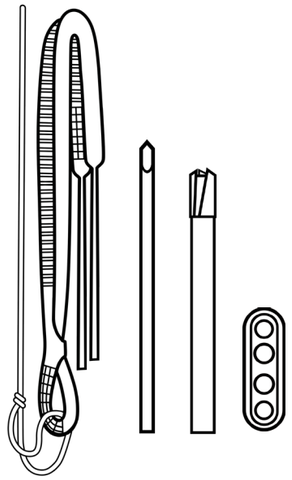

Infinity-Lock™ Button System

Instructions for use

CE 0086

GMDN 62000

neoligaments™

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11/2019 LAB 261 4.00

Ordering Information (supplied sterile)

Infinity-Lock Button System:

102-1204 Infinity-Lock Button System Tape:
Infinity-Lock Tube-Tape, 7 mm x 240 mm

202-1204 Infinity-Lock Button System Button:
Infinity-Lock Button, 4 mm x 12 mm

202-1205 Infinity-Lock Button System Instrument Set, Includes:
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:
202-1411 CC-Hook, with a curved end, Left
202-1413 CC-Hook, with a curved end, Right

Patient Information
The following information is provided for use by clinicians, however as the learned intermediary between the company and the patient, the clinician must convey the aspects they consider relevant to the individual patient. The patient must be informed of the potential adverse effects (risks/complications) contained in this insert (see **POTENTIAL ADVERSE EFFECTS**).

Description
The Infinity-Lock Button System comprises a permanent implantable 240 mm Tube-Tape and titanium alloy Button together with a disposable cannulated drill bit and guidewire. A coracoid passer suitable for passing the tape around the coracoid, such as the Neoligaments CC-Hook, is also required.

Clinical evaluation supports the following clinical benefits:
- Shoulder reduction;
- Cosmetic improvement;
- Improved functional outcome;
- Reduction in pain;
- Return to work/sports.

Testing has shown the following:

Mean Ultimate Tensile Strength (N)*	1054 (SD = 75)
Mean Ultimate Tensile Strength post fatigue (N)*	1263 (SD = 97)

*data on file at Xiros
The device is intended to be used by trained surgeons.

Material Specifications
The Tube-Tape is made from 100% polyethylene terephthalate (polyester) and the Button from 100% implant grade titanium alloy (Ti-6Al-4V) to ISO 5832-3. The cannulated drill and guidewire are made from stainless steel 17-4PH (ASTM F899) and 316 (ASTM A262) respectively. These materials meet applicable specifications established by BS EN ISO 10993-1: 2009 Biological evaluation of medical devices and are appropriate for their intended use.

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.

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

Contraindications
- Known hypersensitivity to implant materials. If the patient is suspected of having any foreign body sensitivity, appropriate tests should be made prior to implantation.
- Infections or any structural or pathological condition of the bone or soft tissue that would be expected to impair healing or secure fixation.
- Patients unable or unwilling to restrict activities to prescribed levels or follow a rehabilitation programme during the healing period.
- Skeletally immature patients are not suited as the Infinity-Lock will not elongate with growth. The use of this medical device and placement of hardware or implants must not bridge, disturb or disrupt the growth plate.

Warnings
- The Infinity-Lock Button System is provided sterile and remains so unless the packaging is damaged or opened. Store in standard conditions. DO NOT RESTERILIZE.
- The Infinity-Lock Button System is for single use only as it would be damaged by reprocessing and the instruments are subject to wear. Do not use after the expiration date. Discard any open, unused product.
- The surgeon must be thoroughly familiar with these instructions and the surgical technique recommended overleaf before using the Infinity-Lock Button System.
- The general principles of patient selection and sound surgical judgement apply to the reconstruction procedure. Do not use the device for procedures which do not necessitate surgical intervention, including Type I and II injuries.
- In revision cases where the recommended position of the bone tunnel has been compromised there is a risk that the more oblique direction of the repair could cause the device to fail.
- There is limited data on the use of the device for chronic injuries and as such treatment of chronic injuries should be based on professional user judgement.

