

neoligaments™

Leeds-Ruff Patch™

For Rotator Cuff Reinforcement

Surgical Technique Manual



CE 0086

Introduction

Leeds-Kuff Patch™

This technique utilizes a non-absorbable polyester patch which is sutured over the torn rotator cuff. It thus provides reinforcement of incompletely repaired rotator cuff tears and those at high risk of re-tear due to weakness in the soft tissue.

The patch reduces the load placed on the repair, and acts as a scaffold to encourage tissue growth and incorporation into the patient's surrounding tissue.

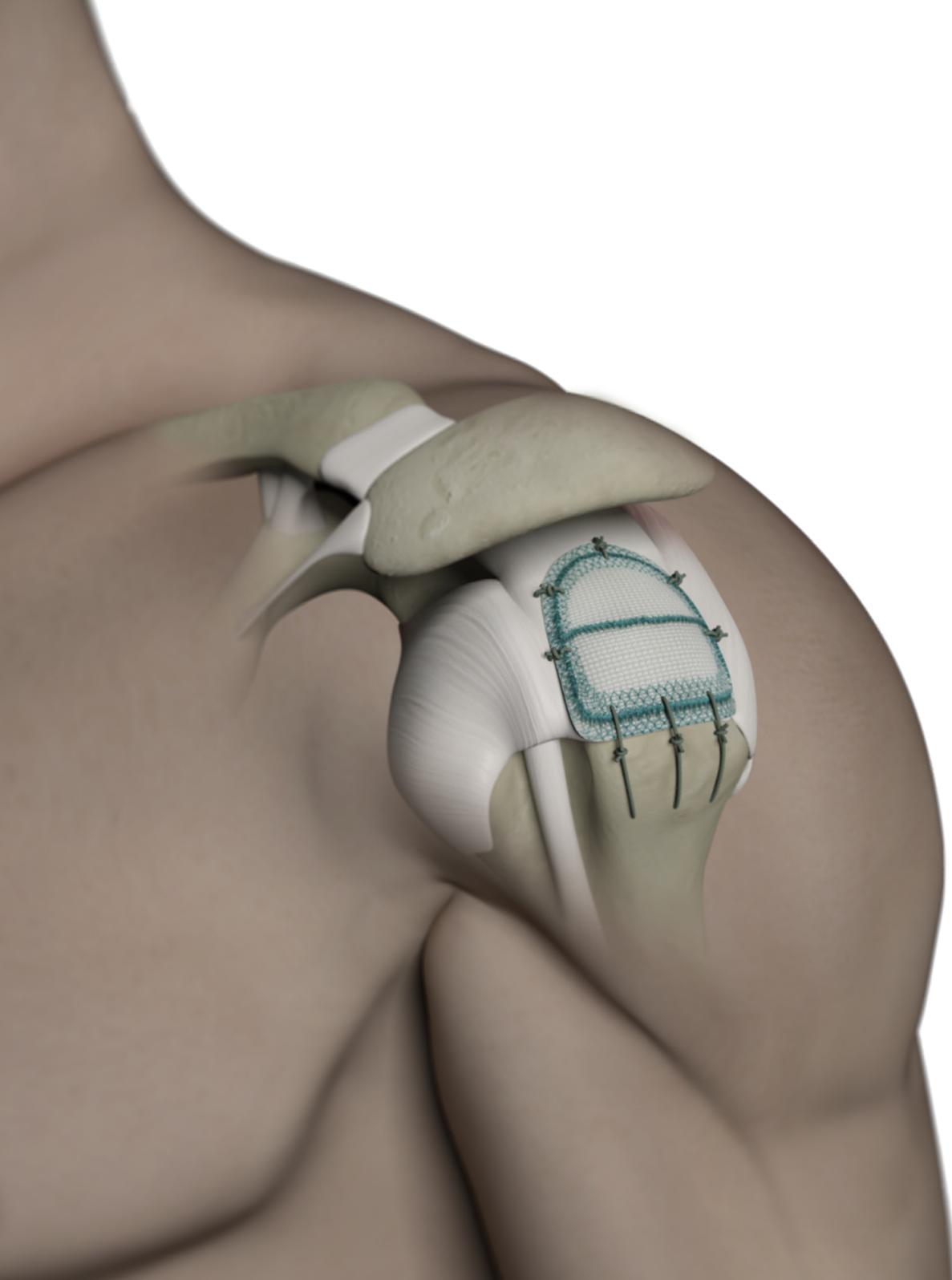
The Leeds-Kuff Patch has the following advantages:

