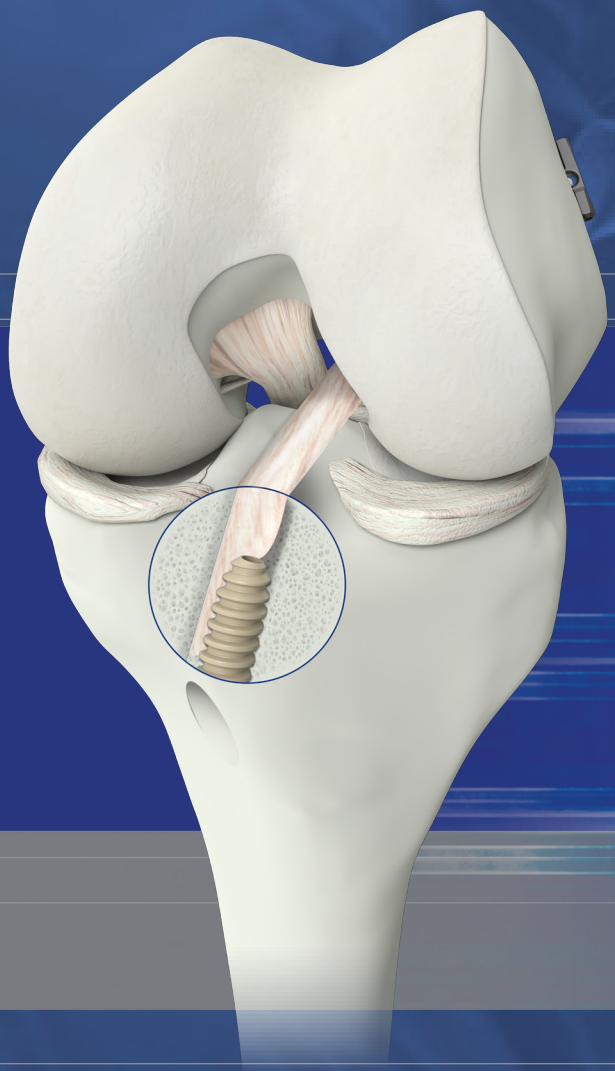
Mecta® Fix CL

FIXATION BUTTON WITH CONTINUOUS LOOP

SINGLE BUNDLE ACL



Surgical Technique

Joint | Spine | **Sports Med**

Medacta International

NOTICE

This document describes the Medacta Single Bundle ACL surgical technique implanting a harvested autologus tendon using Mecta®Fix CL fixation button with continuous loop and MectaScrew interference screw.

INDEX

1. INTRODUCTION

This surgical technique describes how to perform a Single Bundle ACL reconstruction using Medacta MectaFix CL Fixation Button with continuous loop on the femoral side and Medacta Interference Screw on the tibial side.

CAUTION
Federal law restricts these devices to sale, distribution and use by or on the order of a physician.

1.1 INDICATIONS OF USE

MectaFix CL Fixation Button with continuous loop is indicated for use in reconstructive treatment and extracortical femoral fixation of an implanted anterior cruciate ligament reconstruction.

MectaScrew Interference Screw: reconstructive treatment of ruptured anterior and posterior cruciate ligaments by means of auto-, allo-, and synthetic grafts providing a suitable and secure intratunnel graft fixation.

1.2 CONTRAINDICATIONS

Medacta Single Bundle ACL reconstruction using Medacta MectaFix CL Fixation Button with continuous loop and Medacta Interference Screw is contraindicated where there is:

- Osteoporosis and osteomalacia
- Degenerative osteopathies
- Adiposity or patient obesity, leading to excessive strain on the fixation button
- Osteomata in the area in which the fixation button is to be placed
- Deformities of the bone, or general conditions of the bones which exclude implantation of a fixation button in the opinion of a physician
- Systemic diseases and metabolic disorders that may compromise the output of the surgery

2. IMPLANTS AND INSTRUMENTS OVERVIEW

2.1 MECTAFIX CL - FIXATION BUTTON WITH CONTINUOUS LOOP

The MectaFix CL Fixation Button with continuous Loop is used for the extra-cortical femoral fixation of the graft.

1.

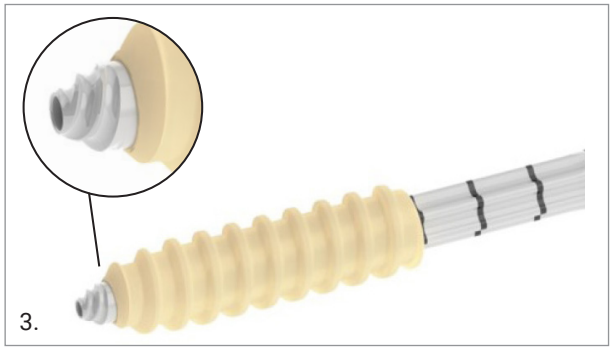
The implant assembled with the graft is represented in image 2. It is preloaded with a suture loop available in various length options and with a pulling / flipping suture to pull the implant through the prepared bone tunnel and to subsequently flip it after passing the femoral lateral cortex.

2.

2.2 INTERFERENCE SCREW

Interference screws are used for the tibial fixation of the transplanted graft.

When inserting the interference screw, high fixation strength of the graft is achieved immediately after the reconstruction thanks to the press fit obtained between the screw and the graft within the prepared bone tunnel.



3.

The interference screws are provided in different lengths and diameters (see table below). Select the appropriate configuration according to reinforced graft size and use the related screwdriver (see paragraph 2.6).

SCREW DIAMETER (mm)

SCREW LENGTH (mm)	Ø 6	Ø 7	Ø 8	Ø 9	Ø10	Ø11	Ø12
15	■	■	■				
20	■	■	■	■	■		
25	■	■	■	■	■		
30		■	■	■	■	■	
35							■

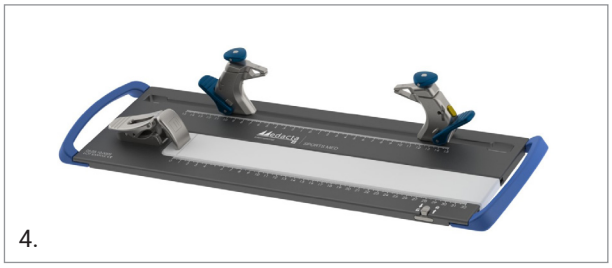
3. INSTRUMENTS OVERVIEW

3.1 PREPARATION TABLE

The preparation table is designed to enable cleaning and preparation of the tendon graft or the ligament implant.

