XIROS

Infinity-Lock™ Button System

For Fixation of Acromioclavicular Separations due to Coracoclavicular Ligament Disruption

Surgical Technique Manual

CE 2797

Infinity-Lock Button System

INTRODUCTION

The **Infinity-Lock** Button System provides a non-harvesting, simple and reproducible mini-open technique for the stabilisation of a separated acromioclavicular (AC) joint.

This technique is used for Grade IV-VI AC separations, together with Grade III separations which require operative treatment.

The **Infinity-Lock** Button System comprises a permanent implantable Tube-Tape with integral eyelet which is looped around the coracoid, together with a titanium alloy Button for clavicle attachment. Clavicle tunnel drilling is made easier with the supplied disposable cannulated drill bit and guidewire. A left or a right **CC-Hook** instrument can be used for optimum passage of the Tube-Tape around the coracoid.

We would like to thank **Emeritus Professor W Angus Wallace**, Academic Orthopaedics, Trauma & Sports Medicine, University of Nottingham, and **Mr Matt Ravenscroft**, Consultant Shoulder Surgeon, Stepping Hill Hospital, Manchester, for their work in developing this device and technique.

INTENDED USE

The **Infinity-Lock** Button System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption.

INDICATION

The **Infinity-Lock** Button System is indicated for patients with acromioclavicular separations resulting from disruption to the coracoclavicular ligaments.

Please refer to the general contraindications, warnings and precautions listed in the Instructions for Use leaflet (LAB 253), packaged with the device.

Product Overview

IMPLANTS

The **Infinity-Lock** Button System uses a woven 7 mm wide by 240 mm long Tube-Tape with integral eyelet, with each limb tapered into a 140 mm long cord. This continuous structure is made from polyethylene terephthalate (polyester). The Tube-Tape is attached to a Button made from implant grade titanium alloy (Ti-6Al-4V) to ISO 5832-3.

The **Infinity-Lock** delivers reliable and reproducible outcomes through the following structural features and associated benefits:

- Loop fixation around the coracoid eliminates the need for a bone tunnel, reducing risk of coracoid fracture.
- Wide and soft 7mm Tube-Tape distributes the load across the coracoid to reduce the likelihood of bone abrasion (cheesewiring) associated with abrasive sutures.
- Single 4mm diameter clavicle tunnel reduces the risk of bone fracture.
- Titanium alloy Button maintains the reduced anatomical (vertical) position during implantation of the device.
- Button and cerclage knotting technique provides high strength clavicular fixation, together with a low profile designed to reduce soft tissue irritation.
- Non-absorbable polyester scaffold construction allows on-growth and in-growth, eliminating the need for tissue graft and the associated morbidity (autograft) and addtional cost (allograft).
- Long Tube-Tape provides a one-size-fits-all, eliminating potential for mis-sizing, and reducing inventory and stock holding.
- High strength Tube-Tape exceeds native coracoclavicular ligament loads* to facilitate maintaining long term reduction.

