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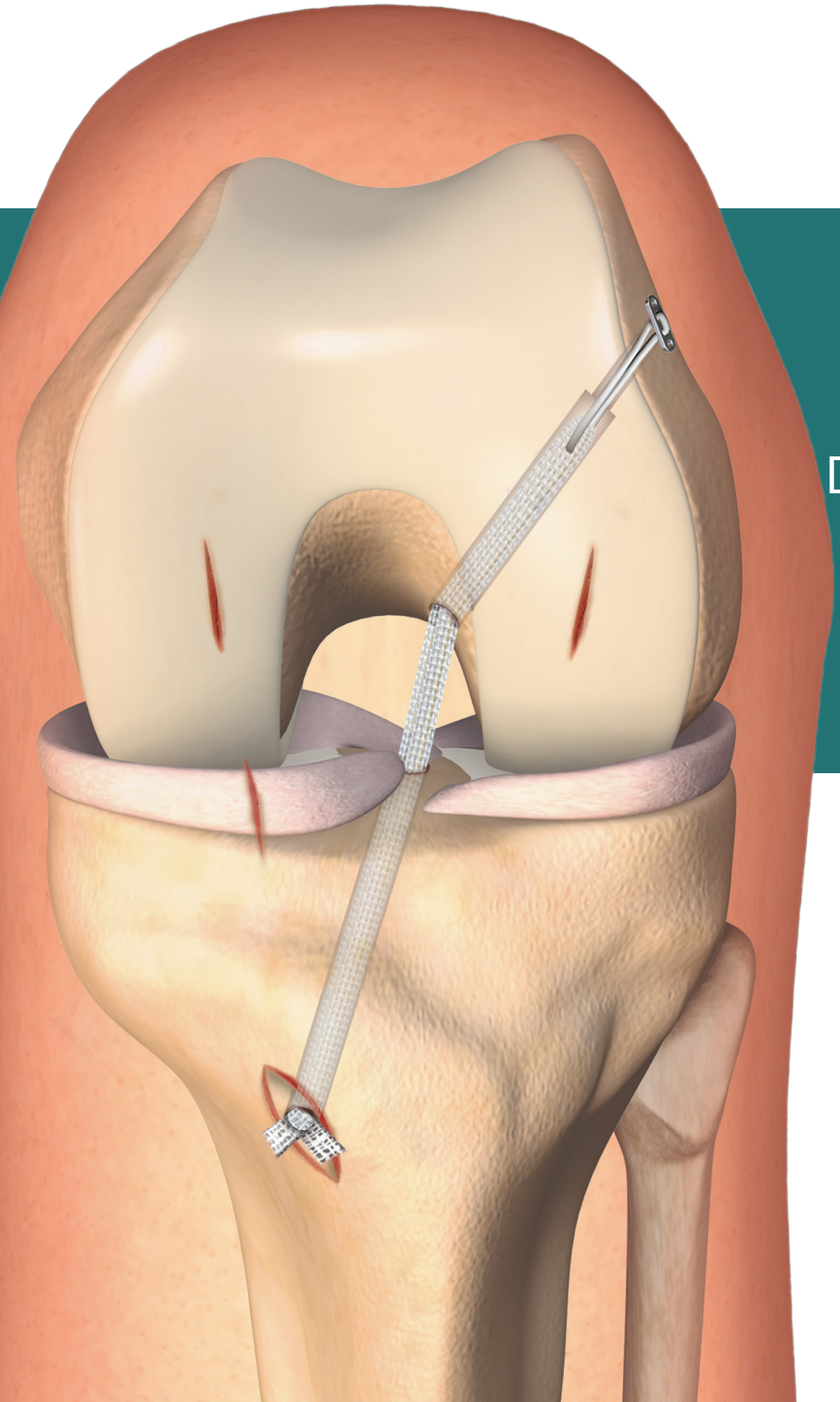


JewelACL™

The Tissue Graft Sparing Device for Anterior Cruciate Ligament Reconstruction

Surgical Technique Manual

JewelACL™

Introduction

The **JewelACL** is a tissue graft sparing device for the reconstruction of the anterior cruciate ligament (ACL).

It has been designed for use in partial or total tissue sparing ACL reconstruction with hamstring tendons. In a partial tissue graft sparing (PGS) reconstruction procedure the **JewelACL** may be used in conjunction with either the semitendinosus or the gracilis tendon. In a total tissue graft sparing (TGS) reconstruction the **JewelACL** may be implanted alone.

These approaches will either significantly reduce or totally eliminate the amount of autologous tissue used in the reconstruction. These two approaches reduce the surgical time for graft harvest and help to reduce (PGS) or avoid (TGS) donor site morbidity and the deficiency that would otherwise be created in the hamstring muscle group.

When used in a partial or total tissue graft sparing procedure the **JewelACL** allows early weight bearing and mobilisation, allowing potential for early rehabilitation

Autografts and allografts will re-model over time with an associated period where they may demonstrate less favourable mechanical properties before achieving their full potential. During this time grafts may be at greater risk of stretching and the rehabilitation programme must be adapted to reduce this risk.

The **JewelACL** is specifically designed for implantation with approaches that are familiar to most surgeons. Thus bone tunnels may be prepared with appropriate standard instrumentation in current use. Also, the **JewelACL** (alone or in combination with a hamstring graft) may be secured to the bone with cortical suspensory fixation with loop or soft threaded interference screw fixation. Further details are included later in the surgical technique.