It is composed of a main board (Ref. 05.05.10.0009), a plastic cleaning panel (Ref. 05.05.10.0011), two graft clamps (Ref. 05.05.10.0009), a loop sizer (Ref. 05.05.10.0083) and dedicated implant/suture supports (Ref. 05.05.10.0012 and Ref. 05.05.10.0014).

The clamps' shape allows for graft fixation and extra-cortical Medacta femoral button lodging. These clamps can slide along a scaled track to adequately tension the graft. The scale allows for evaluation of the length of the tendon graft or ligament implant. To insert/remove the plastic cleaning board, verify that the fixation button of the metal board is in the open position and slide in/out the board from the side of the table. The plastic board fixation clamp can be used, if desired, to fix one side of the graft before performing the cleaning phase.



4.

The preparation table enables:

- Preparation of the tendon graft and set of its length
- Setting of the button loop length (for this step, a dedicated loop sizer, Ref. 05.05.10.0083, is available)
- Strengthening of the femoral and tibial tips of the tendon graft by applying reinforcing sutures (reinforcement phase)

A dedicated implant support can be assembled (independently) within one of the graft clamps to allow Medacta implant coupling with the reinforcing sutures coming from the graft. To insert the implant, press the dedicated supports legs.

5.

An additional support is available, if desired, to manage sutures coming from the graft. It can be positioned on the graft clamp (like the other supports). Sutures can be wrapped around the suture support central shaft.

6.

GRAFT CLAMP

The graft clamp holds the Medacta supports and the edge of the tendon graft during the preparation phase.

By moving the clamp along the board track it is possible to tension the graft. Press down the lower bar to fix the clamp.

To prevent graft slippage during the reinforcement phase, the graft edge needs to be fixed in the clamp, and locked using the upper wheel.

To insert/remove the Medacta supports, press the gold locking button positioned at the rear of the clamp.

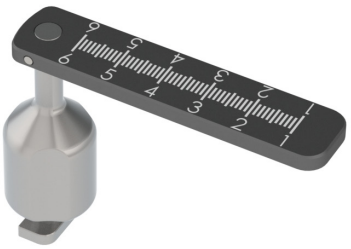
7.

LOOP SIZER

This instrument has to be coupled with the preparation table during the graft preparation phase.

Insert the instrument within the rail of the preparation board, in between the two graft clamps, maintaining the instrument perpendicular to the rail during insertion. Rotate the device counterclockwise to stabilize it on the preparation table (only one direction of rotation is allowed). Slide the instrument up to the desired position. To properly evaluate the length of the button loop, the instrument has to lie against the femoral button support.

To disassemble the device, rotate the instrument by 90° within the preparation table rail (only one direction of rotation is allowed) and remove it.



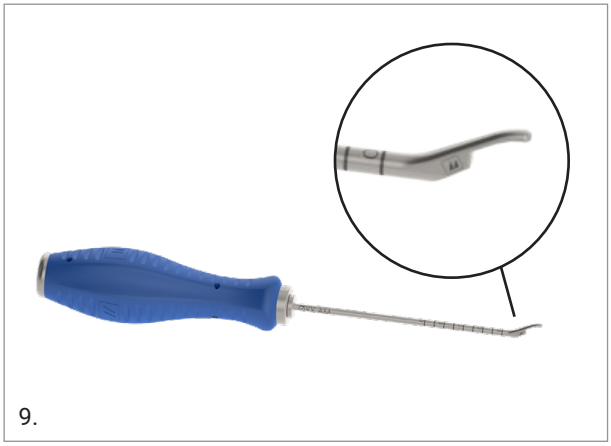
8.

3.2 FEMORAL AIMER

It is used to properly place a Ø2.4 mm k-wire in the femur bone. Furthermore, it features a tip that allows for direct vision of the insertion site of the ACL and a nose for proper fitting on the femoral condyle.

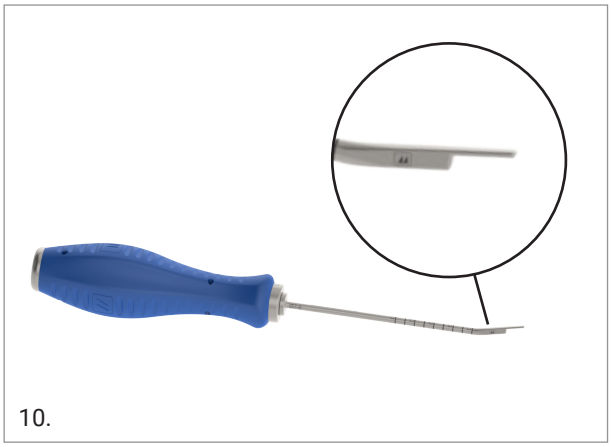
Different versions are available according to preferred surgical approach (antero-medial or transtibial). For each version, two tip configurations are available: one for Ø7/8 mm tunnel drilling (with 2 mm back wall offset with respect to tunnel size of Ø8 mm) and a second one for Ø9/10 mm tunnel drilling (with 2 mm back wall offset with respect to tunnel size of Ø10 mm).

Femoral aimer for antero-medial (AM) approach:



9.

Femoral aimer for transtibial (TT) approach:



10.

According to reinforced graft size, please select the femoral aimer that enables to better aim the ACL femoral insertion. The tip is blunt in order to facilitate the positioning on the ACL femoral insertion.

3.3 DILATOR

It can be used on both femur and tibia.

Each dilator is cannulated in order to be slid along a Ø2.4 mm k-wire. Different sizes are available (head diameter from Ø6 mm up to Ø12 mm, by 0.5 mm increment) that need to be selected according to the size of the reinforced graft.

The dilator tip features two flat portions to facilitate dilator insertion/removal decreasing the friction within the bone tunnel. In order to evaluate the tunnel depth, the dilator is graduated.