- Coloured reinforced perimeter provides high suture retention strength, and helps identify correct suture placement during surgery
- No need to soak before use
- Easy to handle
- Soft edges to reduce buckling and consequently the patch being proud of the repair, which can otherwise cause irritation
- Strength and consistency; unlike allograft material, there is no concern with variation of donor tissue quality, and no quick degradation during the healing phase
- Readily available and easy to store, with a long shelf life; no freezer or defrosting procedures are required
- Cost effective compared to traditional tissue patches
- Porous structure acts as a scaffold for tissue ingrowth
- Reduces the risk of excess tension being applied to the repair, which can otherwise cause failure

Additionally:

- Unlike allograft and xenograft materials, the Leeds-Kuff Patch is a synthetic material and poses no risk of collagen rejection or donor disease transmission

We would like to thank **Mr. R. G. Hackney**, Consultant Orthopaedic Surgeon, Chapel Allerton Hospital, Leeds, UK, for his work in developing this product and technique.



INDICATIONS

The Leeds-Kuff Patch is a single use device intended to be used for reinforcement of the rotator cuff following or during repair by suture or suture anchors, where one or more of the following exist:

- The tear cannot be completely repaired using normal methods
- The quality of the soft tissue is poor

Contraindications, warnings and precautions: Please refer to the general Contraindications, Warnings and Precautions listed in the Leeds-Kuff Patch Instructions for Use leaflet (LAB 201) packed with the implant.

The Leeds-Kuff Patch is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the repair. The Leeds-Kuff Patch reinforces the rotator cuff and provides a scaffold that is incorporated into the patient's own tissue.