The **JewelACL** thus offers flexibility in ACL reconstruction by the way of approach, graft selection and graft anchoring to the bone.

Flexibility

Surgical Approaches

Anteromedial Approach
Femoral tunnel is drilled through the anteromedial (AM) portal

or

Transtibial Approach
Femoral tunnel is drilled through the tibial tunnel

Graft Choices

Partial Tissue Graft Sparing (PGS)
The reconstruction is performed utilising a single hamstring tendon alongside or inside the JewelACL

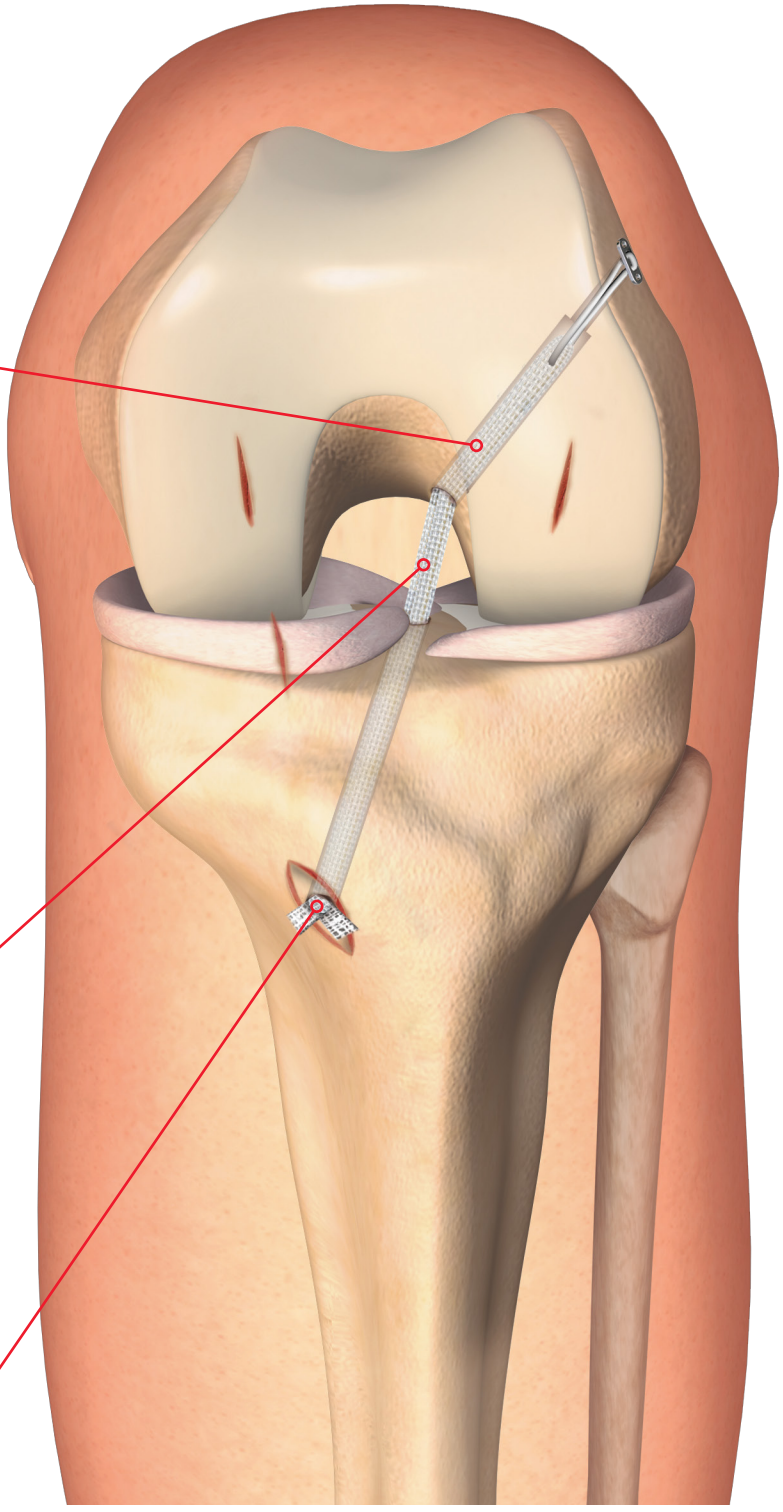
or

Total Tissue Graft Sparing (TGS)
The reconstruction is performed with the JewelACL alone, thus avoiding hamstring harvest, donor site morbidity and preserving function

Fixation Options

Femoral Fixation
A cortical suspensory type fixation device for femoral fixation can be used.

Tibial Fixation
A soft-threaded interference screw can be used.



Product Overview

IMPLANT

Structure

The JewelACL is a specialised textile implant which is rendered versatile for use in ACL reconstruction by various structural features. These features are shown in the illustration (on the next page) and include:

- The continuous tubular form which can accommodate a hamstring tendon; this is facilitated by the suitably placed side openings
- The woven sections with appropriate spacing to allow the natural process of tissue integration surrounding the JewelACL and into the spaces within the structure.

Material and Surface Properties

- The JewelACL is manufactured from Polyethylene Terephthalate (polyester) which has been used in ligament reconstruction for over 25 years
- The JewelACL is treated with a proprietary gas plasma treatment process that renders it hydrophilic.