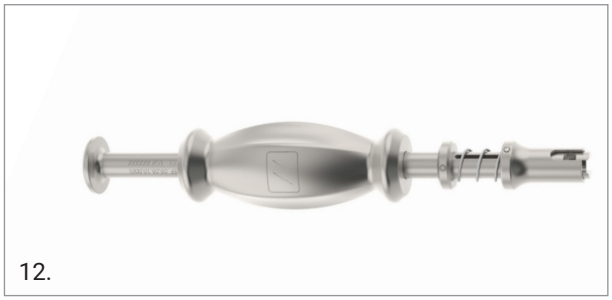
A unique handle is available with a dedicated button system to quickly and safely assemble/disassemble each tip.

11.

To insert the dilator, tap it from the back using a hammer. To remove it, use a hammer or the slide hammer (see paragraph 2.4), coupling it with the backside of the dilator handle.

3.4 SLIDE HAMMER

The slide hammer has been designed with a self-locking mechanism to be coupled with the femoral or the tibial dilators. It enables easy removal of the dilators in case of significant friction between the dilators tip and bone.



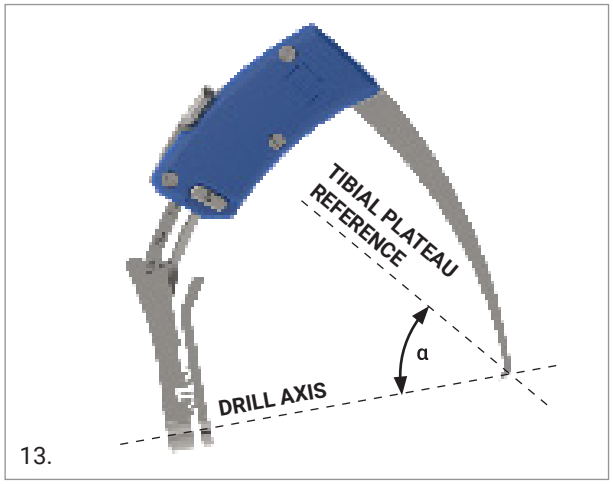
12.

NOTE: as an alternative, the standard hammer (Ref. 05.05.10.0050) can be used.

3.5 TIBIAL AIMER

It consists of two different components:

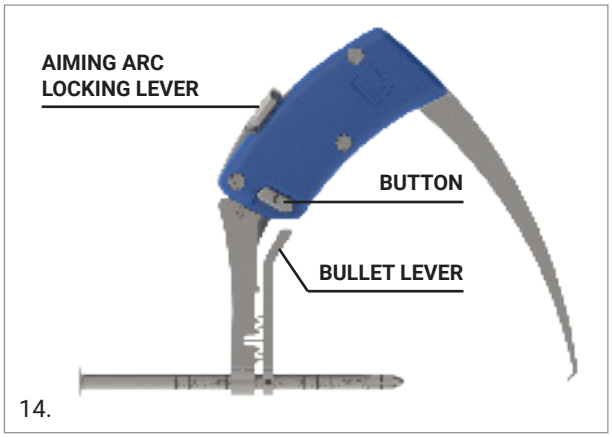
- Aiming arc with adjustable angle (from 45° up to 70°, **α** on the picture above) between the drilling axis and the tibial plateau reference plane (tip reference)
- Cannulated bullet for the use of a Ø2.4 mm k-wire. It is designed in a way that prevents accidental disassembling during usage



13.

With reference to the following image, the aiming arc features:

- A tip that allows proper positioning and firm fixation of the aimer on the ACL tibial insertion point
- A dedicated lever (bullet lever) that allows bullet fixation, preventing slippage from the lower arc body
- A dedicated locking lever (aiming arc locking lever) that allows the fixation of the lower arc body into the desired working configuration, which can be checked on the scale marked on the lower arc body
- A dedicated button (button) prevents, if the aiming arc locking lever is opened, accidental disassembling of the lower arc during usage
- Tip to tip design, which permits to evaluate the exit point of the k - wire, before its placement



14.

Once the working configuration has been selected, insert the bullet into the aiming arc from behind by pushing the aiming arc bullet lever. In order to properly position the bullet, insert it and slide it up to the end of the bayonet. At this point rotate the bullet by 60° (clockwise).

3.6 REAMERS AND DRILLS


15.

Cannulated headed reamers (from Ø 4.5mm up to Ø 12mm with 0.5 mm increments) and manual cannulated drills (from 6mm up to 12mm) with dedicated quick connection T-handle are both available to slide along a Ø 2.4mm k-wire.

3.7 SCREWDRIVER

The screwdriver is used to properly place the Medacta MectaScrew interference screw, ensuring the appropriate fixation of the graft. Both fixed and quick connect ratchet handle are available.

SCREW DIAMETER (mm)

SCREWDRIVER TORX	Ø 6	Ø 7	Ø 8	Ø 9	Ø10	Ø11	Ø12
T20	■						
T25		■	■	■	■		
T40						■	■

4. GRAFT PREPARATION

The tendon is harvested using a tendon stripper (as per surgeon's preferred technique) and then cleaned and reinforced using the preparation table and its accessories according to the following steps:

- The tendon is cleaned on the plastic board
- The tendon is positioned between the two clamps noses
- The tendon is reinforced on both sides as per standard technique
- The tendon is folded according to surgeon preference on the plastic preparation board
- Before assembling the femoral implant with the graft, the loop length of the MectaFix CL needs to be determined. In order to do so, proceed with the femoral tunnel creation

4.1 GRAFT THICKNESS MEASUREMENT

The graft sizer features holes to help for the evaluation of the reinforced graft cross section size.

Each hole features an opening through which sutures coming from the graft can be passed. All the edges are rounded to avoid harming of the tendon during usage.

The instrument is designed with two components that can be rotated obtaining two working configurations:

- Open configuration: the suture slots of the two components are coincident and sutures can be passed through these. Graft holes are not coincident between the two components (the tendon cannot be inserted through these openings)
- Closed configuration: the suture slots of the two components are not coincident and sutures cannot exit from these. Graft holes are coincident between the two components (the tendon can be inserted through these openings)

Two different configurations are available:

- Small: holes from Ø4.5 mm up to Ø8.5 mm
- Large: holes from Ø9 mm up to Ø12 mm

16.