* Data on file at Xiros

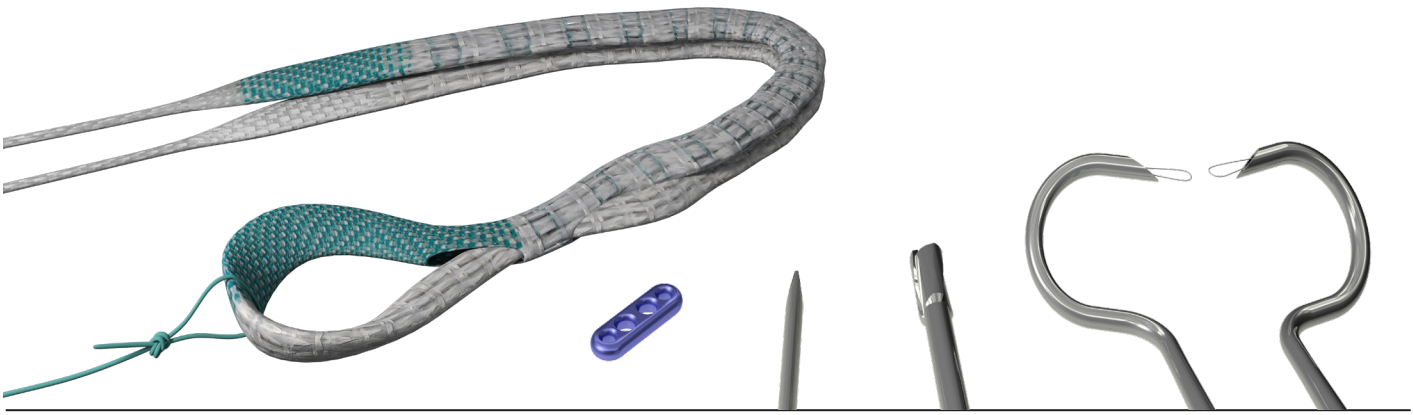
INSTRUMENTS

The following instruments are packed with the implant devices:

- Cannulated drill bit, plain shank to fit Jacobs chuck, 4.0 mm diameter x 120 mm
- Guidewire, diameter 2.0 mm x 150 mm

The user can also order the following single use, disposable, instruments to aid passing the Tube-Tape around the coracoid:

- **CC-Hook**, with a curved end, Left
- **CC-Hook**, with a curved end, Right

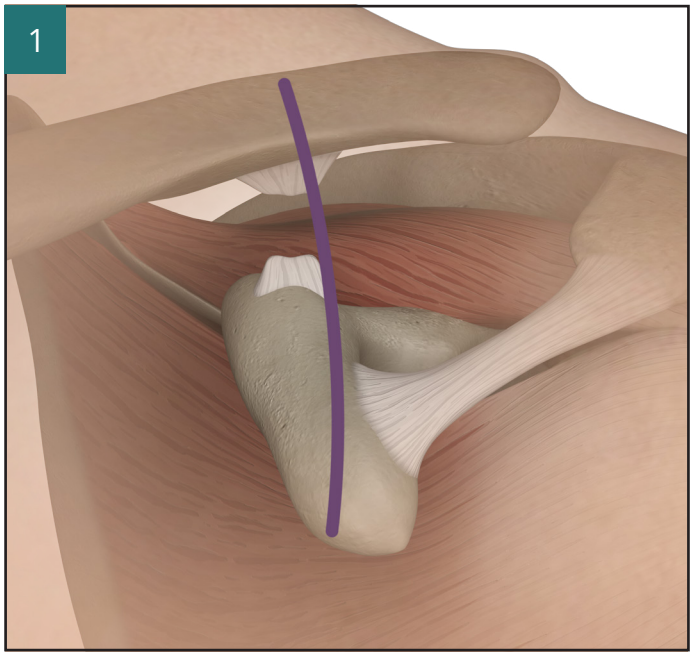


Surgical Technique

PREPARATION AND INSPECTION

The patient is placed in the lateral decubitus or Beach Chair position under a general anesthesia, supplemented with a scalene block (if desired).

NOTE: It is recommended that patients are placed on prophylactic antibiotics prior to surgery, to minimise the risk of latent infections developing at the implant site. Use aseptic technique throughout the procedure.