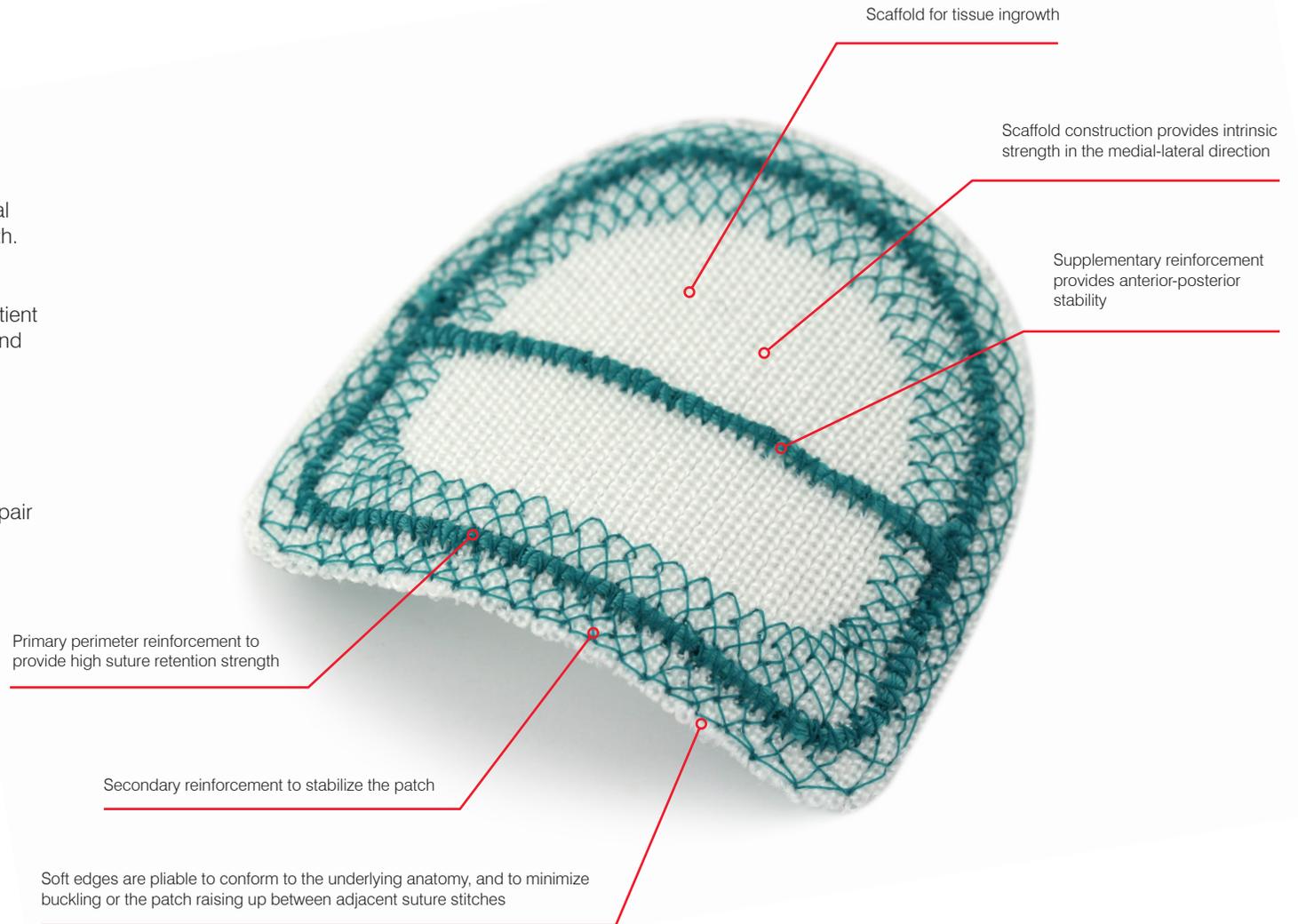
Product Overview

IMPLANT

The Leeds-Kuff Patch is an implantable device constructed from a knitted polyester fabric with integral reinforcement around its perimeter and across its width. The perimeter reinforcement increases the security of suture attachment providing high suture retention strength. It is available in three sizes to suit varying patient anatomy, size of tear, or extent of poor quality tissue and must not be cut to size. The device is supplied sterile.

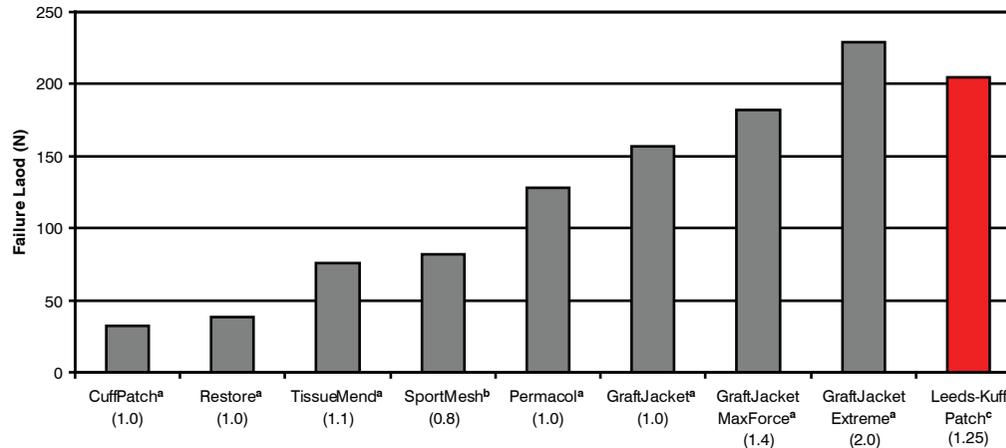
INSTRUMENTATION

No specialized instrumentation is needed for this operation. However, the user should ensure that the standard shoulder instruments for open rotator cuff repair are available before starting surgery.