17.

The instrument, positioned in the open configuration, is inserted from one side of the graft, while it is assembled on the preparation table. After its insertion, the device is rotated by 90 degrees and positioned in the closed configuration around the suture filaments. The device is then moved through the reinforcement filaments. When moving the device, a slight resistance should be felt.

5. FEMORAL TUNNEL CREATION – ANTEROMEDIAL APPROACH

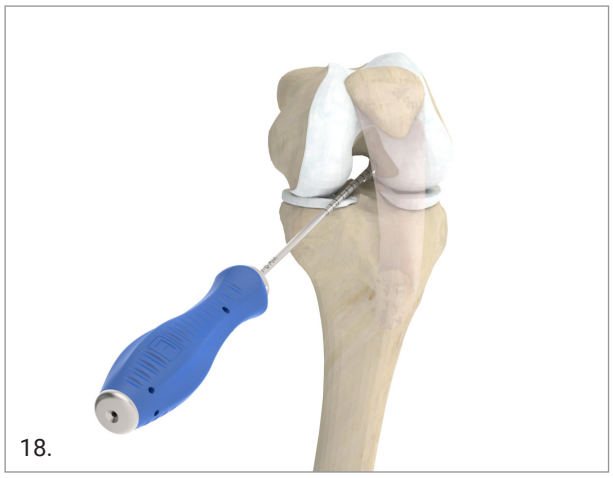
NOTICE: this step has to be performed if the Antero-Medial approach has been selected. In case of Trans-Tibial approach, go to paragraph 5.

5.1 K- WIRES POSITIONING AND DRILLING

Bend the knee to 120° of flexion.

Position the femoral aimer on the ACL femoral insertion site.

NOTICE: before placing the k-wire and the femoral aimer, it is possible to mark the desired ACL femoral insertion with a 60° microfracture instrument.

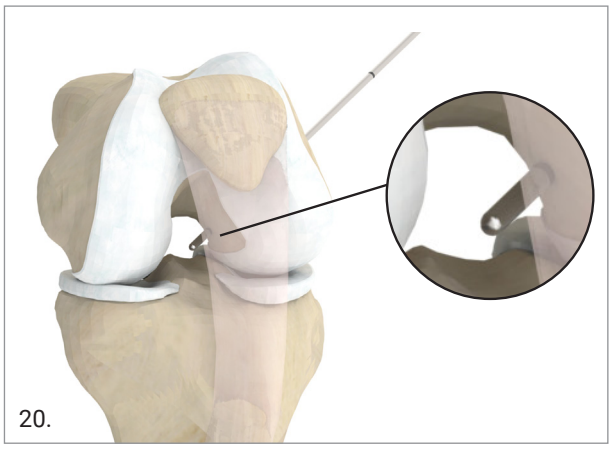


18.

Insert the k-wire in the hole of the aimer and drill it through the femur. The k-wire has to come out at the extra cortical femoral button desired position.

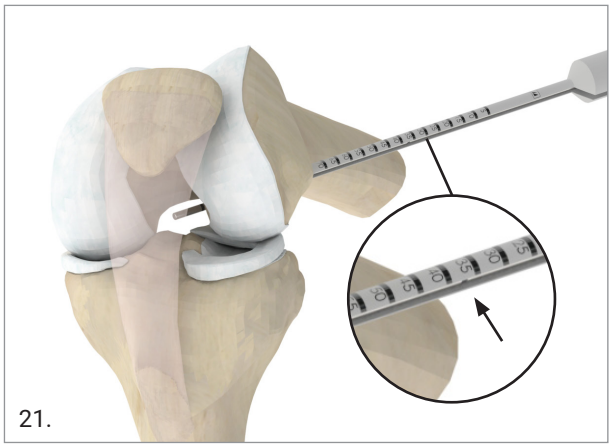
19.

Remove the aimer and insert further the k-wire in order to align the proximal k-wire laser marking with the femoral condyle intra-articular cortical surface. Check if the k-wire is properly placed.



20.

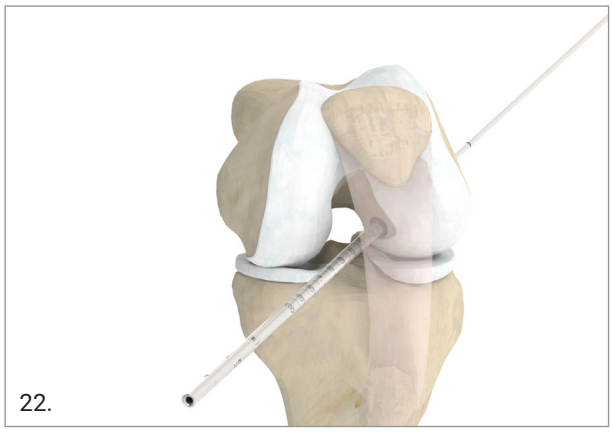
Slide the reverse length gauge from the distal portion of the k-wire that protrudes from the femur. Using the distal marking on the k-wire check the femoral tunnel length on the length gauge.



21.

Over-drill the k-wire with a cannulated headed reamer. Its size has to be selected according to the dimension of the reinforced harvested graft.

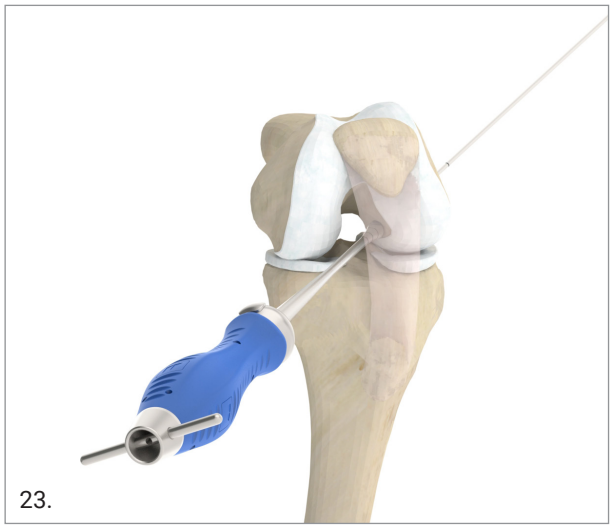
In addition to the recommended femoral graft fixation length of 20-25 mm, an extra 6 mm of drilling is required in order to provide sufficient space for the implant flipping once it passes the femoral cortex (i.e., desired Femoral Socket Depth + 6mm).



