



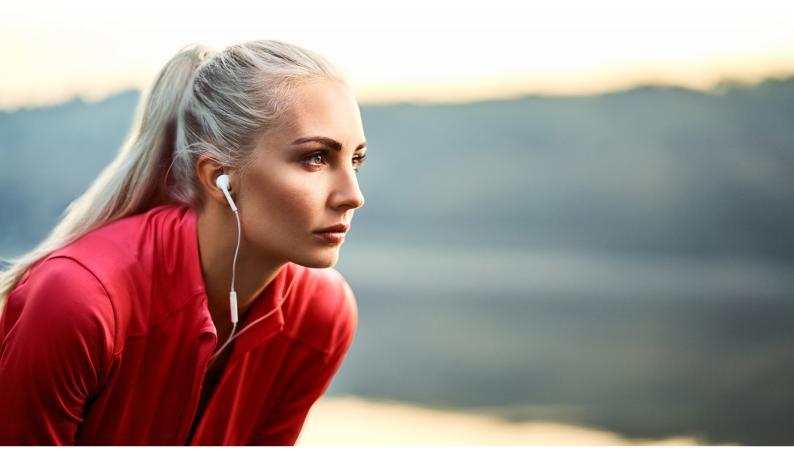
Repair, Reinforce, Reconstruct

Implants for Ligament & Tendon Reconstruction

XIROS (Ki-ros)

Research in olutions

Why textile implants?



Textile implants offer many benefits

The factors that made textile implants so appealing when they were first introduced remain as relevant and valid as ever. Their use for ligament and tendon reconstruction offers the following benefits:

- They remove the need for harvesting autologous tissues and so eliminate the pain, muscle deficiency and donor site morbidity associated with the harvesting procedure
- Their use shortens the surgical procedure by the time consumed in graft harvesting and/or preparation
- Where they are used instead of allografts, the risk of cross-infection is eliminated
- They offer consistency as they have specific properties and dimensions, whereas tissue grafts vary in both properties and dimensions
- Textile implants retain their initial strength, which is sufficient to permit weight bearing and return to activities than in comparison with tissue grafts which require time to remodel over an extended period
- Because textile implants are readily available in abundance they facilitate complex reconstruction procedures where a recipient has sustained multiple injuries to ligaments in one joint

Manufactured from polyester, a material with many years of implant history

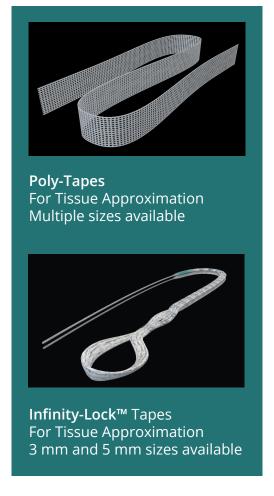
The Xiros textile implants are manufactured in-house, at dedicated manufacturing sites in the UK, from polyethylene terephthalate (PET) which is commonly known as polyester. Polyester has mechanical properties which, with careful design, can match the biomechanical properties of natural tissue. It is therefore ideal for the manufacture of implants for ligaments and tendons.

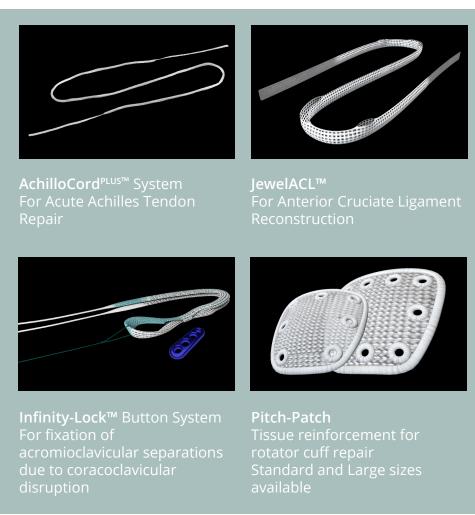
This nonabsorbable material has been used for more than 40 years in the manufacture of arterial grafts, aortic implants as well as synthetic ACL grafts, making it one of the most common polymers used in medical implants.

Product Portfolio

The Xiros product portfolio comprises textile implants for orthopaedic applications. These synthetic implant solutions fall into two types: **Multi-application Poly-Tapes** and **Speciality Devices**.

