Jewel ACL™

The Tissue Graft Sparing Device for Anterior Cruciate Ligament Reconstruction

Product Support
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### Useful Information
Background
Anatomy

Muscles
- The major muscle groups of the knee joint involved with bending and straightening the knee are quadriceps and hamstrings

Ligaments
- Ligaments are strong, dense structures made of connective tissue that control movement of a joint and supply it with stability
- They connect bone to bone across the joint
- The Anterior Cruciate Ligament (ACL) is one of the most important of four strong ligaments connecting the bones of the knee joint

Function
- The function of the ACL is to provide stability to the knee and minimize stress across the knee joint
- It restrains excessive forward (anterior) movement of the lower leg bone (the tibia) in relation to the thigh bone (the femur)
- It limits rotational movements of the knee
Injury

A tear to the ACL results from overstretching of this ligament within the knee

- Usually due to a sudden stop and twisting motion of the knee, or a force or “blow” to the front of the knee
- The extent of the tear can be partial or complete
- Individuals experiencing a tear to the ACL may feel a pop at the time of the injury
- It is often injured together with other structures inside the knee, namely the medial collateral ligament and medial meniscus

Facts about ACL Tears

- Of the four major ligaments in the knee, the ACL and the medial collateral ligament are most often injured in sports
- Reconstruction of a torn ACL is now a common procedure with over 200,000 hospital admissions per year in the US
- With society's increasing interest in physical fitness, primary care physicians are seeing more athletic injuries
- Today's athletes have a greater than 90% chance of returning to their pre-injury level of sports participation
- ACL reconstruction is a highly successful operation
- With good rehabilitation, 90 - 95% of individuals who undergo this surgery can expect to return to full sports participation within six months
Classification

- Clinical diagnosis of an ACL injury is usually made by the Lachman, anterior drawer and pivot shift tests, as well as through MRI
- Additionally, the injury may also be classified as a grade I, II, or III sprain

Grade I sprain
- The fibres of the ligament are stretched but there is no tear
- There is a little tenderness and swelling
- The knee does not feel unstable or give out during activity

Grade II sprain
- The fibres of the ligament are partially torn
- There is a little tenderness and moderate swelling
- The joint may feel unstable or give out during activity

Grade III sprain
- The fibres of the ligament are completely torn (ruptured); the ligament itself has torn completely into two parts
- There is tenderness (but not a lot of pain, especially when compared to the seriousness of the injury), there may be a little swelling or a lot of swelling
- The ligament cannot control knee movements. The knee feels unstable or gives out at certain times

ACL avulsion
- Occurs when the ACL is torn away from either the upper or lower leg bone
- This type of injury is more common in children than in adults
- An avulsion fracture occurs when the ACL is torn away from the leg bone with a piece of the bone
Incidence

- The ACL is one of the most commonly injured ligaments of the knee
- The incidence of ACL injury in the US is currently estimated to be approximately 60 per 100,000 of the population each year [1,2] with around half of these requiring ACL reconstruction

- There are no specific references for the incidence rate in the UK
- However, they may be assumed to be comparable to those for the US described above i.e. approximately 30-60/100,000 of the population each year, which compares well with a study of incidence in New Zealand that states an incidence rate of 36.9/100,000 [3]

Product
Overview

The JewelACL was specifically designed for versatility and to provide a range of options with regard to approach, graft and fixation, which are familiar to most surgeons and hence reduce the need for users to learn new techniques.

Approach
- The JewelACL can be implanted using modern ACL guidewire systems with a similar anteromedial or transtibial surgical technique to that utilized for ACL reconstruction with hamstring grafts.

Graft
- The JewelACL can be implanted alone or together with a harvested tendon.

Fixation
- The JewelACL can be secured to the bone with a range of approved fixation devices which include suspension devices, cross pins and interference screws:
  - EndoButton CL Ultra (Smith & Nephew)
  - TransFix (Arthrex)
  - RCI Screw (Smith & Nephew)
  - Interference screw (Medgal)
  - Fastlok (Neoligaments)
Overview

Construction
- The JewelACL has a 7 mm internal diameter and is 710 mm long
- Its open weave mesh is designed to act as a scaffold for soft tissue ingrowth and neoligament formation
- The scaffold is treated with a proprietary gas plasma treatment process that increases its surface energy and renders it hydrophilic, promoting tissue ingrowth
- It is manufactured from polyester, a biocompatible material that has been used for ligament and tendon reconstruction for over 25 years

Availability
- The device is available in one size only to meet all requirements
Indications

The JewelACL is indicated for ACL reconstruction.