22.

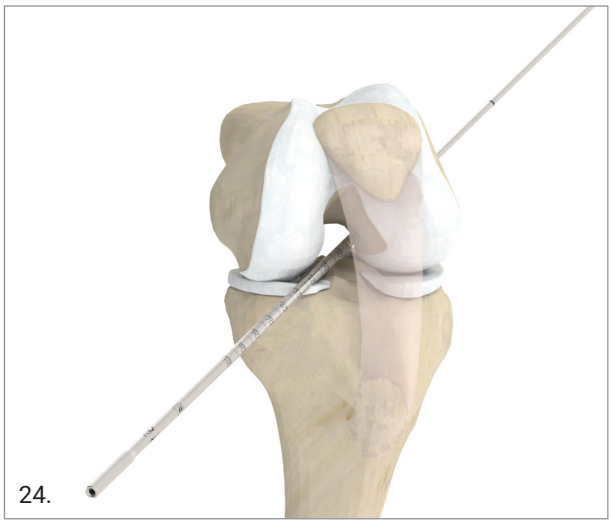
OPTION

A smaller reamer with respect to the size of the reinforced graft can be used and, after this, the bone should be dilated using an oval dilator with the head diameter size equal to the reinforced graft size. Rotate the dilator during insertion in order to obtain the correct final shape of the tunnel.



23.

Over-drill the k-wire with a Ø4.5 mm cannulated headed reamer, up to the opposite side.



24.

The final femoral tunnel (20-25 mm minimum depth, same diameter of the reinforced graft) is now created.

6. TIBIAL TUNNEL CREATION

6.1 K- WIRES POSITIONING AND DRILLING

Insert the bullet into the aiming arc from behind (see black arrow). To do so, press the arc lever.

Select the desired working configuration according to patient anatomy.

25.

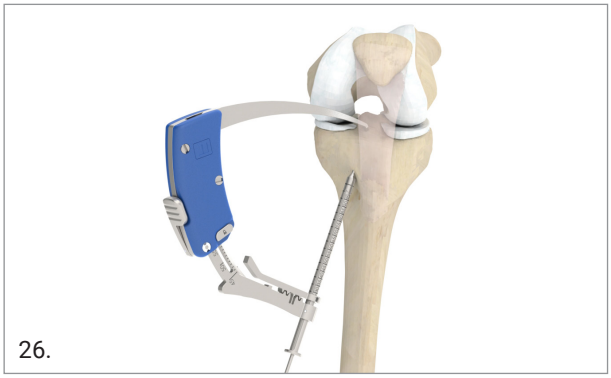
The tip is inserted into the medial portal and is positioned targeting the ACL tibial insertion site (use the anterior horn of the lateral meniscus as a reference). Thanks to the tip to tip design of the aimer, the tip shows the k-wire exit point.

The bullet is advanced towards the tibia.

The length of the tibia drilled tunnel can be read using the scale marked on the bullet. The tunnel should be at least 35 mm long.

Drill the k-wire through the bullet.

NOTICE: stop drilling as soon as the tip of the k-wire touches the tip of the aimer.

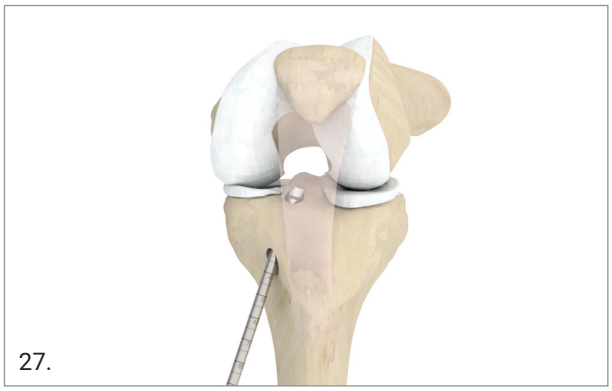


26.

Remove the aiming arc and the bullet, leaving the k-wire in place. Insert the k-wire until it is visible in the joint. Over-drill the k-wire using a cannulated headed reamer.

Its size has to be selected according to the dimension of the reinforced harvested graft.

NOTICE: manual cannulated drills with dedicated quick connection handle are also available to perform this step.



27.

OPTION

A smaller reamer with respect to the size of the reinforced graft can be used and, after this, the bone has to be dilated using an oval dilator with head diameter size equal to reinforced graft size. Rotate the dilator during its insertion in order to obtain the correct final shape of the canal.

28.

Final result.

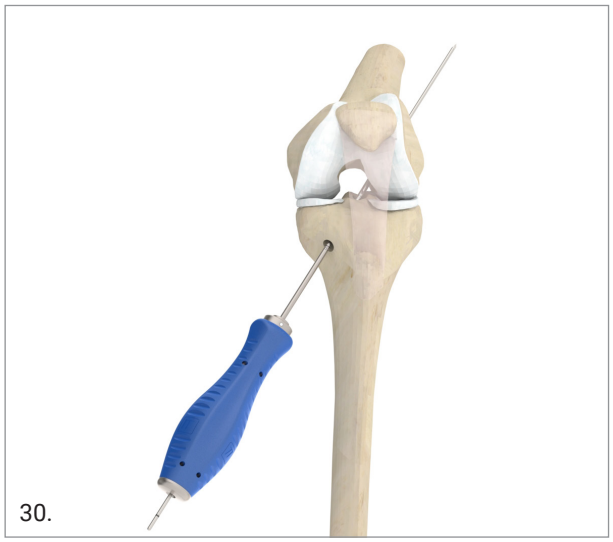
29.

7. FEMORAL TUNNEL CREATION – TRANSTIBIAL APPROACH

NOTICE: this step has to be performed if the Trans-tibial approach has been selected. If Antero-Medial approach has been selected, go to par. 7.