Mechanical Properties

- As a single strand the JewelACL has a strength matched to that of the semitendinosus tendon
- When doubled, its strength is similar to that of the natural ACL

APPLICATIONS

The JewelACL can be used in either partial or total tissue sparing ACL reconstruction procedures. These are briefly described below:

Partial Tissue Graft Sparing ACL Reconstruction

In this procedure the JewelACL is used in conjunction with only one hamstring tendon which is harvested from either the semitendinosus muscle or the gracilis muscle. The use of the gracilis reduces donor site morbidity and also reduces the deficit in the hamstring muscle group power.

Total Tissue Graft Sparing ACL Reconstruction

In this procedure the JewelACL is used alone for the reconstruction of the ACL, an option that offers many
advantages. The use of the JewelACL eliminates operative time associated with graft harvest and preparation. It also eliminates donor site morbidity associated with the harvesting procedure. Additionally, it eliminates the risk of cross-infection where the JewelACL replaces allografts or xenografts.

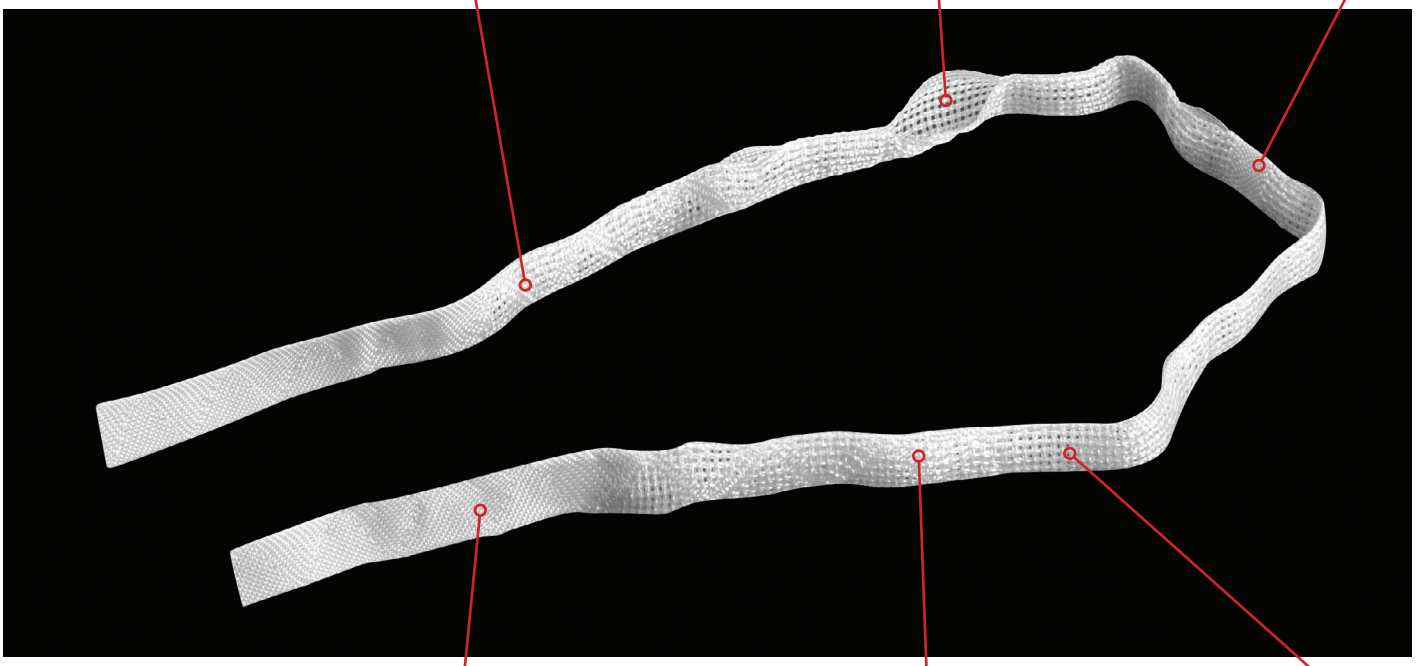
It is ideal for ACL reconstruction in cases where a patient has sustained multiple injuries to other knee ligaments, such as the PCL and MCL. In such cases there is typically insufficient autologous tissue for multiple reconstructions.

Product Overview

The surface is modified with a unique gas plasma treatment process that renders the surface hydrophilic[1, 2]

Openings allow harvested tissue to be placed inside the implant

Dense structure indicates mid-length where the device is looped around a femoral suspension fixation device



Dense construction to improve handling when applying tension prior to tibial fixation

Tensile strength for a single strand matches that of the semitendinosus tendon which is typically 1200 N. This facilitates early mobilisation and rehabilitation. There is no need to wait until the end of the typical tissue remodelling phases of autografts and allografts

The woven structure allows natural tissue ingrowth

Indication

INDICATION

The JewelACL is indicated for ACL insufficiency requiring reconstruction.

INSTRUMENTATION

The JewelACL can be implanted using contemporary cruciate reconstruction drill guide systems which support surgical technique as used for hamstring grafts.

Fixation Devices

EXAMPLE FIXATION DEVICES TESTED

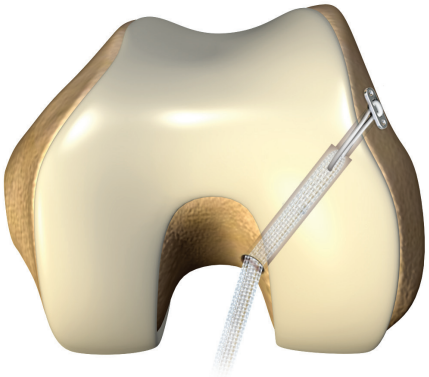
The JewelACL may be secured with suspensory fixation devices and with soft threaded interference screws. The decision to use any specific fixation device is the responsibility of the operating surgeon. The device types listed in the tables on the following pages as provided as a guide only. Principles of screw diameter oversizing relative to the tunnel diameter should be observed.

