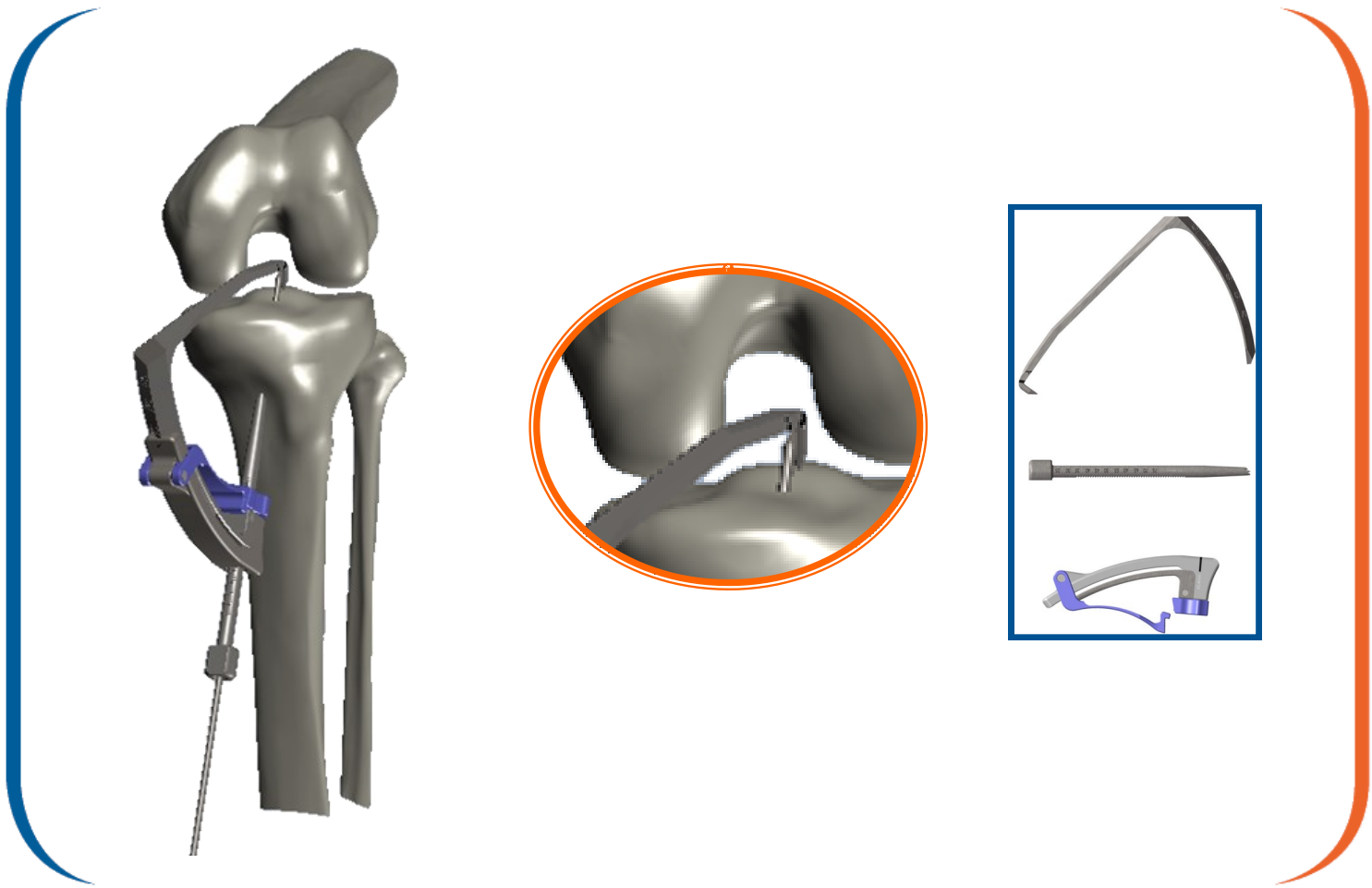
- Harvest the semi tendinosus and gracilis with the open stripper

CALIBRATION



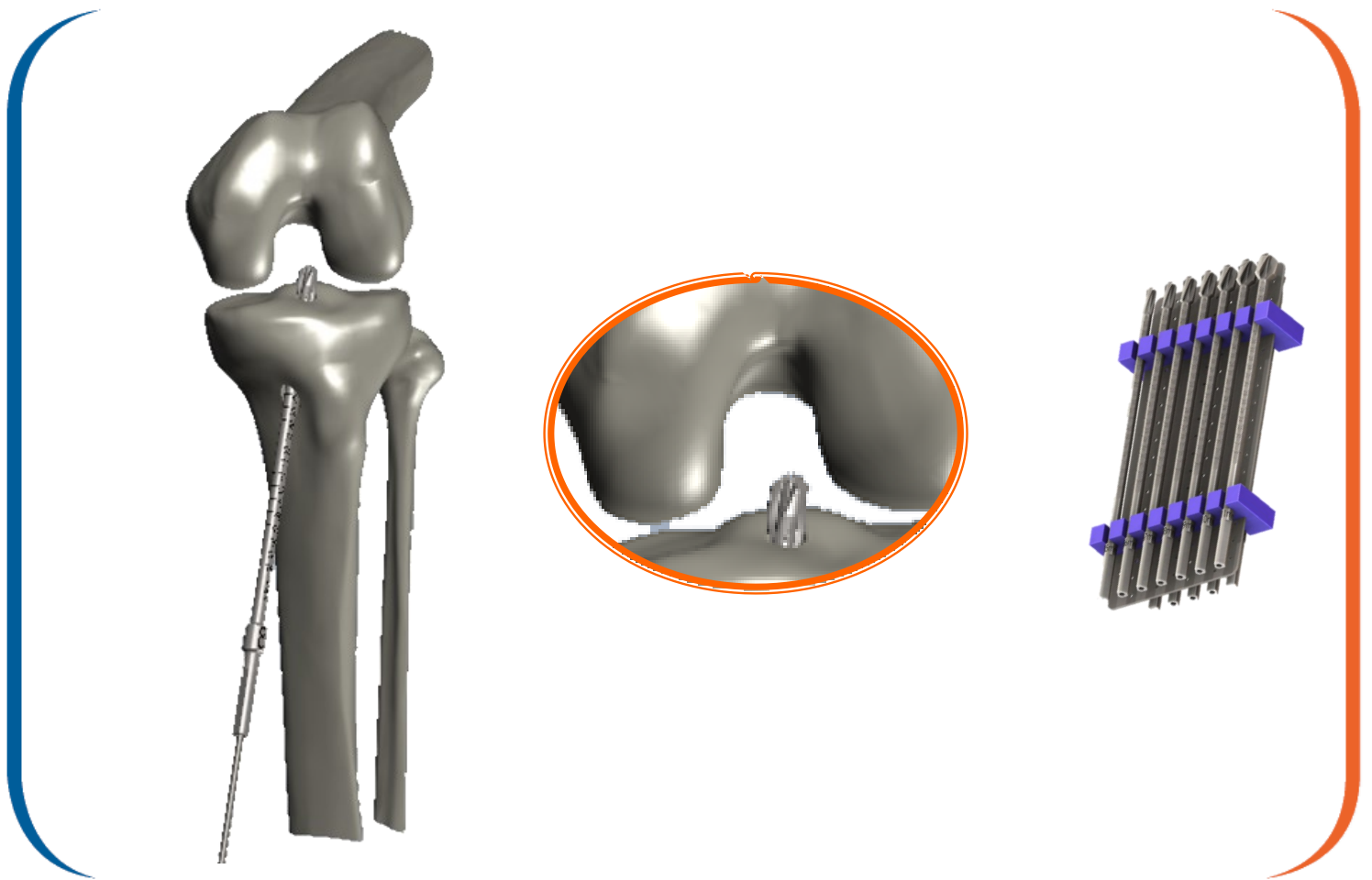
- Calibrate (diameter and length) the graft using graft sizer

TUNNEL TIBIAL LOCATION



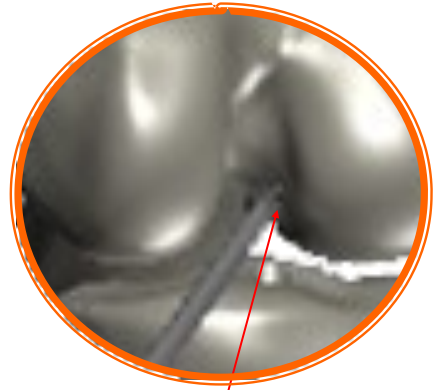
- Assemble the tibial guide and select the angulation
- Place the tip of the tibial guide on the ACL Footprint
- Use the laser marking to estimate the exit point of the guide wire
- Insert the tibial guide sleeve, flat surface facing upware. Just apply a single « clic » after the contact with the cortex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

TIBIAL DRILLING



- Place the reamer or short reamer with diameter that matches the graft over the wire pin guide and drill the tibial tunnel

FEMORAL TUNNEL LOCATION



Measure the length of the total femoral tunnel (cortex to cortex)

- 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 eyelet pin through the femoral guide until pass the lateral cortex and skin
- Control the eyelet pin positioning

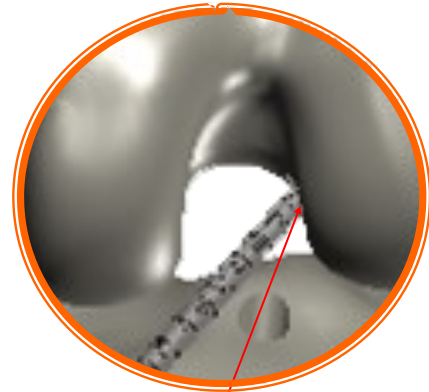
Note:

You can determinate the total length of total femoral tunnel (or intraosseous tunnel) with the threaded graduated eyelet pin

trans-tibial technic:

- Place the femoral guide on the tibial tunnel

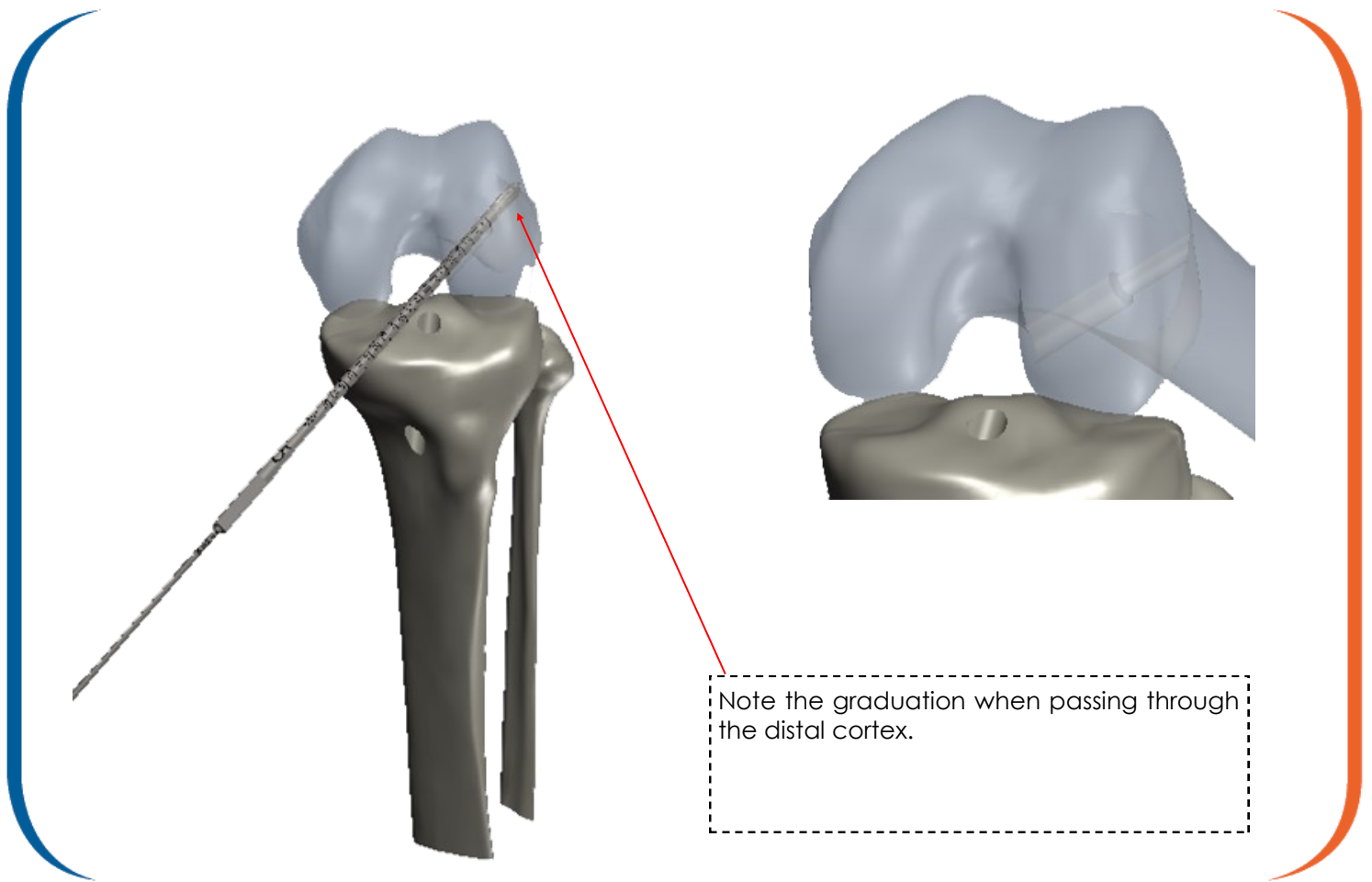
FEMORAL DRILLING



depth of the femoral tunnel

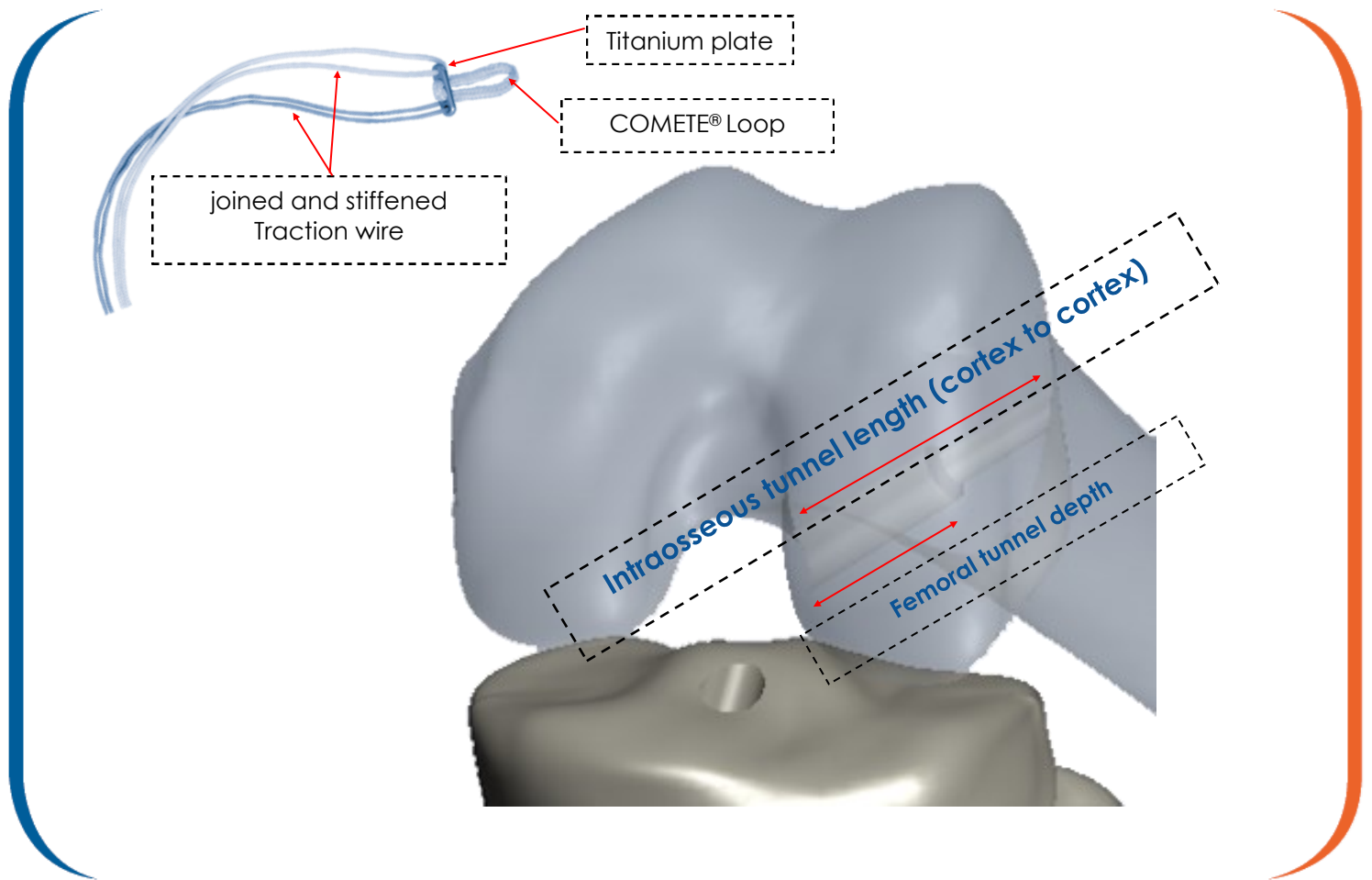
- Select the reamer or short reamer wick matches the graft diameter
- Drill the femoral tunnel over the eylet pin at the desiderated depth

COMETE[®] DRILLING



- Drill the total femoral tunnel (intraosseous tunnel) with the 5 mm reamer
- Note the graduation when the femoral distal cortex is felt to get the depth of the length cortex to cortex (CTC)

