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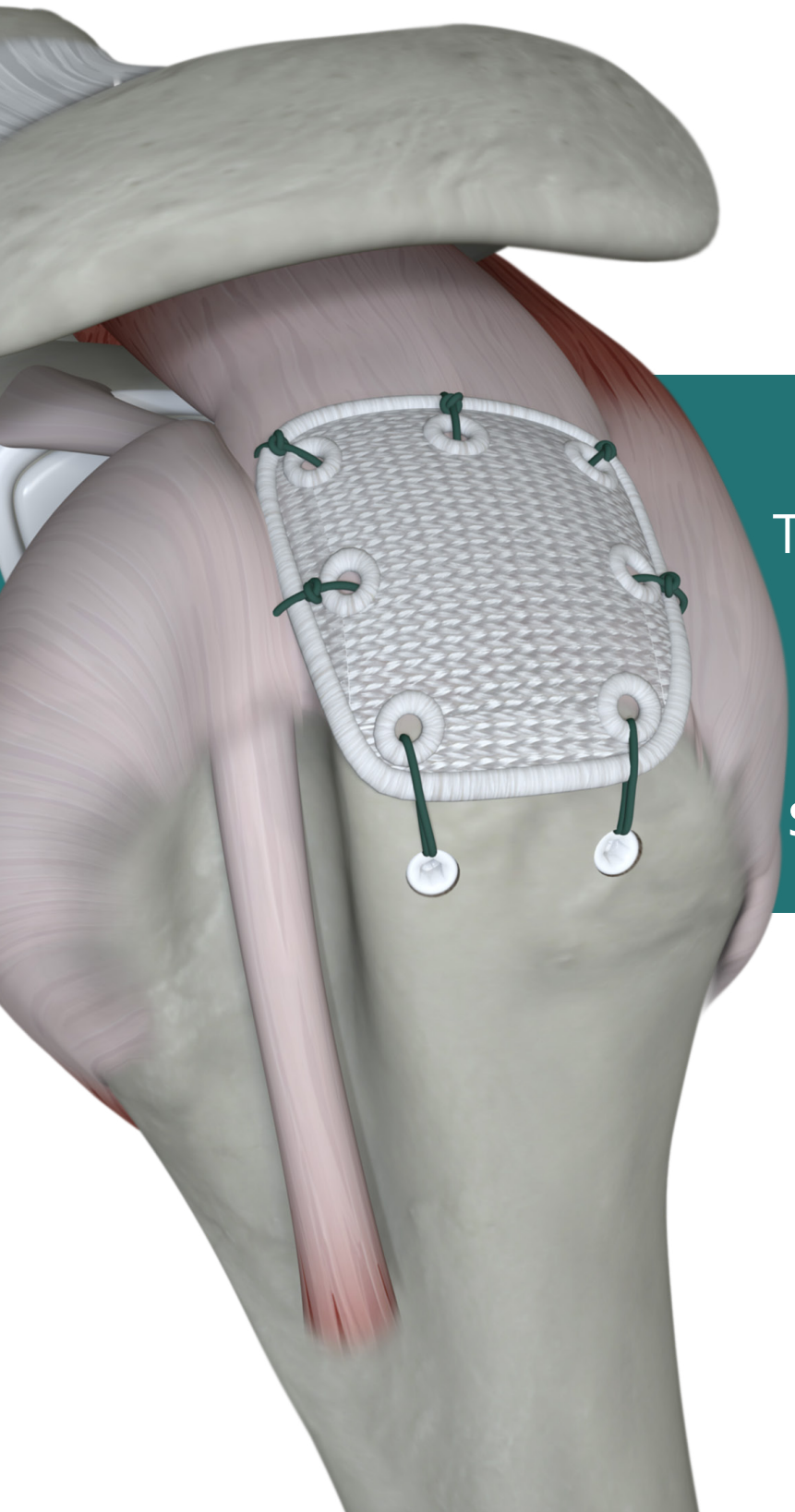

