

NOTE

This document describes the M-ARS ACL (Medacta Anatomic Ribbon Surgery) surgical technique using a harvested autologous semitendinosus ligament.



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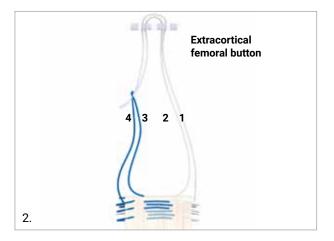
1. IMPLANTS OVERVIEW

1.1 EXTRACORTICAL FEMORAL BUTTON

The Extracortical Femoral Button (Ref. 05.05.001) is used for the femoral fixation of the graft. It has to be loaded through the two central holes, with two USP#2/EP5 sutures with a needle at one end. Two additional USP#2/EP5 sutures (preferably in two different colours) have to be loaded on the side holes to pull the implant (pulling suture) towards the femoral tunnel and to flip it (flipping suture) once it has reached an extracortical position (inside-out technique). The flip length of the Medacta Extracortical Button is about 7 mm.



The graft, assembled with the sutures and the Extracortical Femoral Button (without the flipping and pulling sutures) is represented in image 2. The sutures necessary to create the loop have to be fixed on the graft in accordance with paragraph 3.4. Sutures for pulling and flipping are assembled only after suturing the graft.

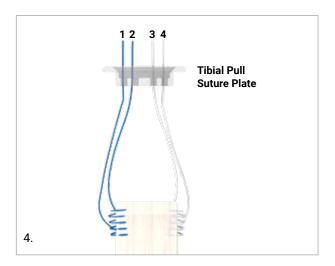


1.2 TIBIAL PULL SUTURE PLATE (PSP)

The Tibial Pull Suture Plate (Ref. 05.05.002) (PSP) is an extracortical fixation device which is fixed in correspondence to the tibial tunnel using a dedicated impactor described in paragraph 2.8.



The implant has to be assembled with two USP#2/EP5 sutures as represented in image 4. These sutures have to be used for suturing the graft as described in paragraph 3.4. Use sutures of different colours on each side of the graft.





2. INSTRUMENTS OVERVIEW

2.1 PREPARATION TABLE

The preparation table is designed to clean and prepare the tendon.

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. 05.05.10.0010)
- A loop sizer (Ref. 05.05.10.0083)
- Dedicated implants/suture supports (Ref. 05.05.10.0012, Ref. 05.05.10.0013 and Ref. 05.05.10.0014).

The clamp allows for graft fixation and extracortical buttons lodging and can slide along a scaled track to adequately tension the graft. The scale allows for evaluation of the length of the tendon.

To insert/remove the plastic panel, verify that the fixation button of the metal board is in the open position and slide the plastic panel in/out. The panel fixation clamp can be used to fix one side of the graft before cleaning the graft.



The preparation table enables:

- Graft preparation and length assessment
- Setting of the button loop length (a dedicated loop sizer, Ref. 05.05.10.0083, is available)
- Suturing and preparation of the graft

Dedicated implant supports can be assembled on the back of the clamps to ease loading of sutures in the button. To insert the implant, press support legs.



An additional support is available to manage sutures coming from the graft. Sutures can be wrapped around the suture support central shaft.



GRAFT CLAMP

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

By moving the clamp along the rail 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 end needs to be fixed in the clamp, and locked using the upper wheel.

To insert/remove the Medacta supports, press the golden locking button positioned at the rear of the clamp and slide the supports into/out of the dedicated slot.



LOOP SIZER

This instrument (Ref. 05.05.10.0083) is used with the preparation table during the graft preparation phase.

Mantaining the loop sizer perpendicular to the preparation board rail, insert the instrument in between the two clamps. Rotate the device counterclockwise to stabilize it on the preparation table (only one direction of rotation is allowed). Slide the instrument 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 degrees and remove it.



2.2 FEMORAL AIMER

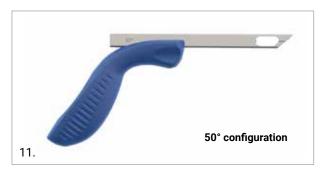
The femoral aimer is used to create three parallel holes in the femoral bone in correspondence with the ACL femoral insertion.