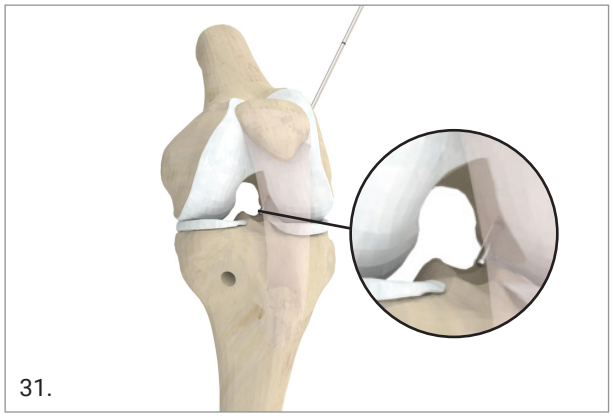
7.1 K- WIRES POSITIONING AND DRILLING

With the knee flexed at around 90°, insert the femoral aimer through the created tibial tunnel targeting the ACL femoral insertion site. Insert the k-wire in the hole of the aimer and drill it through the femur. The k-wire has to come out in the extra cortical femoral button desired position.

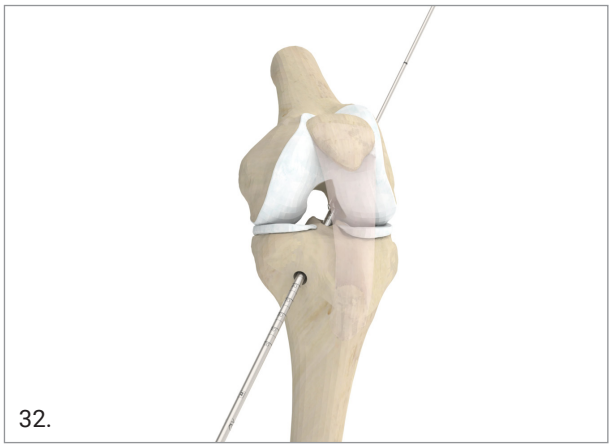

30.

Remove the aimer and insert further the k-wire in order to align the proximal laser marking with the femoral condyle intra-articular cortical surface. Check if the k-wire is properly placed.

In order to measure the length of the tunnel, slide the reverse length gauge from the distal portion of the k-wire that protrudes from the femur. Using the distal marking on the k-wire check the femoral tunnel length on the length gauge.

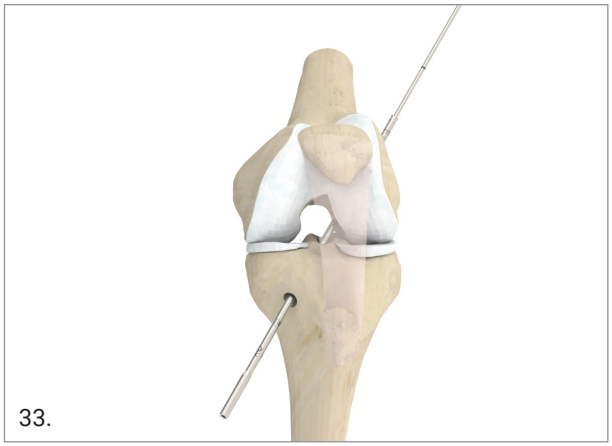

31.

Over-drill the k-wire with a cannulated headed reamer, its size has to be selected according to the dimension of the reinforced harvested graft. In addition to the recommended femoral graft fixation length of 20-25 mm, an extra 6 mm of drilling is required in order to provide sufficient space for the implant flipping once it passes the femoral cortex (i.e., desired Femoral Socket Depth + 6mm).

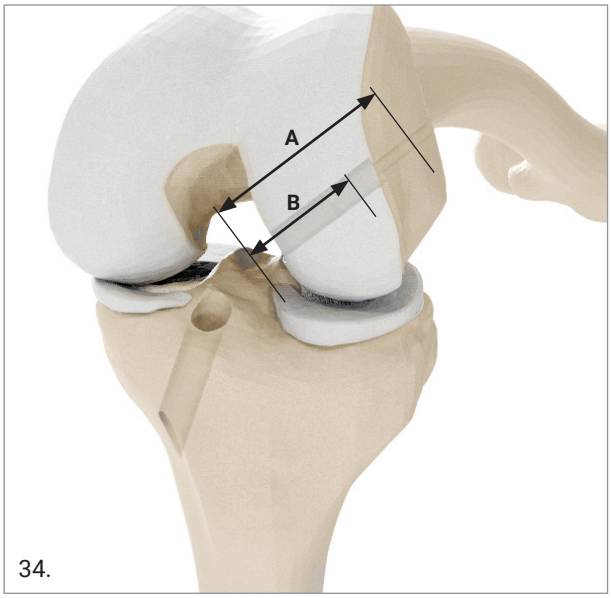

32.

Over-drill the k-wire with a Ø4.5 mm cannulated headed reamer, up to the opposite side.

The final femoral tunnel (20-25 mm minimum depth, same diameter as the reinforced graft) is now created.


33.

8. FEMORAL IMPLANT LOOP LENGTH DETERMINATION



34.

Knowing the Femoral tunnel length (A) and the Femoral Socket Drilling Depth (B) the required loop length can be determined with the following formula:

Loop length = Femoral Tunnel Length (A) – Femoral Socket Drilling Depth (B) + 6 mm.

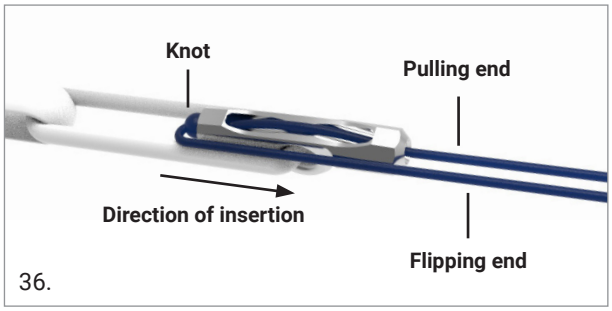
Choose the next size loop length available.