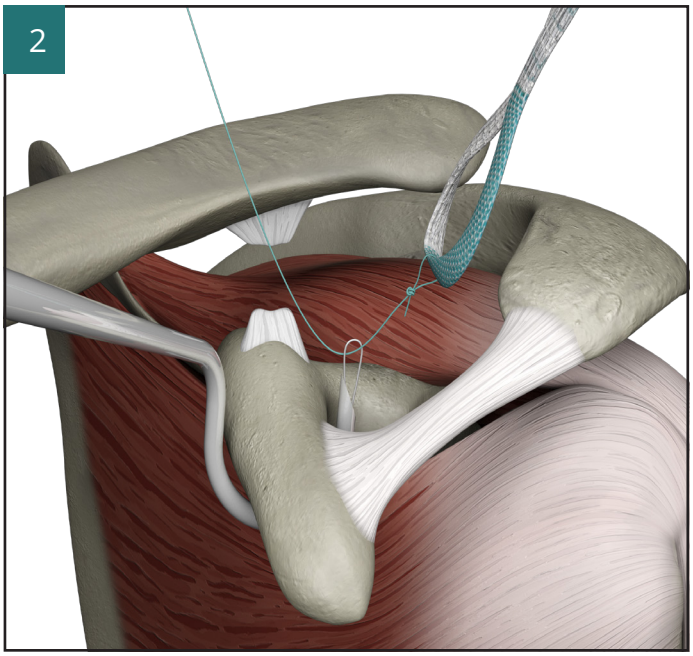
RECOMMENDED APPROACH

With the patient in the beach chair position use a vertical 5 cm skin incision starting at the level of the clavicle and 1-2 cm medial to the tip of the coracoid (Care should be taken to make the incision lateral to where the button will sit over the drill hole, 3-4 cm from the distal tip of the Coracoid). Incise the fascia and the deltoid vertically and then divide the periosteum over the posterior clavicle laterally as far as the AC joint.

Carry out a sub-periosteal dissection creating an "L" shaped flap then insert a stay suture into the apex of the flap to aid retraction.

Gently apply a self-retaining retractor to aid access to the coracoid process. Take care to clear soft tissues from around the coracoid to enable the Tube-Tape to sit securely.

NOTE: Take care to avoid nerves and other anatomical hazards during surgery, as well as taking all reasonable precautions to avoid possible infection.



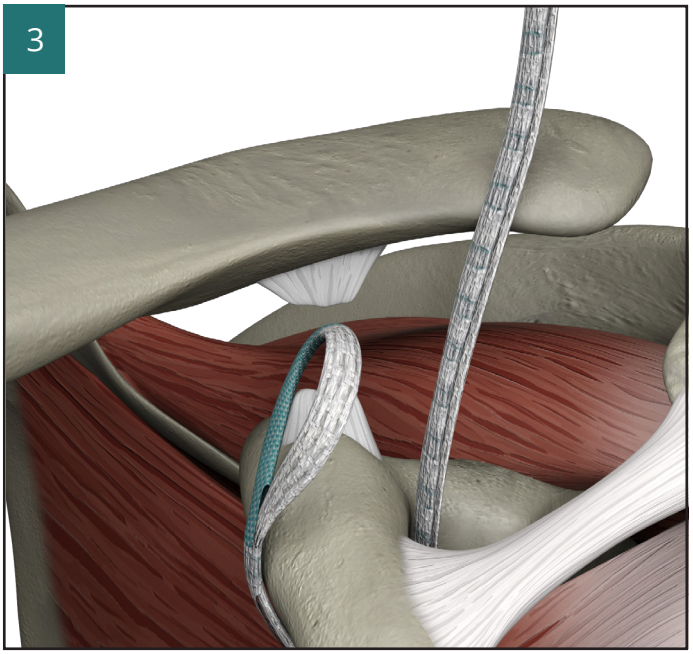
CORACOID LOOP ATTACHMENT

Insert a coracoid passer under the coracoid and follow this around and under the neck of the coracoid from medial to lateral.

NOTE: Take care to avoid potential injury to the medial structures and musculo-cutaneous nerve.

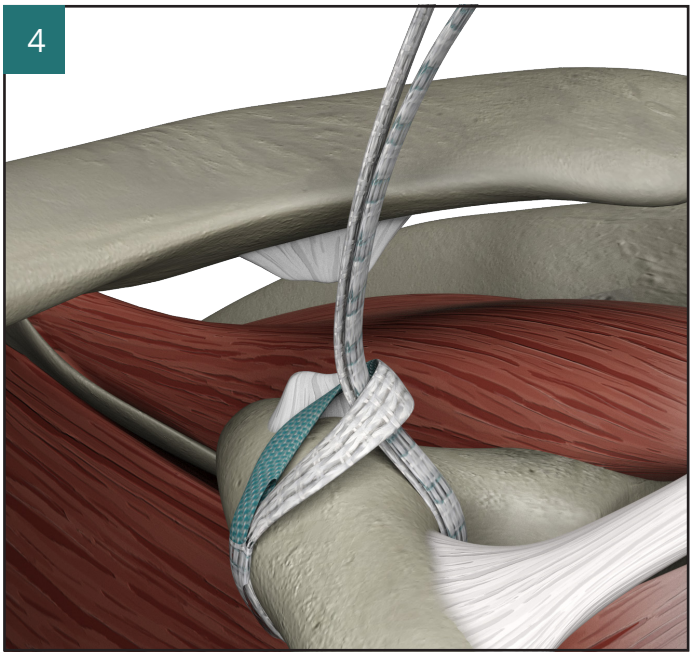
It is recommended to use the Xiros **CC-Hook** which has been specifically designed to facilitate this procedure. See the Instructions for Use supplied with the coracoid passer for further details.

