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1. TECHNICAL FEATURES

1.1 FAIRFIX ADJUSTABLE BUTTON SYSTEM



2. RECOMMENDED USE

2.1 INDICATIONS

The Medacta FairFix Adjustable Button is an implantable device indicated for knee ligament (i.e. ACL, PCL) reconstruction surgery for the fixation of a sutured graft with an extracortical suspensory device (adjustable button).

It consists of a metal button, an adjustable suture loop to be coupled with the graft, a pulling suture to pull the construct through the bone tunnel and a flipping suture to flip the button once the extracortical side has been reached.

The device is provided pre-assembled on a dedicated graft preparation card, aiming to facilitate implant-graft connection if used with a Medacta Preparation Table set.

The FairFix Adjustable Button Extender is intended to be used in association with the FairFix Adjustable Button in case of a cortical blowout or in revision surgery.

2.2 CONTRAINDICATIONS

- Any known allergy or hypersensitivity to implant materials (see IFU Ref 75.09.136). When sensitivity to a material is suspected, appropriate tests must be done to check that no sensitivity is detected prior to implantation.
- Insufficient bone quantity or quality. Note: The efficacy
 of the Medacta Adjustable Button implant is directly
 linked to the quality of the bone in which the implant is
 inserted.

- Insufficient blood supply and recent infections that could delay healing.
- Active infection.
- Conditions that limit the ability or willingness of the patient to slow down his/her activities or follow recommendations during the healing period.
- This medical device could be contraindicated for patients with insufficient bone density. Physicians must carefully evaluate bone quality before performing orthopedic surgery on patients who have not yet reached full skeletal maturity. The implant and fixation devices must not overlap, hinder or damage the growth plates.
- Do not use for surgeries other than those indicated.

2.3 SURGICAL APPROACH

The following hamstring tendon technique presents the steps of the In-Out technique for the ACL reconstruction with a FairFix Adjustable Button. The Medacta Adjustable Button can however also be used with other ligaments and tendons (autografts, allografts and synthetic tendons). It is the responsibility of the surgeon to verify the instrumentation compatibility. Other surgical approaches are possible and remain the choice of the surgeon.

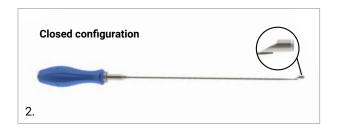


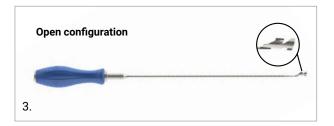
3. SOFT TISSUE ACL RECONSTRUCTION

3.1 GRAFT HARVEST AND PREPARATION

An incision is made over the insertion site of the semitendinosus and if needed also the gracilis tendon. The tendons are identified and whip-stitched. Make sure to free the tendons of any distal attachments that might cause early truncation of the tendons during harvesting.

Harvest with a Medacta Closed (Ref. 05.05.10.0023) or Open (Ref. 05.05.10.0024) Tendon Stripper the semitendinosus tendon alone or with the gracilis tendon. The tendon stripper is carefully advanced towards the musculotendinous junction. Firm counter-pressure is maintained while advancing the tendon stripper until the tendon is released from its muscular attachment.





The tendons are brought to the back table where they are inspected and stripped of any remaining muscle tissue. The ends of the tendons are now whip-stitched and the graft is sized to determine its diameter.

Mount the Suture Support (05.05.10.0014) on the Graft Clamp (05.05.10.0010) and position the graft preparation card on them, opening the clamp mouth. To fix the card, close the clamp mouth by rotating the clamp upper wheel.







Caution: ensure that the button lies against the suture support peg, as shown in the next image.



Pass the graft through all suture loops of the FairFix Adjustable Button. Do not remove the implant from the card at this stage.



Attention is now turned back to the femoral and tibial tunnel creation while the graft is being tensioned.

3.2 FEMORAL TUNNEL PREPARATION

Place the knee in flexion and use either a Medacta Anteromedial Femoral Aimer (Ref. 05.05.10.0085 or Ref. 05.05.10.0086) or a Medacta Transtibial Femoral Aimer (Ref. 05.05.10.0057 or Ref. 05.05.10.0058) to position the femoral tunnel. Use a 2.4 mm k-wire to orient the femoral passing tunnel.

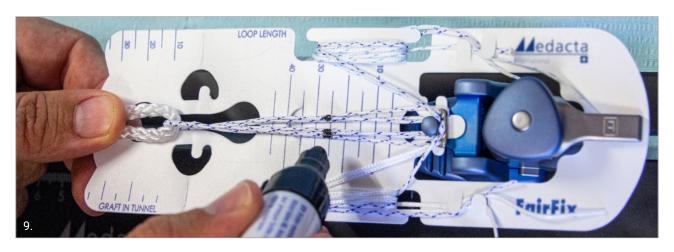
Then use two diameters of reamers to produce the femoral tunnel: a Ø4.5 mm cortical tunnel for passing the implant through the tunnel and the femoral socket corresponding to the graft diameter.

Note: a disposable cortical reamer pin (05.05.10.0135), with dedicated reusable Anteromedial Femoral Aimers

(Ref. 05.05.10.0136 or Ref. 05.05.10.0137), is available to create the 4.5mm tunnel in a single step. The pin is graduated, allowing for tunnel length evaluation by hooking the instrument tip on the cortex after drilling and can be over-drilled to create the socket according to graft diameter.

