Patellar Tape System™
For Patellar Tendon Reconstruction
Surgical Technique Manual
The PatellarTape System comprises a wide open weave Poly-Tape prosthesis, associated instrumentation and optional Fastlok™ titanium alloy staple to repair a ruptured patellar tendon, without the need to harvest autogenous tissue.

We would like to thank Mr. A. D. Toms, Consultant Orthopaedic Surgeon, Royal Devon and Exeter Hospital, Exeter, UK, and Mr. S. H. White, Consultant Orthopaedic Surgeon, Robert Jones and Agnes Hunt Orthopaedic Hospital, Shropshire, UK, for their work in developing this technique."
IMPLANTS
The Poly-Tape recommended for patellar tendon repairs is the 30 mm wide by 800 mm long prosthesis. It is an open weave polyester mesh, designed to act as a scaffold for soft tissue ingrowth and neoligament formation.

Advantages of the Poly-Tape prosthesis:
• Provides excellent intrinsic strength and allows early mobilization
• Use of metalwork and wire cerclage is unnecessary; the associated high complication rate and problems of secondary removal are thus avoided
• Prosthesis carries none of the risks or availability problems of allograft
• No donor site morbidity as encountered with autograft
• Simple, easy to learn technique with a low complication rate

Various methods can be used to secure the Poly-Tape which include knotting and stapling. Neoligaments recommends the Fastlok if stapling is preferred.

The Fastlok is made from a titanium alloy and consists of a staple and buckle. It provides a unique triple clamping action to minimize slippage under repeated loading.

INSTRUMENTATION
The following single use instruments are packaged with the implant set:
• 20 cm malleable probe with eye for passing the Poly-Tape through the soft tissue
• 4.5 mm diameter drill bit (plain shank)

If the Fastlok is chosen as the method of fixation, the user can also order the following standard items:
• Fastlok Impactor/Extractor
• Fastlok Sliding Hammer

INDICATIONS
The use of the Poly-Tape for patellar tendon reconstruction is particularly recommended for the following types of cases:
• Where the diagnosis of rupture is delayed
• Ruptures where prolonged immobilization would be undesirable
• Patients who have a total knee arthroplasty in situ
• Cases where a previous patellectomy has been performed
• Complex patellar fractures

Contraindications, warnings and precautions: Please refer to the general Contraindications, Warnings and Precautions listed in the Poly-Tape and Fastlok Instructions for Use leaflets (LAB 028 and LAB 108), packaged with the implants.
PREPARATION AND INSPECTION
The patient is positioned supine. Broad spectrum antibiotic prophylaxis is administered intravenously. A side support and sandbag are useful to facilitate knee positioning. The leg is prepared and draped using aseptic technique.

RECOMMENDED APPROACH
A midline approach is recommended. Adequate exposure is essential and should provide sufficient access for the proximal and distal placement of the prosthesis. The ends of the tendon or ligament are identified as well as any additional pathology.

NOTE: It is necessary particularly in chronic cases to free up any adhesions involving the quadriceps mechanism. This will facilitate optimal postoperative rehabilitation.

A transverse bone tunnel is positioned at the level of the tibial tuberosity. A 4.5 mm diameter drill bit (as provided in the system pack) is used to make the tunnel from the lateral side to the medial.

NOTE: Where possible, round the tunnel edges to prevent abrasion of the Poly-Tape.

The Poly-Tape is threaded through the eyelet of the probe (as provided in the system pack). The probe is used to pass the Poly-Tape transversely through the distal quadriceps tendon at its patellar insertion.

The Poly-Tape is brought distally, crossing over itself on the anterior aspect of the patella. The medial end of the Poly-Tape is passed through the bone tunnel. The ends of the Poly-Tape are pulled tight with the knee in 20° of flexion.

The position is then secured with stay sutures to allow the range of motion and tissue tension to be assessed.
Both ends of the Poly-Tape are then either secured to the lateral tibial metaphysis using two bone staples under cover of the tibialis anterior muscle, or the ends may be tied in a knot.

NOTE: Alternatively a single 8 mm Fastlok (Neoligaments) is used for tibial fixation. Please see the Instructions For Use leaflet (LAB 108), which is packaged with the Fastlok for the implantation technique.

NOTE: The protruded profile of the Fastlok may cause pain or irritation to some recipients and so may need removal on some such occasions after biological fixation between the graft and tunnel is achieved.

