Pitch-Patch Tissue reinforcement for

rotator cuff repair

Surgical Technique Manual

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Pitch-Patch

Introduction

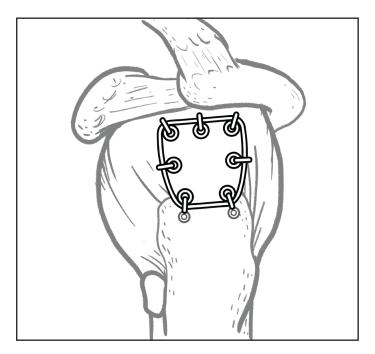
The Pitch-Patch concept;

- The Pitch-Patch is a Polyester (polyethylene terephthalate) patch for reinforcement of the rotator cuff following repair by sutures or suture anchors.
- The shape is designed to fit the anatomy.
- It features a reinforced border and incorporates reinforced, prepared holes for the sutures, up to size #5.
- It is available in two sizes to cover different tear sizes of the rotator cuff:
 30 mm x 20 mm and 35 mm x 25 mm.
- Polyester implants have a long history of routine use in joint surgery. They are well tolerated and show little foreign body tissue reaction.
- Unlike biological tissue, the polyester material used for the Pitch-Patch does not cause any immunological reaction.
- Testing of this special design has shown a very high average strength of over 400 N and 550 N for the medium and larger patches respectively.
- The Pitch-Patch can be applied using an open or arthroscopic technique for the reinforcement of the rotator cuff.
- The Pitch-Patch is not intended for stand-alone bridging (replacement of the cuff with insufficient closure).

Indications

- The Pitch-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 weakness exists in the soft tissue.
- The Pitch-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 Pitch-Patch reinforces the rotator cuff and provides a scaffold that is incorporated into the patient's own tissue.
- The Pitch-Patch is indicated for patients requiring reinforcement of the rotator cuff where either the tear cannot be completely repaired using normal methods and/or the quality of the soft tissue is poor.
- Further information regarding indications and contraindications are available in the Instructions For Use (IFU) LAB 195.

Reinforcement overview



For the open surgical technique, the Pitch-Patch is fixed with high strength non-absorbable sutures after the initial closure of the tendon and over the repaired tissue.

It is recommended to use sutures **medially** at the tendon-muscle junction.

Laterally the fixation should be made with either knotted or knotless suture anchors or with a transosseous technique.

Care should be taken to repair the deltoid proximally.

General Considerations

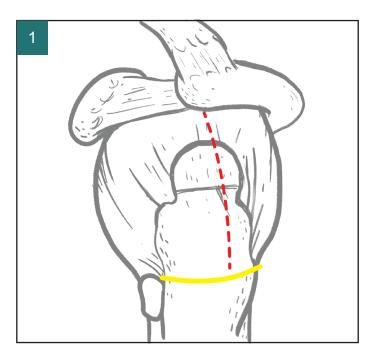
Preparation and Inspection

- The open procedure is typically performed in the beach chair position.
- Pre-operative antibiotics are usually administered.
- The limb should be prepared and draped using standard aseptic techniques.

Joint Access

- The subacromial bursa may need to be excised to improve visualisation 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.

Open Technique

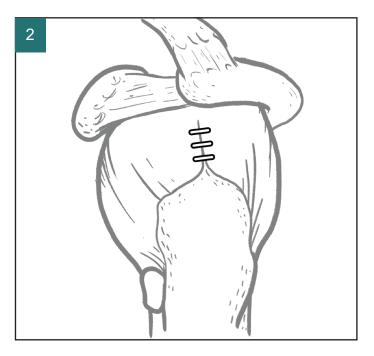


Recommended surgical approach

A lateral deltoid splitting approach allows good access to the infraspinatus when posteriorly subluxed.

In this case, a 4-5 cm incision is made in the anterior-lateral deltoid sub-periosteally from the acromion.

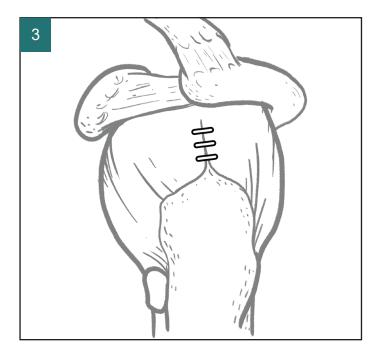
The lower limit of dissection should be superior to the axillary nerve (indicated in yellow).



Cuff repair and Closure

After analysis of the rupture, the cuff is mobilised appropriately.

The rotator cuff is then repaired with a suture technique.



Pitch-Patch selection

Size selection of Pitch-Patch is made to offer appropriate coverage of the repaired tissue.