Pitch-Patch

Tissue reinforcement for rotator cuff repair Open Technique

Surgical Technique Manual

CE 2797

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Pitch-Patch Open technique

Introduction

The **Pitch-Patch** concept;

- The **Pitch-Patch** is a permanently implantable patch constructed from non-absorbable Polyester (poly (ethylene terephthalate) fibres), for reinforcement of the rotator cuff following or during repair by sutures or suture anchors.
- The **Pitch-Patch** has a warp knitted structure that allows a natural body response whereby native tissue integrates into the device.
- 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 when fully sutured along the medial edge (3 sutures) for the standard patch [1].
- 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 sutures or suture anchors, where weakness exists in the soft 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.
- 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 suture anchors, used to attach the tissue to the bone, provide mechanical strength for the repair.
- Further information regarding indications and contraindications are available in the Instructions For Use (IFU) LAB 195.

etzelclinic and the Pitch-Patch story

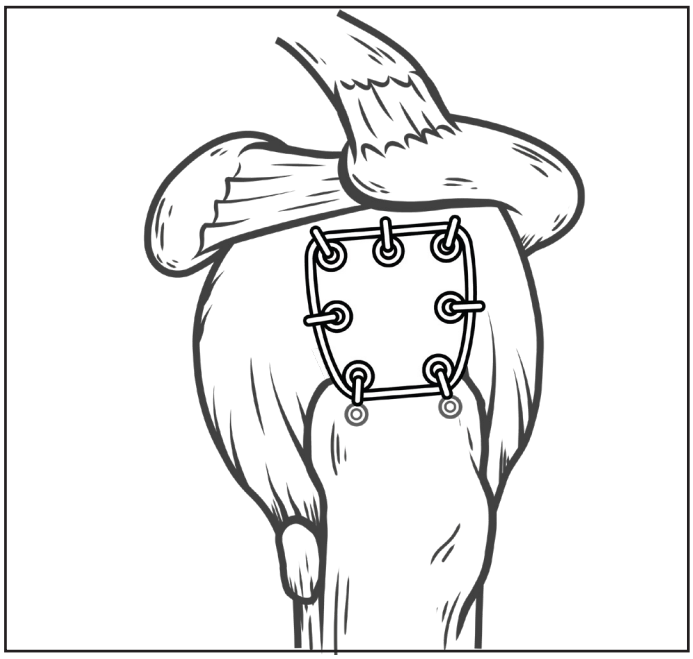
The **Pitch-Patch** was devised by Dr. Med. Jan Leuzinger of the etzelclinic with first implantations in 2012. As rotator cuff (RC) repair techniques developed, with improved anchors, high strength sutures and effective suture passing devices, RC repair still suffered from reported high re-tear rates. [2, 3, 4]

The remaining weak link was the quality of the native tissue available for repair. A number of patch techniques and materials have been devised for the repair of massive RC tears. Dr Leuzinger proposed a poly-ethylene terephthalate (polyester) anatomically shaped and reinforced device, that would offer immediate strength and allow a standardised rehabilitation programme determined by the underlying tissue repair and not modified due to the patch itself.

A study published in the JSES in 2019 concluded for the **Pitch-Patch**; “patch augmentation in massive RC reconstruction leads to a substantially lower retear rate.” [5]

Introduction

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 trans-osseous technique.

Care should be taken to repair the deltoid proximally.