It consists of a central guide hole for a 380 mm Ø2.4 mm k-wire and two adjacent guide holes for 220 mm Ø2.4 mm k-wires. Furthermore, it features a window at its tip to view the insertion site of the ACL. The tip features a pin to avoid the instrument slipping off the femoral condyle allowing at the same time for adjustment of the aimer's orientation.

The tip is blunt in order to facilitate the positioning on the ACL femoral insertion. The central k-wire (Ø2.4 mm) has to be drilled in the middle of the ACL femoral insertion site.

Femoral aimers with two different tip configurations are available: 35° and 50° inclinations. According to patient anatomy select the aimer that better enables targeting of the ACL femoral insertion site.





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To improve the femoral tunnel positioning and depending on surgeons preference, it is also possible to use an anteromedial femoral aimer before using the Medacta M-ARS dedicated femoral aimer.

2.3 FEMORAL DILATOR

The three parallel femoral holes are dilated using the femoral dilator. Three different sizes are available (Small, Medium and Large). Select the size according to the dimension of the sutured graft.

The femoral dilator is cannulated in order to slide on the central Ø2.4 mm k-wire placed previously.

The tip features a flat, chamfered design to create the rectangular femoral tunnel. To evaluate the femoral tunnel depth, the femoral dilator is graduated.



2.4 SLIDE HAMMER

The slide hammer features 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 dilator tip and the bone.



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

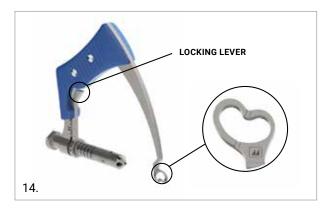


2.5 TIBIAL AIMER

The tibial aimer is used to create three parallel holes with a C-shaped pattern.

It consists of two different components:

- Aiming Arc (available in right and left configurations)
- Bullet, available in two sizes (Small and Medium)



The aiming arc tip features two pins which prevent the aimer tip from slipping or rotating on the tibial plateau. Moreover, a C-shape slot enables direct visualization of the tunnel footprint and orientation before its creation.

A locking lever allows the bullet to be advanced/locked in the desired position.

The aiming arc is set in a fixed configuration to ensure the correct C-shape drilling pattern orientation.

The bullet features a longitudinal slot which guarantees that no accidental disassembly can occur during usage.

2.6 SPECIAL K-WIRE

The special k-wire (Ref. 05.05.10.0032) features a diametric reduction in its proximal portion to be easily introduced into the tibial aimer bullet tip, preventing posterior slippage.

The tip of the wire protrudes approximately 2 mm from the tip of the bullet.



2.7 TIBIAL DILATOR

The tibial C-shaped hole is dilated using the tibial dilator. The size of the tibial dilator corresponds to the dimension of the graft. Three sizes are available (Small, Medium and Large).

To avoid incorrect orientation of the dilator during insertion, the head is introduced in the tibia with the help of two lateral guidewires (Ø2 mm, Ref. 05.05.10.0115). These wires are sliding freely along the dilator avoiding any possible condylar damage during dilation.

Tap the tibial dilator, the lateral wires will slide up the tibial tunnel until they are arthroscopically visible within the joint. As the lateral wires are automatically sliding back there is no risk of damaging the cartilage.



2.8 PULL SUTURE PLATE IMPACTOR

The impactor is used to impact the PSP implant at the entrance of the tibial tunnel. The tip design mimics the inner contour of the PSP implant. Use this instrument to ensure the appropriate extracortical fixation of the PSP in correspondence with the tibial tunnel.