It has been designed for use in both total and partial tissue sparing ACL reconstructions, which use hamstring grafts if required.
Features and Benefits

- A continuous tubular form which can accommodate a hamstring tendon; this is facilitated by the suitably placed side openings
- Open weave sections with appropriate spacing to encourage tissue ingrowth into the scaffold
- Bio-enhanced surface properties to promote tissue ingrowth
- Densely woven sections improve handling when applying tension prior to tibial fixation
Graft Choice

The JewelACL can be used in either partial or total tissue sparing ACL reconstruction procedures.

Partial Tissue Graft Sparing ACL Reconstruction (PGS)
- The JewelACL can be used with only one hamstring tendon, which is harvested from either the semitendinosus or gracilis muscle.
- The use of the smaller gracilis tendon reduces donor site morbidity and also reduces the deficit in the power of the hamstring muscle group.

Total Tissue Graft Sparing ACL Reconstruction (TGS)
- The JewelACL can be used alone for the reconstruction of the ACL, an option that offers many advantages:
  - Reduces operative time by eliminating the period required for autologous tissue harvesting and subsequent preparation.
  - Eliminates donor site morbidity associated with the harvesting procedure.
  - 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 ligament reconstructions.
Fixation Choice - Femoral

EndoButton

Fixation device: EndoButton CL Ultra (Smith & Nephew)
Procedure: Total tissue graft sparing (TGS) or Partial tissue graft sparing (PGS)
Bone tunnel: 4.5 mm diameter tunnel (TGS) or PGS sized to overall graft diameter
Tunnel approach: Anteromedial or Transtibial
Strength of femoral fixation: 1296 N for TGS device

TransFix Pin

Fixation device: TransFix Pin (Arthrex)
Procedure: Partial tissue graft sparing (PGS) only
Bone tunnel: PGS sized to overall graft diameter
Tunnel approach: Transtibial only
Strength of femoral fixation: 1977 N for PGS device
Fixation Choice - Tibial

Fixation device: Fastlok, 8 mm (Neoligaments)
Procedure: Total tissue graft sparing only
Bone tunnel: 4.5 mm diameter tunnel (TGS)
Tunnel approach: Anteromedial or Transtibial
Strength of tibial fixation: 968 N (TGS)

Fixation device: RCI Screw (Smith & Nephew) or Interference Screw (Medgal)
Procedure: Total or Partial tissue graft sparing
Bone tunnel: 6.5 mm diameter tunnel for RCI Screw (TGS), 5.5 mm diameter tunnel for Medgal Screw (TGS), or sized to the overall graft diameter (PGS)
Tunnel approach: Anteromedial or Transtibial
Strength of tibial fixation: 1202 N (TGS) – RCI Screw
1544 N (TGS) – Medgal Screw
Surgical Technique
Overview

The information summarised hereafter MUST NOT be used to perform the surgical technique. Always refer to the Surgical Technique Manual LAB 138 which contains detailed information and essential warnings and precautions.
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The instructions hereafter 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 (Endobutton CL Ultra from Smith & Nephew) and to the tibia with an interference screw (e.g. Megdal, which is available from Komak, Poland, or RCI Screw from Smith & Nephew).

Standard anterolateral (AL) and anteromedial (AM) portals are established with the knee flexed at 90°.

A low accessory medial portal is also established.

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

Correct graft placement is critical to the success and clinical outcome of ACL reconstruction. The femoral tunnel exit in the intra-condylar notch should be located as far posterior and proximal as possible while remaining within the ACL footprint.

The knee is flexed beyond 90° (typically 130°) and a femoral notchplasty is performed. An appropriate zero or small offset femoral aimer is used to drill a passing pin into the femur and out through the anterolateral cortex.

An appropriate hamstring tendon is harvested and placed inside the JewelACL. This composite graft is folded in half over the Endobutton CL Ultra loop to create 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.