When using these devices it is critical to follow the instructions for use supplied with them and to observe the conditions and necessary adjustments required in the technique described in the notes section in the following tables.

The strength figures quoted in the tables have been obtained from a rigorous in-house testing programme. Each test was repeated on six units of each of the devices listed in the tables. For more detailed information on the test conditions please see the white paper “Mechanical properties and fixation performance testing of the JewelACL” (WP 006).

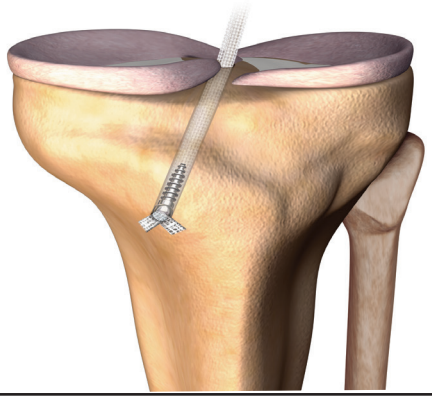
Fixation Devices

Femoral Fixation with a suspensory fixation device

	
Fixation device type	Device type: Cortical suspensory fixation device with loop Device tested: EndoButton CL Ultra (Smith & Nephew)
Procedure	Total tissue graft sparing (TGS) or Partial tissue graft sparing (PGS)
Bone tunnel diameter	TGS: 4.5 mm PGS: Sized to overall graft diameter
Approach to making the tunnels	Anteromedial, outside-in or transtibial
Strength of tibial fixation	TGS: 1296 N [4] PGS: Since fixation strength is adequate when the JewelACL is tested on its own, the test was not repeated with a PGS graft which uses the hamstring graft inside the JewelACL.
Notes	***Benefit:*** Small diameter tunnel aids anatomic placement. Snug fit between the tunnel wall and the graft. ***Technique:*** When implanting the JewelACL alone (TGS), it is recommended to use a small offset femoral aimer to place the femoral tunnel in an isometric position. Since only a single diameter tunnel of 4.5 mm is required for the Total Graft Sparing construct. There is no need to over-drill to create a stepped bone tunnel. With a fixed loop suspensory device, It is recommended to use a shorter loop to maximise the length of the device in the bone tunnel. When incorporating a tissue graft with the JewelACL,(PGS), follow the manufacturer's instructions to create a stepped bone tunnel with the appropriate offset aimer and cannulated drill matched to the total graft diameter.

Fixation Devices

Tibial Fixation with a soft threaded interference screw

	
Fixation device type	Device type: Soft threaded interference screw. Devices tested: RCI Screw (Smith & Nephew) Interference Screw (Medgal)
Procedure	Total tissue graft sparing (TGS) or Partial tissue graft sparing (PGS)
Bone tunnel diameter	TGS (RCI Screw): 6.5 mm TGS (Interference Screw, Medgal): 5.5 mm PGS (RCI Screw or Interference Screw, Megdal): Sized to overall graft diameter
Approach to making the tunnels	Outside-in or inside-out
Strength of tibial fixation	TGS (RCI Screw): 1202 N [4] TGS (Medgal Screw): 1544 N [4] PGS (RCI & Medgal Screw): Dependent on graft size/choice
Notes	***Benefit:*** Low profile fixation with intra-tunnel placement, so no external hardware and associated wound sensitivity. ***Technique:*** The screw is placed centrally in the bone tunnel between the two strands of the graft. When using the JewelACL alone (TGS), either a 7 mm diameter by 30 mm long screw (Interference Screw, Medgal) or a 7 mm diameter by 25 mm long screw (RCI Screw) is used. The JewelACL may be knotted directly over the back of the screw to provide additional fixation and reduce the potential for it slipping past the screw. The knot is small and so can be located in the mouth of the tibial tunnel to provide a low profile fixation. When incorporating a tissue graft (PGS), the tibial tunnel is sized to that of the overall graft diameter, making sure that the interference from the screw is not so great that both strands of the graft end up on the same side of the screw. The tibial tunnel is typically 6.5 mm in diameter. Under such conditions an 8 mm diameter by 30 mm long screw (Interference Screw, Megdal), or an 8 mm diameter screw with a length of the surgeon's preference (RCI Screw) is used. Excess hamstring graft is trimmed from the tibial tunnel distal aperture.

JewelACL Surgical Technique

INTRODUCTION

The JewelACL can be implanted using an anteromedial or transtibial surgical technique similar to that followed when reconstructing the ACL with hamstring grafts. The technique followed may be determined by the surgeon's preference or may be dictated by the preferred fixation devices. The reconstruction can therefore be performed using commonly available contemporary cruciate reconstruction guide systems.

The instructions to follow describe an anteromedial approach with the JewelACL incorporating a single hamstring tendon to produce a partial tissue sparing graft which is fixed to the femur with a cortical suspension device and to the tibia with a soft treaded interference screw.