3. GRAFT PREPARATION

3.1 SETTING THE GRAFT LENGTH

The graft path inside the bone consists of three different portions:

- Femoral tunnel (minimum length 30 mm)
- Intra-articular path (depending on joint anatomy, 20-35 mm)
- Tibial tunnel (minimum length 35 mm)

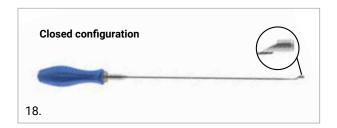
Depending on the length of the harvested graft, the following folding methods can be adopted:

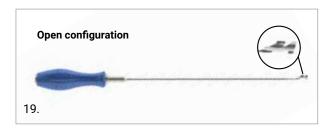
SOURCE	PREPARATION	MINIMUM RECOMMENDED LENGTH [cm]
Comitandinacus	3 Fold Preparation	18
Semitendinosus	4 Fold Preparation	24

3.2 EXTRACTION AND PREPARATION OF THE SEMITENDINOSUS

The semitendinosus is harvested using a tendon stripper. Depending on surgeon's preference, two different tendon stripper designs are available:

- Closed (Ref. 05.05.10.0023)
- Open (Ref. 05.05.10.0024)





The graft is harvested and cleaned on the plastic panel of the preparation board. The tendon is cut longitudinally up to its core following the direction of the tendon fibers.



Spread the tendon using the back end of a scalpel or using the leg of a tissue forceps.



A ribbon shaped structure is obtained (i.e., 1-2 mm thickness, 10-15 mm width).

3.3 GENERAL INFORMATION ABOUT GRAFT PREPARATION

The graft is prepared following these steps:

- The tendon is folded according to the length of the harvested tissue on the preparation table
- The tendon is fixed between the clamps. Alternatively, the tendon can be fixed only on one side and held at the opposite end using a Lahey Tissue Grasping Forceps (Ref. 05.05.10.0116)
- The tendon is sutured on both sides
- Two additional sutures are assembled with the extracortical femoral button for its insertion (pulling suture) and flipping (flipping suture)

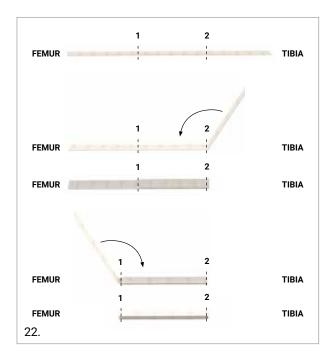
CAUTION

During the surgical procedure, after the graft has been harvested and prepared, it should be stored in a moist gauze while other surgical tasks are completed (e.g. meniscal pathologies or femoral and tibial tunnel creation).



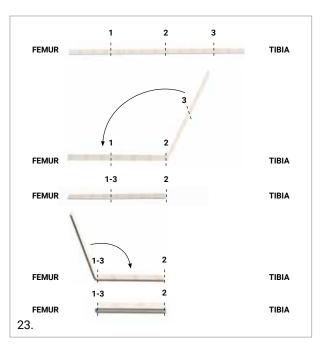
THREEFOLD PREPARATION

Divide the graft in three equal parts and then fold 1/3 of the graft from both sides towards the middle (image 22, line 1 and 2). The graft is tensioned and fixed on the preparation table. Suture each side using the preparation table as described in paragraph 3.4.



FOURFOLD PREPARATION

Divide the graft in four equal parts and then fold the graft twice in the middle (image 23).



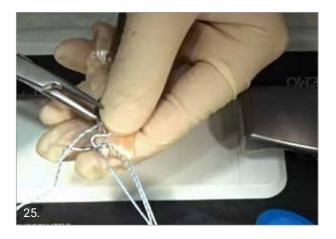
3.4 SUTURING OF THE GRAFT

FEMORAL SIDE

Suture the femoral side of the graft using two sutures (ideally a different colour for each side) as represented in paragraph 1.1. Suturing can eigther be performed by fixing the grat between the clamps or alternatively by fixing only one side and grabbing the opposite side using a Lahey Tissue Grasping Forceps (Ref. 05.05.10.0116), as represented in image 24.



With reference to the description in paragraph 1.1 (image 2) and to the following images, start the suturing on one side, obtaining free ends 1 and 2. Create at least three locked whipstitches starting approximately 2 mm from the femoral edge of the graft and moving distally (towards the tibial side).



Using an additional suture perform the same stitching pattern to suture the graft on the opposite side, obtaining free ends 3 and 4.