General Considerations

Preparation and Inspection

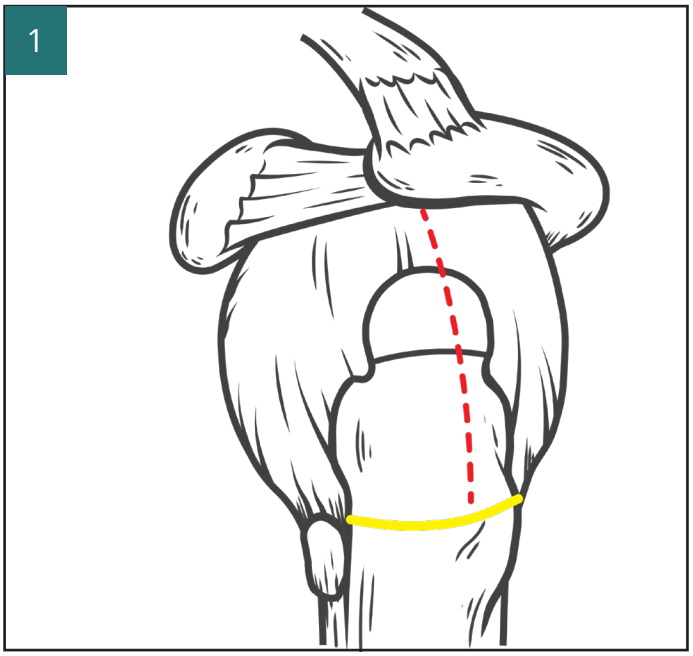
- The open procedure is typically performed in the beach chair position.
- Pre-operative antibiotics are usually administered.
- The limb should be prepared and draped using standard aseptic techniques.

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.

Surgical Technique

Open Technique

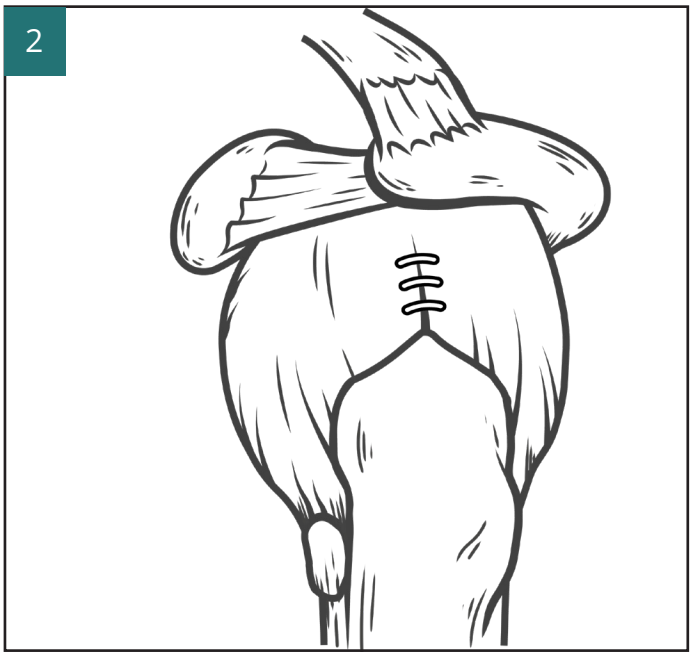


Recommended surgical approach

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.

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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**, Standard 30 mm x 20 mm (supplied sterile)
- 102-1091XI **Pitch-Patch**, Large 35 mm x 25 mm (supplied sterile)

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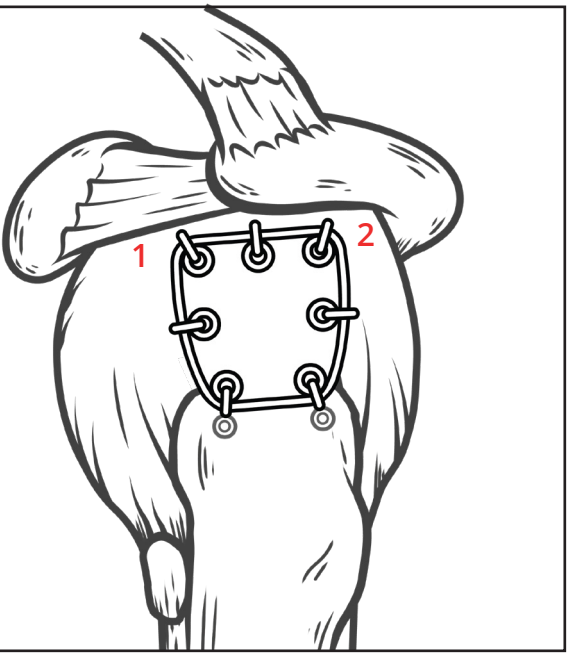

Pitch-Patch suture sequence – Medial first

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.