Multi-application Poly-Tapes Xiros Textile Implants Speciality Devices





Multi-application Poly-Tapes

The **Poly-Tapes** are intended to be used for soft tissue approximation. They are available in various widths. They are available in two shapes: a single thickness flat tape, or a double thickness tubular tape (**Infinity-Lock** tape). Each of these may have an open or dense structure. The strength increases with width to improve the resistance to failure. The surgeon can select from this range the device best suited to the repair.

Speciality Devices

Speciality devices are those which have been optimised to repair a particular tissue. These include the Infinity-Lock™ Button System, for fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and JewelACL™, for anterior cruciate ligament (ACL) reconstruction. These devices typically include a mix of specific structural features such as sections of open and dense weave, pockets, or cords for pulling the implant through bone tunnels. The dimensions, strength and stiffness characteristics of these devices are biomechanically designed to suit their intended application. This ensures that the implant can withstand the load placed on it without failure and permits correct load transfer to encourage tissue ingrowth and remodelling.

Applications

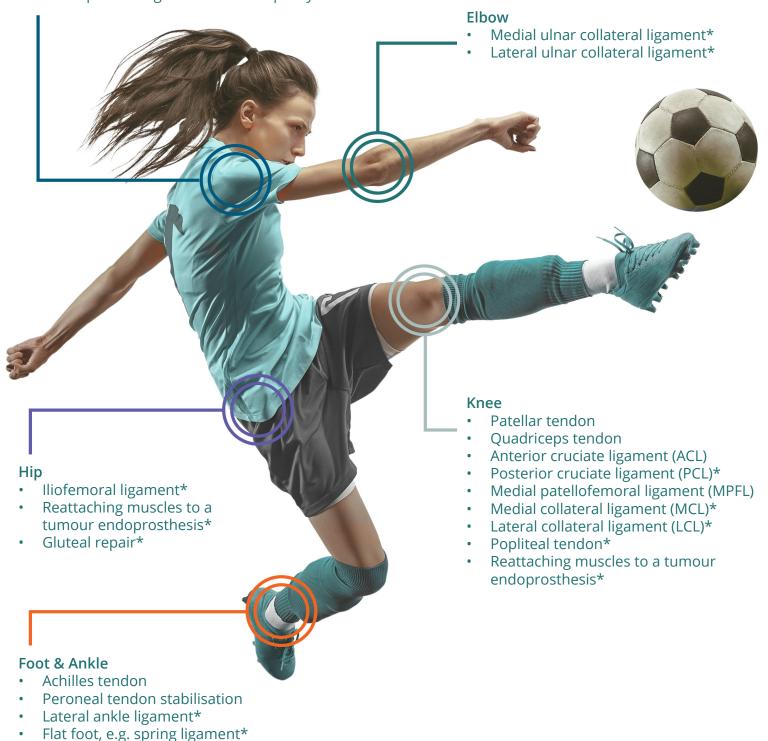
The Xiros product portfolio is very versatile, and surgeons have used these implants for repair or reconstruction of many ligaments and tendons in the joints of both the lower and upper limbs.

Shoulder

Rotator cuff

Medial deltoid ligament*

- Acromioclavicular joint and coracoclavicular ligaments
- Antero-inferior gleno-humeral ligament capsular reinforcement*
- Augmented subscapularis muscle transposition for rotator cuff repair during shoulder arthroplasty*



^{*} Xiros has not clinically evaluated those procedures marked with an asterisk and does not currently supply a surgical technique manual for them. However, the use of the **Poly-Tape** for such procedures has been reported at conferences and in medical journals.

Why Xiros products?

The implants possess high strength to allow early rehabilitation

The textile implants have been thoroughly tested to determine their biomechanical characteristics and their response to simulated exercise. As an example, the JewelACL ligament has undergone cyclic testing for 10.8 million cycles between 50 and 450N at 25Hz. This testing is equivalent to 7 years of simulated exercise from implantation. The results demonstrate that the implant can withstand the loads placed on it without failure. It also indicates that the stiffness is similar to that of the natural ACL so permits correct load transfer to encourage cell growth.