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The tibial footprint (stump) of the ACL is left intact for its proprioceptive and vascular contributions.

The intra-articular tibial attachment should be located slightly medial and slightly anterior to the centre of attachment of the natural ACL.

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

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

The edges of intracondylar exit are chamfered with an ACL tunnel rasp.

The passing pin is over-drilled with a cannulated bone tunnel drill matched in diameter to that of the graft.

Over-drilling is typically performed to a depth of 25 to 30 mm.

The far cortex is breached with a 4.5 mm diameter cannulated drill.

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Overview

To achieve femoral fixation, the EndoButton CL Ultra and graft are pulled into the tunnels.

To achieve tibial fixation, tension is applied to the two strands of the graft and an interference screw is centrally placed between them.

Excess hamstring graft is trimmed from the tibial tunnel entrance.

The remaining strands of the JewelACL are tied using a reef knot over the back of the screw.

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.

Excess strands of the JewelACL are trimmed using sharp scissors.

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Tips and Tricks

Recommended Approach

- When creating the portal the scalpel blades should be directed away from the anterior horn of the medial meniscus to avoid damaging it

Graft harvesting and preparation

- The tendon can be implanted alongside the JewelACL to effectively create a 4 strand graft, or if preferred, be placed inside the tubular JewelACL (see LAB 138)

Femoral tunnel creation

- Avoid drilling into the peroneal nerve or damaging the cartilage surface of the medial femoral condyle
- When making the larger tunnel, ensure the drill does not breach the lateral femoral cortex, otherwise fixation with the EndoButton cannot be performed
Tips and Tricks

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Tibial tunnel creation
- Adequate tunnel length should be produced – this is controlled by the position of the tunnel exit on the medial tibial surface
- 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

Graft insertion and femoral fixation
- When using the EndoButton it should be securely seated on the femoral cortex, as described by the supplier

Tibial fixation with interference screw
- Knot the ends of the JewelACL behind the screw head
- This provides additional fixation and prevents the JewelACL slipping past the screw
- The knot is located in the mouth of the tibial tunnel, thus providing a low profile fixation
Rehabilitation

The following programme provides an overview of what is performed. For a full description refer to the document entitled “JewelACL Rehabilitation Programme for Anterior Cruciate Ligament Reconstruction” (LAB 145)

This Rehabilitation regime was developed in conjunction with Ian Horsley MSc, MCSP, Clinical Lead Physiotherapist, English Institute of Sport (EIS) North West, of BackinAction Physiotherapy and Sports Injury Clinic, Wakefield, UK

Day 1
  - The leg is placed in a Continuous Passive Motion (CPM) machine and subjected to passive flexion of between 20° to 60° for as many hours as possible

Day 2 – 7
  - CPM between 20° and 90° flexion is continued but the range should be reduced to 20° to 60° if the patient complains of any pain

Week 2
  - Active Range of Motion (ROM), allowing flexion and extension, is initiated with the patient wearing a brace limiting the range of motion flexion/extension to 20° to 90° of knee flexion

Week 3
  - Continue with week 2 activities
  - In addition, passive full extension is allowed twice per day as the patient tolerates
  - Partial weight-bearing is commenced with two handed support, e.g. crutches
Rehabilitation

Weeks 4 – 5
- Active ROM exercise, with unblocked brace, is allowed to the patient's maximum flexion/extension capability (this is usually between 90° to 110°)
- Partial weight-bearing is continued with one-handed support, e.g. a cane

Weeks 6 – 10
- Limitation on both flexion and extension is no longer imposed but wearing an unblocked brace is continued
- Full weight-bearing may be commenced at this stage
- Extension training for muscles is begun, aiming at full development of ROM

Weeks 10 – 12
- Light sports activities such as jogging or swimming may be commenced

Weeks 12 – 24
- Gradual return to sporting activities is permitted
- However, it must be noted that the speed of return to full pre-injury sporting activities should be governed by the state of the muscles of the injured leg
- If they are inadequate it is recommended that the patient rehabilitates them to an adequate degree before engaging in any strenuous activities that might jeopardize the reconstructed ligament
- It should also be noted that, on the occurrence of any significant discomfort, it may be necessary to extend the rehabilitation programme accordingly
Key Competitors
Synthetic Ligaments