Be careful to suture only the lateral and not the central parts of the graft (as represented in image 27), otherwise the graft would naturally fold into a round structure.



Additionally, use each suture to perform central reinforcement (spiral seam) of the graft piercing only the upper portion of the tissue. The bottom portion should not be pierced.

Perform this central suturing piercing the graft from the opposite side towards the native one (i.e., with reference to image 2, the central reinforcement using the blue suture has to start from the right grey side moving towards the left blue one).



After suturing the graft, open the femoral clamp mouth, remove the clamp from the rail, turn it by 180 degrees and reinsert it as represented below. Insert the femoral implant within the dedicated support and move two of the sutures through the dedicated central holes creating the loop as represented in paragraph 1.1.



NOTE: examine if all the graft strands are properly tightened. Apply tension by pulling the femoral strands before fixing the femoral loop length. Fix the femoral loop length in accordance to paragraph 3.5. Perform at least five knots for each couple of sutures in order to fix the femoral loop.

TIBIAL SIDE

Perform the suturing using one suture for each side (using different coloured sutures). Perform 4-5 reinforcement stitches, as represented in the following images.

CAUTION

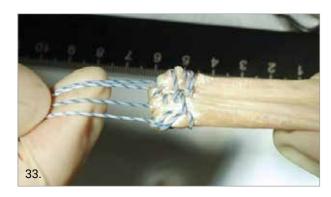
Be careful to suture only the lateral and not the central parts of the graft (as presented in the following images), otherwise the graft would naturally fold into a round structure. The reinforcement has to be performed under tension. Start from the proximal end.









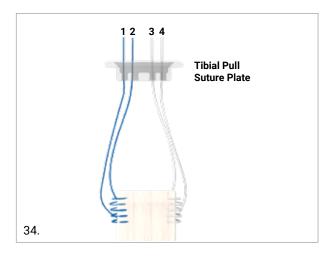


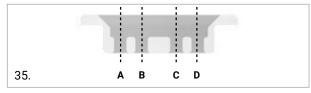
NOTE: this suture scheme allows a sutured graft that, if tensioned, naturally folds into a C-shape, facilitating the insertion within the created tunnel.

With reference to the description in paragraph 1.2 and to images 31-33, start the suturing on one side with one suture, obtaining free ends 1 and 2. Using an additional suture, suture the graft on the opposite side, obtaining free ends 3 and 4.

On the first reinforcement side of the graft (blue suture side in image 34), pass free end 1 through the lateral hole (A) of the implant and pass free end 2 through hole (B) of the implant avoiding cross over. On the second reinforcement side (grey suture side in image 34), pass free end 3 through the hole (C) of the implant and pass free end 4 through the lateral hole (D) of the implant avoiding cross over.

Once passed through the respective holes, tie suture 1 with 3 and 2 with 4, or 1 with 4 and 2 with 3. Use sutures of differing colours for each side of the graft, as represented.





3.5 FEMORAL BUTTON LOOP LENGTH

NOTE: this step has to be performed after the creation of the femoral tunnel.

To set the button loop length, deduct the graft in tunnel length (30 mm) from the total femoral tunnel length and add a flip path of at least 7 mm. For example:

- Total femoral tunnel length: 40 mm
- Graft in tunnel length: 30 mm
- Flip path: x mm

In this case, the button loop length has to be set at (40 mm - 30 mm + x mm).

If the button loop length is too long, it leads to a reduced contact between the graft and bone, affecting the stability of the reconstructed ACL.

To facilitate the evaluation of the button loop length, a loop sizer is available. Insert the device within the rail of the preparation board, between the graft clamps, keeping the instrument perpendicular to the rail. To evaluate the button loop length, insert the loop sizer within the rail of the preparation board by keeping the instrument perpendicular to the rail.

To fix the loop sizer rotate it counterclockwise (as represented in image 36). The device has to lie against the femoral button support.



3.6 GRAFT SIZE EVALUATION

The graft sizer has three slots for the evaluation of the sutured graft diameter. Each slot features an opening through which sutures coming from the graft can be passed. All the edges are rounded to avoid harming the tendon during usage.