Example:
- Femoral tunnel Length (A): 44 mm
- Femoral Socket Depth (B): 26 mm
- 44 – 26 + 6 = 24 mm
- Implant loop length to be selected: 25 mm

9. GRAFT INSERTION AND FIXATION

Load the graft onto the loop of the MectaFix CL Fixation Button with continuous loop.


35.



36.

Both ends of the Pulling/Flipping Suture are inserted transtibially using a passing k-wire. Thereafter, pull the graft into position using the Pulling/Flipping suture of the MectaFix CL Fixation Button with continuous loop, ensuring throughout the process to pull mainly with the pulling suture end. The pulling end can be identified by the resistance perceived during pulling (i.e. the suture does not slide).

CAUTION
Pulling the incorrect suture end could result in removal of the suture. This must be avoided.

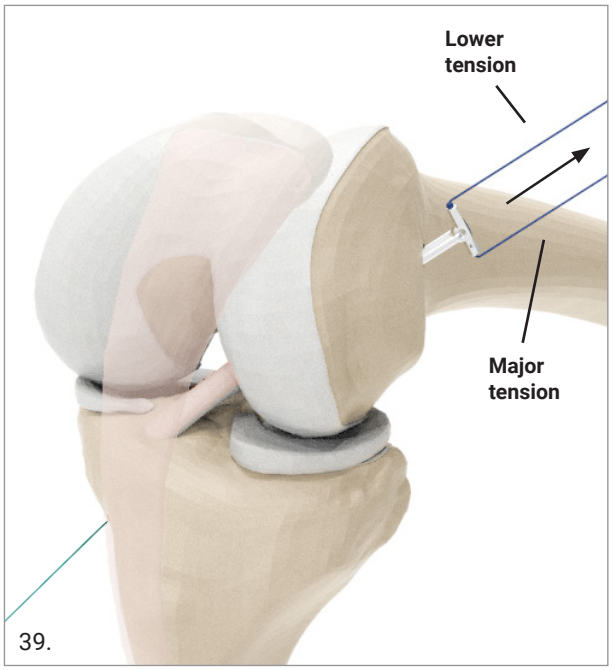
Pull the button of the MectaFix CL Fixation Button with continuous loop through the femoral cortex.


37.

In order to flip the MectaFix CL Fixation Button with continuous loop, mantain a consistent firm tension on the pulling end (to prevent the suture to slide through the button) and apply a slight counter-tension on the flipping end.

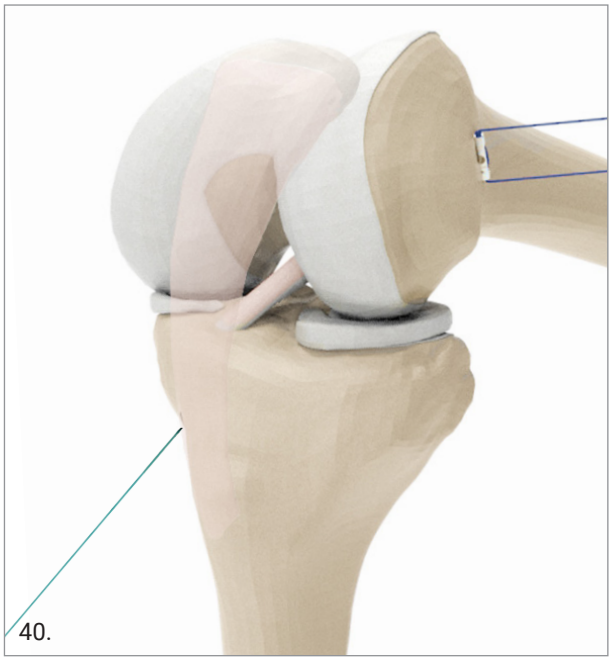

38.

A flipping sesation will be felt when the button is flipped.

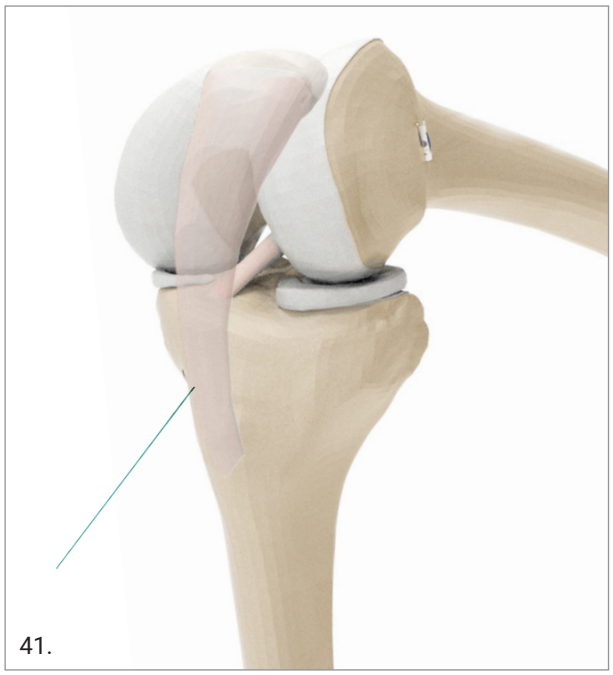


39.

A slight counter tension applied on the graft construct from the tibial side will move the flipped button back in contact with the lateral femoral cortex. By pulling the graft backwards check that the button of the MectaFix CL is in contact with the cortical bone and holds the graft firmly. The graft should remain at least 20 mm inside the femoral tunnel.