Strength (N) Stiffness (N/mm) 4000 2000 1000 ACL Native tissue

The structure provides a scaffold for tissue ingrowth

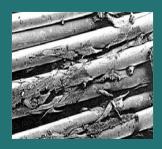
Xiros textile implants are predominantly of woven construction, comprising parallel longitudinal (warp) and transverse (weft) fibres which cross at right angles. The implants typically possess an "open structure" that acts as a scaffold, allowing bone and tissue ingrowth. This new tissue protects the device from abrasion and, as it matures, it provides additional strength. This scaffold implant is not to be confused with a prosthesis type implant, which replaces tissue with no expected significant host tissue growth.

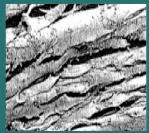
Our unique plasma treatment process speeds cell growth

Selected textile implants are subjected to a proprietary low-power cold gas plasma treatment process. This forms oxidized chemical groups on the material surface, turning the standard hydrophobic polyester into a hydrophilic material.

This has a significant effect, increasing the speed and extent of cell recruitment and their adherence to the implant. In vitro studies have found that tissue ingrowth is approximately four times faster [Rowland et al. 2003; Tsukazaki et al. 2003]. Prompt tissue growth has also been noted clinically via postoperative arthroscopy, biopsy and transmission electron microscope studies on scaffold textile implants used for ACL reconstructions [Sugihara et al. 2006].

Xiros Plasma Treatment Process





Scanning electron microscopy (SEM) showing portions of control (left) and plasma treated (right) polyester scaffolds five days after incubation.

Note the greater coverage of the treated materials by synovial stromal cells.

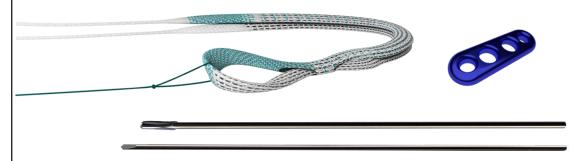




Product Description:
Infinity-Lock™ Button System
Part Code:
102-1089

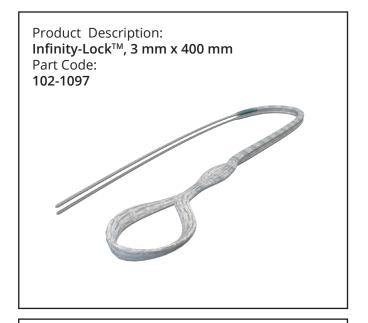
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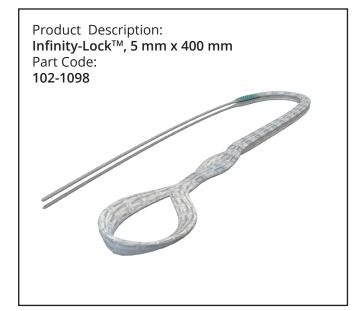
- Infinity-Lock Tube-Tape 7 mm x 240 mm
- Infinity-Lock Button 4 mm x 12 mm
- Cannulated drill bit, plain shank to fit Jacobs chuck, 4.0 mm diameter x 120 mm
- Guidewire, diameter 2.0 mm x 150 mm



Product Description:
CC-Hook™ with curved end,
Left
Part Code:
202-1411



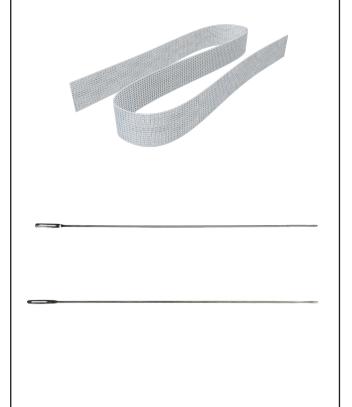




Product Description: QuadsTape System™ Part Code: 102-1061

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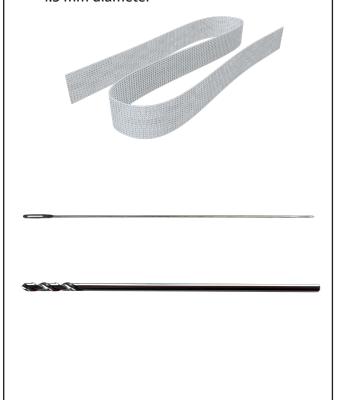
- Poly-Tape, 30 mm x 800 mm
- Malleable Probe with eye, stainless steel,
 20 cm
- · Rigid Probe with eye, stainless steel, 20 cm