LARS AC – Corin Group Plc

- These ligaments are indicated for acute ACL repair
- They are available in a range of sizes (AC80 to AC160) with associated increasing strength, so that the surgeon can select the most appropriate size according to patient weight and activity level, for example:
  - AC80: 80 fibres – resistance of 3600 Newton
  - AC100: 100 fibres – resistance of 4700 Newton
- They are manufactured from polyethylene terephthalate
- The structure consists of a central intra-articular portion of parallel fibres combined with warp knitted extra-articular end portions
- Each size is available in a left or right configuration, where the central fibres are oriented with a slight twist clockwise or counter-clockwise to mimic the natural ACL of the right or left knee
- This central structure of parallel fibres claims a high resistance to fatigue, especially in flexion, as well as providing a porosity favouring fibroblastic ingrowth which then isolates the synthetic fibres
- Titanium interference screws and spiked staples are provided for fixation and they recommend using two fixation devices in a “belt and braces” approach for tibial fixation

Advantages (taken from their literature)

- Rapid recovery
  - Minimally invasive surgery
  - No long period of immobilization required
  - Full range of motion after 3 weeks
- No muscular atrophy
- Less pain: 90% of patients feel no pain postoperatively
- Less swelling: 95% of patients have no swelling or light swelling tendencies postoperatively
- Less restriction: 86% of patients have minimal restrictions postoperatively
Synthetic Ligaments

LARS Actor – Corin Group Plc

- These ligaments are indicated for chronic ACL repair, where an autograft is placed inside its tubular structure
- They are available in two sizes with associated increasing strength, so that the surgeon can select the most appropriate according to weight and activity
  - ACTOR 8: 40 fibres – failure load of 1800 N
  - ACTOR 10: 44 fibres – failure load of 2000 N
- They are manufactured from polyethylene terephthalate
- They have a similar structure to the acute LARS ACL ligaments, which consist of a central intra-articular portion of parallel fibres combined with warp knitted extra-articular end portions
Synthetic Ligaments

ABC Ligament – Surgicraft

- The Active Bioprosthetic Composite (ABC) ligament is a scaffold indicated for treatment of partial or completely ruptured anterior or posterior ligaments
- There are two versions
  - A braided polyester and carbon fibre ligament with a polyester core, which has an ultimate tensile strength of 3500 N
  - A similar structure entirely manufactured from polyester
- It has eyelets at each end for fixation via a bollard
Synthetic Ligaments

Ligastic – Orthomed

- Non-braided, non-woven, non-sheathed ligament manufactured from polyethylene terephthalate
- It is knitted in such a way that all longitudinal fibres are fully extended, perfectly straight and parallel, and in optimum conditions to work simultaneously
- This ligament is used to augment a graft
- Its aim is to prevent graft elongation or rupture during the remodelling period when the mechanical properties of the graft are temporarily reduced
- It is available in two sizes
  - RTF22, 360 mm long, 9 mm wide
  - RTF18, 360 mm long, 7 mm wide
Synthetic Ligaments

Sectile flat braid Biolig – Cousin Biotech
- Used like a Kennedy LAD to reinforce the ACL
- 200 mm long with a flat width of 5.1 mm
- 400 mm suture attached at one end of which the last 200 mm has been stiffened to aid implantation
- 200 mm loop of suture attached to the other end
- It is made from polyethylene terephthalate
- The device has a breaking strength of 215 daN (2150 N) and an elongation of 19%
Synthetic Ligaments

Reinforcement net Biolig – Cousin Biotech

- It is used to reinforce bone patella tendon bone (BPTB) grafts for ACL reconstruction
- It is made from polyethylene terephthalate
- It is 200 mm long and has an open tube structure which allows a graft to be placed inside
- To retain the graft inside the structure the tube is then closed via suturing
- The device has a breaking strength of 215 daN (2150 N) and an elongation of 19%
- Fixation is achieved with interference screws
Synthetic Ligaments