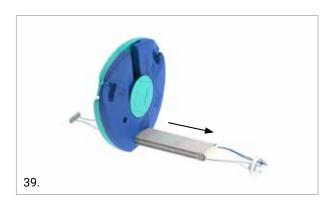


The instrument is designed with two components that can be rotated obtaining two working configurations:

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

With the graft tensioned in the preparation table, slide the sutures of the graft in open configuration in the graft sizer. Change now to the closed configuration and determine graft diameter (small, medium or large). When moving the device, a slight resistance should be felt.





Access graft diameter (small, medium or large) and use corresponding femoral and tibial dilator size.



4. FEMORAL TUNNEL CREATION

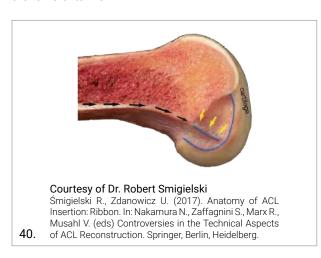
The femoral tunnel creation consists of two main steps.

4.1 K- WIRES POSITIONING

Perform this step with the knee at 110-120 degrees of flexion.

Select the appropriate femoral aimer and insert it through the anteromedial portal positioning the aimer tip on the ACL femoral insertion site. If desired, slightly hammer the proximal flat area of the aimer to strictly fix the pin at the tip into the bone, reducing the risk of instrument slipping during use.

NOTE: use the posterior cortical line (black arrows in image 40) as reference for the aimer positioning: the direct insertion of midsubstance fibers of the ACL (yellow arrows in image 40) is in line with the posterior femoral cortex. During surgery, this allows to double check the position of the femoral tunnel.





Insert the central k-wire in the central hole of the femoral aimer and drill it through the femur. The exit point of the k-wire represents the desired position of the Extracortical Femoral Button.

CAUTION

Pay attention to properly orientate the guide for a correct tunnel placement.

NOTE: if desired, before placing the aimer, mark the femoral ACL insertion site using a microfracture device (Ref. 05.05.10.0084).



Insert the central k-wire until the proximal laser marking is aligned with the entrance point of the femoral tunnel. Remove the aimer and verify if the k-wire is properly placed.



If desired, measure the length of the tunnel using the reverse length gauge (Ref. 05.05.10.0022). Insert the reverse length gauge on the distal portion of the central k-wire and slide the gauge until touching the cortical bone. (if necessary, make a small skin incision to facilitate instrument positioning). Evaluate the femoral tunnel length using the distal marking of the k-wire and the scale of the length gauge. Make sure that the proximal laser marking is still at the entrance point of the femoral tunnel.



CAUTION

Pay attention to the sharp k-wire tip when inserting the reverse length gauge on the k-wire.

Reinsert the femoral aimer on the protruding portion of the central k-wire and drill the two lateral shorter k-wires up to approximately 30 mm.



Remove the aimer from the joint and over drill the lateral k-wires with a \emptyset 4.5mm cannulated headed reamer to a depth of approximately 30mm (Ref. 05.05.10.0034). Check the depth of the hole using the scale marked on the reamer.



Remove the lateral k-wires and keep the central one in place.

4.2 FEMORAL DILATION

Create a femoral tunnel corresponding to previously measured graft diameter.

Insert the dilator along the central k-wire by tapping the back of the instrument using the hammer (Ref. 05.05.10.0050). Proceed slowly to avoid potential posterior blow out. Read the markings to create a socket of 30 mm. After the dilation, check absence of bony fragments in the canal. It is also necessary to ensure that the cortex has not been damaged and is suitable for the fixation of the button.

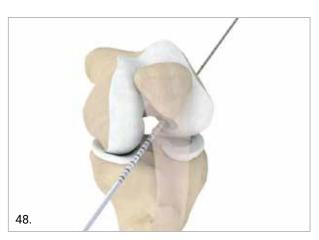


CAUTION

Carry out the dilation phase starting from the smallest dilator and then proceeding step by step increasing the instrument size (i.e., for a medium size graft, start dilating with size small and only then proceed with the medium size).

