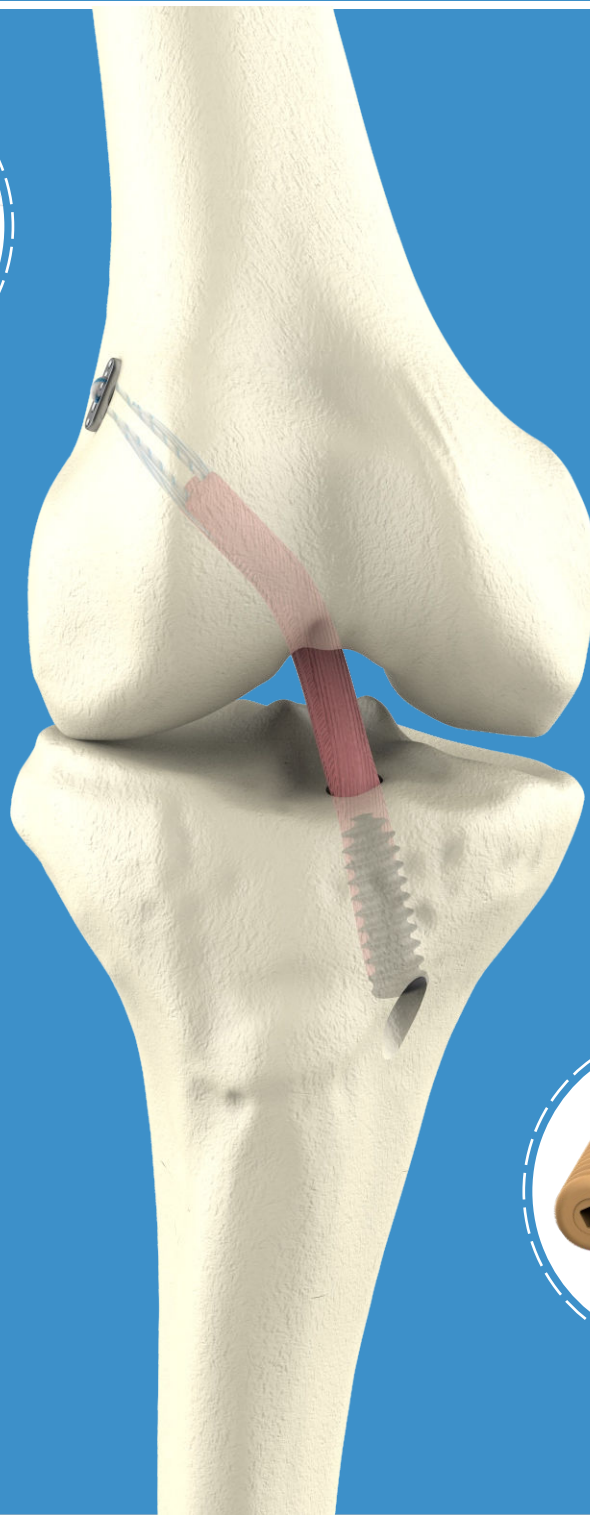
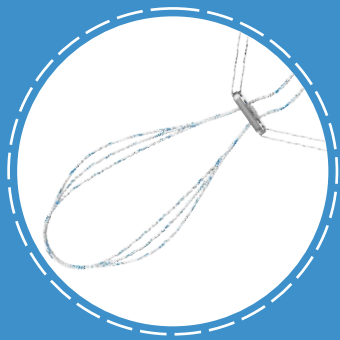


Surgical Technique

ACL Reconstruction using AUXILOCK[®] GFS Ultimate and
AUXILOCK[®] Interference Screw



About us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 80 countries worldwide.

Achievements

- US FDA 510K Cleared (Arthroscopy | Spine | Nailing | Locking Plates | Screws)
- EC Certificate - Class IIa & IIb
- ISO 13485:2016
- India FDA Approved
- India MDR 2017



80+
Countries
Covered



150+
Distributors
Network



1200+
Implants
Range



20M+
Patients
Treated



Disclaimer

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This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit www.auxein.com for additional product information.

Auxein Medical does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Animations and virtual reality are provided as a visual guide based on surgical techniques; a written copy of the surgical technique is available at www.auxein.com or from your local representative. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

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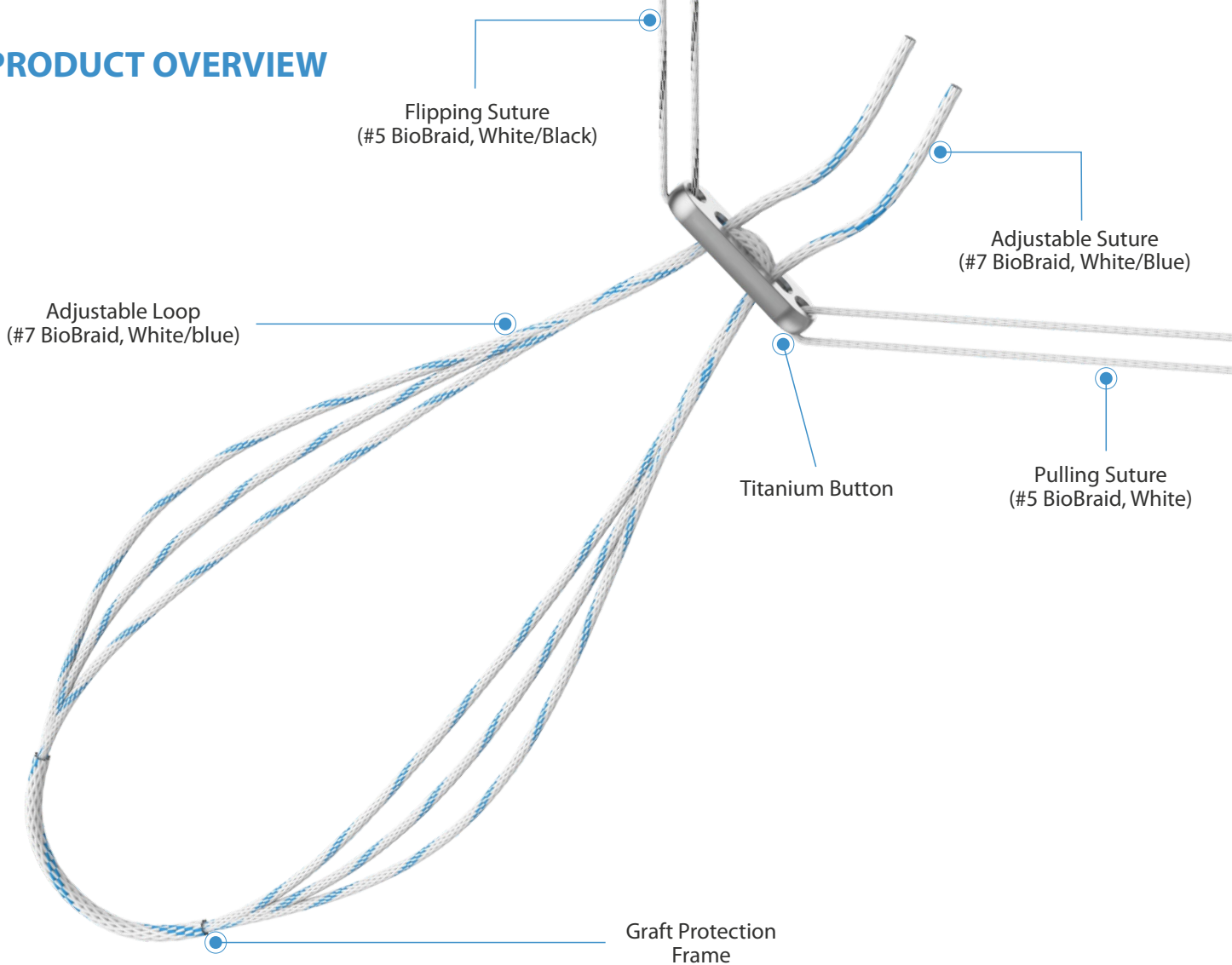