COMETE® PRESENTATION AND LENGTH CHOICE



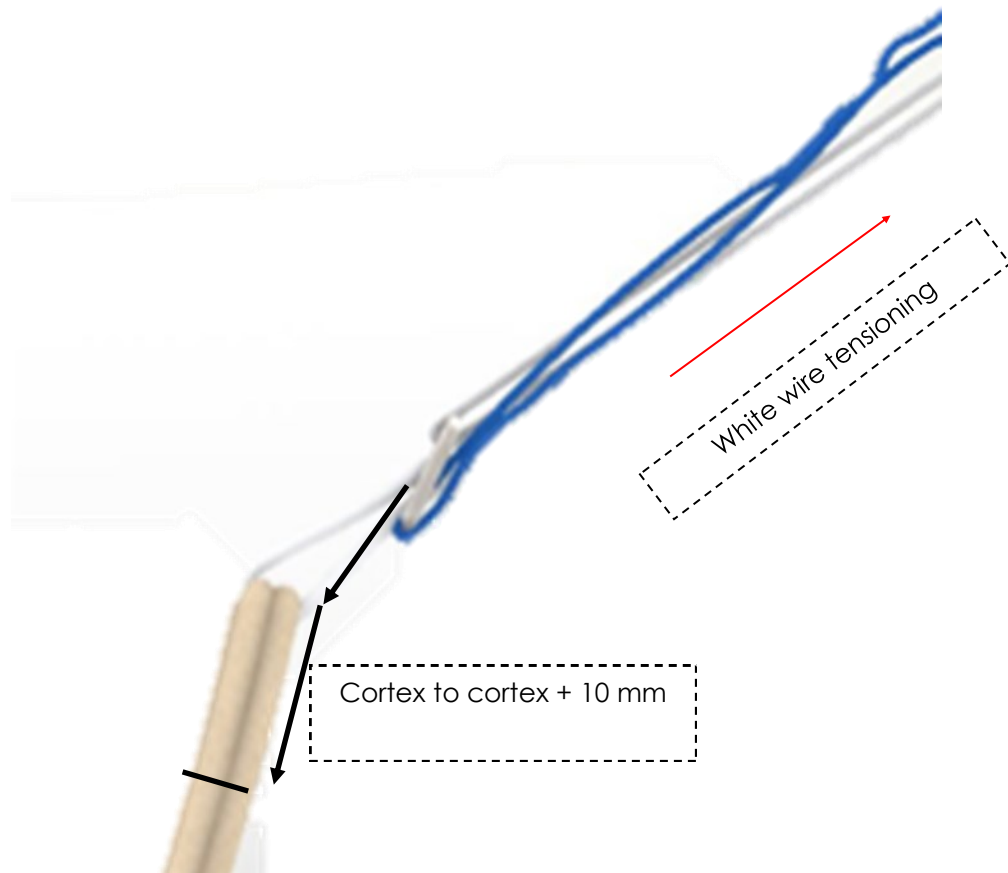
○ COMETE® Length : 15, 20, 25, 30 and 35 mm

○ Select COMETE® length loop : the COMETE® length must be greater or equal than the intraosseous length minus the femoral tunnel - plus 5 mm

Example:

- Intraosseous tunnel **60 mm**
- Femoral tunnel **40 mm**
- COMETE® length : $60-40+5 =$ **25 mm**

GRAFT PREPARATION



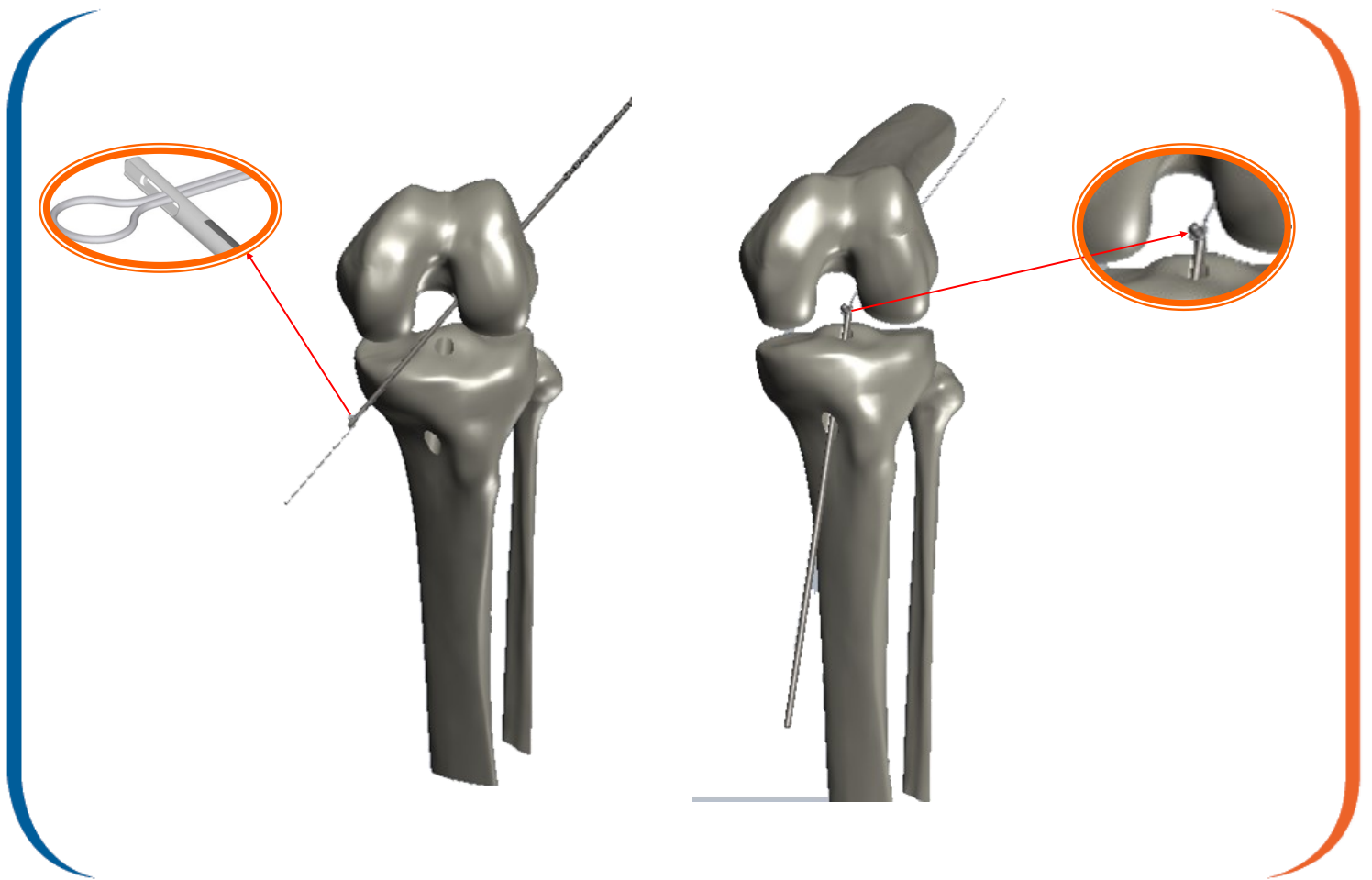
- Pass the Semi Tendinosus and Gracilis through the COMETE® Loop
- The graft can be sutured proximally and distally
- Mark the graft to evaluate when the button exits from the cortex

The distance of the mark is measured from the button and the distance is the intraosseous length plus 10 mm.

Note:

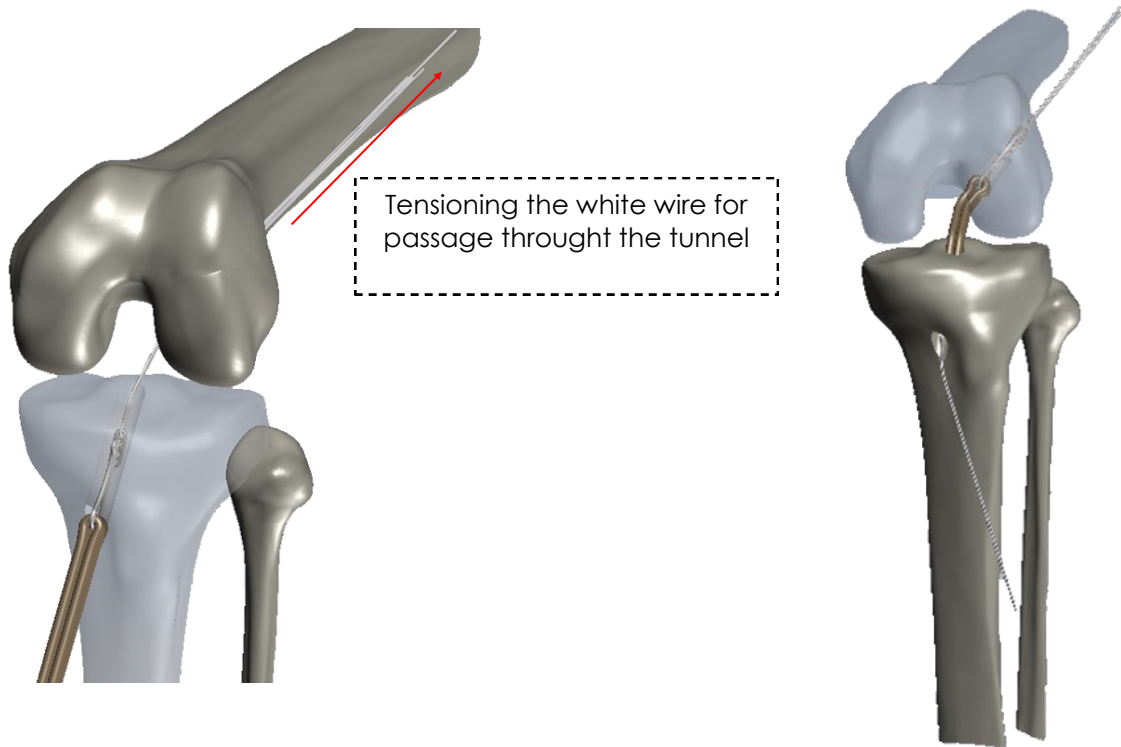
Tensioning the blue or white wire allows the board to be oriented for its passage through the tunnels