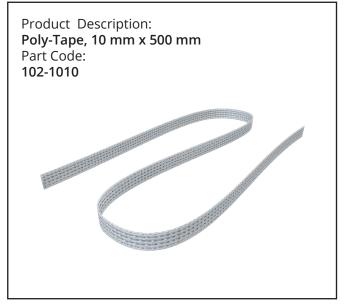


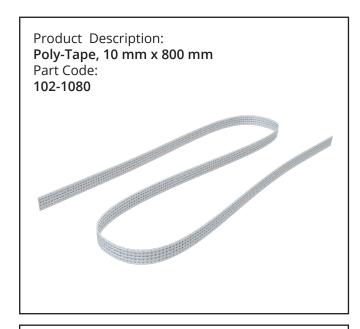
Product Description: PatellarTape System™ Part Code: 102-1062

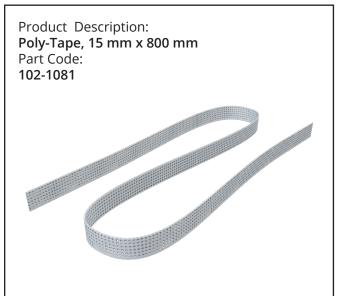
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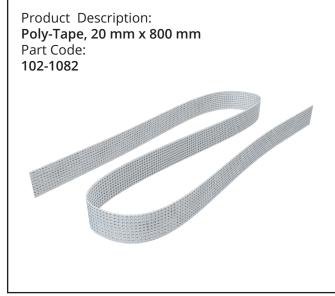
- Poly-Tape, 30 mm x 800 mm
- Malleable Probe with eye, stainless steel, 20 cm
- Rigid Probe with eye, stainless steel, 20 cm
- Drill Bit, plain shank to fit Jacobs Chuck, 4.5 mm diameter

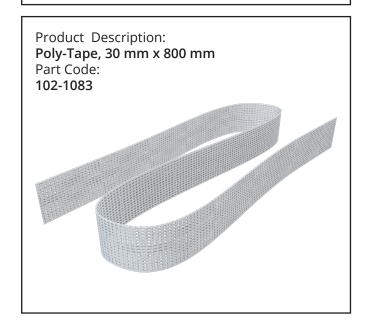


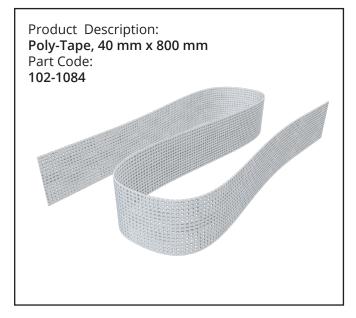


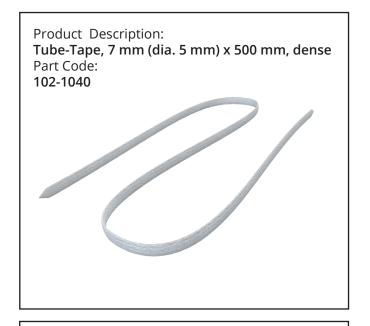


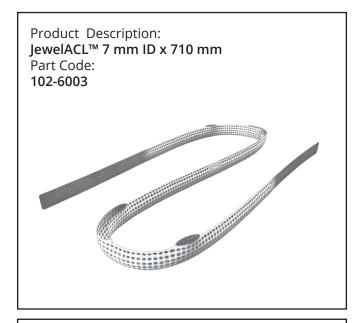








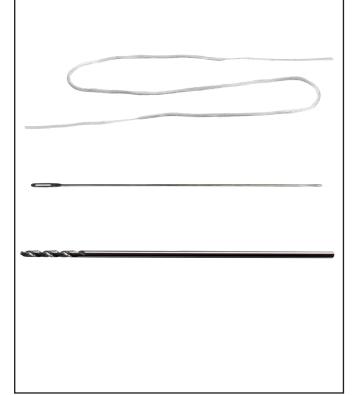




Product Description:
AchilloCordPLUS™ System Implant Set
Part Code:
102-1142

Contains:

- AchilloCordPLUS™, 5 mm x 800 mm
- Rigid Probe with eye, stainless steel, 20 cm
- Drill Bit plain shank to fit Jacobs Chuck, 3.2 mm diameter



Product Description:

Malleable Probe with eye, stainless steel, 20 cm
Part Code:
202-3026

Product Description:
Rigid Probe with eye, stainless steel, 20 cm
Part Code:
202-3023





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