Capture the green lead suture of the Tube-Tape with the coracoid passer.

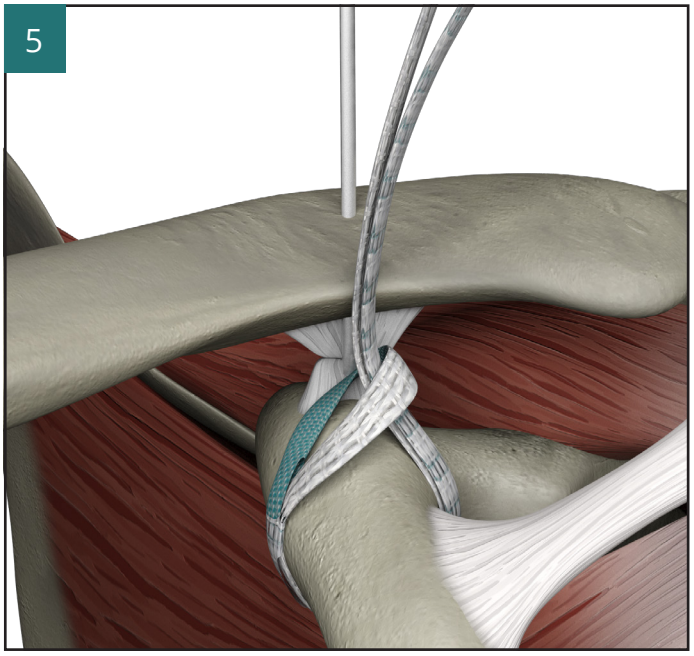


Pull the coracoid passer medially under the coracoid to withdraw the instrument, which simultaneously pulls the green lead suture around the bone. Pull the green lead suture to position the Tube-Tape around the coracoid so that the loop is accessible. Remove the green lead suture from the Tube-Tape when satisfied with its position.

NOTE: Avoid damage when handling the Tube-Tape. Avoid crushing or crimping when using surgical instruments such as forceps or needle holders.



Pass both limbs of the Tube-Tape through the loop, lassoing the coracoid. Move the Tube-Tape from side-to-side to tighten the noose down onto the coracoid.

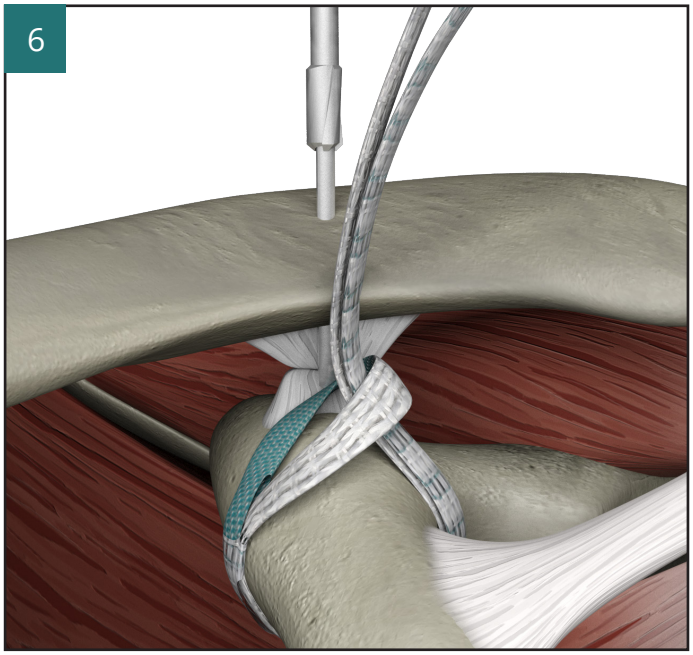


CLAVICLE ATTACHMENT

Reduce the injury to achieve the correct anatomical position before identifying the tunnel location. Reduction is achieved by pushing downward on the clavicle while simultaneously pushing up on the elbow to support the arm.