TRACTION WIRE



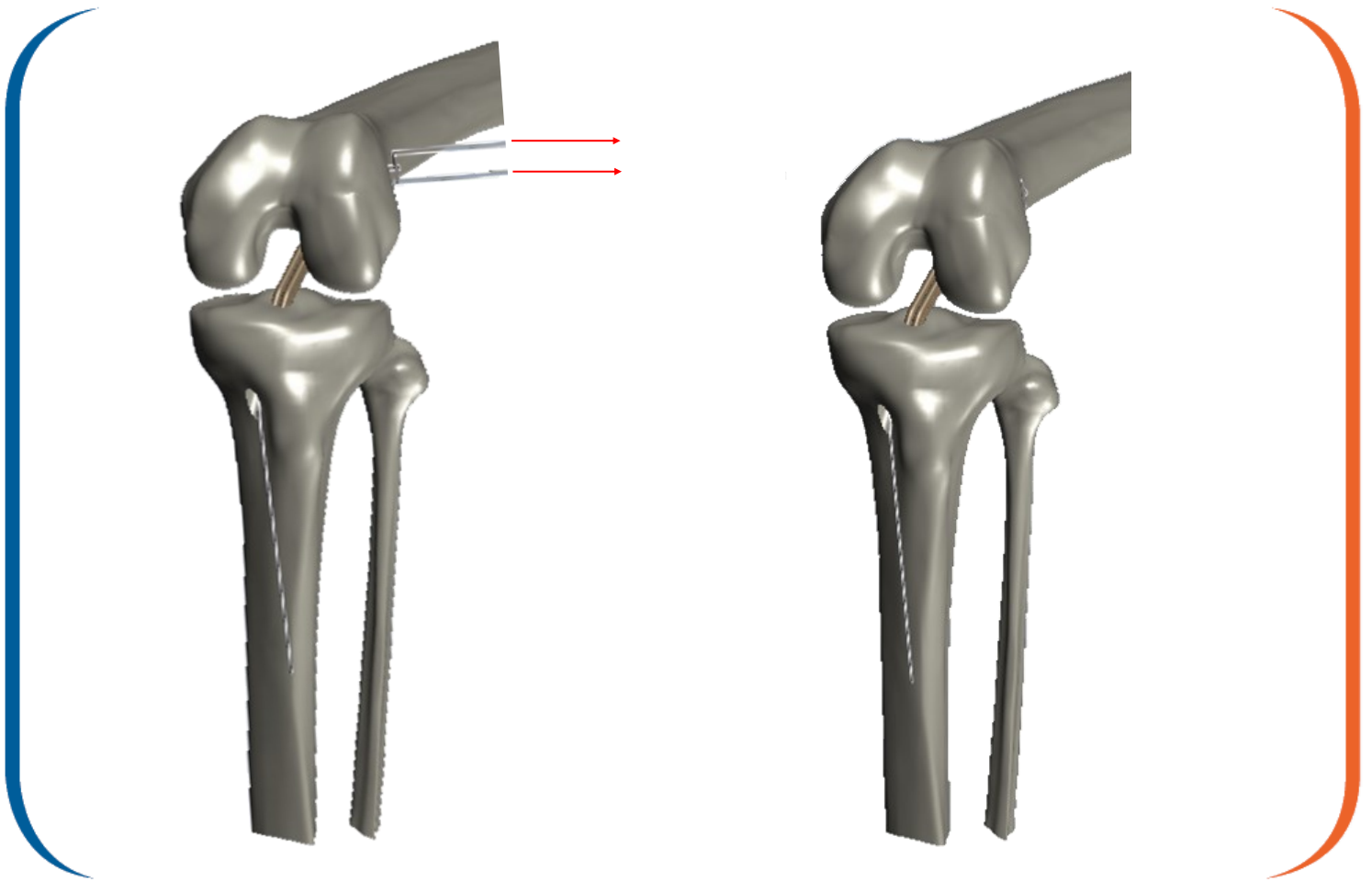
- Pass a suture loop through the eylet pin
- The eylet pin is pulled until the suture comes out the femoral skin
- The suture loop is pulled through the tibial tunnel

COMETE[®] POSITIONING



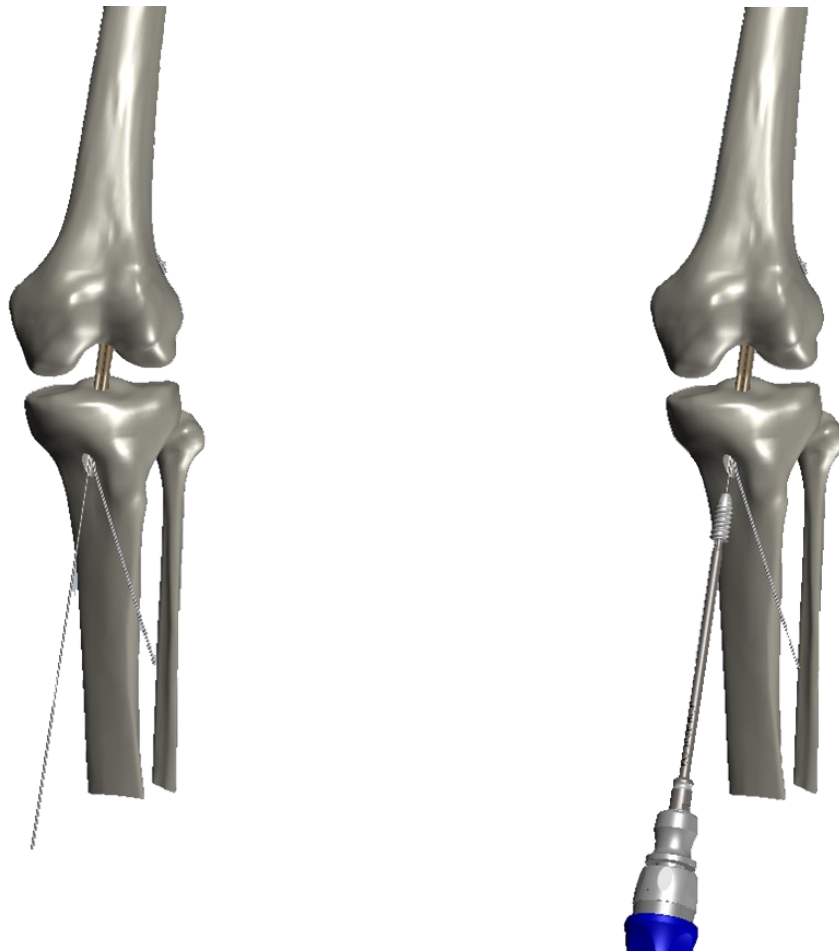
- Dissociate the COMETE[®] Pullwire to facilitate the tunnel passage
 - Pass the COMETE[®] Pullwire on the suture loop and tract it until the COMETE[®] Wire emerges from the skin surface
 - Pull the white COMETE[®] Pullwires to orientate the COMETE[®] titanium plate and pass the COMETE[®] and the graft through the tibial and femoral tunnels
- Stop to pull when the mark on the graft reaches the internal femoral tunnel aperture

COMETE[®] IMPLANT FIXATION



- Lock the COMETE[®]. Keep a tension on the white COMETE[®] Pullwire and pull the blue COMETE[®] Pullwire. To make sure the titanium plate is perpendicular to the femoral cortex. Pull back the graft to control the fixation

TIBIAL FIXATION



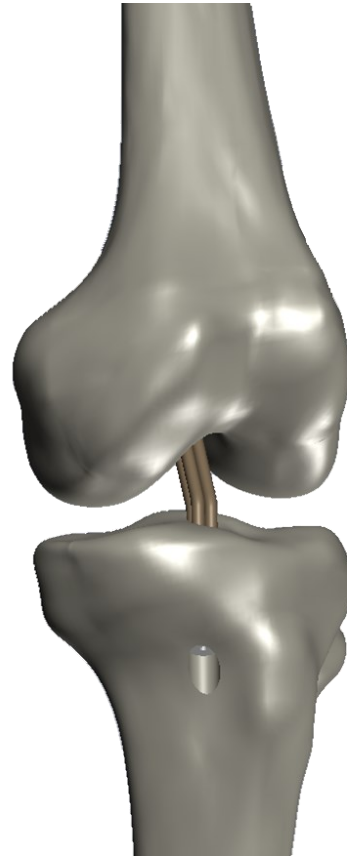
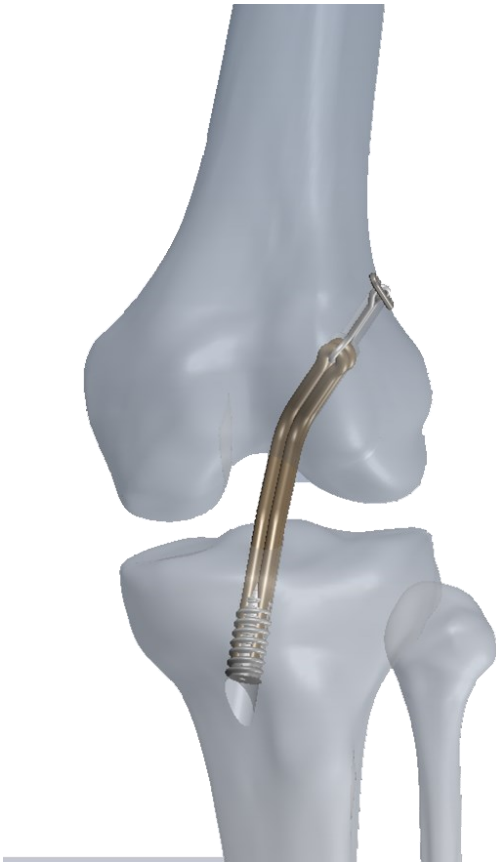
○ Tapping :

- Case of use of shank screw starter \varnothing 7mm : assemble the shank starter \varnothing 7mm to the ratcheting handle
- Pull the suture wire of the graft at the tibial level
- Place the screwguide wire into the tibial tunnel
- Pass the assembled instrument or the Starter Tap for interference screws L 20-25-30mm through the tibial tunnel