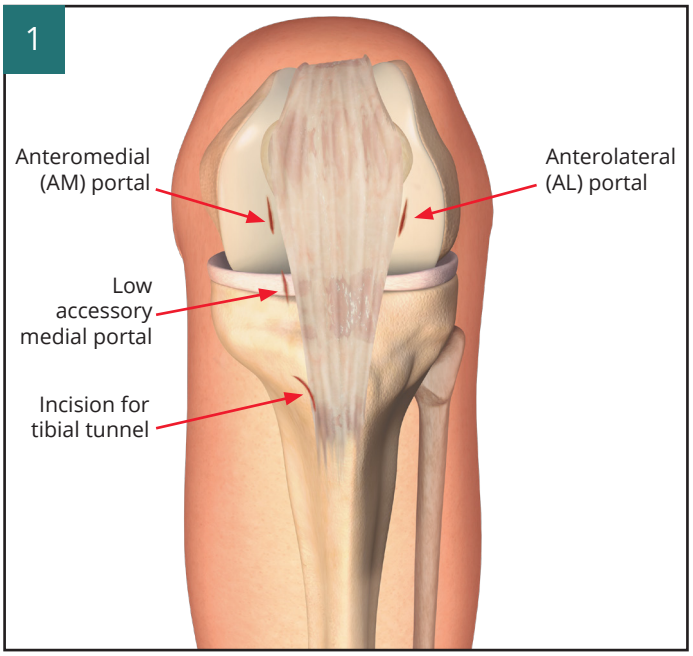
Since the above procedure for ACL reconstruction is well known, the following text focuses on the important differences from a standard ACL technique.

PATIENT PREPARATION

The procedure is performed with the patient in the supine position under general anaesthesia with a tourniquet inflated. Pre-operative antibiotics are administered.

The pre-operative preparation of the patient is carried out following standard procedures. When adopting an anteromedial approach the patient should be positioned so that the knee can be flexed beyond 90º.

Surgical Technique

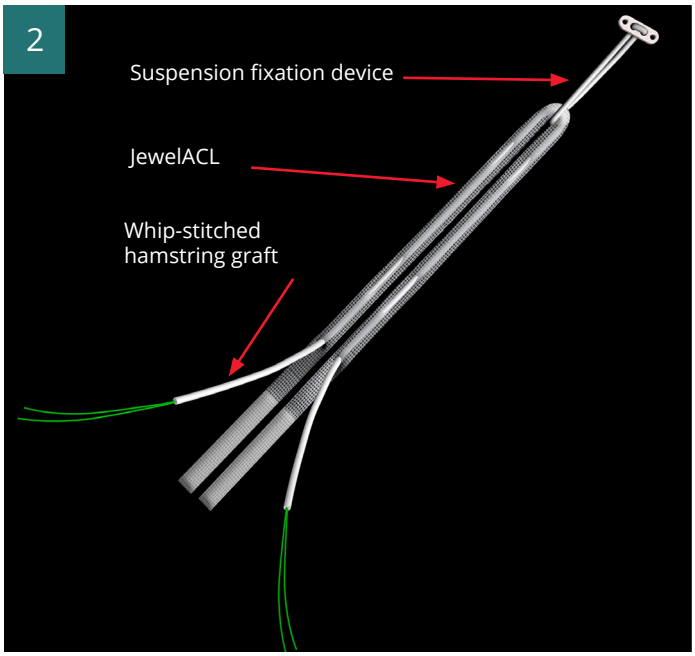


APPROACH
Standard anterolateral (AL), anteromedial (AM) and accessory medial portals are established with the knee flexed at 90°. Although the AM or accessory AM portal can be used to create the femoral tunnel, as a cortical suspension device is used in this technique, a low medial accessory portal as described by Brown[3] is preferred when creating the femoral tunnel so as to maximise tunnel length.

The low medial accessory portal should be located as low as possible but above the medial joint line while avoiding the anterior horn of the medial meniscus.

The medial-lateral placement of this portal should be close to the medial edge of the patellar tendon to maximise the tunnel length for such a cortical suspension device.

NOTE: When creating the portal the scalpel blade should be directed away from the anterior horn of the medial meniscus to avoid damage to this soft tissue.

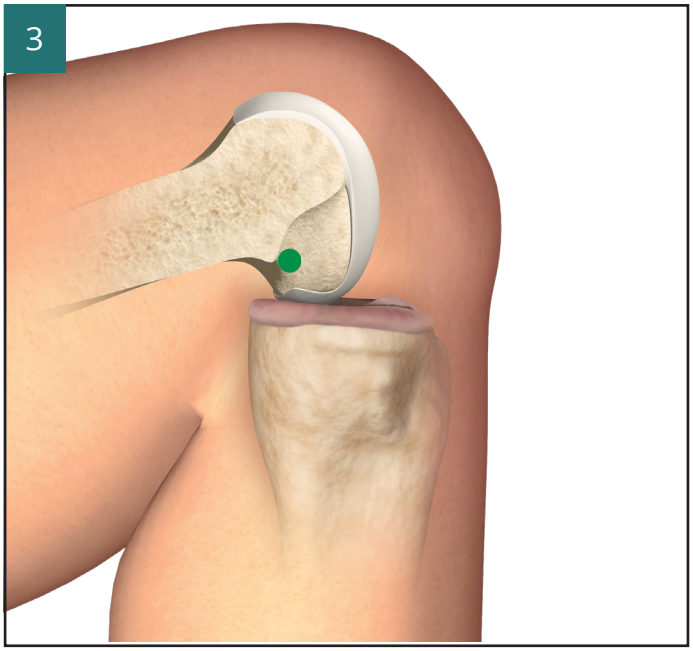


GRAFT HARVESTING AND PREPARATION
An appropriate hamstring tendon is harvested using standard techniques and instruments (not provided).