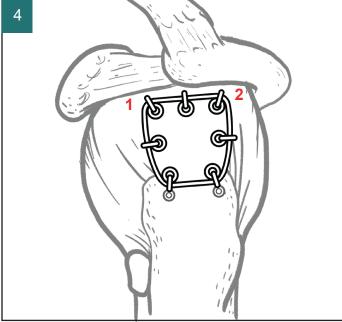
Pitch-Patch sizes available:

- 102-1090XI Pitch-Patch 30 mm x 20 mm
- 102-1091XI Pitch-Patch 35 mm x 25 mm

Pitch-Patch suture sequence – Medial first

The Pitch-Patch is laid flat to the rotator cuff.

#2 high strength sutures are placed through the reinforced holes and cuff tissue using the anteromedial and the posteromedial holes. The sutures are each tied securely with a locked knot and then cut.



Pitch-Patch suture sequence – Lateral anchor fixation

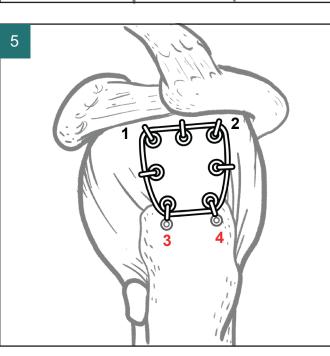
High strength #2 sutures are placed through the lateral reinforced holes in the Pitch-Patch and, if possible, rotator cuff tissue.

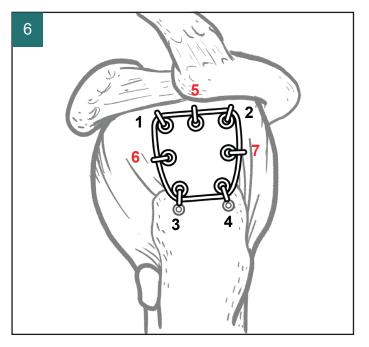
The construct is then tensioned and fixed with the surgeon's choice of knotless suture anchor.

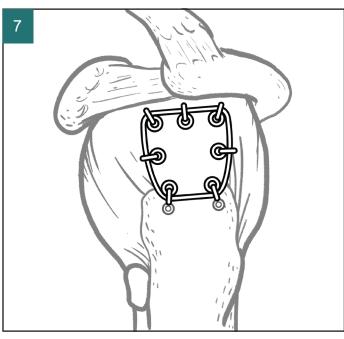
As an alternative to suture anchor fixation, a transosseous technique may be used.

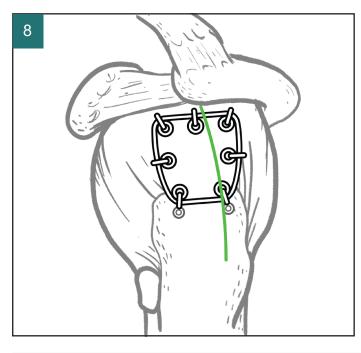
Note: The sequence may need to be adapted if knotted suture anchors are to be used.

Goal: To achieve appropriate tension and tendon-to-bone apposition with the Pitch-Patch overlaid.









Pitch-Patch suture sequence – Centre-medial and mid patch fixation

The centre-medial reinforced hole of the Pitch-Patch is sutured to the cuff tissue using a #2 high strength suture. The suture is tied securely with a locked knot and cut.

#2 high strength sutures are then placed through the reinforced holes and cuff tissue using the midanteromedial and the mid-posteromedial holes. The sutures are each tied securely with a locked knot and then cut.

Goal: To achieve appropriate tension and tendon-tobone apposition with the Pitch-Patch overlaid.

Note: Additional sutures can be placed through the cuff tissue and reinforced holes of the Pitch-Patch to supplement patch to tendon fixation.

Final Construct

The Pitch-Patch lays snug on the rotator cuff.

The force of the muscle is directly applied to the humerus.

Thus, the tendon-bone interface can heal well.

Wound Closure

The deltoid is carefully repaired proximally using #1 braided sutures with a mattress stitch.

The edges of the incision in the deltoid are repaired. A #2-0 absorbable suture with a stitch for fat can be used if applicable and a subcuticular suture to skin.

Postoperative management

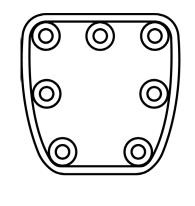
Postoperative rehabilitation is according to the guidelines for rehabilitation of the rotator cuff reconstruction.

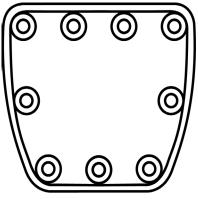
Contact Xiros for further details if required.

Implant

102-1090XI Pitch-Patch Tissue Reinforcement (30 mm x 20 mm)

102-1090XI Pitch-Patch Tissue Reinforcement (35 mm x 25 mm)





Please refer to the Instructions for Use leaflet packed with the Pitch-Patch for essential information including Use, Sterility, Indications, Contraindications, Warnings and Precautions, Potential Adverse Effects and Storage. Additional copies may be obtained from the Neoligaments™ Sales Department, or downloaded from http://www.neoligaments.com

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