Organised by:  **Auxein**

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PRODUCT OVERVIEW



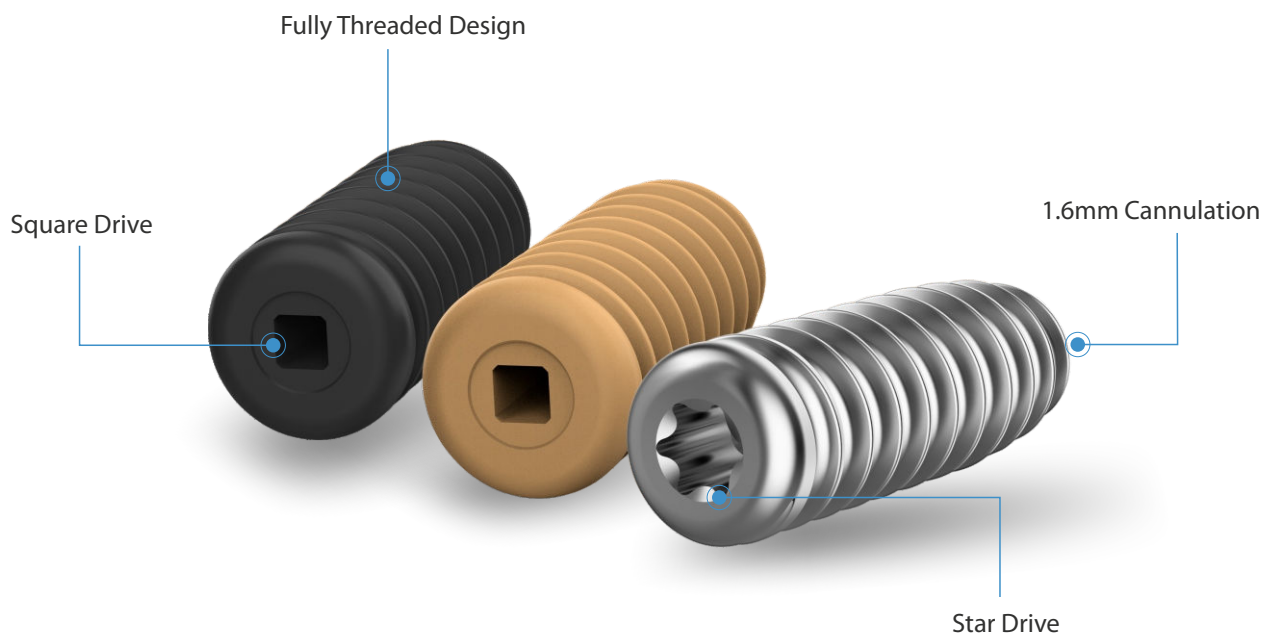
GFS Ultimate Mini is an adjustable loop with an oblong shaped titanium button used for Cruciate Graft Reconstructions. GFS Ultimate provides a double locking mechanism which eliminates the need for knot tying. GFS Ultimate Mini provides three sutures (UHMWPE):

Adjustable Suture (#7, White/Blue): It allows the surgeon to maximize the amount of graft inside the femoral tunnel, thereby optimizing the healing process. It also enables calibration of the loop to its optimum size.

Pulling Suture (#5, White): It is available to pull the graft inside the tunnel.

Flipping Suture (#5, White/Black): It ensures the flipping of the button.

GFS Ultimate Mini



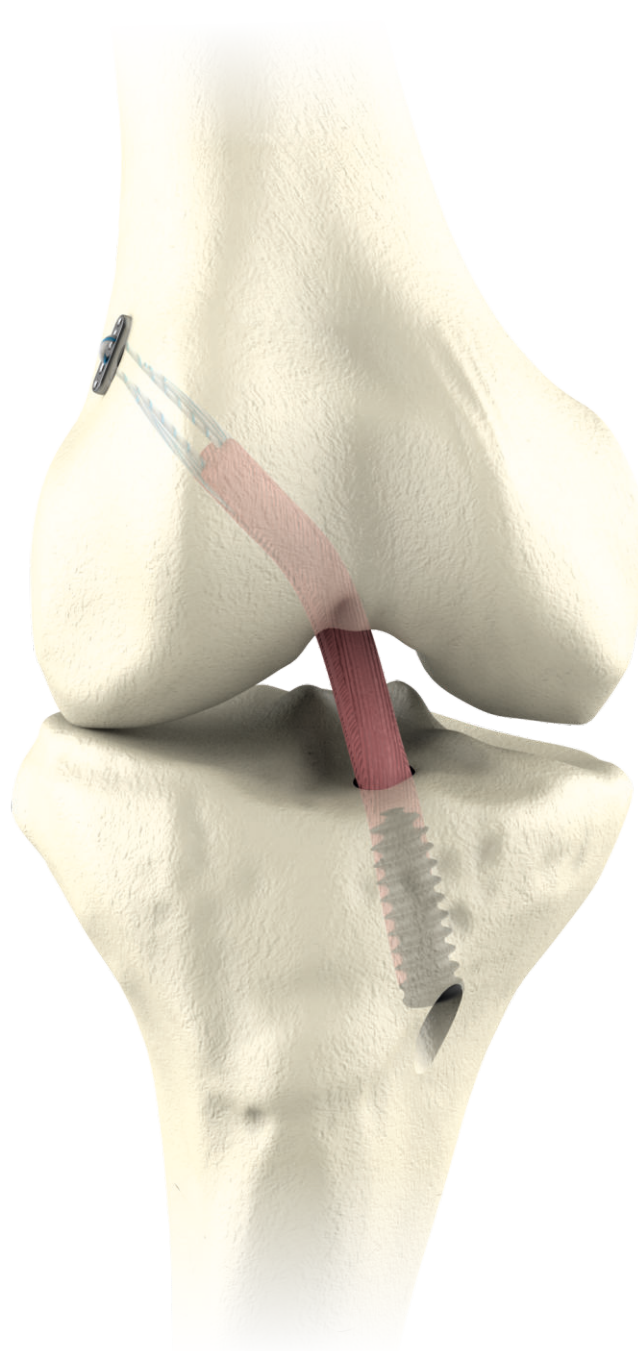
The Interference Screws are available in Titanium, PEEK OPTIMA and PEEK CF. The Interference Screw has a fully threaded design which provides strong mechanical fixation for both bone tendon bone (BTB) and soft tissue grafts. Being a cannulated screw, it is used with a guide wire and a cannulated screw driver. It is available in diameter ranging from 7mm to 12mm. The PEEK OPTIMA and PEEK CF are renowned for their radiolucent properties, less imaging artefact and for being MR safe. Both interference screws offer revision ability of an absorbable screw.

Diameter in mm	Length in mm (Polymer)	Length in mm (Ti)
7	20, 25, 30	20, 25, 30, 35
8, 9	20, 25, 30, 35	20, 25, 30, 35
10, 11, 12	25, 30, 35	25, 30, 35

INDICATION

The AUXILOCK[®] GFS Ultimate Mini is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

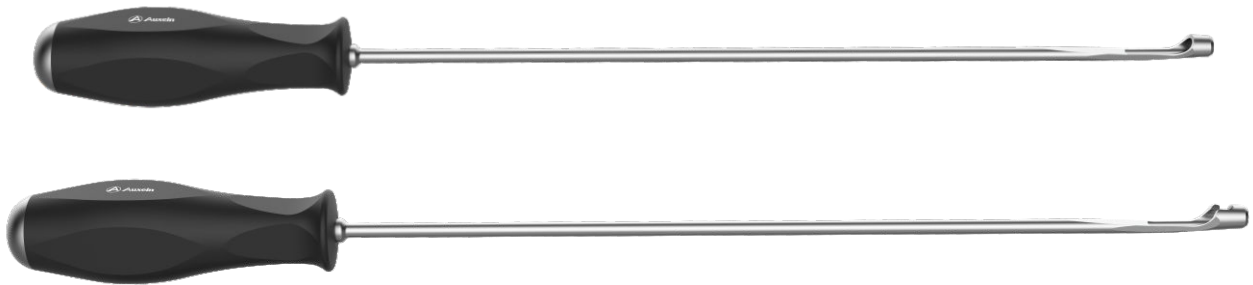
The AUXILOCK[®] Interference Screws are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.