MRI information
Non-clinical testing demonstrated that the Infinity-Lock Button System is MR conditional. A patient with this device can be scanned safely in an MR system under the following conditions:
- Static magnetic field of 1.5-Tesla and 3-Tesla, only.
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e. per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the Infinity-Lock Button System is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing the image artefact caused by the Infinity-Lock Button System extends approximately 15 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR System.

Precautions
Packaging
- The device is supplied pre-packaged and sterile.
- Inspect the device, packaging and labelling prior to use and do not use if damaged. Contact Xiros if the package has been opened or altered.

Handling and storage
- No specific storage conditions are required other than good warehousing practice.
- Avoid damage when handling the Tube-Tape. Avoid crushing or crimping when using surgical instruments such as forceps or needle holders.
- Use aseptic technique throughout the procedure.

Pre-operative
- It is recommended that patients are placed on prophylactic antibiotics prior to surgery, to minimize the risk of latent infections developing at the implant site.

Intra-operative
- Care should be taken to avoid nerves and other anatomical hazards during surgery, as well as possible infection.
- Take care to round the upper edges of the bone tunnel to prevent abrasion of the Tube-Tape.
- Ensure there is sufficient bone around the tunnel in the clavicle to resist expected forces, taking account of the quality of the bone.
- Check that the repair is physiological and does not restrict range of motion.
- When trimming the Tube-Tape to length, cut straight across at right angles to minimize the generation of loose fibres and carefully remove any created from the wound.
- When drilling the bone tunnel ensure the tape is positioned away from the underside of the clavicle to prevent accidental damage from the drill.

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

Potential Adverse Effects
Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device including 1) risks associated with any surgical procedure; 2) risks associated with acromioclavicular joint reduction; 3) risks associated with synthetic implants for acromioclavicular joint reduction. Additional surgery may be required to correct some of these events.

1) Pertinent risks associated with any surgical procedure include: Infection and pain.

2) Pertinent risks associated with acromioclavicular joint reduction include: Loss of reduction; Lack of reduction; Recurrence; Bone fracture; Impaired wound healing; Ligament calcification/Ossification and; Arthritis/Degenerative arthropathy.

3) Risks associated with synthetic implants for acromioclavicular joint reduction, including the Infinity-Lock Button System, include: Irritation; Allergic and/or inflammatory tissue reactions; Device failure and; Clavicular osteolysis/erosion.

As with any procedure of this type, there is a risk that surgery may not be effective in treatment or may cause worsening symptoms.

Surgical Technique
1. With the patient in the beach chair position use a vertical 5 cm skin incision starting at the level of the clavicle and slightly medial to the 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.
2. 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.
3. 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.
4. Insert a cholecystectomy-type forceps under the coracoid and follow this with the coracoid passer, passed under the neck of the coracoid from medial to lateral. See the coracoid passer instructions for use for further details.
5. Capture the green lead suture of the Tube-Tape with the coracoid passer (Figure 1) and pull it medially under the coracoid so that the loop of the Tube-Tape is accessible (Figure 2). Remove the lead suture when satisfied.
6. Pass both limbs of the Tube-Tape through the loop, lassoing the coracoid. Move the Tube-Tape from side-to-side to tighten it down onto the coracoid.
7. 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 to 3.5 cm from the un-excised lateral end of the clavicle.
8. Reduce the end of the clavicle to the normal anatomical position by pushing downward on it while the elbow is simultaneously pushed upward. Ensure this position is maintained in the subsequent steps of the procedure.
9. Drill the 2 mm guidewire perpendicularly through the middle of the clavicle at the point identified.
10. 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.
11. Adjust the angle of the loop around the coracoid to minimise the distance from the exit of the bone tunnel to the point at which the limbs of the Tube-Tape exit the loop. Take care to ensure the loop remains fully tightened.
12. 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, if being used (Figure 3).
13. Pass the limbs of the Tube-Tape through the central holes of the Infinity-Lock Button, using the suture and needle if necessary (Figure 4). While maintaining the previous reduction, apply appropriate tension to the Tube-Tape (Figure 4). Take care to avoid damaging the Tube-Tape. If desired an optional half-knot may be tied over the top of the Button (Figure 5) but avoid creating a knot stack (Figure 6).
14. 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 inferiorly with a surgeons knot (Figures 5 & 7). If there is insufficient space below the clavicle the knot may be tied anteriorly. Ensure the knot is securely locked.
15. Cut any excess Tube-Tape with scissors at right angles to its length to minimize the generation of loose fibres (Figure 8). Take care to remove any loose fibres that are created. Stitch the cut ends of Tube-Tape back on itself (Figures 5 & 7).
16. 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.