The range of motion and tissue tension is assessed. If this is satisfactory, each surplus end of the Poly-Tape is cut with scissors at right angles to its length. This will minimize the generation of loose fibres. A short tail is left when cutting each end.

**IMPORTANT:**

- Any loose fibres created when trimming the Poly-Tape to length must be carefully removed from the incision site
- After trimming to length it may be necessary to restrain the cut ends by stitching them back to the Poly-Tape
- Where possible, ensure the knot is buried in tissue

The remnants of the ruptured tendon are sutured over the Poly-Tape, to encourage fibrous ingrowth and distance the prosthesis from the superficial wound.

**WOUND CLOSURE**
The wound is irrigated and a vacuum drain is put in place. Haemostasis is achieved. The dead space is closed with absorbable sutures before skin closure with a subcuticular, absorbable suture. The wound is covered with a dressing followed by a wool and crepe bandage.

**TECHNIQUE FOR RECONSTRUCTION OF EXTENSOR MECHANISM RUPTURE POST PATELLECTOMY**
The Poly-Tape is passed transversely through a 4.5 mm diameter tunnel at the level of the tibial tuberosity.

The Poly-Tape is crossed over the torn extensor mechanism. It is passed through the remnant of the quadriceps tendon and muscle. The free ends are brought out proximally and laterally, knotted and sutured to the surrounding extensor mechanism.

The patellar retinaculum is repaired and the Poly-Tape is sutured to the fibrous tissue envelope.
POSTOPERATIVE MANAGEMENT
The rehabilitation programme (below) provides only an outline of the prescribed regime. For a full description refer to the document entitled “PatellarTape System Rehabilitation Programme for Patellar Tendon Reconstruction” (LAB 133).

The rehabilitation programme should be supervised by a specialist physiotherapist. All mobilization and exercises should be performed within the pain free range of movement.

As in any implant surgery, satisfactory wound healing is of paramount importance.

The patient should be warned not to exceed the prescribed activity levels or to overload the repair before complete healing has occurred.

This rehabilitation programme was developed in conjunction with Ian Horsley MSc, MCSP, Clinical Lead Physiotherapist, English Institute of Sport (EIS) North West, of BackinAction Physiotherapy and Sports Injury Clinic, Wakefield, UK.

Weeks 0-1
- The patient may fully weight bear using crutches for stability (3 point gait moving towards reciprocal gait).
- A brace or splint is used to allow the patient to mobilize between physiotherapy sessions.
- The rehabilitation programme is commenced with active extension. Do not aggressively push flexion.

Weeks 1-3
- Rehabilitation is continued with increasing repetitions and static cycling and pool work are commenced.
- Crutches are discarded when the patient has a reciprocal gait pattern.
- The brace is discarded when full terminal knee extension control is achieved.
- Sutures are typically removed at this stage.

Weeks 3-6
- Balance exercises and proprioceptive training are commenced.

Weeks 6-12
- Elliptical trainer and functional training are commenced.

Week 12 onwards
- Jog-walk and jog-run exercises are commenced.
- On agreement with the physiotherapist, return to activity is allowed.

REFERENCE

For further references on this procedure please refer to the document “Neoligaments Scientific Articles” (LAB 144). This may be obtained from the Neoligaments™ Sales Department, or downloaded from http://www.neoligaments.com/doclib/
Ordering Information

102-1062  PatellarTape System, includes:

Poly-Tape, 30 mm x 800 mm (supplied sterile)

Packaged with the following disposables:
  Malleable Probe with eye, nickel silver, 20 cm (supplied sterile)
  Drill Bit, plain shank to fit Jacobs Chuck, 4.5 mm diameter (supplied sterile)

102-1381  Optional Implant (dependent on method of fixation chosen by the user):

Fastlok, 8 mm x 23 mm (supplied sterile)

Fastlok Instruments:

202-1137  Impactor/Extractor (non-sterile)
202-1118  Sliding Hammer (non-sterile)

Individual re-order codes:

102-1083  Poly-Tape, 30 mm x 800 mm (supplied sterile)
202-3008  Malleable Probe with eye, nickel silver, 20 cm (supplied sterile)
202-3021  Drill Bit, plain shank to fit Jacobs Chuck, 4.5 mm diameter (supplied sterile)

Please refer to the Instructions for Use leaflets packaged with the Poly-Tape and Fastlok 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/doclib/