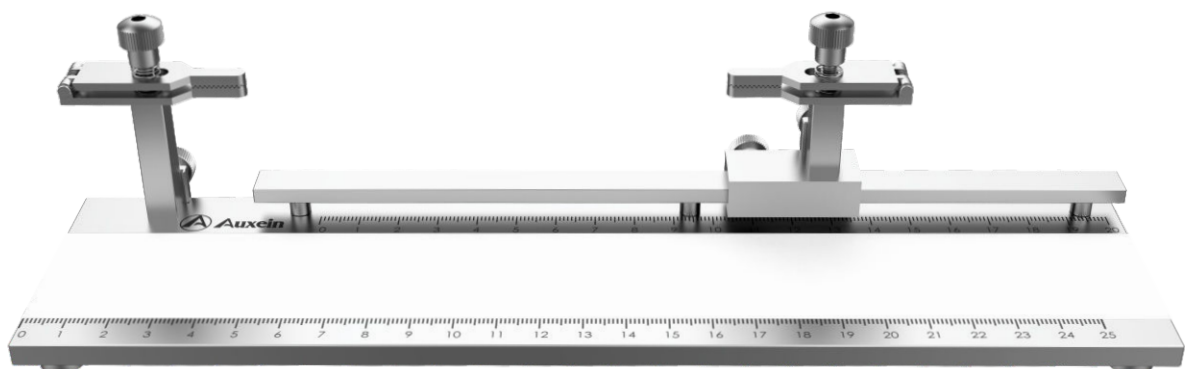
SURGICAL TECHNIQUE

Graft Harvest and Preparation

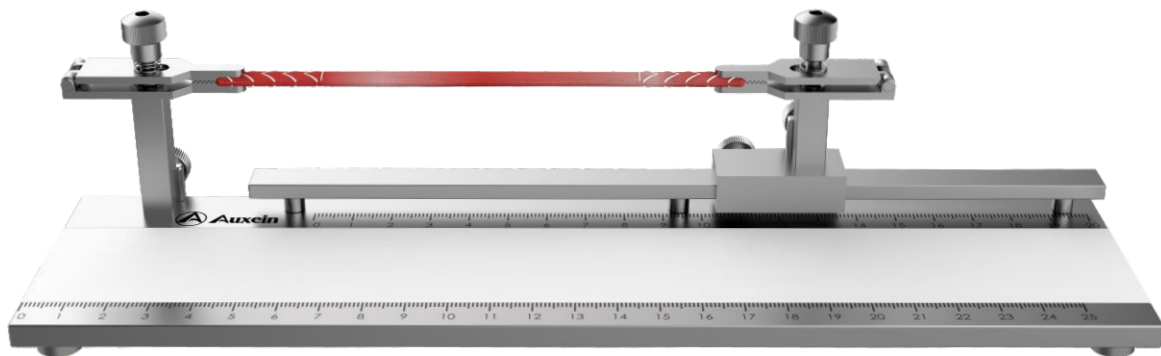
Harvest desired tendons using tendon stripper (Open end/Closed end) (7-014-48, 7-014-49, 7-014-50, 7-014-51, 7-014-52, 7-014-53). Put the tendons on the graft station (7-017-01, 7-017-02, 7-017-03, 7-017-04, 7-017-05, 7-017-06) where residual muscle is removed.



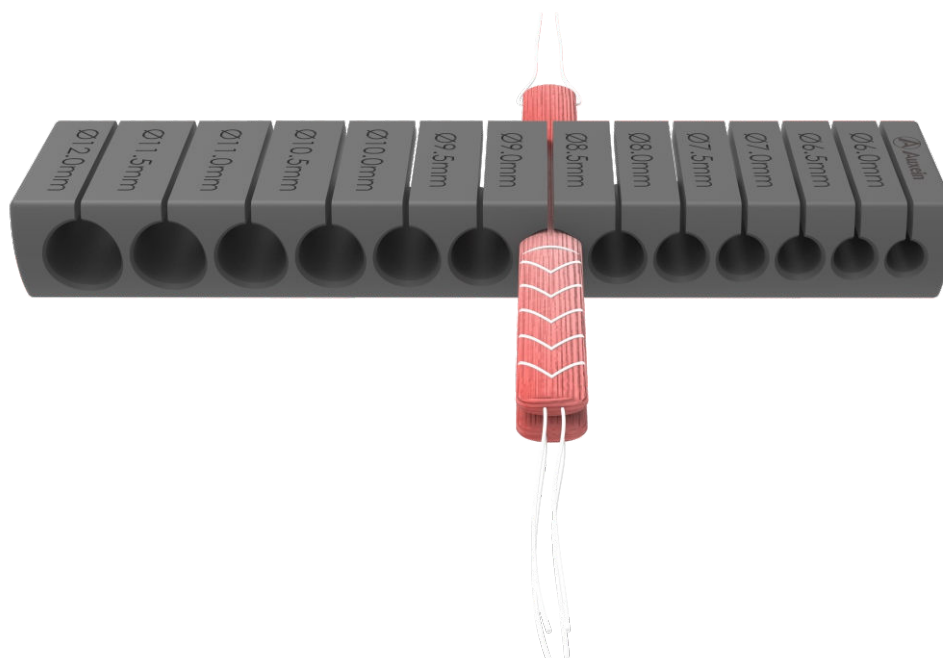
Assemble graft grasper clamps (7-017-03, 7-017-04), sliding base (7-017-02) and the graft station together.



Whip-stitch end of the graft using BioBraid sutures or BioBraid infinity loop with needles. Make sure the graft is in good tension by adjusting the clamp. The graft should be covered by a moist sponge.



Fold up the graft and measure the diameter using the Graft sizer (7-014-54). The graft should moderately pass through the hole, not too tightly not too loosely.



Femoral Tunnel Preparation

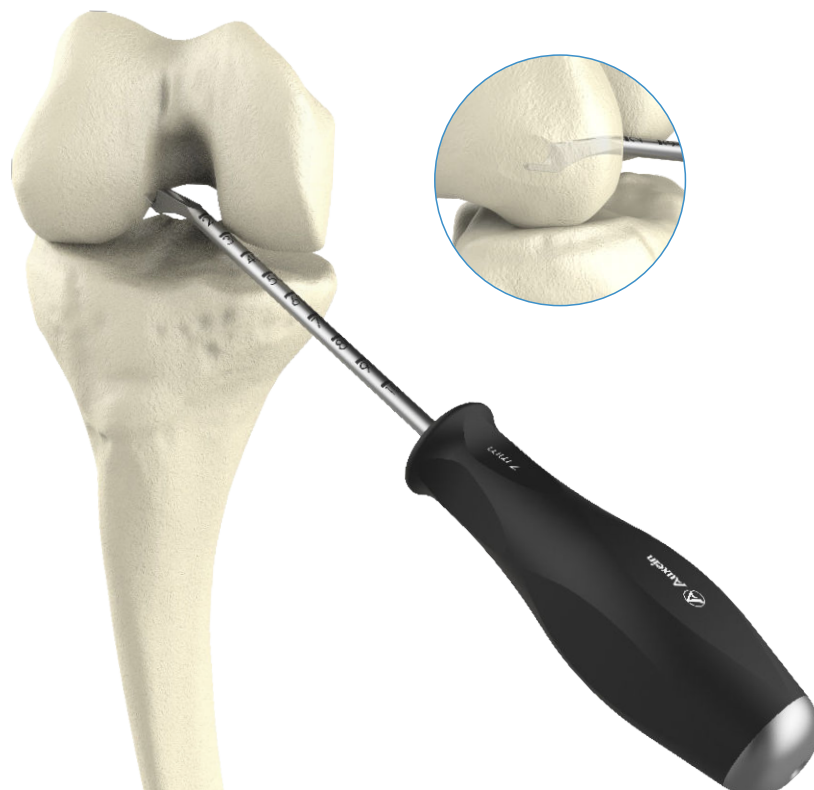
Select the appropriate size of the Femoral Offset Guide (7-014-01, 7-014-02, 7-014-03) Auxein provides Femoral Guide with different offsets (5/6/7mm). Always ensure that enough posterior cortex (at least 2mm) remains.

Femoral Offset Guide size = Radius of the tunnel + 2mm posterior cortex.

(E.g. If Femoral tunnel diameter is 8 mm, Femoral Offset Guide = 4 + 2 = 6mm)



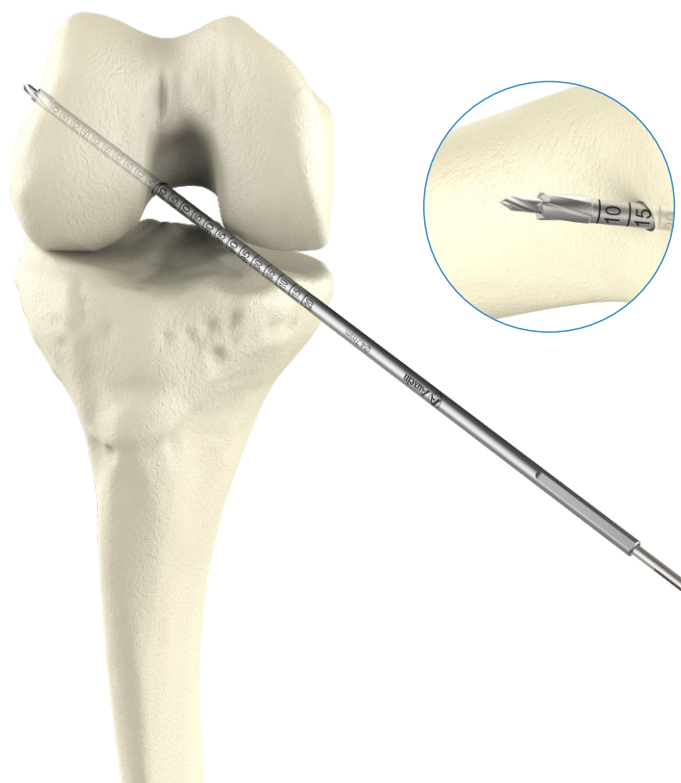
Insert Transportal Femoral Offset Guide through anteromedial portal. Place the hook of the Femoral Offset Guide at the over-the-top position, in direct contact with the bony cortex. For ideal position of the footprint of ACL, use 10–11 o'clock in the right knee or 1–2 o'clock in the left knee as the reference.