GRAFT SIZE	Small	Medium	Large
DILATOR SIZE	Small	Small + Medium	Small + Medium + Large

Remove the dilator and overdrill the central k-wire with a Ø4.5 mm cannulated headed reamer (Ref. 05.05.10.0034) until the extracortical cortical bone is reached.



The socket (rectangular cross section) with a central Ø4.5 mm tunnel has now been created. Remove the central k-wire.



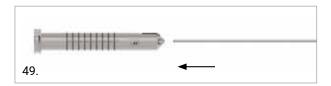
5. TIBIAL TUNNEL CREATION

The tibial tunnel creation consists of two main steps.

5.1 K- WIRES POSITIONING AND DRILLING

Load the special k-wire from the tip of the bullet (see black arrow in image 49). The tip of the special k-wire is protruding by approximately 2 mm out of the bullet tip).

NOTE: whilst handling the bullet, keep in mind that the special k-wire cannot slip out on the back part of the bullet but only in the front.



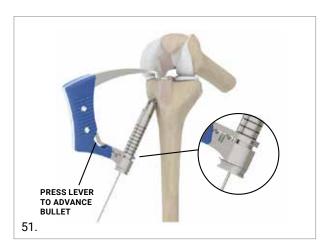
Insert the bullet into the aiming arc (see black arrow in image 50) aligning the bullet's longitudinal engraving with the black marking on the aimer (a). Then rotate the bullet clockwise (b) and insert by pressing the lever down (c). The arc is designed that no wrong orientation or accidental disassembly of tibial aimer can occur.



The tibial aimer tip is inserted through the anteromedial portal and is oriented targeting the ACL tibial insertion site (use the anterior horn of the lateral meniscus as a reference).

The bullet is advanced towards the tibia.

The length of the tibial tunnel can be evaluated using the scale marked on the bullet.



Drill the special k-wire, until the tip is visible within the joint. If the k-wire is not in the center of the tunnel footprint, check if the tibial aimer has been displaced. Repeat the previous steps until the k-wire is placed in the center of the C-shaped tip.

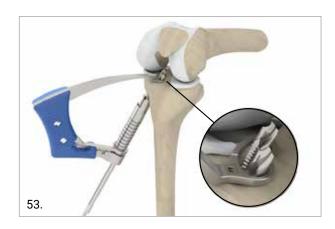
NOTE: the line engraved on the aimer tip indicates the correct position of the special k-wire. As represented in image 52, the special k-wire lies on the line marked on the tibial aimer tip.



Drill the first hole using the shorter Ø4.5 mm drill (Ref. 05.05.10.0051) until its tip is visible within the joint. Pay attention to not damage the femoral cartilage.

Leave the drill in place so that when working together with the central wire, aiming arc rotation is prevented.

Drill the second hole using the longer Ø4.5 mm drill (Ref. 05.05.10.0052) until its tip is visible in the joint.

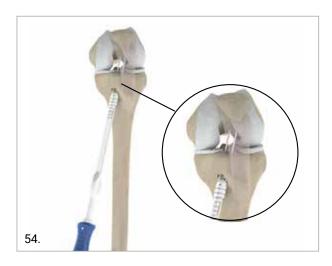


A C-shaped hole pattern is obtained.

Remove both drills, the bullet and the aimer. Do only keep the special k-wire in place and overdrill it with a Ø4.5mm cannulated headed reamer (Ref. 05.05.10.0034). Remove the special k-wire.

5.2 TIBIAL DILATION

Insert the two lateral guidewires (Ref. 05.05.10.0115) into the tibial dilator from its tip. The guidewires are advanced into the two lateral $\emptyset 4.5$ mm holes until they are visible within the joint, thereby avoiding incorrect alignment of the dilator during usage (the wires show the orientation of the dilator during the entire dilation procedure).



Insert the dilator in the tibia by tapping the back of its handle using a hammer (Ref. 05.05.10.0050).



CAUTION

Carry out the dilation phase starting from the smallest dilator and then proceeding step by step increasing the instrument size (i.e., for a medium size graft, start dilating with size small and only then proceed with the medium size).