Figure 1

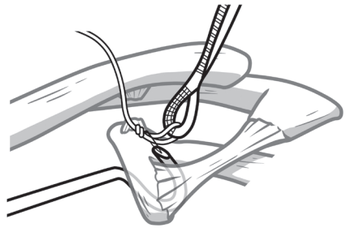


Figure 2

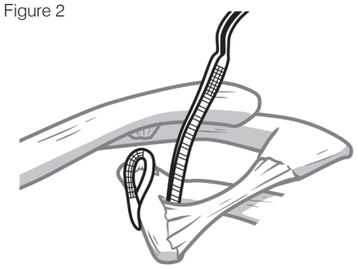
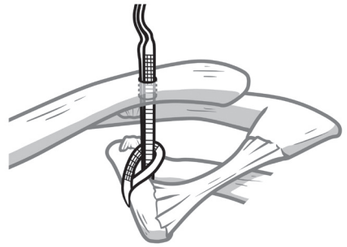


Figure 3



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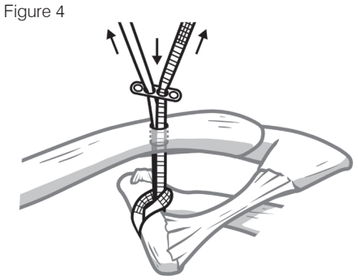
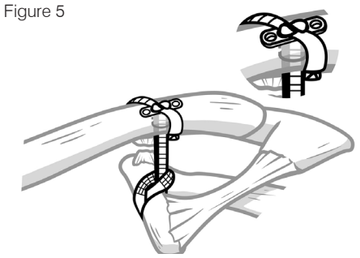


Figure 5



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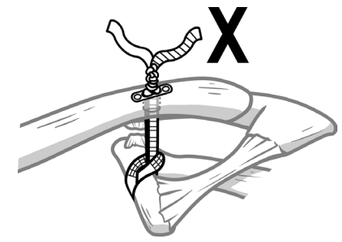


Figure 7

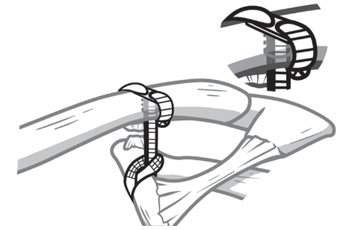
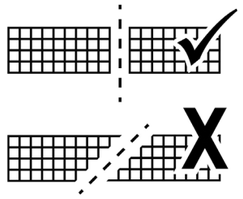


Figure 8



Disposal
No specific disposal requirements other than handling contaminated items as clinical waste.

Device Retrieval Methods
Should it be necessary to remove an Infinity-Lock Button System device, contact Xiros prior to the scheduled surgery for product/tissue retrieval information.

Complaints
Any health care professional who has any complaints or experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, usability, effectiveness, and/or performance, should notify the manufacturer and distributor immediately.

If the product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the manufacturer and relevant local regulatory authority should be notified immediately by telephone, email or written correspondence.

When filing a complaint, provide the component(s) name and number, lot number(s), your name and contact details and the nature of the complaint.


Caution


Do not use if package is damaged


Consult instructions for use


Do not resterilize


Do not reuse


Use by date


Manufacturer

Batch code

Catalogue number

Sterilized using irradiation

CE 0086

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