The graft is prepared according to standard procedures, such that each end is whip-stitched with sutures to a length of approximately 35-40 mm.

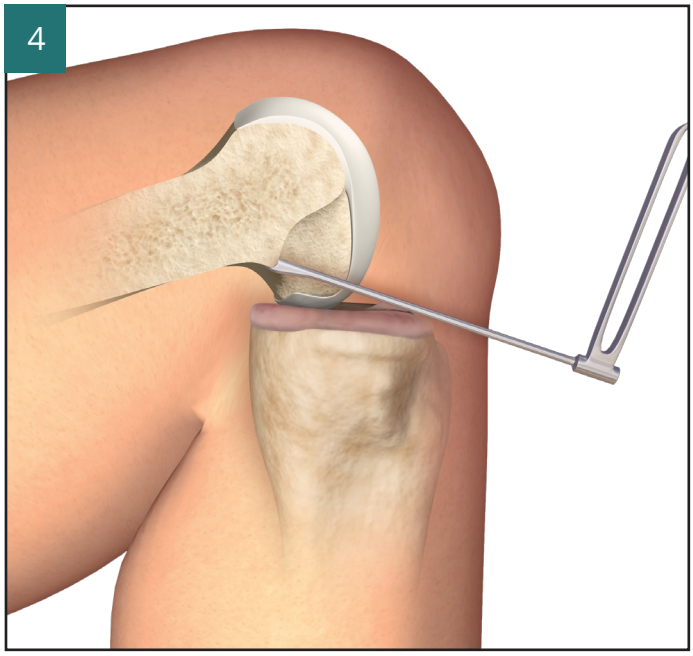
NOTE: The tendon can be placed alongside the JewelACL to effectively create a 4 strand graft, or preferably placed inside the tubular JewelACL as follows.

The end of the sutures are threaded through the eyelet of a passing pin. The pin is passed through the appropriate openings in the JewelACL, taking care not to pierce it with the pin. The passing pin is used to pull the tendon inside the JewelACL such that the tendon is located midway along the length of the JewelACL, thus forming a composite graft.



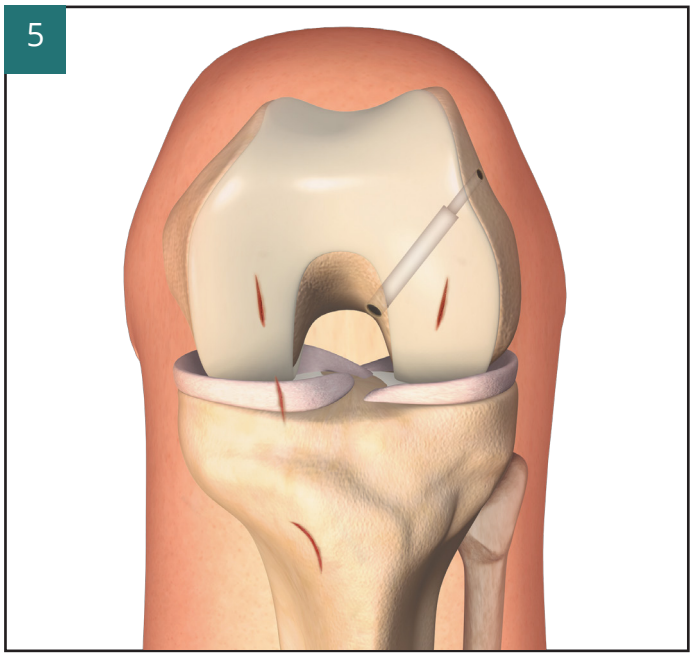
FEMORAL TUNNEL LOCATION
Correct graft placement is critical to the success and clinical outcome of ACL reconstruction. Misplacement of the femoral bone tunnel is a common cause of failed reconstructions.

The femoral tunnel exit in the intercondylar notch should be located as far posterior and proximal as possible while remaining within the ACL footprint.



Where a shallow intercondylar notch is likely to cause impingement the knee should be flexed beyond 90º (typically 130º) and a femoral notchplasty performed through the AM portal.

The appropriate small offset femoral aimer (as preferred by the surgeon) is positioned through the low medial accessory portal at the over-the-top position on the femur. It must be ensured that the tunnel has an adequate wall thickness to prevent posterior tunnel wall break-out.



FEMORAL TUNNEL CREATION
A passing pin is drilled through the femoral aimer, into the femur and out through the anterolateral cortex.

NOTE: Care should be taken to avoid drilling into the peroneal nerve, or damaging the cartilage surface of the medial femoral condyle.

The aimer is removed, leaving the passing pin. The passing pin is over-drilled with a 4.5 mm cannulated bone tunnel drill until the cortex is breached. The length of the tunnel is measured and the appropriate cortical suspensory fixation device is chosen and assembled with the graft following the technique described by the manufacturers to form a two-strand graft. A sizing block is used to determine the appropriate diameter of the cannulated drill bit used to create the bone tunnels.

The femoral socket is drilled to the appropriate depth with a drill matched to the graft size. The edges of the distal tunnel at its intercondylar exit are chamfered with an ACL tunnel rasp where possible.

NOTE: Care should be taken to ensure the drill does not breach the lateral femoral cortex, otherwise fixation with a suspensory device may not be possible.