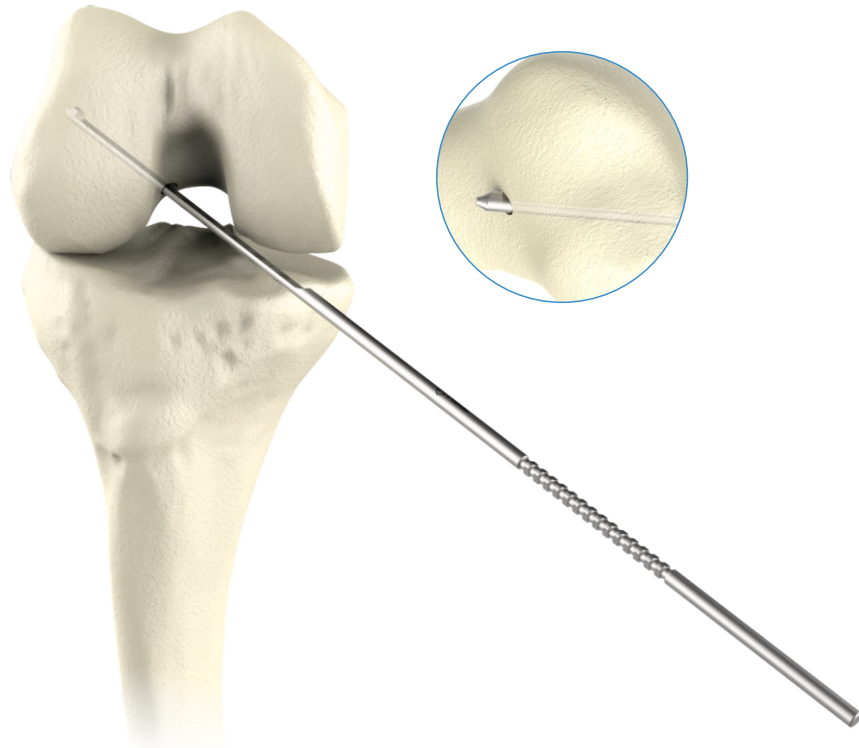
Use the Pin, Drill Tip, Ø2.4mm (7-014-66, 7-014-67) to drill through the femur and penetrate the skin.



An Cannulated Headed Reamer, Ø4.7mm (7-014-06) is used over Drill Tip pin to make the femur passing tunnel.



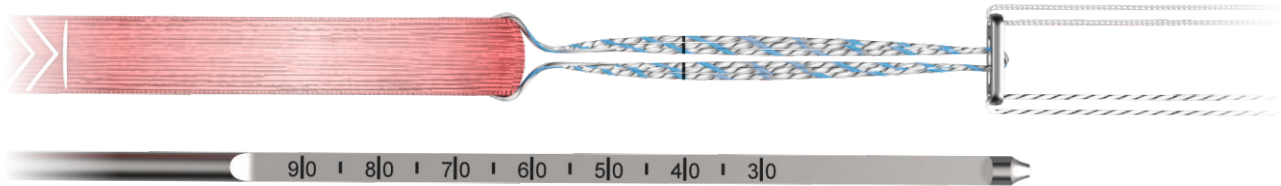
Measure the total length of passing tunnel using the Depth Gauge for Knee ACL/PCL Instrument (7-014-44).



Pass graft through the loop of GFS Ultimate.

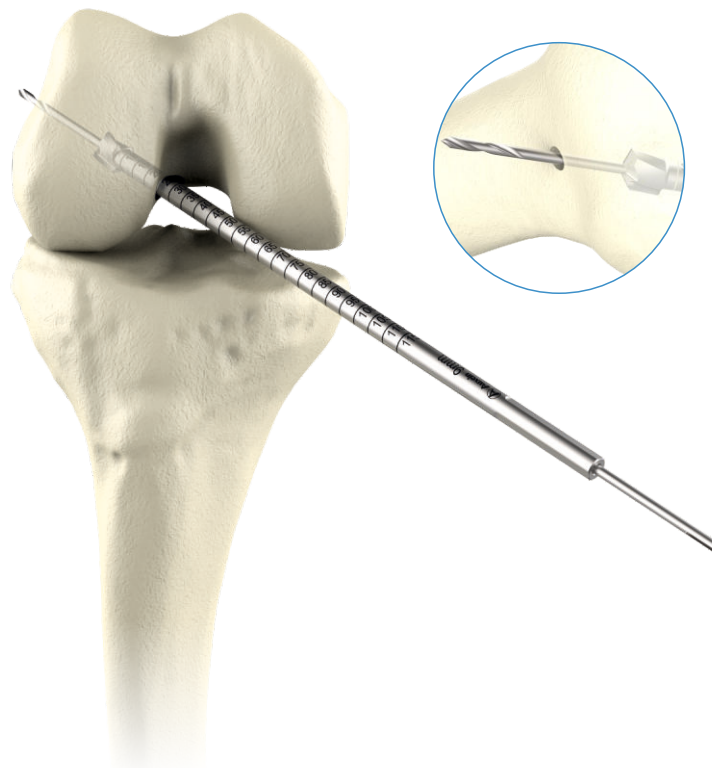


Mark the loop of GFS Ultimate according to the total femoral tunnel length. This mark signals when the button is ready to be flipped.



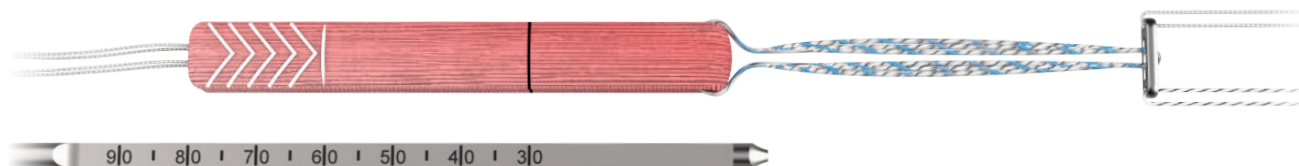
Select the appropriate sized Femoral Cannulated Reamer (7-014-20 to 7-014-32) over the Drill Tip pin that corresponds to the graft size needed to create the femoral tunnel. Then remove Femoral Cannulated Reamer, Drill Tip pin is left in place.

Note: Any breach of the cortical bone of femur creating a hole larger than that created by an appropriately sized headed reamer may compromise the fixation. If the distal cortex of the femur is breached, use of GFS Ultimate Large Device (Button Dimensions: L 16.5mm X W 3.9mm X H 1.5mm) may be required.



Mark a line on the graft (From distal of the loop of GFS Ultimate) according to the socket depth. When this mark is flush with the tunnel aperture, the graft has completely filled the socket.

Tip: Mark the graft 5.0mm shorter than the socket depth. When this mark reaches the tunnel aperture, you can stop tensioning. The 5.0mm is left for tension post tibial fixation. Insert your tibial screw and then tension the graft the rest of the 5.0mm to get the perfect tension on the graft.



Tibial Tunnel Preparation

Assemble the ACL tibial drill guide (Drill Guide Handle, 7-014-33, ACL Tip/ ACL Tip O, 7-014-38, 7-014-37, ACL Tip C Aimer 7-014-35, 7-014-36 and ACL Elbow Aimer 7-014-99).

Fix the angle on Drill Guide Handle (To achieve a longer tibial tunnel, increase the angle of Drill guide handle).

Place the tip of drill guide in the centre of ACL footprint.



Use the Dia. 2.4mm Passing pin (7-014-68) to drill through the tibia. (Monitor the passing pin not to damage the femoral cartilage).

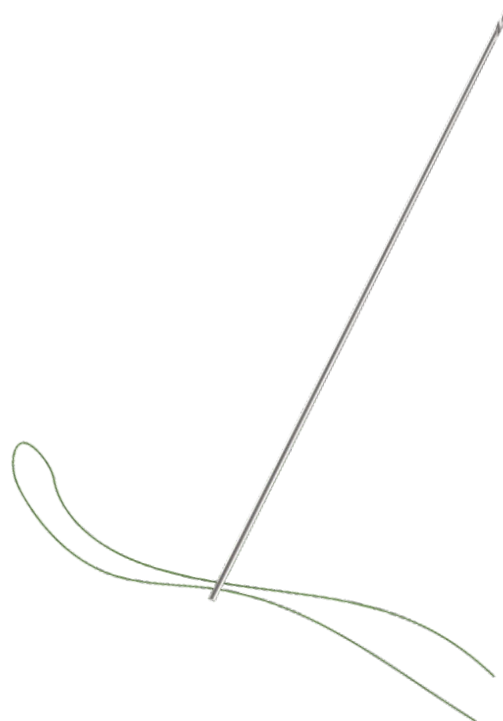
Disassemble the tibial drill guide. Leave only the Passing pin in place.

Drill the tibial tunnel using the corresponding Tibial Cannulated Reamer (7-014-07 to 7-014-19) that matches the graft diameter.