NOTE: the bullet is available in two configurations for preparation of a Small or Medium C-shaped tunnel pattern. Follow the instructions listed below for Medium and Large size grafts (especially in case of a hard/sclerotic bone).

GRAFT SIZE	Small	Medium	Large
DILATOR SIZE	Small	Small + Medium	Small + Medium + Large





6. GRAFT INSERTION

In image 57, the femoral button is shown with the graft reinforcement scheme described in paragraph 3.4. Arrows 1 and 2 indicate specifically:

- Femoral button hole for pulling suture
- Femoral button hole for flipping suture

On the tibial side, the Pull Suture Plate (PSP) is represented with the suture path described in paragraph 1.2.

To facilitate handling and to avoid implant disassembly, clamp the sutures coming out from the PSP.

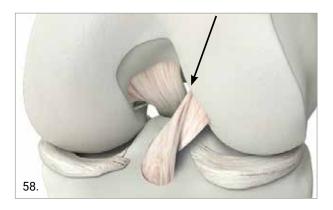


NOTE: use USP#2/EP5 for tilting and pulling sutures.

To better control the twisting of the graft in the joint during the insertion, it can be helpful to mark the posteromedial edge of the ligament with a marker. Both the pulling and the flipping sutures of the femoral button are inserted transtibially using a passing wire (Ref. 05.05.10.0030), with the knee in an extended position.

CAUTION

Once the femoral end of the graft is visible in the joint, in order to mimic the rotation of the cruciate ligament, the posteromedial portion of the graft is twisted anteriorly using a probe. The graft is twisted and at the same time pulled in the femoral tunnel by pulling on the pulling suture. This results in the anterior tibial portion of the graft coming into contact with the femur posteriorly (see arrow in image 58) mimicking the twisting of the anteromedial and posterolateral portions of the ACL in flexion.



Once the femoral button is outside the femoral tunnel, pull on the flipping suture to flip the femoral button. Pull the graft backwards providing counter tension to the entire construct. Check that the femoral button is in contact with the cortical bone and holds the graft firmly in place. The graft should remain at least 20 mm inside the femoral tunnel.

If the button loop length is too short and therefore the femoral button cannot be properly flipped, pull the graft out of the femoral tunnel and further dilate the femoral tunnel using the femoral dilator to create enough space to flip the button.

 $\label{eq:continuity} \mbox{Articulate the knee to improve the graft seating and tension.}$

NOTE: Check the correct alignment of the PSP in the tibial tunnel entrance to ensure proper accomodation of the button.

7. TIBIAL FIXATION WITH THE PULL SUTURE PLATE (PSP)

Approximate the PSP to the tibia.

NOTE: if desired, dilate the first portion of the bone using the largest dilator to better accommodate the tibial button.

Pull the suture until the PSP body is sunk into the tibial tunnel and its edges are seated on the tibial cortex.

Use the PSP impactor (Ref. 05.05.10.0025) to properly position the button.

Perform 4/5 knots to fix the implant. The tensioning/knotting phase should be performed in 30 degrees of flexion. Compare the mobility and stability of the knee with the contralateral one. Cycle the leg at least 20 times before the final fixation of the pull suture plate.

Knot the sutures coming from the PSP central holes with 5 knots. If desired, the knot can be pushed with a knot holder (not provided). The protruding threads should be cut 2-3 mm above the knots.

8. IMPLANTS AND INSTRUMENTS NOMENCLATURE

REF. NO.	DESCRIPTION	PICTURE
05.05.0001	Tibial Pull Suture Plate (PSP)	
05.05.0002	Extracortical Femoral Button	6000

REF. NO.	DESCRIPTION	PICTURE
05.05S.001	Sports medicine - Knee general tray – (1 level)	
05.05S.002	Sports medicine - M-ARS ACL tray - (2 levels)	77.00 7.30 7.30 7.30 7.30 7.30 7.30 7.30
05.058.004	Sports medicine - Knee prep. table tray – (1 level)	
05.05.10.0132	M-ARS ACL wires kit	
05.05.10.0084	Knee microfracture 60°	



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, EU 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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M-ARS ACL Surgical Technique

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