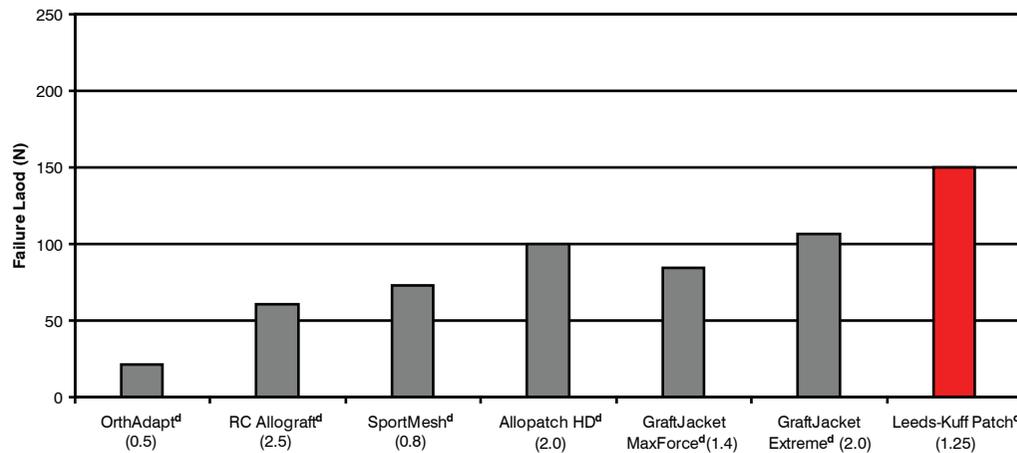


Failure Load for Commercially Available Reinforcement Graft Materials

Mattress Stitch: Single Horizontal Configuration with #2 FIBERWIRE® Suture



Simple Stitch: Single Horizontal Configuration with #2 FIBERWIRE® Suture



NOTE: Graft thickness in mm is given in brackets

The Leeds-Kuff Patch provides a high suture retention strength compared to other commercially available graft materials

Designed for use with a simple stitch

Limited joint space often restricts access, so the easier to place simple stitch is typically used instead of the mattress stitch. The Leeds-Kuff Patch has therefore been designed with integral reinforcement that allows a high suture retention strength to be achieved with a simple stitch. A simple stitch through the Leeds-Kuff Patch can thus provide comparable suture retention strength to a mattress stitch placed in other commercially available graft materials of similar thickness.

Results taken from:

- a. **Barber FA, Herbert MA, Coons DA.** Tendon augmentation grafts: biomechanical failure loads and failure patterns. *Arthroscopy*. 2006;22(5):534-538.
- b. **Biomet.** SportMesh Sales brochure. Data on file at Artimplant. 2007;BSM01 12.0, REV113007.
- c. **Neoligaments.** Data on file.
- d. **Barber FA, Aziz-Jacobo J.** Biomechanical testing of commercially available soft-tissue augmentation materials. *Arthroscopy*. 2009;25(11):1233-9.

Surgical Technique

FUNCTIONAL ANATOMY/PATHOPHYSIOLOGY

The function of the rotator cuff is to centralize the humeral head into the glenoid and to assist in motion of the glenohumeral joint. Rotator cuff tears usually start in the supraspinatus and extend posteriorly. The aetiology seems largely to be related to age. The majority of tears start on the articular side and become full thickness.

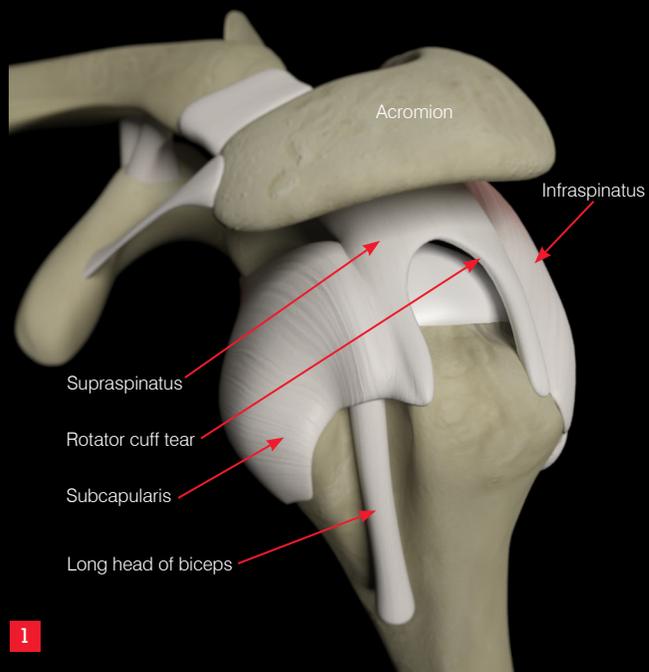
Small and moderate sized tears, less than 3 cm in diameter, can be effectively repaired using arthroscopic, mini-open or open techniques. Large tears, 3-5 cm maximum diameter, and massive tears, greater than 5 cm in diameter, are not always repairable. An incomplete repair is at increased risk of re-tearing. Poor quality of tendon in an older patient with muscle atrophy is also at risk of re-tearing following conventional repair.