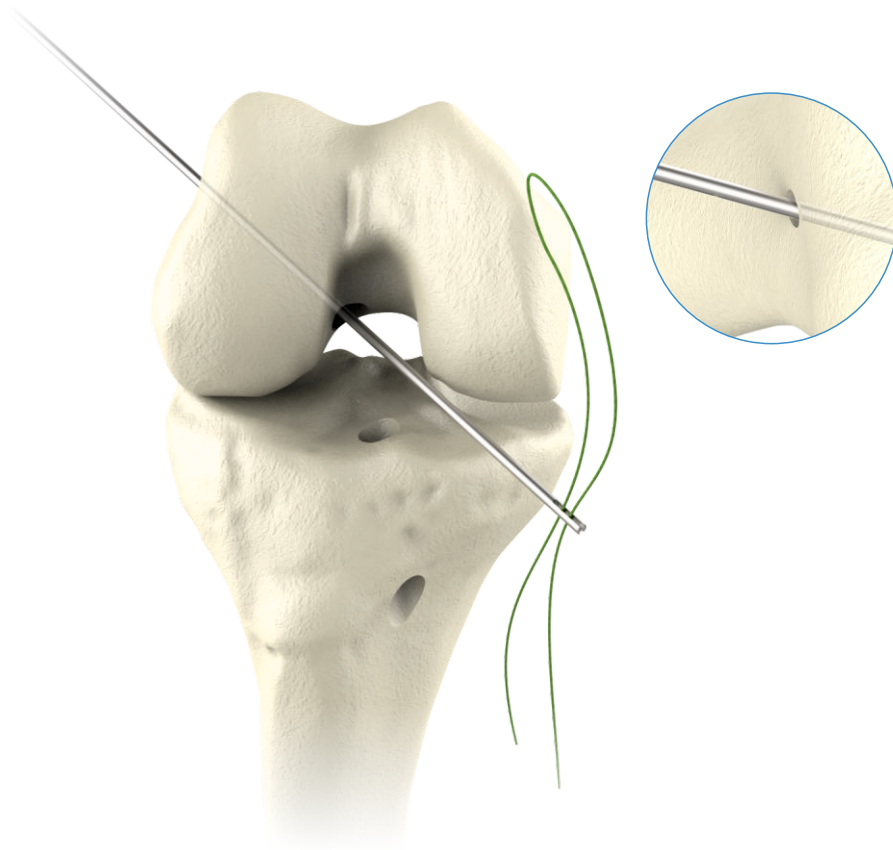


Femoral Fixation

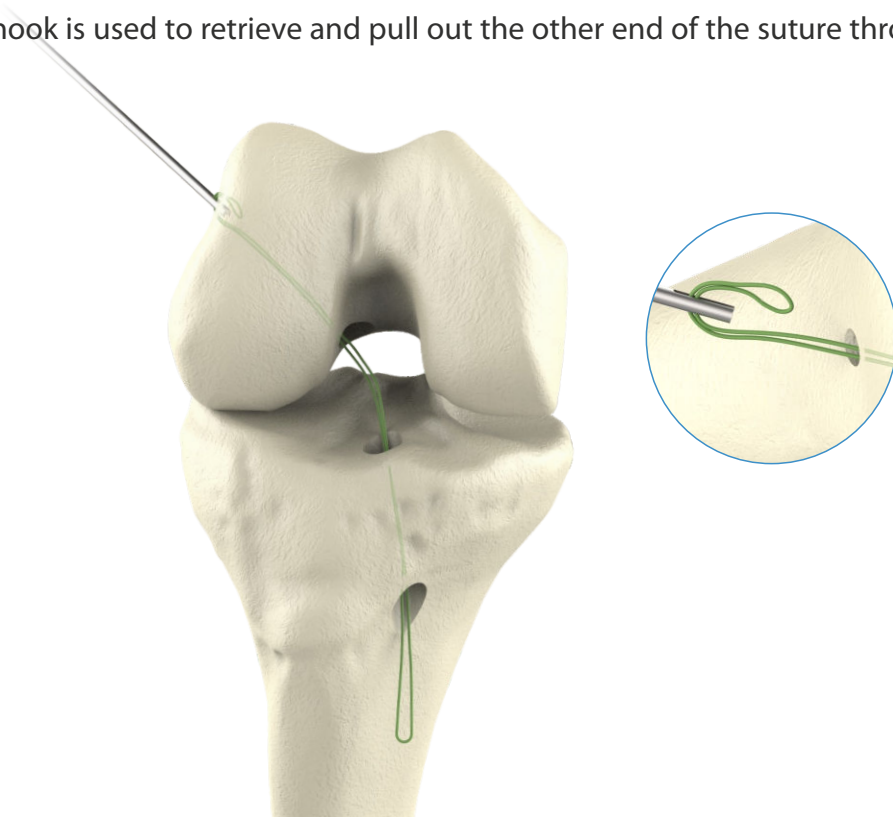
Load a #2 or #5 polyester suture as the passing suture through the eyelet of the Ø2.4mm Drill Tip pin.



Pull the pin through the femoral tunnel. Pass one end of the suture out of the knee joint via femoral tunnel and leave another end of the suture in the knee joint.



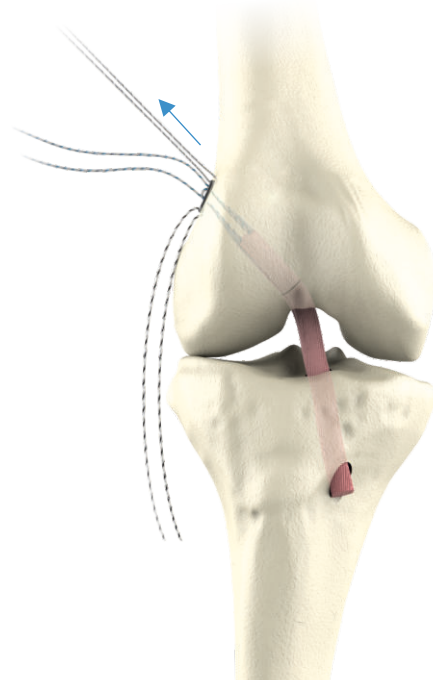
A suture retriever/hook is used to retrieve and pull out the other end of the suture through the tibial tunnel.



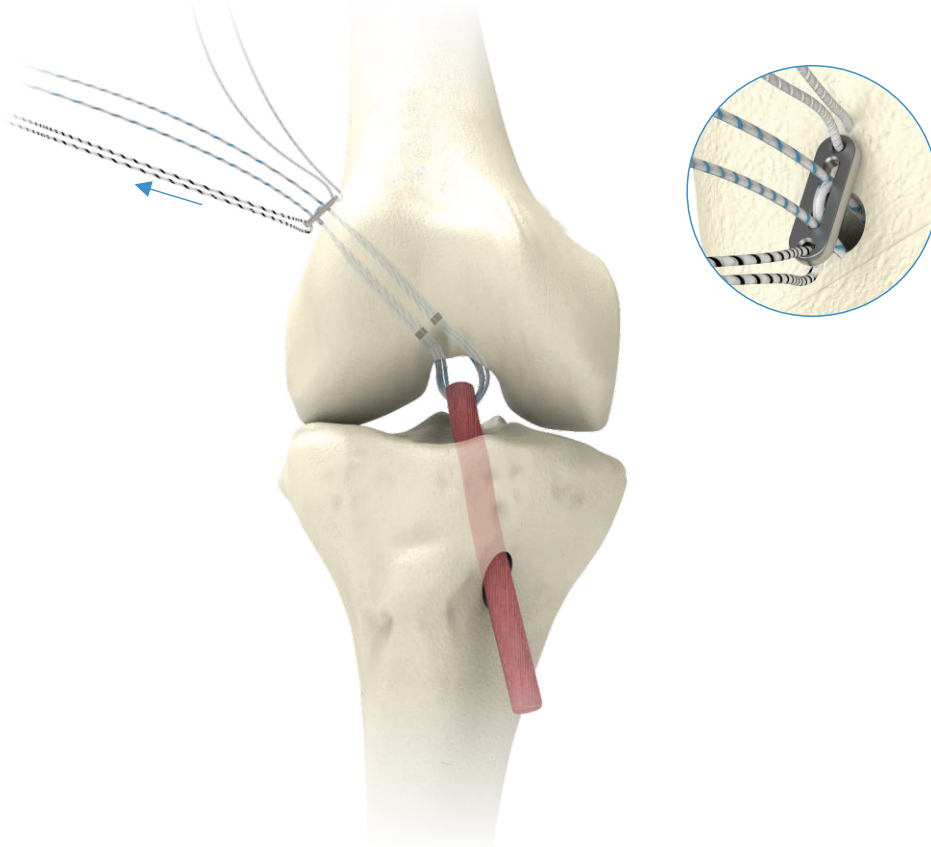
Load all the sutures (Pulling, Flipping and Adjustable) of GFS Ultimate loop on the passing suture. Pull the passing sutures to pull all the sutures of GFS Ultimate on lateral side. Then remove the passing suture.