○ Screwing :

- Case of use of shank screw driver ECLIPSE® BCP / Profil or shank screwdriver ECLIPSE® BCP / Profil \varnothing 7-12 mm: assemble shank screwdriver to the ratcheting handle
- Position the interference screw (ECLIPSE® BCP or ECLIPSE® PROFIL) onto the assembled instrument or the Universal screwdriver Biomatlante \varnothing 7-8-9-10-11-12mm
- Insert the screw into the tibial tunnel over the screw guide wire by hold a tension on the suture wire of the graft

FIXATIONS IMPLANTS



- ECLIPSE® BCP Composite Interference screw



- ECLIPSE® Profil polylactic interference Screw

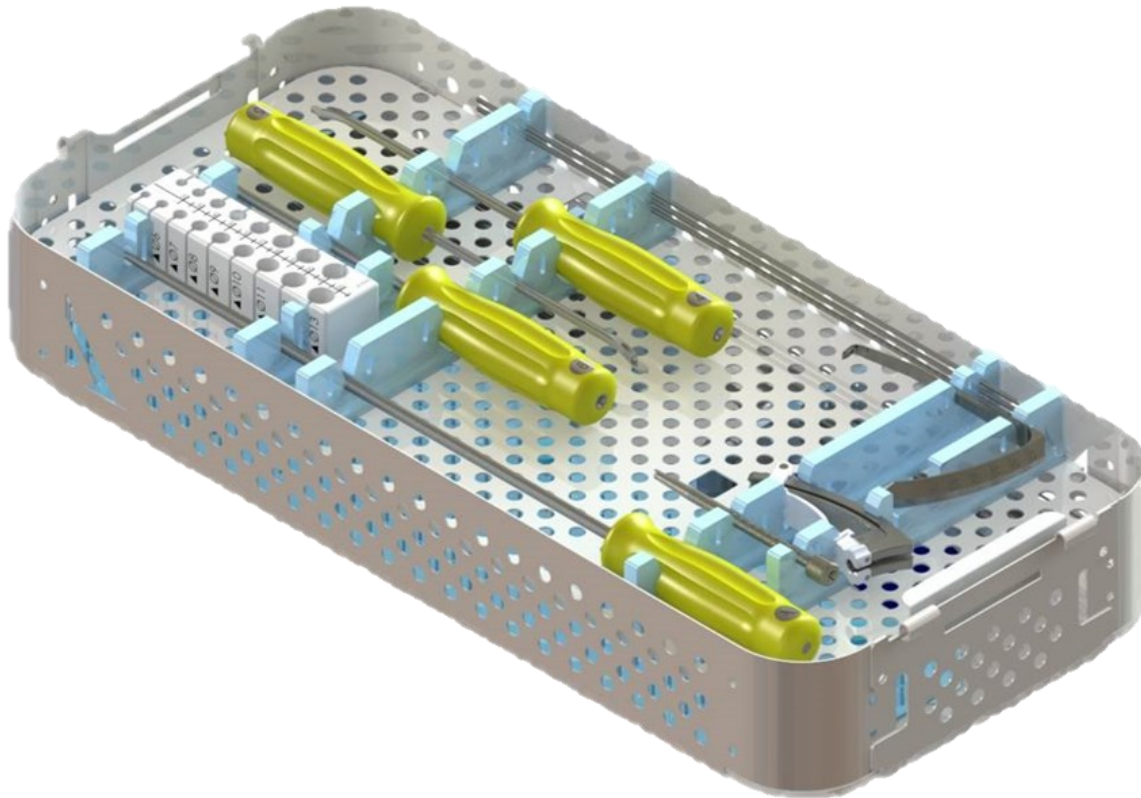


- COMETE®



INSIDE OUT MODULAR INSTRUMENTATION SET 2-0299940

OVERHEAD TRAY

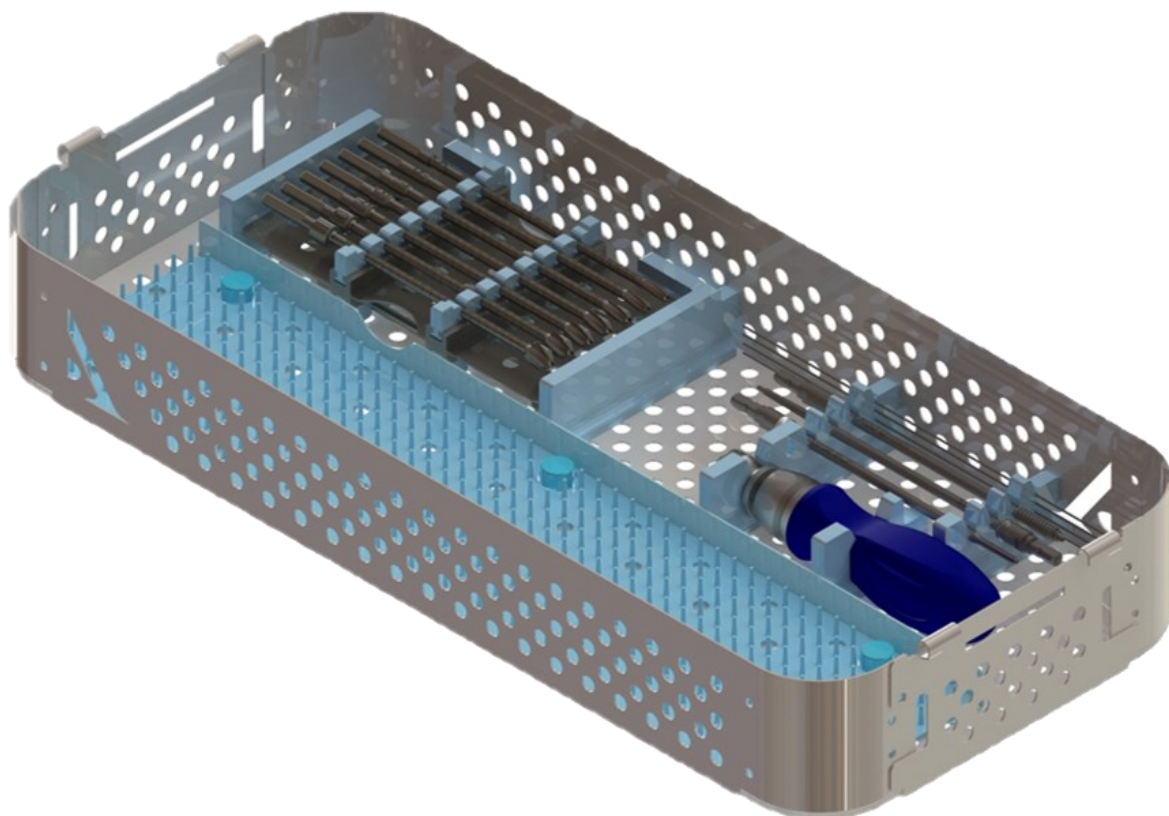


5mm IN/OUT femoral guide.....	2-0405305
6mm IN/OUT femoral guide.....	2-0405306
7mm IN/OUT femoral guide.....	2-0405307
Graft sizer.....	2-0401800
Open Stripper Ø5mm.....	2-0405505
Modular guide body / handle.....	2-0404800
Modular tibial sleeve.....	2-0404900
Modular tibial aimer.....	2-0405000
Threaded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

INSIDE OUT MODULAR INSTRUMENTATION SET

2-0299940

LOW TRAY

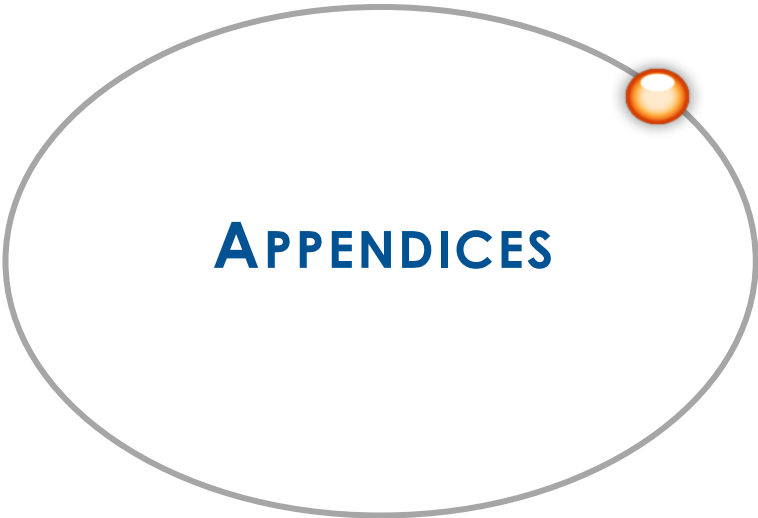


Reamer Ø5mm.....	2-0405210
Reamer Ø5,5mm.....	2-0405215
Reamer Ø6mm.....	2-0405220
Reamer Ø6,5mm.....	2-0405225
Reamer Ø7mm.....	2-0405230
Reamer Ø7,5mm.....	2-0405235
Reamer Ø8mm.....	2-0405240
Reamer Ø8,5mm.....	2-0405245
Reamer Ø9mm.....	2-0405250
Reamer Ø9,5mm.....	2-0405255
Reamer Ø10mm.....	2-0405260
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 Ø7-12 mm.....	2-0409300
or	
Shank screwdriver ECLIPSE® BCP / Profil.....	2-0406200
Shank starter Ø 7mm.....	2-0406300

INSIDE OUT MODULAR INSTRUMENTATION SET 2-0299940

LOW TRAY (FOLLOW UP)