CLINICAL PRESENTATION

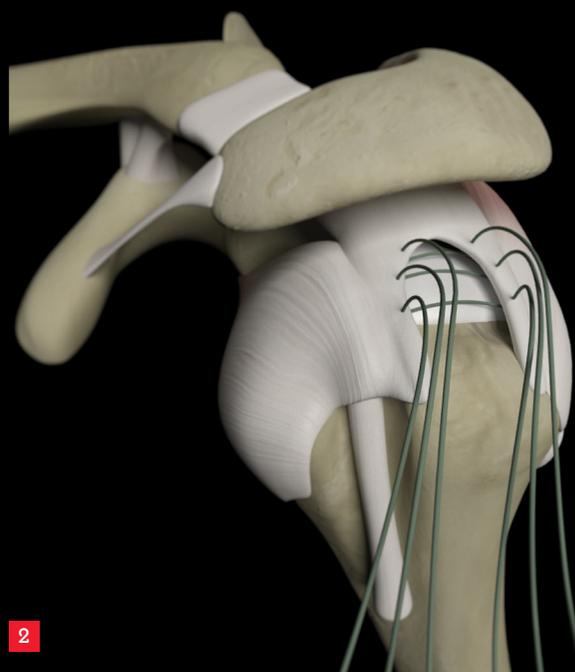
Symptoms of rotator cuff tears include significant night pain with an inability to lie on the affected side, loss of overhead activity, weakness, and difficulty dressing and undressing. Large and massive tears tend to present with weakness in external rotation, hitching of the shoulder in abduction, and in extreme cases, a flail shoulder.

POSITIONING

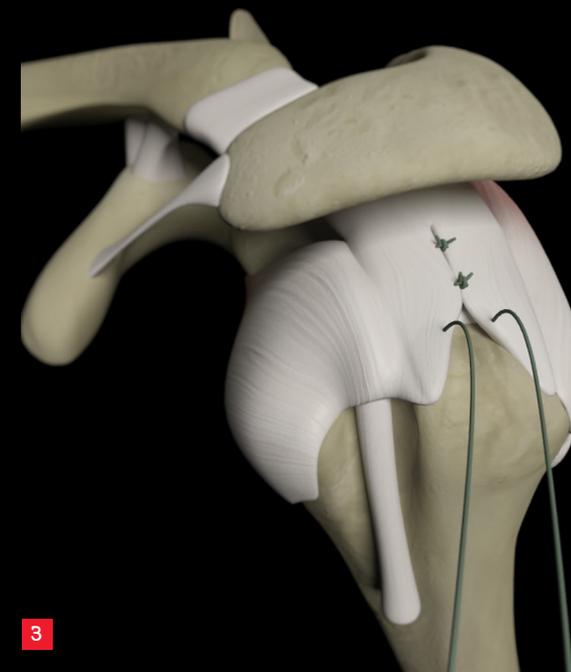
The procedure is performed with the patient in the beach chair position. A hydraulic shoulder positioner (e.g. Spider Limb Positioner, Smith & Nephew) is useful in applying traction and to vary the position of the arm to gain access to the rotator cuff. A protective covering such as an loban is applied. Preoperative antibiotics should be given.



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RECOMMENDED APPROACH

The shoulder is arthroscopically evaluated through standard portals. If the tear appears small and the quality of the cuff is good, it should be repaired using appropriate sutures and anchors. Otherwise an incision is made and the cuff is repaired using appropriate sutures and anchors, and is reinforced with the Leeds-Kuff Patch.

The Leeds-Kuff Patch is used in a mini-open approach to cover the gap which remains when a tear cannot be completely repaired using normal methods. An open approach is used when the tear is extensive and requires aggressive mobilization.

A lateral deltoid splitting approach is recommended to achieve maximum access to a posteriorly subluxed infraspinatus. The anterior-lateral deltoid is dissected subperiosteally from the acromion. The deltoid is carefully incised in the line of its fibres. The lower limit of this dissection is the axillary nerve. The majority of cases will not require dissection to this level, which is a minimum of 5 cm from the lateral edge of the acromion. A stay suture can be applied across the deltoid to prevent any further splitting. A self retaining retractor is applied gently.