Trevira Synthetic Ligament – Telos Medical

- The device has a flat, woven structure
- It is manufactured from polyester (KoSa)
- During the implantation procedure the surgeon can twist the intra-articular portion to mimic the structure of the natural ACL
- Inserted into minimal and less traumatic size holes (4.5 mm)
- Its flat structure allows for easy fixation at the bone tunnel exits
- There are 3 sizes, one is used for reconstruction of the ACL and 2 smaller sizes for augmentation to protect the ACL autograft during the early rehabilitation period
  - 8 mm wide x 300 mm long TREVIRA Ligament for cruciate reconstruction
  - 5 mm wide x 300 mm long TREVIRA Ligament for augmentation/protection
  - 3 mm wide x 300 mm long TREVIRA Ligament for augmentation/protection
Historic Synthetic Ligaments

It is worth noting that several types of synthetic ligament were used during the 1980s, but are no longer available due to poor long term clinical results as a result of implant failure, synovitis and inflammation.

A review of failed cases suggested this was due to inadequate fibre abrasion resistance against osseous surfaces, fatigue of the fibres and loss of the textile structure due to unpredictable tissue infiltration during healing [1].

- The Gore-Tex Ligament – W.L. Gore
  - It was a permanent prosthesis, not designed to encourage tissue ingrowth
  - It was made from expanded polytetrafluoroethylene (PTFE)
  - The failure load was 4830 N and the stiffness 322 N/mm

- Stryker-Dacron – Meadox Medical
  - It was a permanent prosthesis, not designed to encourage tissue ingrowth
  - It was made from Dacron (polyethylene terephthalate)
  - It had a core of 4 woven Dacron tapes surrounded by a knitted Dacron tube
  - The failure load was about 3600N

- Kennedy LAD – 3M
  - It was an augmentation device, implanted alongside an autograft
  - It was available in two sizes with a failure load 1730N (8 mm) and 1500N (6 mm), a stiffness of 56 N/mm (8 mm) and 61 N/mm (6 mm)

Biomechanics
Failure Load

The chart shows the ultimate tensile strength (UTS) of the JewelACL [1] in comparison to the natural semitendinosus [2], for which it is intended to be substituted.

It may be seen that the JewelACL matches the natural tissue very well in terms of strength, and so should give a similar physiological performance.

1. Test data on file at Xiros (TR105).
Strength

Relative strengths of a single strand of the JewelACL and a number of competitive devices, as well as a range of natural tissues that are commonly used in ACL reconstruction [1].

Strength of the JewelACL [2] lies between that of the semitendinosus and natural ACL. When the device is doubled up for implantation, as per the semitendinosus, the strength will exceed that of the ACL sufficiently that any fatigue effects will not adversely affect it.

However, it is deliberately designed not to be as strong as some other synthetic devices as this leads to very high stiffness that encourages stress shielding and inhibits the vital tissue ingrowth process.


2. Test data on file at Xiros (TR105).
Initial fixation strength of the JewelACL with different tibial and femoral fixation devices [1]

The lowest of these is approximately 1000 N, compared to a typical *in-vivo* load in the functional ACL of about 450 N.

1. Test data on file at Xiros (TR105).
Fixation Strength After Fatigue

The interference screws were subjected to significant fatigue cycling to ensure that the mechanical fixation strength would remain adequate for at least 6 months of aggressive use, by which point sufficient tissue ingrowth should have occurred to reduce the reliance on mechanical devices.

The screws were tested with the JewelACL alone, and with a JewelACL plus a tissue graft (to simulate a composite graft formed with a harvested semitendinosus).

The JewelACL retains ample fixation strength in the long term in any case.

1. Test data on file at Xiros (TR105).
Useful Information

Promotional Material
- LAB 138 Surgical Technique Manual
- LAB 140 Promotional Flyer
- LAB 145 Rehabilitation Programme
- WP 006 Mechanical properties and fixation performance testing of the JewelACL

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

- Optional Tibial Fixation devices
  - 102-1381 8 mm x 23 mm Fastlok (supplied sterile)

The following devices are manufactured by Medgal and available from Komak, Poland (komak@komak.pl. tel./fax +48 061 662 44 01, tel. +48 664 027 656)
- 7 mm x 30 mm Interference Screw (supplied non-sterile)
- 8 mm x 30 mm Interference Screw (supplied non-sterile)

- Fastlok Instruments
  - 202-1137 Impactor/Extractor
  - 202-1118 Sliding Hammer
Contact

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