Identify the tuberosity on the inferior surface of the clavicle to which the conoid ligament was attached before being avulsed. Alternatively identify a point 3 cm to 4 cm from the un-excised lateral end of the clavicle.

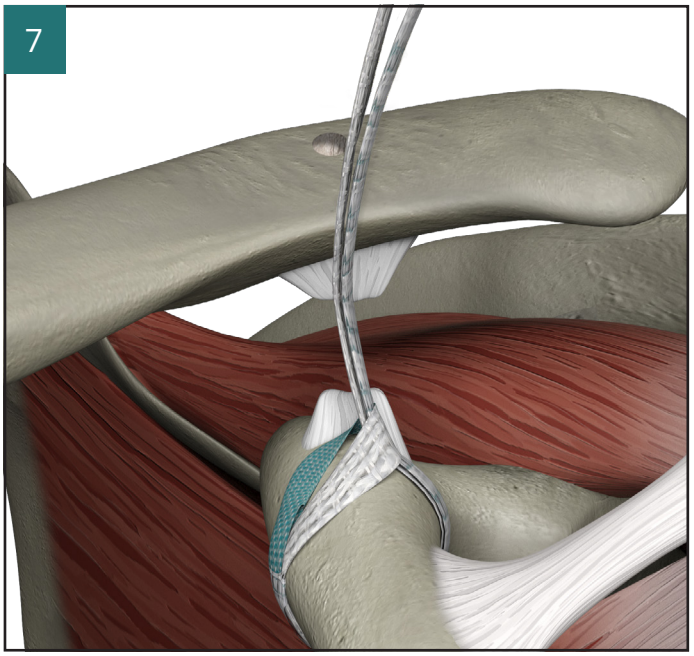
Drill the 2 mm guidewire perpendicularly through the middle of the clavicle at the point identified.



Over-drill with the 4 mm cannulated drill bit to create the final bone tunnel in the clavicle.

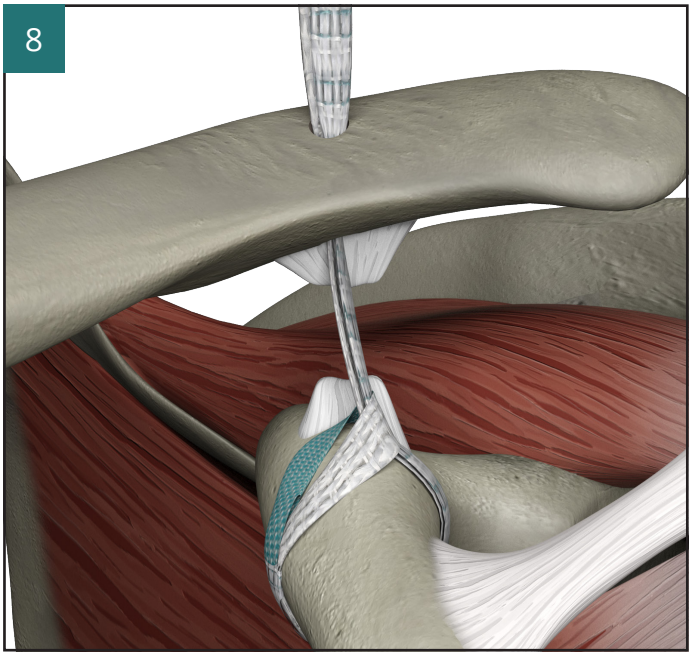
Chamfer the upper edges of the tunnel to prevent abrasion of the Tube-Tape. Take care to leave sufficient bone around the tunnel to resist expected forces.