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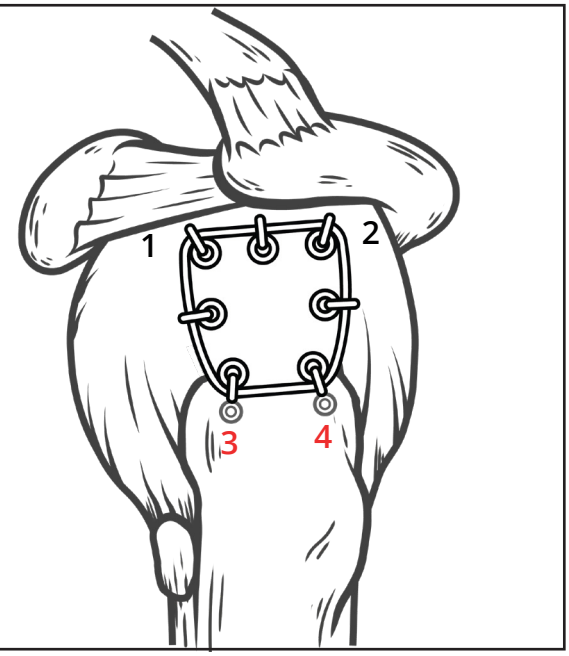

Pitch-Patch suture sequence – Lateral anchor fixation

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.

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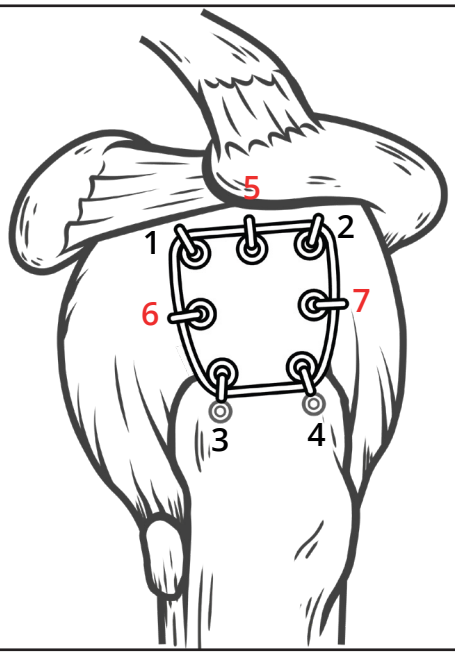

Pitch-Patch suture sequence – Centre-medial and mid patch fixation

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 mid- anteromedial 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-to-bone 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.

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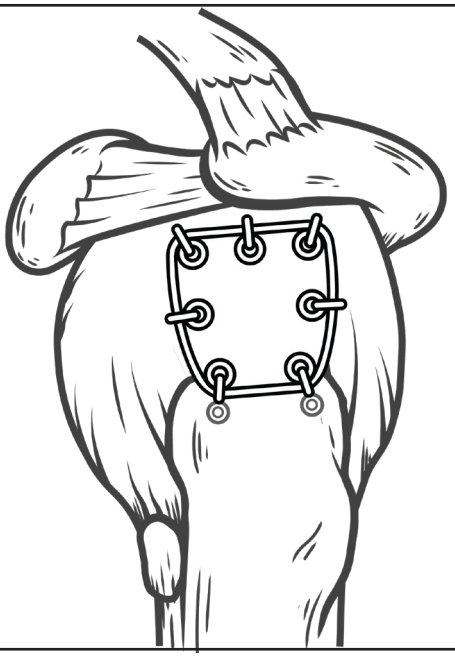

Final Construct

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.