The subacromial bursa may need to be excised to improve vision of the rotator cuff. If there is limited joint space a subacromial decompression may be performed. Care should be taken to avoid damaging the suprascapular nerve.

The shoulder is distracted and rotated to access the anterior and posterior aspects of the cuff repair.

Stay sutures are placed in the cuff. Where space permits access of the integral curved J-shaped needle, #2 Ethibond or preferably a #2 high strength suture is used. With limited access a smaller #1 suture and needle are used.

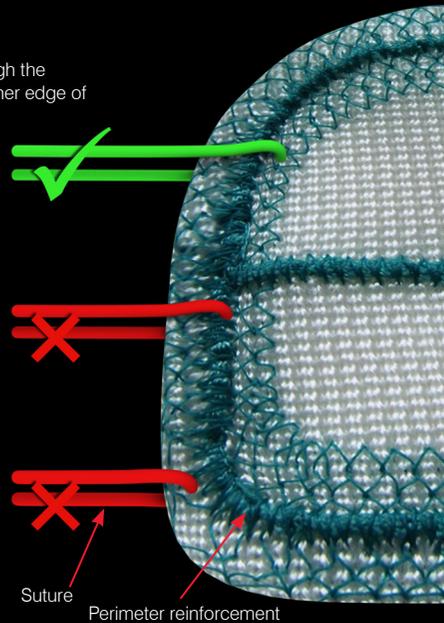
The stay sutures are used to pull the rotator cuff towards the tuberosities. The needles are left attached, as the sutures can be used to attach the rotator cuff to the patch.

The defect in the rotator cuff is repaired as far as possible, tying the stay sutures for a side to side repair where achievable. The tension should be moderate at most. Once partial closure is achieved, or even full closure where the quality of the tendon is poor, then the patch can be applied over the tendon.

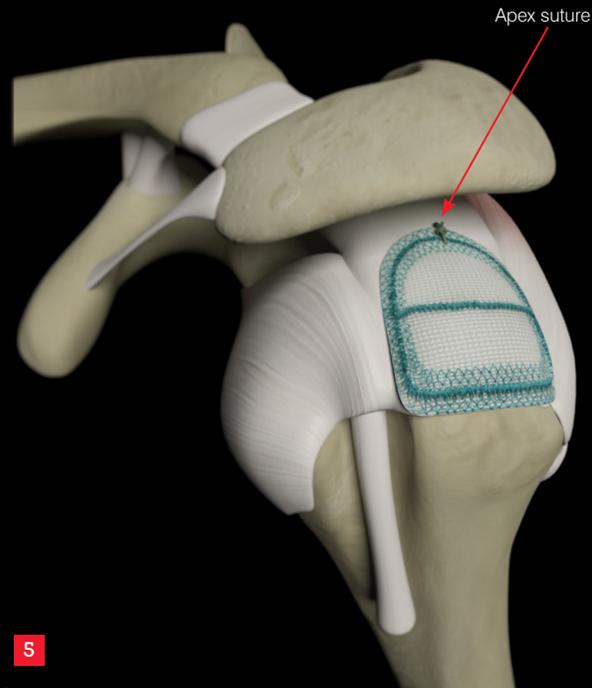
Correct:
Suture placed through the patch, next to the inner edge of the reinforcement