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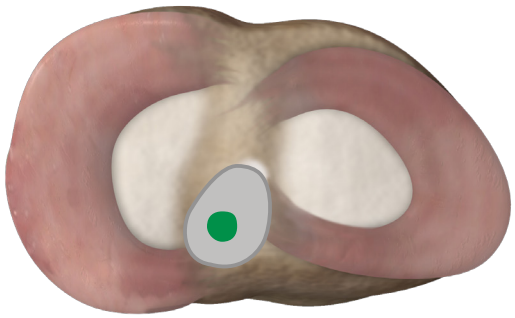

TIBIAL TUNNEL LOCATION
The tibial footprint of the ACL is left intact for its proprioceptive and vascular contributions. Later it will be attached to the JewelACL to provide a cell source for tissue ingrowth and subsequent abrasion protection.

The intra-articular tibial attachment should be located slightly medial and slightly anterior to the centre of attachment of the natural ACL. It should not interfere with the anterior attachment of the medial meniscus and should also avoid damaging the articular cartilage. Placement too far anteriorly should be avoided as this can lead to impingement of the ligament on the roof of the notch at full extension.

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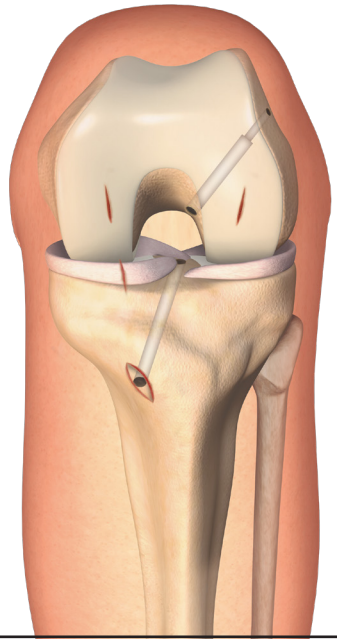

TIBIAL TUNNEL CREATION
An appropriate tibial guide is used to drill a passing pin into the tibia.

NOTE: Ensure an adequate tunnel length is produced to accommodate the interference screw.

The tibial guide is removed. The guidewire is over-drilled with an appropriately sized cannulated bone tunnel drill.

NOTE: A tunnel of an equal diameter to that of the overall graft is drilled, or a tunnel of a diameter that is 1 mm smaller than that of the graft is made and then expanded to the desired size using serial dilators.

Care should be taken to avoid damage to the articular cartilage.

Remove any sharp or rough edges of the tunnel exit with a rasp or shaver.

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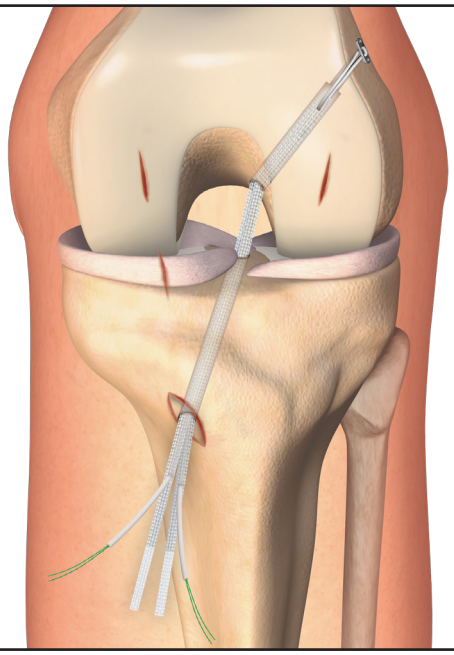

GRAFT INSERTION AND FEMORAL FIXATION
The suspensory fixation device and graft are pulled into the tunnels. The fixation device is deployed following the recommended technique described by the manufacturers.

NOTE: Ensure the button is securely seated on the femoral cortex.

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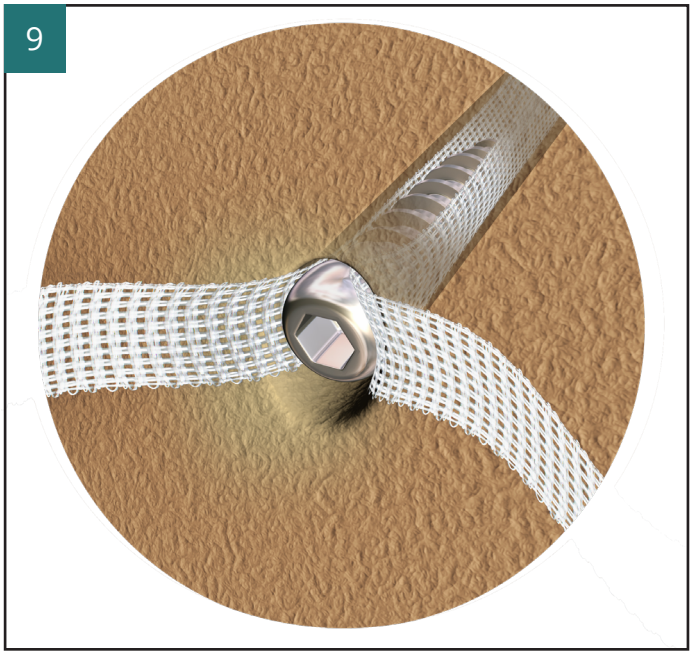

TIBIAL FIXATION

Tension is applied to the two strands of the graft which are separated to allow the screw to be introduced centrally between them in the bone tunnel. Care must be taken to ensure that the strands of the graft do not twist and end up on the same side of the screw. The excess hamstring graft is trimmed from the tibial tunnel entrance and the remaining strands of the JewelACL may be are tied using a reef knot over the back of the screw.