NOTE: When drilling the bone tunnel ensure the Tube-Tape is positioned away from the underside of the clavicle to prevent accidental damage from the drill. Optionally place a retractor inferiorly to the clavicle to prevent damage to surrounding tissues when the drill bit breaks through the cortex.

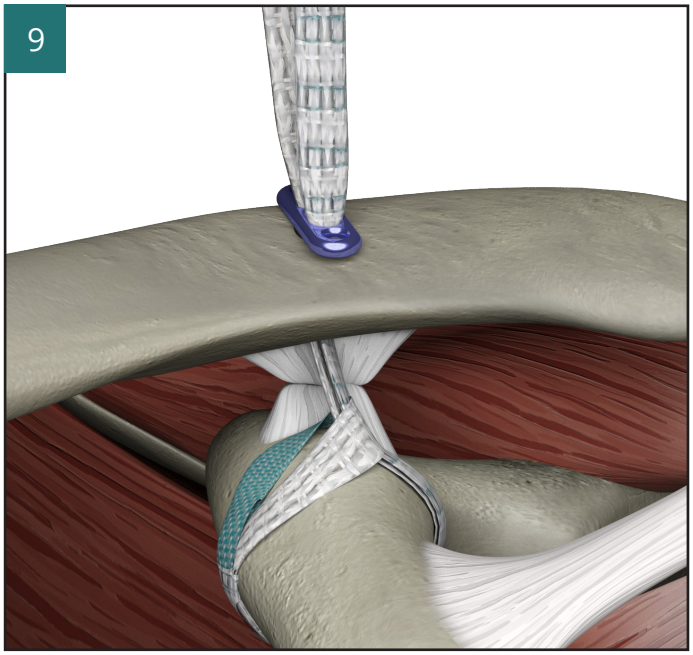


Reduce the injury to the normal anatomical position. Adjust the angle of the loop around the coracoid to minimise the distance from the exit of the bone tunnel to the noose; the point at which the limbs of the Tube-Tape exit the loop. Take care to ensure the loop remains fully tightened.

NOTE: If the noose is incorrectly placed it may rotate post operatively to achieve alignment, creating slack in the repair so allowing the clavicle to lose reduction.



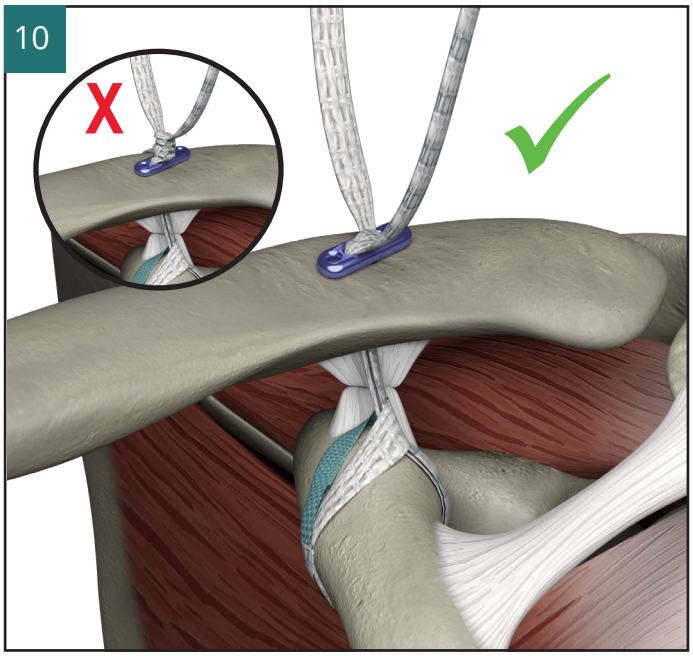
Use a suture and needle to pass the limbs of the Tube-Tape through the bone tunnel one at a time. Alternatively this may be performed with the nitinol wire from the **CC-Hook**.



Pass the limbs of the Tube-Tape through the central holes of the **Infinity-Lock** Button, using the suture and needle if necessary.

While maintaining the previous reduction, apply appropriate tension to the Tube-Tape. Take care to avoid damaging the Tube-Tape. Push the Button down the limbs of the Tube-Tape until it locates against the clavicle.