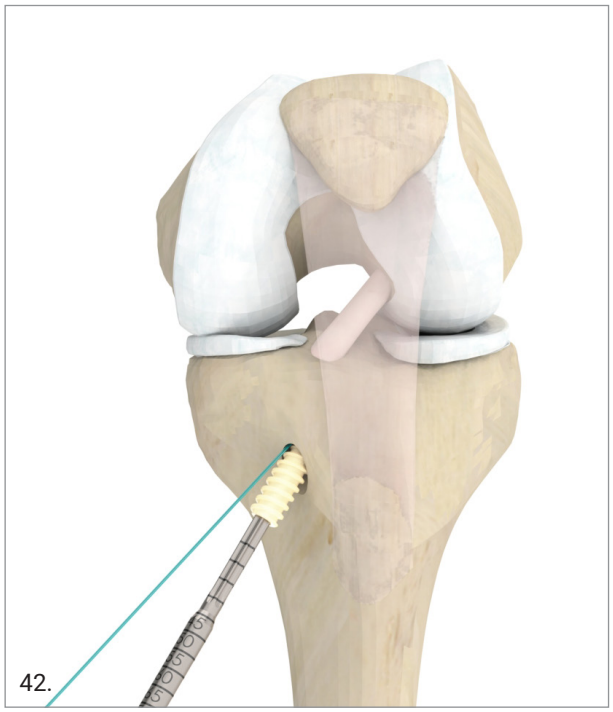

40.

Remove the Pulling/Flipping suture by pulling on the trailing end.



41.

With the knee flexed, fix the tibial end of the graft using a MectaScrew placing it on the lateral side of the graft.



42.

Final result.

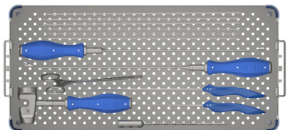
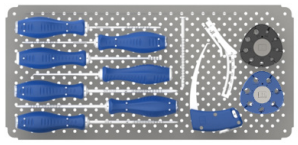
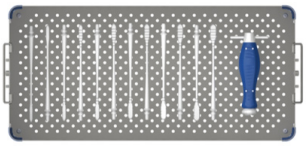
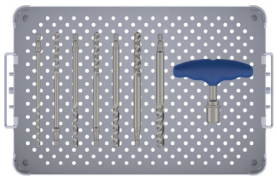
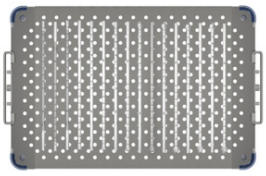
43.

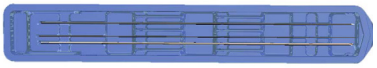
10. IMPLANTS AND INSTRUMENTS NOMENCLATURE

REF. NO.	DESCRIPTION	PICTURE
05.05.0003	Interference Screw 6x15 T20	
05.05.0004	Interference Screw 6x20 T20	
05.05.0005	Interference Screw 6x25 T20	
05.05.0006	Interference Screw 7x15 T25	
05.05.0007	Interference Screw 7x20 T25	
05.05.0008	Interference Screw 7x25 T25	
05.05.0009	Interference Screw 7x30 T25	
05.05.0010	Interference Screw 8x15 T25	
05.05.0011	Interference Screw 8x20 T25	
05.05.0012	Interference Screw 8x25 T25	
05.05.0013	Interference Screw 8x30 T25	
05.05.0014	Interference Screw 9x20 T25	
05.05.0015	Interference Screw 9x25 T25	
05.05.0016	Interference Screw 9x30 T25	
05.05.0017	Interference Screw 10x20 T25	
05.05.0018	Interference Screw 10x25 T25	
05.05.0019	Interference Screw 10x30 T25	
05.05.0020	Interference Screw 11x30 T40	
05.05.0021	Interference Screw 12x35 T40	
05.05.0022	MectaFix Continuous Loop 15 mm	
05.05.0023	MectaFix Continuous Loop 20 mm	
05.05.0024	MectaFix Continuous Loop 25 mm	
05.05.0025	MectaFix Continuous Loop 30 mm	
05.05.0026	MectaFix Continuous Loop 35 mm	
05.05.0027	MectaFix Continuous Loop 40 mm	
05.05.0028	MectaFix Continuous Loop 45 mm	
05.05.0029	MectaFix Continuous Loop 50 mm	
05.05.0030	MectaFix Continuous Loop 55 mm	
05.05.0031	MectaFix Continuous Loop 60 mm	

Metal trays designed with dedicated brackets to contain the instruments of the set.

The MectaACL SB Set (Ref. 05.05.10.9003) is available in different configurations. Femoral aimers are customizable according to the chosen surgical approach (anteromedial or trastibial). If cannulated screwdrivers are chosen, the tray is completed with Ø 1.1 mm Nitinol guidewires.

REF. NO.	DESCRIPTION	PICTURE
05.05S.001	Sports Medicine - Knee General Tray	
05.05S.004	Sports Medicine - Knee Preparation Table Tray	
05.05S.003	MectaACL SB Tray - Transtibial Approach & Cannulated Screwdrivers	 
05.05S.005	MectaACL SB - Anteromedial Approach & Cannulated Screwdrivers	
05.05S.006	MectaACL SB Tray - Anteromedial Approach & NonCannulated Screwdrivers	
05.05S.007	MectaACL SB Tray - Transtibial Approach & NonCannulated Screwdrivers	
05.05S.011	MectaACL SB Tray – Anteromedial Approach & Cannulated Screwdrivers, w/o dilators	
05.05S.012	MectaACL SB Tray – Anteromedial Approach & NonCannulated Screwdrivers, w/o dilators	
05.05S.013	MectaACL SB Tray – Transtibial Approach & Cannulated Screwdrivers, w/o dilators	
05.05S.014	MectaACL SB Tray – Transtibial Approach & NonCannulated Screwdrivers, w/o dilators	
05.05S.017	SportsMed Cannulated Drills with T-Handle.	
05.05S.008	Cannulated Headed Reamers Tray	

REF. NO.	DESCRIPTION	PICTURE
05.05.10.0133	Ligament reconstruction wires kit	
05.05.10.0118	Cannulated Screwdriver Shaft T20	
05.05.10.0120	Cannulated Screwdriver Shaft T25	
05.05.10.0122	Cannulated Screwdriver Shaft T40	
05.05.10.0124	Quick Connect Ratchet Handle cannulated	
05.05.10.0134	T-Handle Zimmer Hall connection	

Part numbers subject to change.

NOTE FOR STERILISATION

If not specified, the instruments are not sterile and must be cleaned before use and sterilised in an autoclave in accordance with the regulations of the country, US directives where applicable and following the instructions for use of the autoclave manufacturer. For detailed instructions please refer to the document “Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices” available at www.medacta.com.

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