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



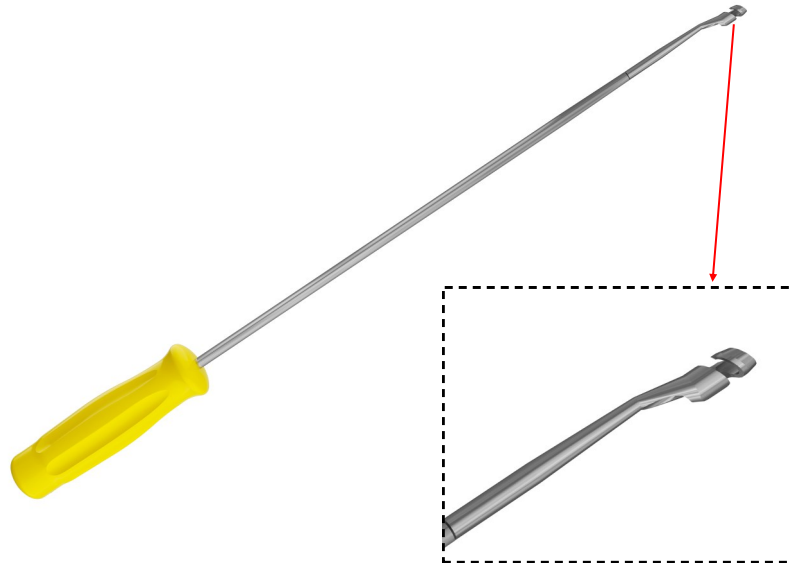
APPENDICES

Instrumentation Set Presentation

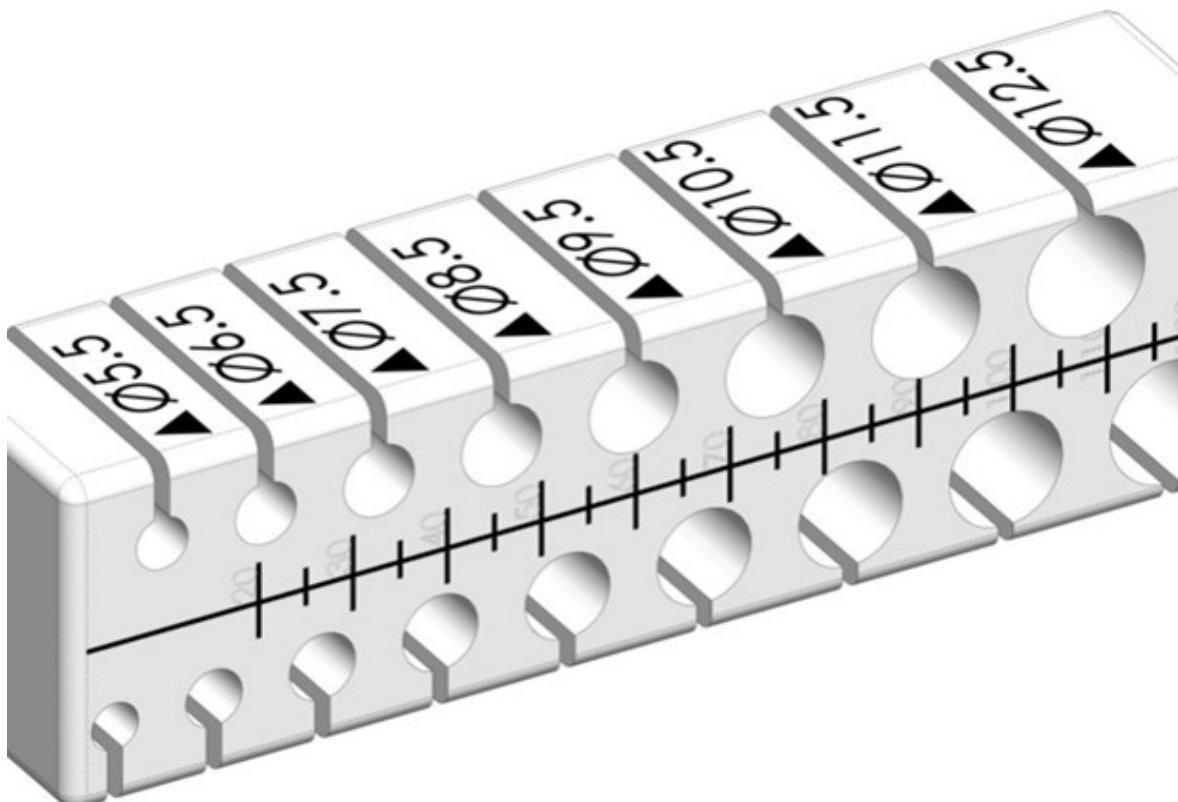
INSTRUMENTATION SET - DESCRIPTION

HARVESTING

- Open Stripper \varnothing 5mm: length 350 mm



- Graft sizer: diameter and length



INSTRUMENTATION SET - DESCRIPTION

FIXATION

- Ratcheting handle



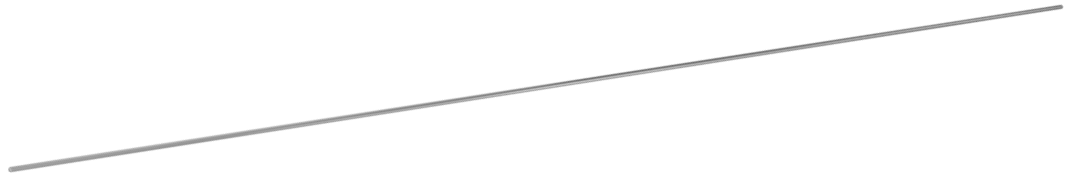
- Shank starter \varnothing 7mm



- Shank screwdriver ECLIPSE® BCP / Profil ECLIPSE \varnothing 7-12 mm
- Or Shank screwdriver ECLIPSE® BCP / Profil



- Wire Nitinol \varnothing 1.1mm length 300mm and Wire pin guide \varnothing 2,4mm Lg300mm



- Universal screwdriver Biomatlante \varnothing 7 to 12mm



- Starter Tap for interference screws

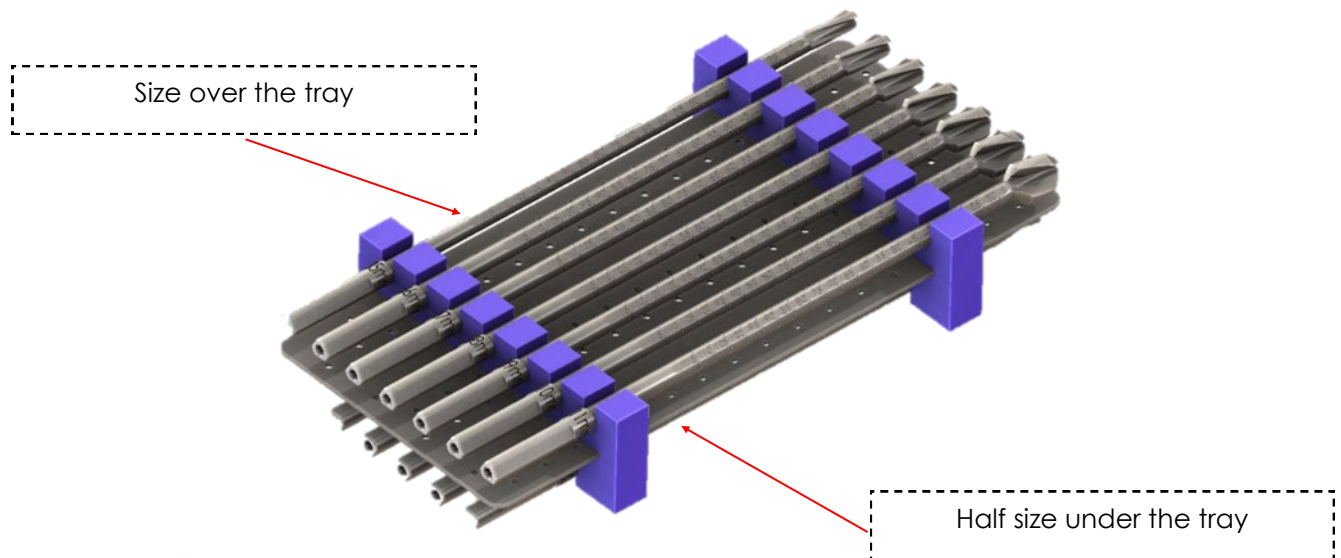


INSTRUMENTATION SET - DESCRIPTION

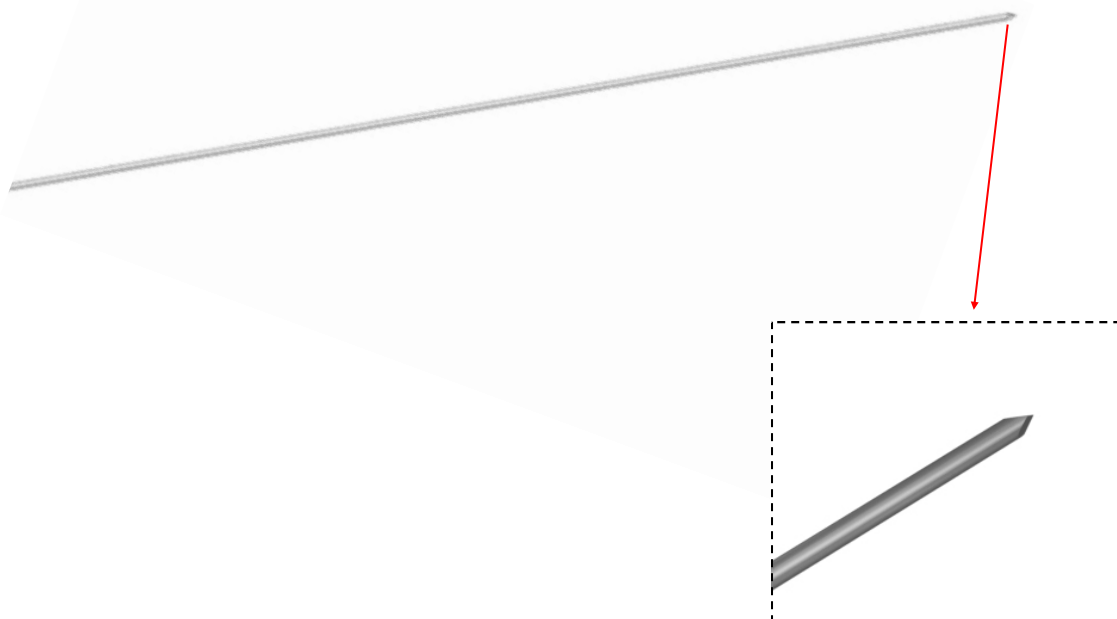
DRILLING

○ Reamers and short reamer

- Diameters: 5 / 5.5 / 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9 / 9.5 / 10 and 11 mm.
- Proximal cutting only to PCL friendly