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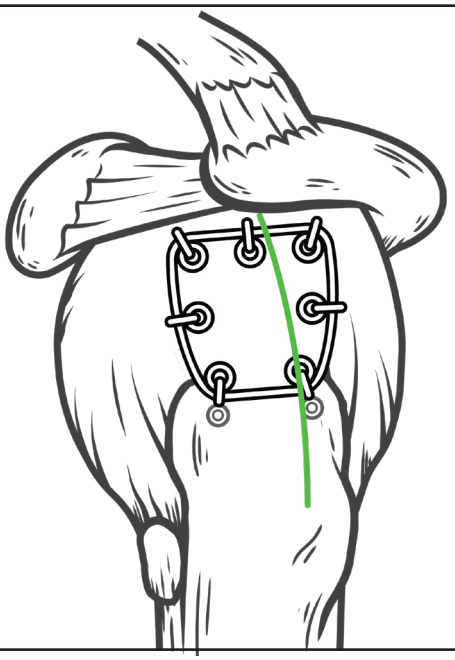


Wound Closure

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 management

Immediate post-operative care

As per standard rotator cuff protocols. The developing surgeons routinely use shoulder sling, +/- abduction cushion to reduce tension in the repair construct. Cryotherapy and pain relief medication including NSAR's as required.

Post-operative rehabilitation programme

The **Pitch-Patch** Rehabilitation Programme (LAB 303) offers further information of the developing surgeon's preferred rehabilitation programme. This programme has been translated and reproduced with the kind permission of the shoulder team at the etzelclinic.

Please go to www.xiros.co.uk for a downloadable version.

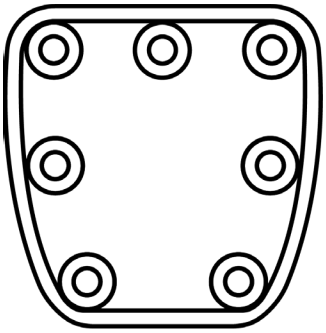
References

1. **Xiros.** Data on file
2. **Chung SW, Kim JY, Kim MH, Kim SH, Oh JH.** Arthroscopic Repair of Massive Rotator Cuff Tears: Outcome and Analysis of Factors Associated With Healing Failure or Poor Postoperative Function. The American Journal of Sports Medicine. 2013;41(7):1674-1683. doi:10.1177/0363546513485719
3. **Kim JR, Cho YS, Ryu KJ, Kim JH**. Clinical and radiographic outcomes after arthroscopic repair of massive rotator cuff tears using a suture bridge technique: assessment of repair integrity on magnetic resonance imaging. Am J Sports Med. 2012 Apr;40(4):786- 93. doi: 10.1177/0363546511434546. Epub 2012 Feb 3. PMID: 22307079.
4. **Choi S, Kim MK, Kim GM, Roh YH, Hwang IK, Kang H.** Factors associated with clinical and structural outcomes after arthroscopic rotator cuff repair with a suture bridge technique in medium, large, and massive tears. J Shoulder Elbow Surg. 2014 Nov;23(11):1675-81. doi: 10.1016/j.jse.2014.02.021. Epub 2014 May 24. PMID: 24862247.
5. **Smolen D, Haffner N, Mittermayr R, Hess F, Sternberg C, Leuzinger J.** Application of a new polyester patch in arthroscopic massive rotator cuff repair-a prospective cohort study. J Shoulder Elbow Surg. 2020 Jan;29(1):e11-e21. doi: 10.1016/j.jse.2019.05.015. Epub 2019 Aug 9. PMID: 31405714.

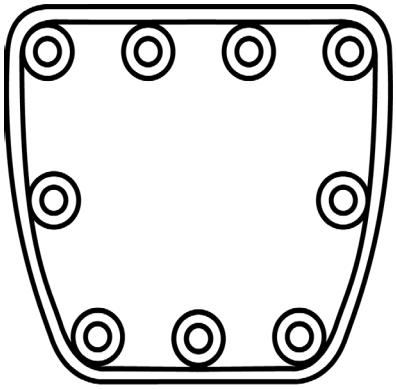
Ordering Information

Implant

102-1090XI **Pitch-Patch**, Standard, 30 mm x 20 mm



102-1091XI **Pitch-Patch**, Large, 35 mm x 25 mm



Xiros products and their indications are subject to regional variations. To confirm availability in your region/country please contact enquiries@xiros.co.uk

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 Xiros™ Sales Department, or downloaded from www.xiros.co.uk

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