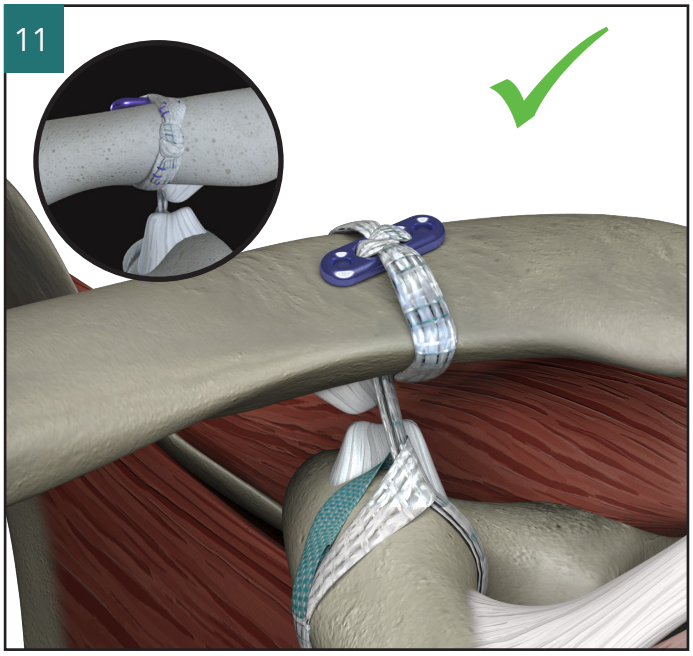
NOTE: If desired, insert a K-wire through the acromion and into the clavicle to maintain reduction while performing the procedure.



Tie a half-knot over the top of the Button. This half-knot helps maintain reduction during the procedure.

NOTE: Do not create a knot stack over the Button. A single throw has sufficient strength and further knots may cause tissue irritation.

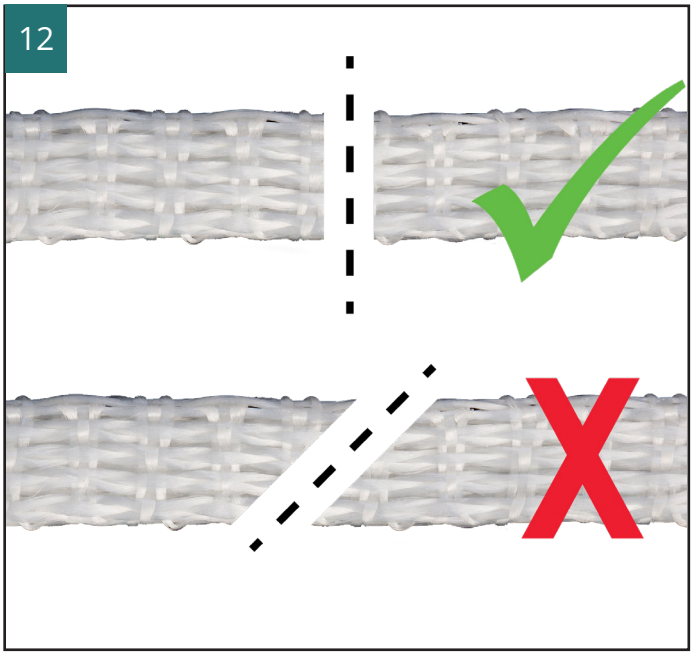
NOTE: If desired, the fixation can be performed without the half-knot over the button. This provides a lower profile repair.