Incorrect:
Suture through the reinforcement

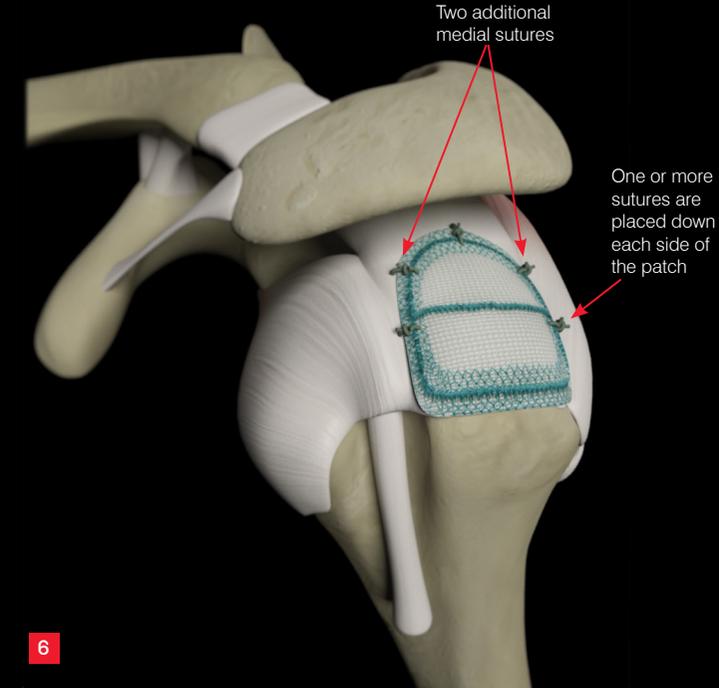
Incorrect:
Suture through the outer edge



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All sutures used to attach the Leeds-Kuff Patch to soft tissue and bone for the purpose of load transfer must be placed through the patch, next to the inner border of the perimeter reinforcement.

Sutures should not pierce the perimeter reinforcement.

Load bearing sutures placed in the area between the perimeter reinforcement and the outer edge of the patch, or towards the centre of the patch, may break or pull through the device.

A simple stitch or mattress stitch is used to attach the Leeds-Kuff Patch to the tissue. A simple stitch is preferred since it is easy to place and when encircling the perimeter reinforcement it provides high suture retention strength.

Supplementary sutures used to ensure apposition of the patch to the underlying cuff may be placed within the centre of the patch. The previously placed stay sutures can be used to provide such a function.

Take care to select the most suitable size of Leeds-Kuff Patch for the repair based on patient anatomy, size of tear, or extent of poor quality tissue.

NOTE: The Leeds-Kuff Patches must not be cut to size.

The edges of the patch are sewn over the superior edges of the rotator cuff tendon so that it sits flush with the tendon.

The Leeds-Kuff Patch is first fixed at the apex with a vertical stitch. A #2 high strength suture is preferably used.

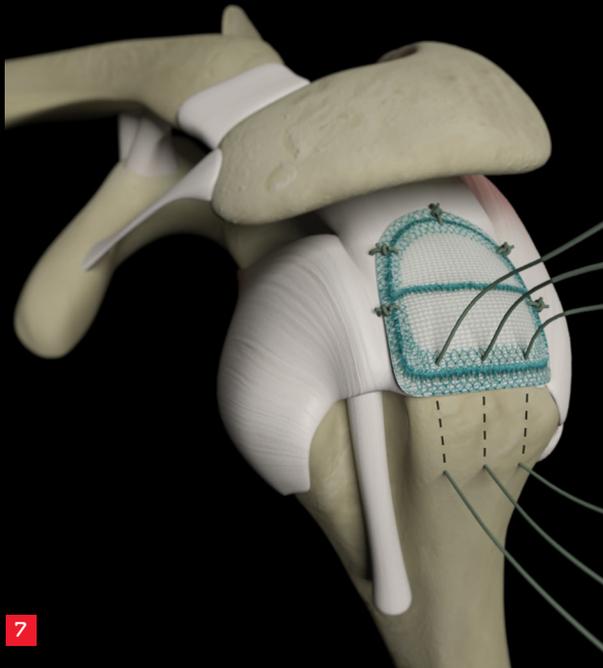
NOTE: When handling the Leeds-Kuff Patch (and appropriate sutures used to repair the tear and attach the Leeds-Kuff Patch to soft tissue and bone), care should be taken to avoid damage from handling. Avoid excessive crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders.

Two stitches are placed anterior to and posterior to the apex suture.

Stitches are then placed on the anterior and posterior edges of the patch. If the size of tear is large or the quality of the tendon is weak, more than one stitch on each side may be required to distribute the load.

The stay sutures placed in Step 2 may be used to provide supplementary attachment to ensure apposition of the patch to the underlying cuff.

Appropriate tension is applied to avoid over- or under-tensioning. Under-tensioning may allow billowing of the patch and over-tensioning may cause premature failure of the repair.