NOTE: The optional knot provides additional fixation and prevents the graft slipping past the screw. The knot is small and so can be located in the aperture of the tibial tunnel, thus providing a low profile fixation.

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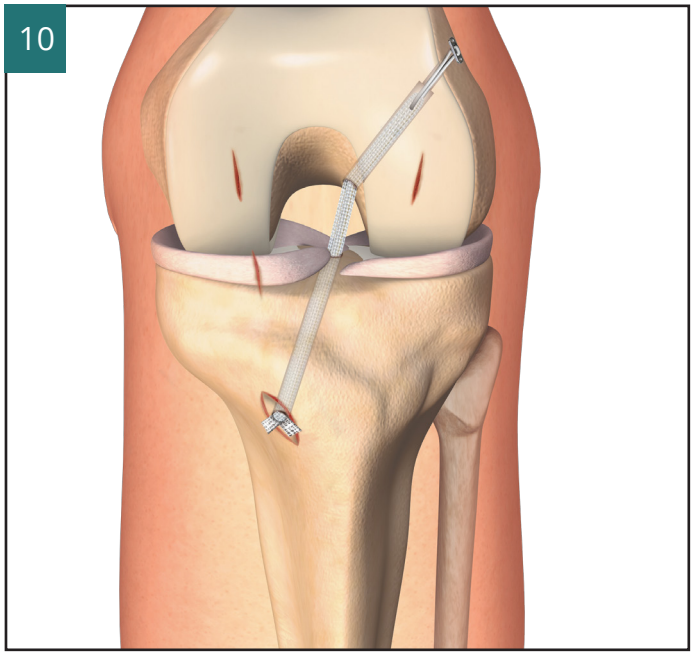


TIBIAL ACL STUMP ATTACHMENT AND TRIMMING TO LENGTH

Where possible attach the remnants of the ACL to the synthetic graft using appropriate sized sutures.

The knee is cycled through a full range of motion while examining the graft arthroscopically to ensure that it has been placed isometrically and allows a full range of motion with no graft impingement.

Ensure the knot is locked before trimming any excess strands of the JewelACL. Each cord is cut with scissors at right angles to its length, to minimise the generation of loose fibres.

IMPORTANT:

- Any loose fibres created when trimming to length must be carefully removed from the incision site.
- It is vital to ensure that the knot is covered with, and remains buried in, tissue.

Postoperative Management

The JewelACL does not require any specific modifications to standard ACL rehabilitation protocols. An example programme developed in conjunction with **Ian Horsley MSc**, MCSP, Clinical Lead Physiotherapist, English Institute of Sport, BackinAction Physiotherapy and Sports Injury Clinic, Wakefield, UK, is available for download from the Xiros website. Document reference; JewelACL Rehabilitation Programme: For Anterior Cruciate Ligament Reconstruction (LAB 145).

The rehabilitation programme should be supervised by a specialist physiotherapist. All mobilisation and exercises should be performed within the pain free range of movement.

References

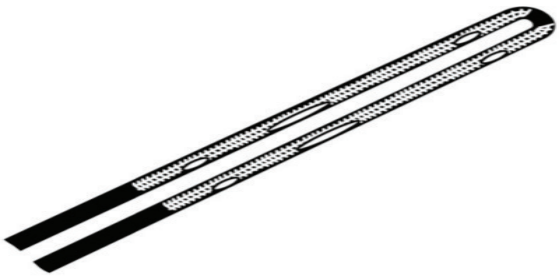
REFERENCES

1. **Rowland JR, Tsukazaki S, Kikuchi T, Fujikawa K, Kearney J, Lomas R, Wood E, Seedhom BB.** Radio frequency-generated glow discharge treatment: potential benefits for polyester ligaments. J Orthop Sci. 2003;8(2):198- 206.
2. **Tsukazaki S, Kikuchi T, Fujikawa K, Kobayashi T, Seedhom BB.** Comparative study of the covered area of Leeds-Keio (LK) artificial ligament and radio frequency generated glow discharge treated Leeds-Keio (Bio-LK) ligament with synovial cells. J Long Term Eff Med Implants. 2003;13(4):355-62.
3. **Brown CH Jr, Spalding T, Robb C.** Medial portal technique for single-bundle anatomical Anterior Cruciate Ligament (ACL) reconstruction. International Orthopaedics. 2013;37(2):253-269. Doi: 10.1007/s00264-012-1772-9.
4. **Xiros Ltd**, data on file.

Ordering Information

Implant

102-6003	JewelACL 7 mm ID x 710 mm (supplied sterile)



Please refer to the Instructions for Use leaflet packed with the JewelACL for essential information including Use, Sterility, Indications, Contraindications, Warnings and Precautions, Potential Adverse Effects and Storage. Additional copies may be obtained from the Xiros™ Sales Department, or downloaded from www.xiros.co.uk

Developed and manufactured by

Xiros™ Ltd
Springfield House
Whitehouse Lane
Yeadon
Leeds LS19 7UE
UK

Tel. +44 (0) 113 238 7202
Fax. +44 (0) 113 238 7201
enquiries@xiros.co.uk
www.xiros.co.uk

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