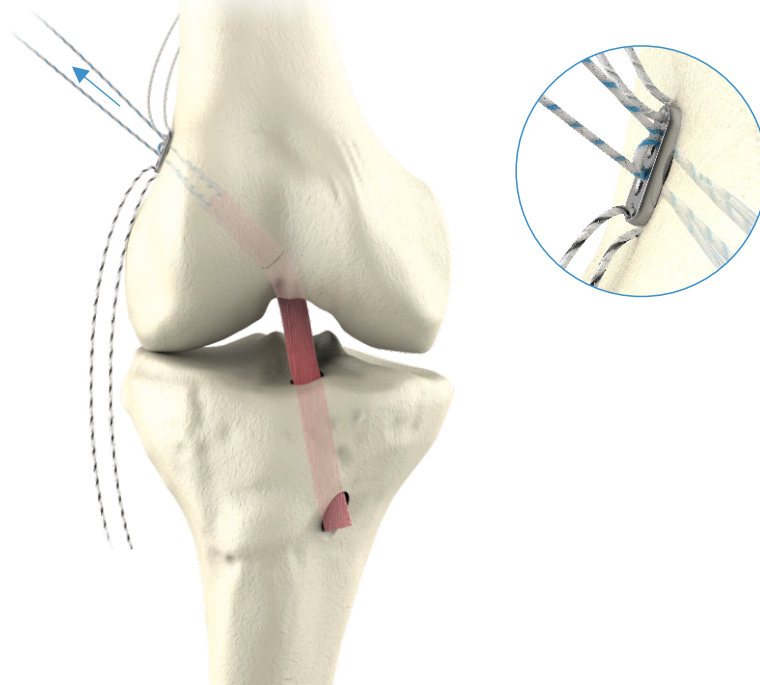
Pull the pulling suture (White) of GFS Ultimate first to advance the ACL graft into femoral tunnel until the marking line on the loop reaches the internal femoral aperture.



Pull the flipping suture (White/Black) to flip the button on lateral cortex. Then pull back the graft to lock the button to the femoral cortex



Then pull the flipping suture (White/Black) to flip the button on lateral cortex. Then pull back the graft to lock the button to the femoral cortex.



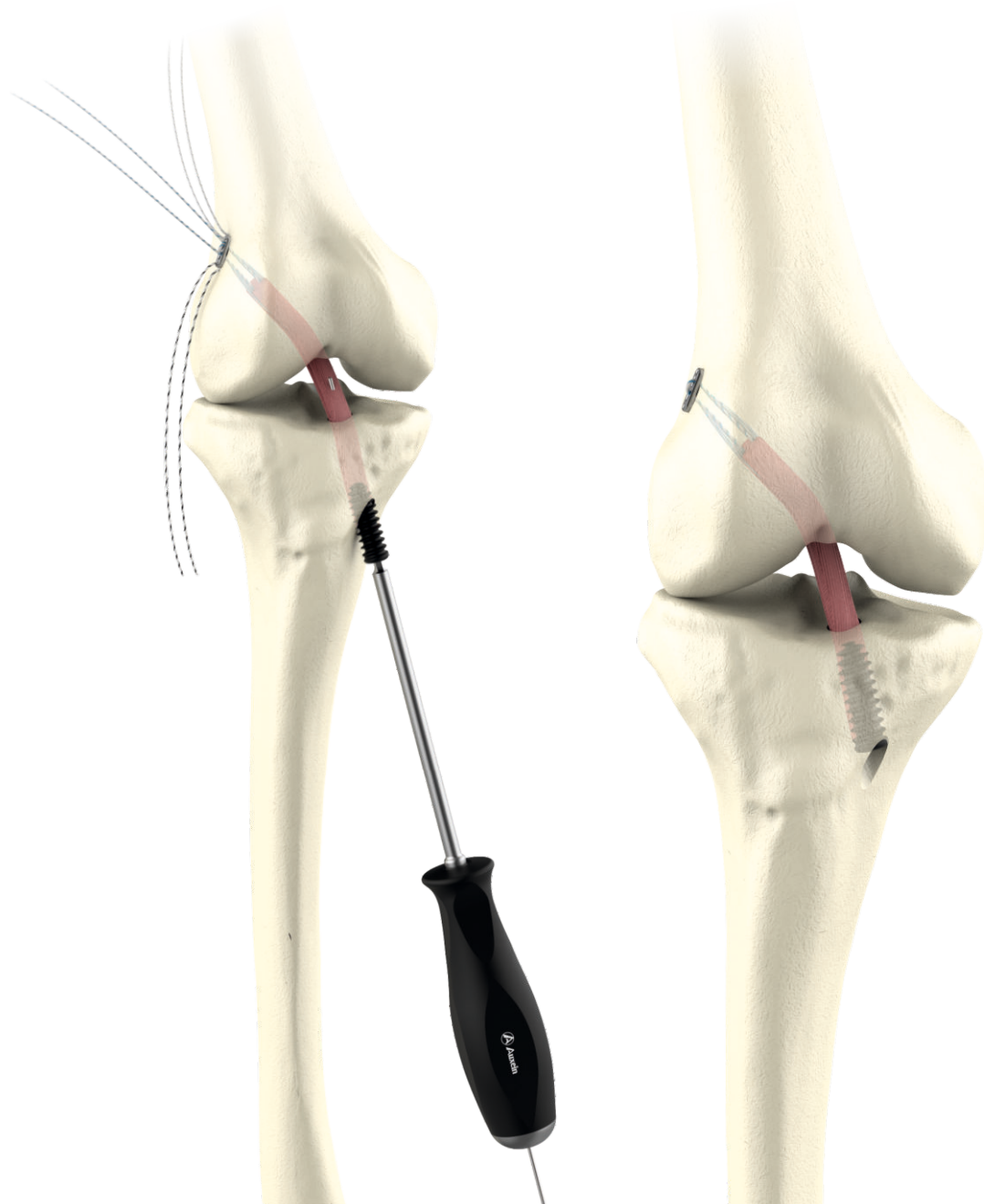
Tibial Fixation

Advance Nitinol Guide Wire Ø1.2mm x Length 400mm (7-014-43) into tibial tunnel. Insert interference screw with the cannulated screwdriver (7-014-04, 7-014-05) (match screwdriver with the interference screw) over the guide wire. Insert the screw up to the tibial plateau, but ensure that the screw tip remains completely inside the bone.

Re-tension the adjustable suture of GFS ultimate to get perfect tension on the graft.

Cut off the excess graft outside the tibial tunnel.

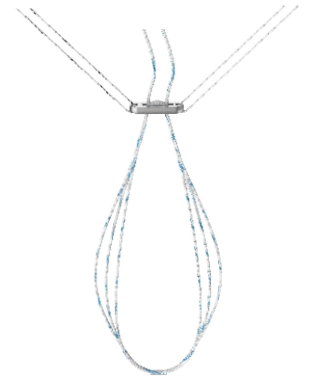
Remove both pulling and flipping suture on femur side by just pulling it. Cut off the adjustment suture with the help of scissors or suture cutter.



ORDERING INFORMATION

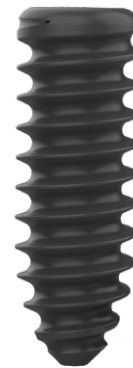
GFS Ultimate Mini

Code	Product Description
6-006-01	AUXILOCK® GFS Ultimate Mini Button, Button L: 12mm, W: 3.9mm (Adjustable Loop)
6-006-02	AUXILOCK® GFS Ultimate Large Button, Button L: 16.5mm, W: 3.9mm (Adjustable Loop)



PEEK CF Interference Screw

Code	Product Description
6-009-01	AUXILOCK® 7mm x 20mm PEEK CF Interference Screw
6-009-02	AUXILOCK® 7mm x 25mm PEEK CF Interference Screw
6-009-03	AUXILOCK® 7mm x 30mm PEEK CF Interference Screw
6-009-04	AUXILOCK® 8mm x 20mm PEEK CF Interference Screw
6-009-05	AUXILOCK® 8mm x 25mm PEEK CF Interference Screw
6-009-06	AUXILOCK® 8mm x 30mm PEEK CF Interference Screw
6-009-07	AUXILOCK® 8mm x 35mm PEEK CF Interference Screw
6-009-08	AUXILOCK® 9mm x 20mm PEEK CF Interference Screw
6-009-09	AUXILOCK® 9mm x 25mm PEEK CF Interference Screw
6-009-10	AUXILOCK® 9mm x 30mm PEEK CF Interference Screw
6-009-11	AUXILOCK® 9mm x 35mm PEEK CF Interference Screw
6-009-12	AUXILOCK® 10mm x 25mm PEEK CF Interference Screw
6-009-13	AUXILOCK® 10mm x 30mm PEEK CF Interference Screw
6-009-14	AUXILOCK® 10mm x 35mm PEEK CF Interference Screw
6-009-15	AUXILOCK® 11mm x 25mm PEEK CF Interference Screw
6-009-16	AUXILOCK® 11mm x 30mm PEEK CF Interference Screw
6-009-17	AUXILOCK® 11mm x 35mm PEEK CF Interference Screw
6-009-18	AUXILOCK® 12mm x 25mm PEEK CF Interference Screw
6-009-19	AUXILOCK® 12mm x 30mm PEEK CF Interference Screw
6-009-20	AUXILOCK® 12mm x 35mm PEEK CF Interference Screw