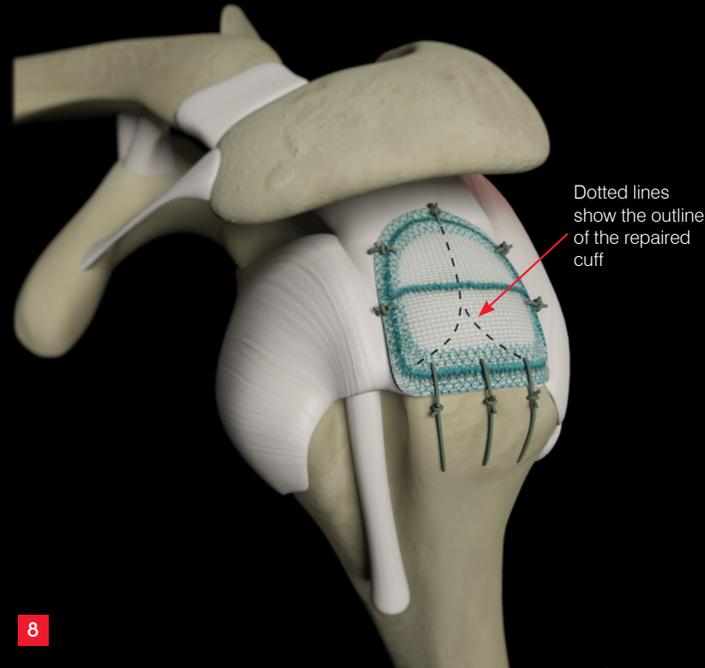


The repair is pulled laterally over the tuberosities. The patch and tendon are then anchored to the tuberosity.

Depending on the size of the patch it is recommended to place up to three per-osseous sutures in the tuberosity. It is recommended to use #5 Ethibond with an integral needle of appropriate size to withstand insertion through the bone. Each suture is placed with a simple stitch through the patch, next to the inner border of the perimeter reinforcement, and through the tendon.

NOTE: Take care to leave an adequate bone thickness between adjacent per-osseous sutures, and between the embedded suture and bone surface, to provide sufficient bony bridge to resist expected forces that will be exerted on the bone by the reconstruction. Take into account the quality of the bone.

Alternatively, suture anchors using one of the high strength suture materials can be used in place of the per-osseous sutures.



Dotted lines show the outline of the repaired cuff

Appropriate tension is applied to ensure the length of the reconstruction is physiological. Over- or under-tensioning is avoided to ensure adequate joint function is achieved and premature failure of the repair is avoided.

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WOUND CLOSURE

The deltoid is carefully repaired proximally using #1 Ethibond sutures with a mattress stitch. The edges of the incision in the deltoid are repaired. A #2-0 Vicryl suture with a stitch for fat can be used if applicable and a subcuticular suture to skin.

POSTOPERATIVE MANAGEMENT

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

As in any implant surgery, satisfactory wound healing is of paramount importance.

The patient should be warned not to exceed the prescribed activity levels or to overload the repair before complete healing has occurred.

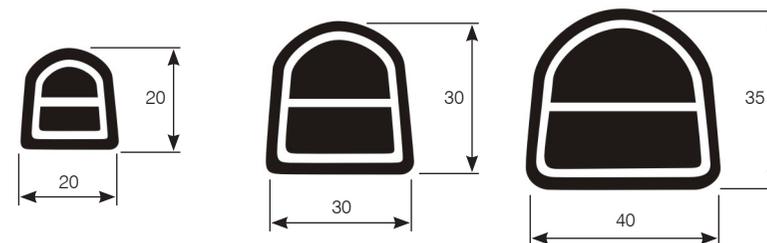
The shoulder is held in an immobilizer for 3 weeks. During this time, only passive movements are permitted. These may include pendular exercises and passive movements to shoulder height in forward flexion and abduction. Passive assisted motion can commence following this, progressing to gentle strengthening work at 6 weeks postoperatively.

These patients often have significant muscle atrophy preoperatively, and a prolonged period of recovery of power and range of motion is to be anticipated.

Ordering Information

Leeds-Kuff Patch (supplied sterile)

102-1071	20 mm x 20 mm Leeds-Kuff Patch, Small
102-1072	30 mm x 30 mm Leeds-Kuff Patch, Medium
102-1073	35 mm x 40 mm Leeds-Kuff Patch, Large





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