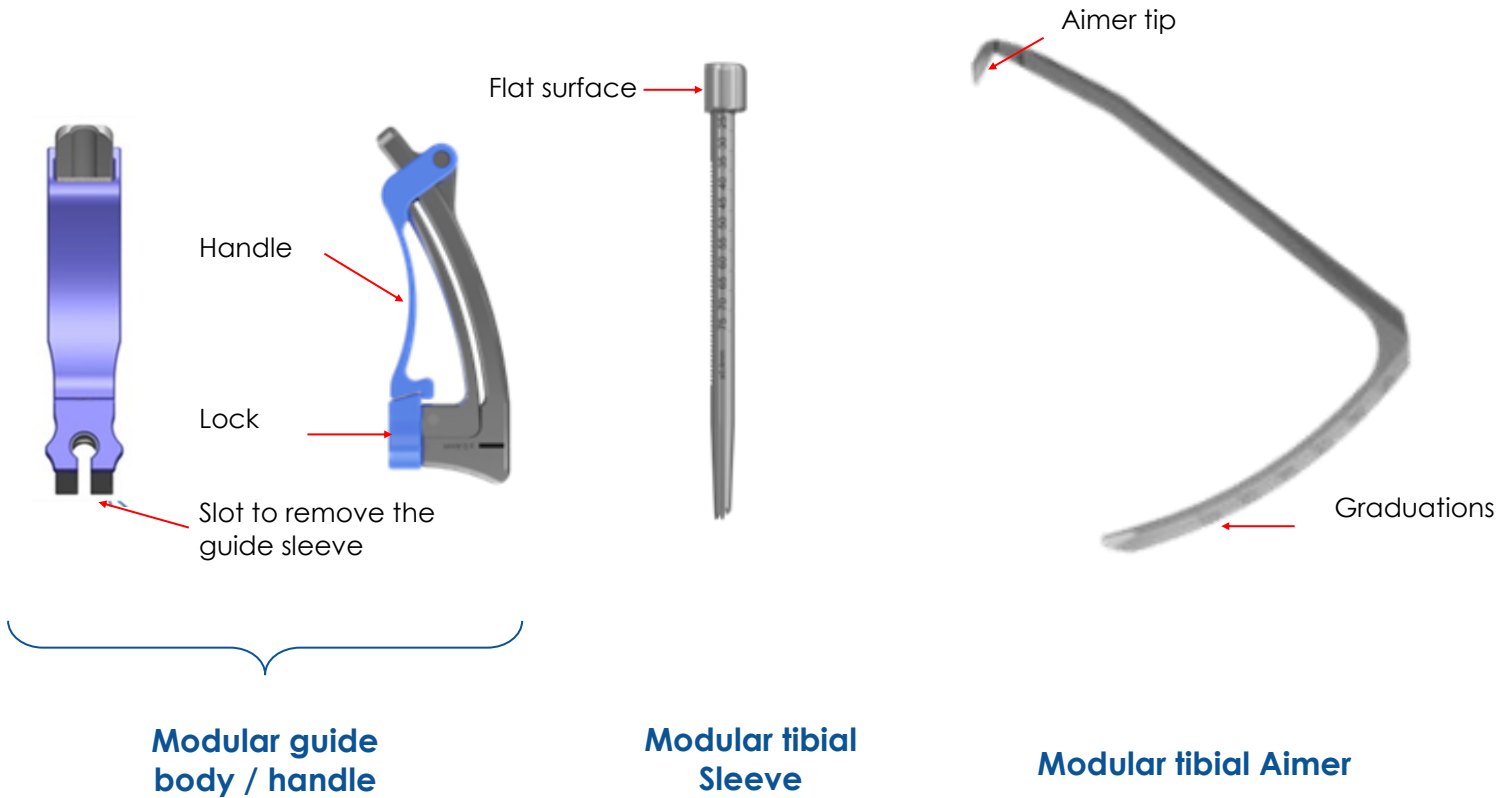
○ Wire pin guide Ø2,4mm Lg300mm



INSTRUMENTATION SET - DESCRIPTION

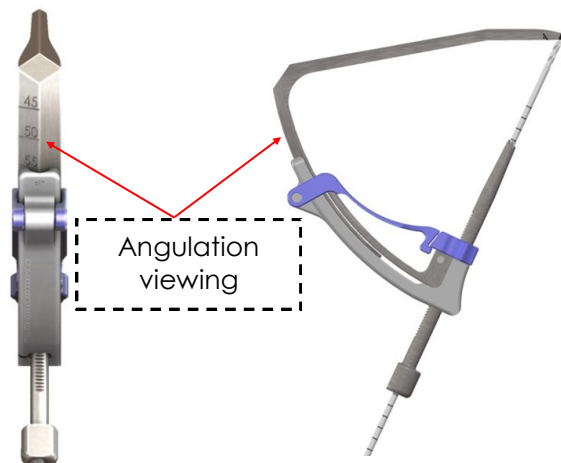
MODULAR TIBIAL GUIDE

Description



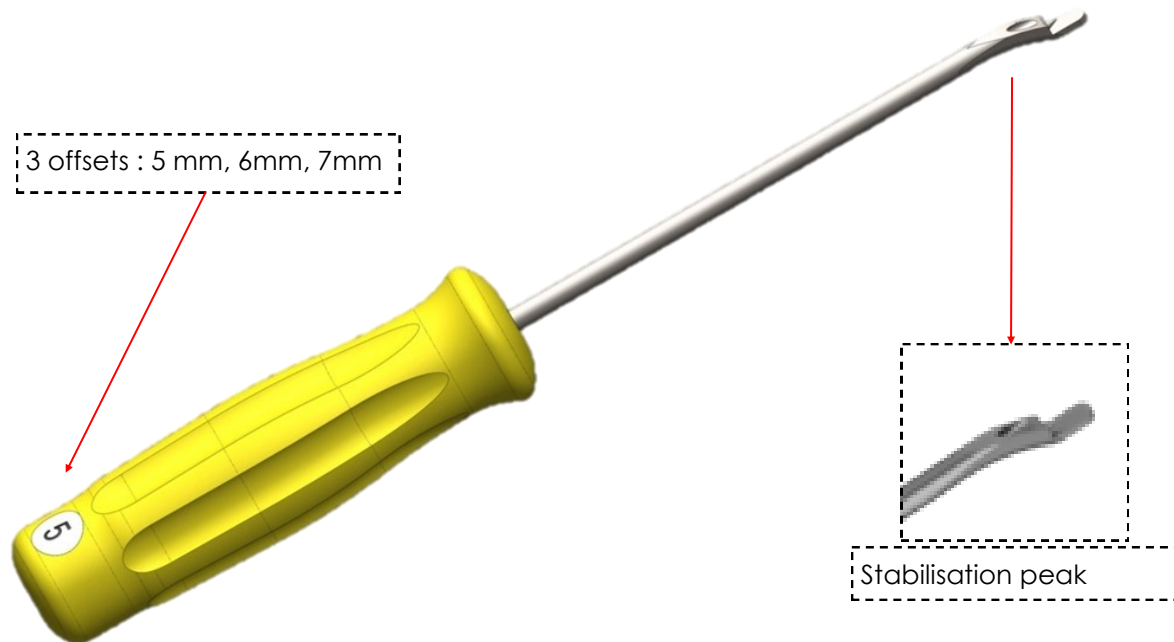
MODULAR TIBIAL GUIDE

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



INSTRUMENTATION SET - DESCRIPTION

INSIDE-OUT FEMORAL GUIDE



THREADED GRADUATED EYELET PIN

- Diameter 2.4 mm, length 350 mm

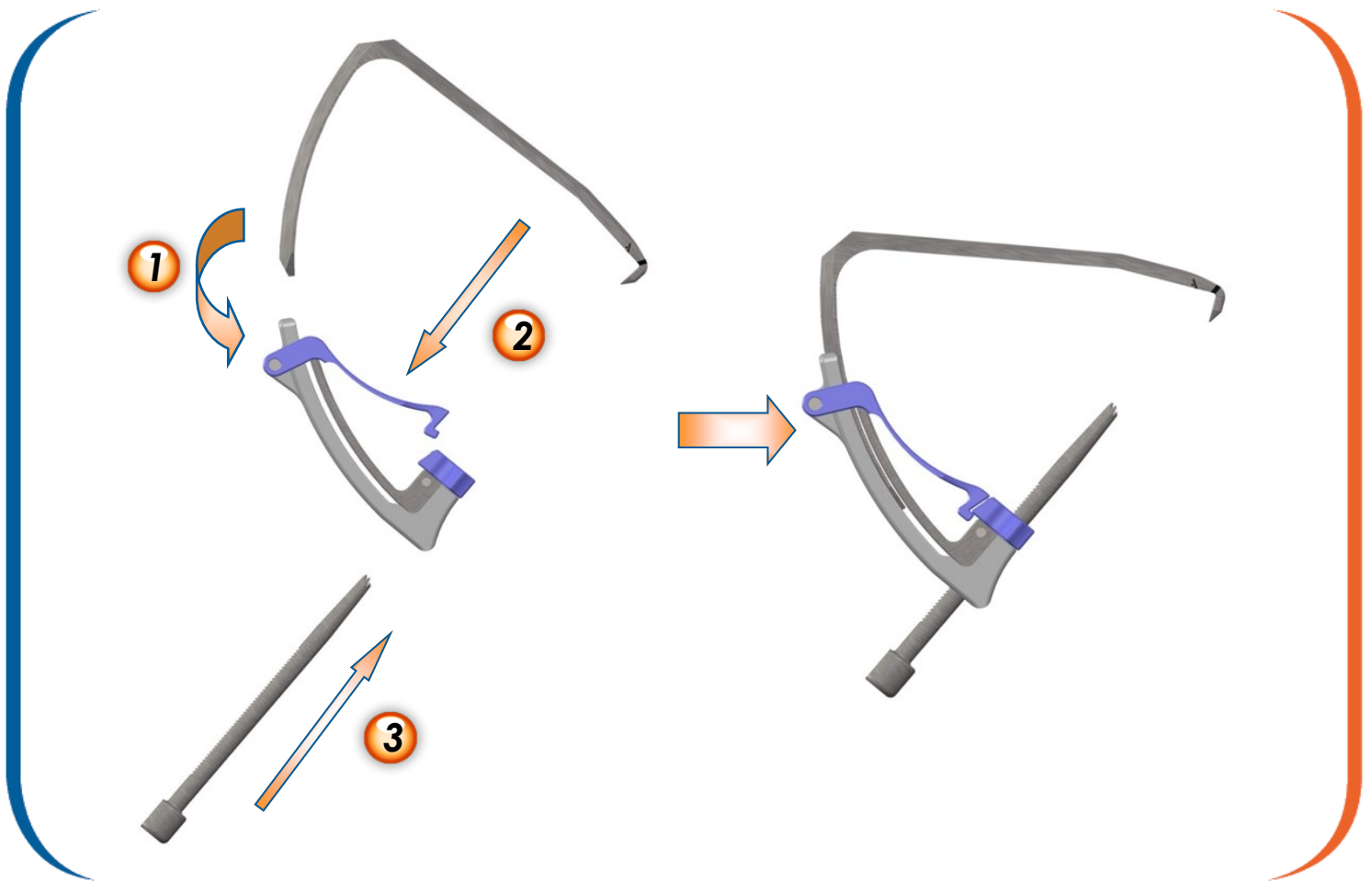


TROCAR EYELET PIN

- Diameter 2.4 mm, length 350 mm



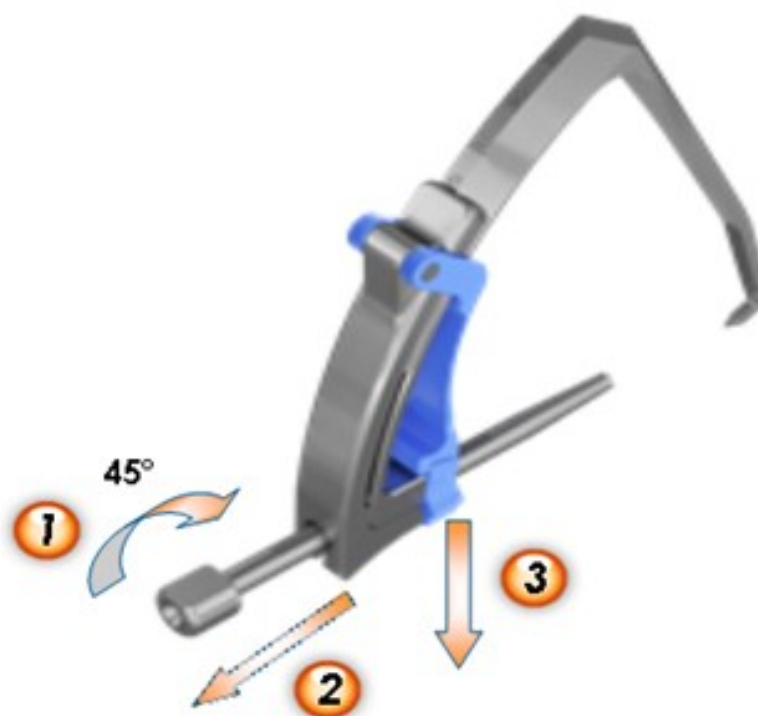
MODULAR TIBIAL GUIDE ASSEMBLY



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

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

CHANGING THE TIBIAL GUIDE ANGLE



- 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 modular tibial aimer (3)
- Change the angulation of the guide
- Lock the guide

1

2

3

INSTRUMENTATION SET - DESCRIPTION

ECLIPSE® PROFIL : CE₀₁₂₃

Composition :

100% PLDLLA (70/30) amorphous

Range :

1-0402771	Polylactic Interference Screw ECLIPSE Profil Ø 7 Lg 20 mm
1-0402772	Polylactic Interference Screw ECLIPSE Profil Ø 7 Lg 25 mm
1-0402773	Polylactic Interference Screw ECLIPSE Profil Ø 7 Lg 30 mm
1-0402781	Polylactic Interference Screw ECLIPSE Profil Ø 8 Lg 20 mm
1-0402782	Polylactic Interference Screw ECLIPSE Profil Ø 8 Lg 25 mm
1-0402783	Polylactic Interference Screw ECLIPSE Profil Ø 8 Lg 30 mm
1-0402791	Polylactic Interference Screw ECLIPSE Profil Ø 9 Lg 20 mm
1-0402792	Polylactic Interference Screw ECLIPSE Profil Ø 9 Lg 25 mm
1-0402793	Polylactic Interference Screw ECLIPSE Profil Ø 9 Lg 30 mm
1-0402702	Polylactic Interference Screw ECLIPSE Profil Ø 10 Lg 25 mm
1-0402703	Polylactic Interference Screw ECLIPSE Profil Ø 10 Lg 30 mm
1-0402714	Polylactic Interference Screw ECLIPSE Profil Ø 11 Lg 35 mm
1-0402724	Polylactic Interference Screw ECLIPSE Profil Ø 12 Lg 35 mm



Manufactured by BIOMATLANTE SA—ZA Les Quatre Nations—5 Rue Edouard Belin—44360 Vigneux de Bretagne—FRANCE