Square Drive

PEEK OPTIMA Interference Screw

Code	Product Description
6-014-01	AUXILOCK® 7mm x 20mm PEEK OPTIMA Interference Screw
6-014-02	AUXILOCK® 7mm x 25mm PEEK OPTIMA Interference Screw
6-014-03	AUXILOCK® 7mm x 30mm PEEK OPTIMA Interference Screw
6-014-04	AUXILOCK® 8mm x 20mm PEEK OPTIMA Interference Screw
6-014-05	AUXILOCK® 8mm x 25mm PEEK OPTIMA Interference Screw
6-014-06	AUXILOCK® 8mm x 30mm PEEK OPTIMA Interference Screw
6-014-07	AUXILOCK® 8mm x 35mm PEEK OPTIMA Interference Screw
6-014-08	AUXILOCK® 9mm x 20mm PEEK OPTIMA Interference Screw
6-014-09	AUXILOCK® 9mm x 25mm PEEK OPTIMA Interference Screw
6-014-10	AUXILOCK® 9mm x 30mm PEEK OPTIMA Interference Screw
6-014-11	AUXILOCK® 9mm x 35mm PEEK OPTIMA Interference Screw
6-014-12	AUXILOCK® 10mm x 25mm PEEK OPTIMA Interference Screw
6-014-13	AUXILOCK® 10mm x 30mm PEEK OPTIMA Interference Screw
6-014-14	AUXILOCK® 10mm x 35mm PEEK OPTIMA Interference Screw
6-014-15	AUXILOCK® 11mm x 25mm PEEK OPTIMA Interference Screw
6-014-16	AUXILOCK® 11mm x 30mm PEEK OPTIMA Interference Screw
6-014-17	AUXILOCK® 11mm x 35mm PEEK OPTIMA Interference Screw



Square Drive

Code	Product Description
6-014-18	AUXILOCK® 12mm x 25mm PEEK OPTIMA Interference Screw
6-014-19	AUXILOCK® 12mm x 30mm PEEK OPTIMA Interference Screw
6-014-20	AUXILOCK® 12mm x 35mm PEEK OPTIMA Interference Screw

Titanium Interference Screw

Code	Product Description
6-010-01	AUXILOCK® 7mm x 20mm Titanium Interference Screw
6-010-02	AUXILOCK® 7mm x 25mm Titanium Interference Screw
6-010-03	AUXILOCK® 7mm x 30mm Titanium Interference Screw
6-010-04	AUXILOCK® 7mm x 35mm Titanium Interference Screw
6-010-05	AUXILOCK® 8mm x 20mm Titanium Interference Screw
6-010-06	AUXILOCK® 8mm x 25mm Titanium Interference Screw
6-010-07	AUXILOCK® 8mm x 30mm Titanium Interference Screw
6-010-08	AUXILOCK® 8mm x 35mm Titanium Interference Screw
6-010-09	AUXILOCK® 9mm x 20mm Titanium Interference Screw
6-010-10	AUXILOCK® 9mm x 25mm Titanium Interference Screw
6-010-11	AUXILOCK® 9mm x 30mm Titanium Interference Screw
6-010-12	AUXILOCK® 9mm x 35mm Titanium Interference Screw
6-010-13	AUXILOCK® 10mm x 25mm Titanium Interference Screw
6-010-14	AUXILOCK® 10mm x 30mm Titanium Interference Screw
6-010-15	AUXILOCK® 10mm x 35mm Titanium Interference Screw
6-010-16	AUXILOCK® 11mm x 25mm Titanium Interference Screw
6-010-17	AUXILOCK® 11mm x 30mm Titanium Interference Screw
6-010-18	AUXILOCK® 11mm x 35mm Titanium Interference Screw
6-010-19	AUXILOCK® 12mm x 25mm Titanium Interference Screw
6-010-20	AUXILOCK® 12mm x 30mm Titanium Interference Screw
6-010-21	AUXILOCK® 12mm x 35mm Titanium Interference Screw



Star Drive

Code	Product Description
6-010-01-S	AUXILOCK® 7mm x 20mm Titanium Interference Screw, Sterile
6-010-02-S	AUXILOCK® 7mm x 25mm Titanium Interference Screw, Sterile
6-010-03-S	AUXILOCK® 7mm x 30mm Titanium Interference Screw, Sterile
6-010-04-S	AUXILOCK® 7mm x 35mm Titanium Interference Screw, Sterile
6-010-05-S	AUXILOCK® 8mm x 20mm Titanium Interference Screw, Sterile
6-010-06-S	AUXILOCK® 8mm x 25mm Titanium Interference Screw, Sterile
6-010-07-S	AUXILOCK® 8mm x 30mm Titanium Interference Screw, Sterile
6-010-08-S	AUXILOCK® 8mm x 35mm Titanium Interference Screw, Sterile
6-010-09-S	AUXILOCK® 9mm x 20mm Titanium Interference Screw, Sterile
6-010-10-S	AUXILOCK® 9mm x 25mm Titanium Interference Screw, Sterile
6-010-11-S	AUXILOCK® 9mm x 30mm Titanium Interference Screw, Sterile
6-010-12-S	AUXILOCK® 9mm x 35mm Titanium Interference Screw, Sterile
6-010-13-S	AUXILOCK® 10mm x 25mm Titanium Interference Screw, Sterile
6-010-14-S	AUXILOCK® 10mm x 30mm Titanium Interference Screw, Sterile
6-010-15-S	AUXILOCK® 10mm x 35mm Titanium Interference Screw, Sterile
6-010-16-S	AUXILOCK® 11mm x 25mm Titanium Interference Screw, Sterile
6-010-17-S	AUXILOCK® 11mm x 30mm Titanium Interference Screw, Sterile
6-010-18-S	AUXILOCK® 11mm x 35mm Titanium Interference Screw, Sterile
6-010-19-S	AUXILOCK® 12mm x 25mm Titanium Interference Screw, Sterile
6-010-20-S	AUXILOCK® 12mm x 30mm Titanium Interference Screw, Sterile
6-010-21-S	AUXILOCK® 12mm x 35mm Titanium Interference Screw, Sterile

RECOMMENDED INSTRUMENTATION

Transportal Femoral Offset Guide

Code	Offset
7-014-01	5mm
7-014-02	6mm
7-014-03	7mm



7-014-04 Screwdriver For Polymer Interference Screw



7-014-05 Screwdriver For Ti Interference Screw, T25 Star Driver



7-014-06 Cannulated Headed Reamer, Ø4.7mm



Tibial Cannulated Reamer

Code	Diameter
7-014-07	Ø6mm
7-014-08	Ø6.5mm
7-014-09	Ø7mm
7-014-10	Ø7.5mm
7-014-11	Ø8mm

Code	Diameter
7-014-12	Ø8.5mm
7-014-13	Ø9mm
7-014-14	Ø9.5mm
7-014-15	Ø10mm

Code	Diameter
7-014-16	Ø10.5mm
7-014-17	Ø11mm
7-014-18	Ø11.5mm
7-014-19	Ø12mm



Femoral Cannulated Reamer

Code	Diameter
7-014-20	Ø6mm
7-014-21	Ø6.5mm
7-014-22	Ø7mm
7-014-23	Ø7.5mm
7-014-24	Ø8mm

Code	Diameter
7-014-25	Ø8.5mm
7-014-26	Ø9mm
7-014-27	Ø9.5mm
7-014-28	Ø10mm

Code	Diameter
7-014-29	Ø10.5mm
7-014-30	Ø11mm
7-014-31	Ø11.5mm
7-014-32	Ø12mm



7-014-33 Drill Guide Handle



7-014-35 ACL Tip C Aimer, Right



7-014-36 ACL Tip C Aimer, Left



7-014-37 ACL Tip O Aimer



7-014-38 ACL Tip Aimer



7-014-39 Drill Guide Bullet



7-014-43 Nitinol Guide Wire Ø1.2mm x Length 400mm (For Interference Screws)