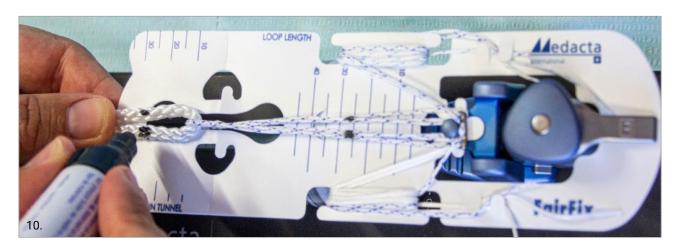
Alternatively measure the total trans-osseous femoral tunnel length by using the Medacta standard depth gauge (05.05.10.0021) or the Medacta reverse length gauge (05.05.10.0022).

Once you know your total transosseous femoral length, you can mark your suture loops at the corresponding depth as a visual cue as to when the button is expected to flip.



Ream a femoral socket corresponding to graft diameter up to the desired length and mark the graft accordingly. Mark

the graft according to the socket depth. When this mark is flush with the tunnel aperture, the graft has completely filled the socket.



Use a passing wire to introduce a looped free suture through the femoral tunnel that will be used to shuttle the graft into the femoral socket later in the procedure. Pass all the implant threads through the suture loop. Tension all the threads by using the suture loop and use the blue pulling suture to pull the button through the external cortical surface.

Flip the button by pulling the white flipping suture. Apply counter tension on distal graft tails and maintain counter tension throughout button flipping process.

Pull alternately on the white/blue suture tail until the implant is locked into place. Firmly pull on the distal to confirm the button is properly seated on the cortex.



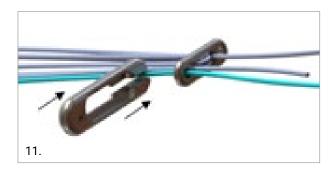
Cut the white/blue suture with the cutting pliers. Remove the blue and the white sutures by pulling on either end.

Note: The graft can be fully inserted into the femur or left partially inserted until tibial passing is complete, so you can retension the graft after tibial fixation.

CAUTION

Always counter tension the graft on the tibial side, this is to minimize risk of the button passing through the Iliotibial (IT) Band and keep it flush to the femoral cortex.

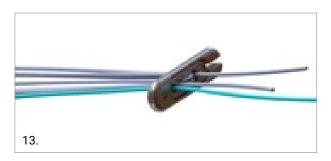
Note: In case of accidental cortical blowout or revision case, with a tunnel diameter bigger than 6mm, the FairFix Adjustable Button Extender can be used to create a larger footprint. The FairFix button fits into the recessed section of the Extender, maximizing button-to-bone contact against the cortex



Remove the white flipping suture from the FairFix Button and slide the Extender over the remaining sutures (Suture Loop and Pulling Suture).



Move the Extender towards the FairFix Button.



Recessed area allows the Fairfix Button to completely fit in the Extender.

3.3 TIBIAL TUNNEL PREPARATION

To position the tibial tunnel, use the Medacta Tibial Guide (Ref. 05.05.10.0073 and Ref. 05.05.10.0074).

Adjust the angle of the guide depending on the graft length. Use a 2.4 mm drill pin to create an anatomic tibial tunnel.



Over-ream the 2.4 mm drill pin with an appropriately sized tibial reamer matching the graft diameter.

Either use a FairFix Adjustable Button coupled with a FairFix Extender (according to §3.2) for your tibial fixation or alternatively, with the knee fully extended or slightly flexed, insert a Medacta MectaScrew Interference Screw on the lateral side.



Note: Depending on surgeon preference cycle the knee several times to remove excess laxity and do not forget to retension the graft on the femoral side

Make sure the knee can be flexed, then use the cutting pliers to cut excess sutures.

4. REFERENCES AND SIZES

REF. NO.	DESCRIPTION	PICTURE
05.05.0091	FairFix Adjustable Button	
05.05.0092	FairFix Adjustable Button Extender	



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 \emptyset 1.1 mm Nitinol guidewires.

REF. NO.	DESCRIPTION	PICTURE
05.05\$.001	Sports Medicine - Knee General Tray	
05.05S.004	Sports Medicine - Knee Preparation Table Tray	
05.05\$.003	MectaACL SB Tray Transtibial Approach & Cannulated Screwdrivers	
05.05\$.005	MectaACL SB Anteromedial Approach & Cannulated Screwdrivers	
05.05\$.006	MectaACL SB Tray Anteromedial Approach & NonCannulated Screwdrivers	[
05.05\$.007	MectaACL SB Tray Transtibial Approach & NonCannulated Screwdrivers	[]]]] [] [] [] [] [] [] [] [
05.05\$.011	MectaACL SB Tray Anteromedial Approach & Cannulated Screwdrivers, w/o dilators	
05.058.012	MectaACL SB Tray Anteromedial Approach & NonCannulated Screwdrivers, w/o dilators	
05.05\$.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.018	Sports Med – Cannulated tibial reamer	
05.05S.008	Cannulated Headed Reamers Tray	
05.05.10.0133	Ligament reconstruction wires kit	

REF. NO.	DESCRIPTION	PICTURE
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	
05.05.10.0135	Ø4.5mm cortical reamer pin	
05.05.10.0136	Femoral Aimer AM Ø7-8 for cortical reamer pin	19191919
05.05.10.0137	Femoral Aimer AM Ø9-10 for cortical reamer pin	(19)



Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It 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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This document is not intended for the US market.

Please verify approval of the devices described in this document with your local Medacta representative.

FairFix Adjustable Button Medacta Anchors Surgical Technique

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