ECLIPSE® BCP : CE₀₁₂₃

Composition :

75 % PLDLLA amorphous
25 % HA et BTCP

Range :

1-0401071	Composite Interference Screw ECLIPSE BCP Ø 7 Lg 20 mm
1-0401072	Composite Interference Screw ECLIPSE BCP Ø 7 Lg 25 mm
1-0401073	Composite Interference Screw ECLIPSE BCP Ø 7 Lg 30 mm
1-0401081	Composite Interference Screw ECLIPSE BCP Ø 8 Lg 20 mm
1-0401082	Composite Interference Screw ECLIPSE BCP Ø 8 Lg 25 mm
1-0401083	Composite Interference Screw ECLIPSE BCP Ø 8 Lg 30 mm
1-0401091	Composite Interference Screw ECLIPSE BCP Ø 9 Lg 20 mm
1-0401092	Composite Interference Screw ECLIPSE BCP Ø 9 Lg 25 mm
1-0401093	Composite Interference Screw ECLIPSE BCP Ø 9 Lg 30 mm
1-0401012	Composite Interference Screw ECLIPSE BCP Ø 10 Lg 25 mm
1-0401013	Composite Interference Screw ECLIPSE BCP Ø 10 Lg 30 mm
1-0401004	Composite Interference Screw ECLIPSE BCP Ø 11 Lg 35 mm
1-0401024	Composite Interference Screw ECLIPSE BCP Ø 12 Lg 35 mm



Manufactured by BIOMATLANTE SA—ZA Les Quatre Nations—5 Rue Edouard Belin—44360 Vigneux de Bretagne—FRANCE

INSTRUMENTATION SET - DESCRIPTION

COMETE® : **CE1639**

Sterile anchore devices

○ Range

OAMGEFX15U	Sterile anchor device COMETE® Lg 15 mm
OAMGEFX20U	Sterile anchor device COMETE® Lg 20 mm
OAMGEFX25U	Sterile anchor device COMETE® Lg 25 mm
OAMGEFX30U	Sterile anchor device COMETE® Lg 30 mm
OAMGEFX35U	Sterile anchor device COMETE® Lg 35 mm

Manufactured by : COUSIN BIOTECH, 8 rue de l'Abbé Bonpain, 59117 WERVIQ-SUD—FRANCE



COMETE® is a class IIb medical device 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



AMPLITUDE [®]

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Tel. : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

E-mail : amplitude@amplitude-ortho.com

Customer Service-Export :

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26000 Valence, France
Tel. : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42

Internet : www.amplitude-ortho.com