7-014-44 Depth Gauge For Knee ACL/PCL Instrument



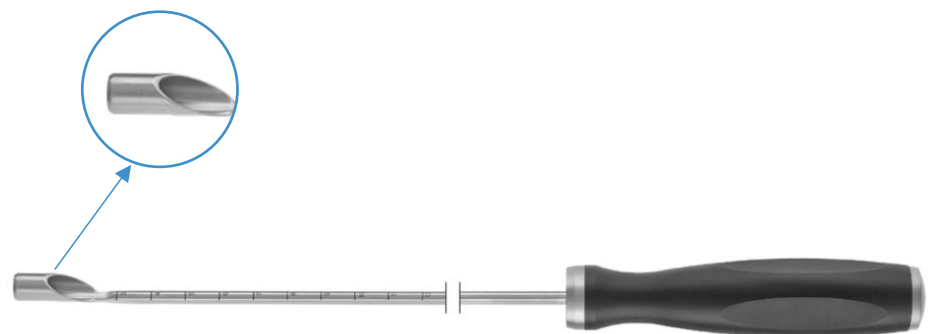
Transtibial Femoral Offset Guide

Code	Offset
7-014-45	5mm
7-014-46	6mm
7-014-47	7mm



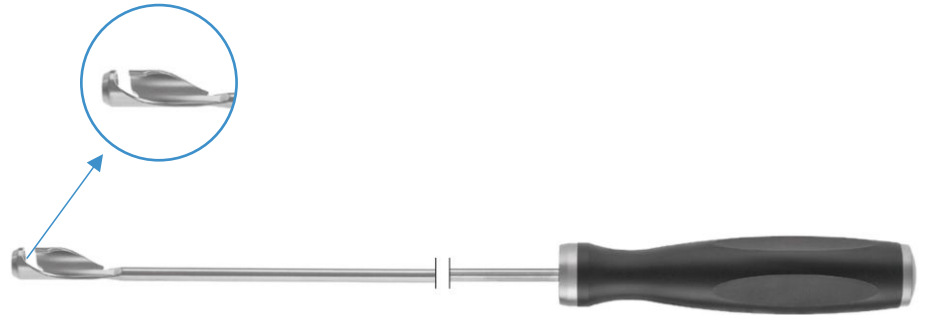
Tendon Stripper (Closed End)

Code	Diameter
7-014-48	Ø6mm
7-014-49	Ø7mm
7-014-50	Ø8mm

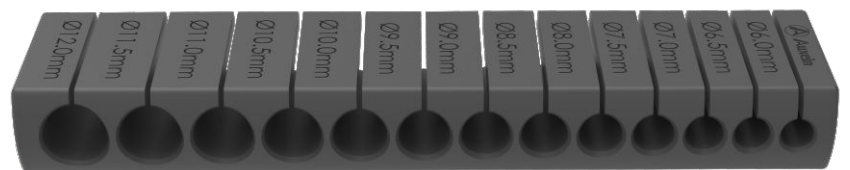


Tendon Stripper (Open End)

Code	Diameter
7-014-51	Ø6mm
7-014-52	Ø7mm
7-014-53	Ø8mm



7-014-54 Graft Sizer, 6mm to 12mm (0.5mm steps)



7-014-55 Quick Coupling T-Handle For Tunnel Dilator



Tunnel Dilator, Cannulated

Code	Diameter
7-014-56	Ø6mm
7-014-57	Ø7mm
7-014-58	Ø8mm
7-014-59	Ø9mm
7-014-60	Ø10mm



Rasp

Code	Shape
7-014-61	Straight Rasp
7-014-62	Convex Rasp
7-014-63	Half-Round Rasp



7-014-64 Curette, 25° Angled Down



7-014-65 Arthroscopic Probe - Knee



7-014-66 Pin, Trocar-Tip, Ø2.4mm x 355mm



7-014-67 Pin, Drill Tip, Ø2.4mm x 355mm

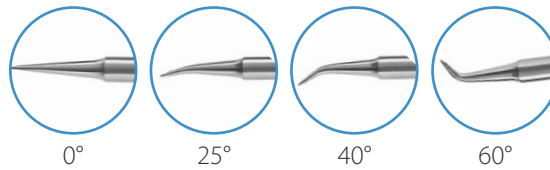


7-014-68 Passing Pin, Ø2.4mm x 250mm



Micro Fracture Awl

Code	Angle
7-014-69	0°
7-014-70	25°
7-014-71	40°
7-014-72	60°

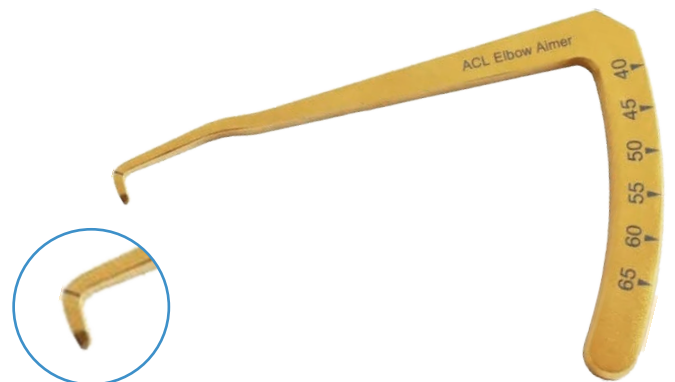


Tunnel Plug

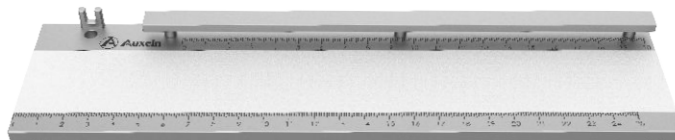
Code	Dia
7-014-73	7-8mm
7-014-74	8-9mm
7-014-75	9-10mm



7-014-99 ACL Elbow Aimer



7-017-01 Graft Station



7-017-02 Sliding Base



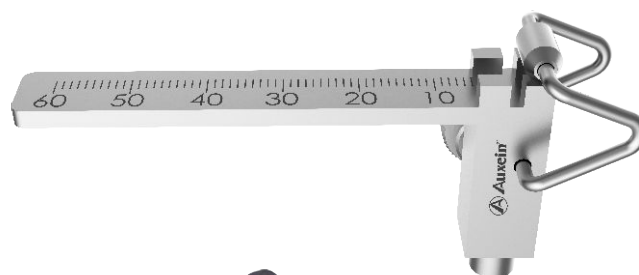
7-017-03 Graft Grasper Clamp - Left



7-017-04 Graft Grasper Clamp - Right



7-017-05 Button Holder With Scale



7-017-06 Suture Holder With Tensioner



OPTIONAL INSTRUMENTS

7-014-42 Ratchet Handle For Hudson Coupling Screwdriver Shaft



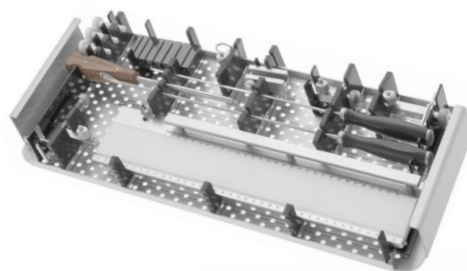
7-014-95 Screwdriver Shaft For Titanium Interference Screw, T25 Star Driver, Hudson Coupling



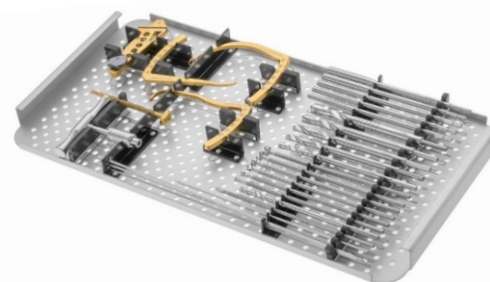
7-014-96 Screwdriver Shaft For Polymer Interference Screw, Hudson Coupling



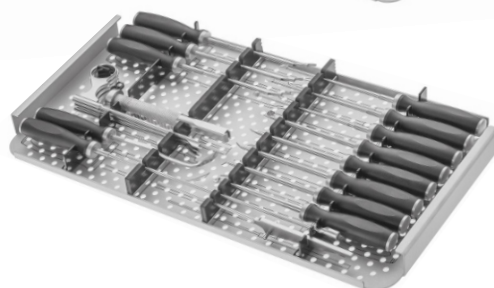
7-014-78 Tray C For Graft Station Instruments



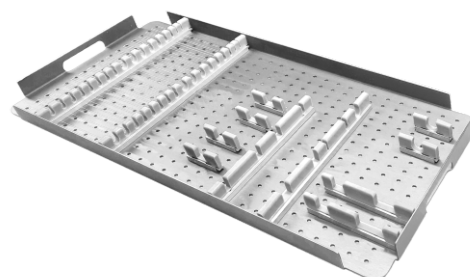
7-014-79 Tray A For ACL/PCL Instruments



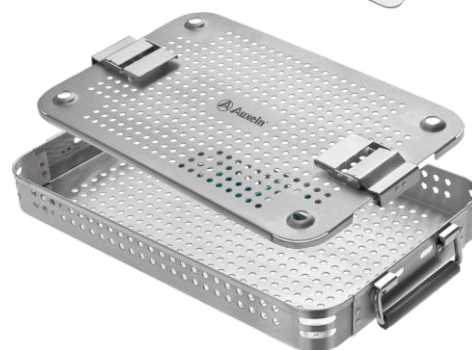
7-014-80 Tray B For ACL/PCL Instruments



7-014-98 Tray D For ACL/PCL Instruments



7-014-81 Container For ACL/PCL Instrument Set



7-014-82 Lid For Container, ACL/PCL Instrument Set





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