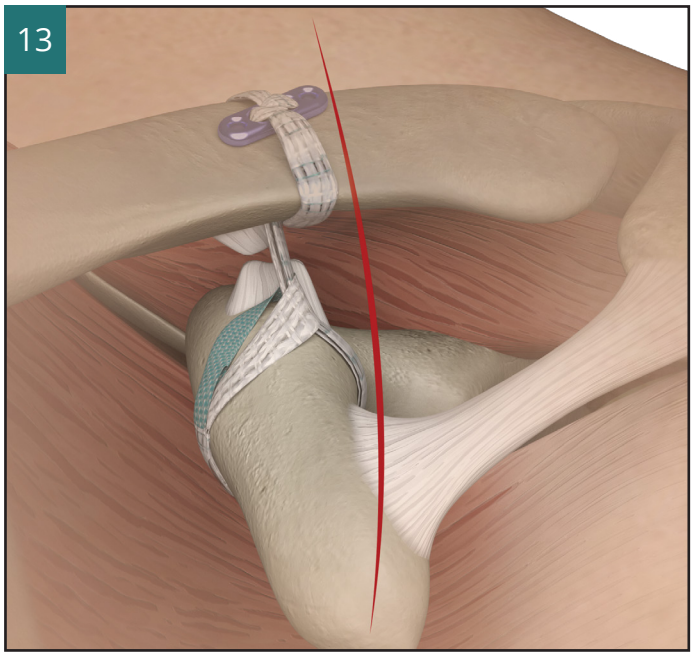
Check the repair is physiological and does not affect range of motion. When satisfied pass the ends of the Tube-Tape either side of the clavicle and secure posteriorly with a surgeons knot. Ensure the knot is securely locked.

NOTE: Do not create a knot stack. This may cause tissue irritation.

Cut any excess Tube-Tape with scissors. A short tail is left when cutting each limb. Stitch the cut ends of Tube-Tape back on itself. A 2-0 vicryl suture can be used for this step in the procedure.



NOTE: Cut the Tube-Tape at right angles to its length to minimise the generation of loose fibres. Take care to remove any loose fibres that are created.



WOUND CLOSURE

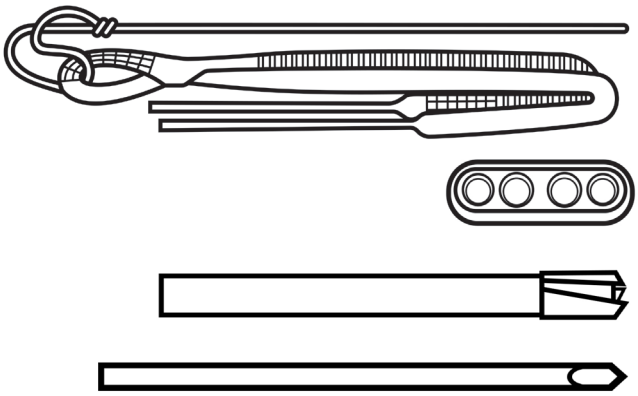
Repair the soft tissues by re-attaching the "L" shaped flap while tensioning the superior acromioclavicular ligament during the repair. Ensure the cut ends of the Tube-Tape are well buried in tissue.

NOTE: Patients should be warned not to exceed appropriate activity levels or to overload the repair before complete healing has occurred.

Ordering Information

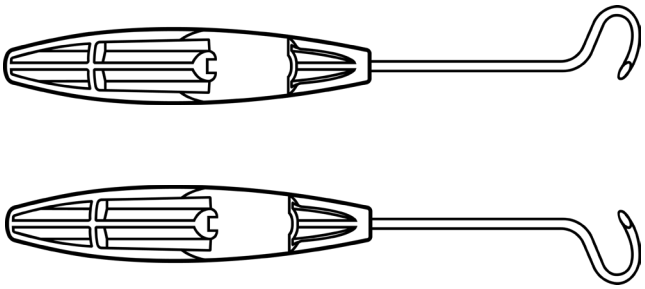
102-1089 Infinity-Lock Button System (supplied sterile) includes:

Infinity-Lock Tube-Tape, 7 mm x 240 mm
Infinity-Lock Button, 4 mm x 12 mm
Cannulated drill bit, plain shank to fit Jacobs chuck, 4.0 mm diameter x 120 mm
Guidewire, diameter 2.0 mm x 150 mm



Optional Disposable Instrument (supplied sterile):

202-1411 **CC-Hook**, with a curved end, Left
202-1413 **CC-Hook**, with a curved end, Right



Please refer to the Instructions for Use leaflet packaged with the **Infinity-Lock** Button System 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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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

Xiros Limited, Registered in England No. 1664824.

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