Hybrid System™
For Anterior Cruciate Ligament Reconstruction

Surgical Technique Manual
The Hybrid System comprises a set of fixation devices that allow the construction of a “Hybrid graft” for the anatomical reconstruction of a ruptured Anterior Cruciate Ligament (ACL). It has the following advantages:

- the surgeon can control the thickness and length of the autograft\(^1\), which also allows short length grafts to be adapted for use in ACL reconstruction\(^2\);
- the structural properties are superior to those where sutures are used and are comparable to the Bone-Tendon-Bone (BTB) graft\(^4,5\);
- it is more resistant to graft tension relaxation than when using sutures for fixation\(^6\);
- when using a double-bundle anatomic technique the two grafts can be easily and simultaneously fixed\(^1\);
- it is particularly suited to multiple ligament injuries.

We would like to thank Professor Kazunori Yasuda, M.D. PhD., and Dr Eiji Kondo, M.D. PhD., Department of Sports Medicine and Joint Surgery, Hokkaido University School of Medicine, Sapporo, Japan, for their work in developing this product and technique.
The Hybrid System offers flexibility in ACL reconstruction by the way of surgical technique, graft selection and construction, and graft anchoring to the bone. It offers:

- anatomic single-bundle or anatomic double-bundle surgical techniques: The anatomic double-bundle procedure is superior to the single-bundle procedure in terms of restoration of the anterior stability and rotational knee stability in both biomechanical and clinical studies;
- variety in graft selection: These can be formed from the semitendinosus and/or the gracilis hamstring tendons;
- variety in graft construction: These can be formed by looped or folded tendons;
- femoral fixation: This is provided by the LK2-H (Neoligaments). It can also be achieved with the EndoButton CL Ultra or EndoButton CL BTB (Smith & Nephew);
- tibial fixation: This is achieved with a 10 mm Poly-Tape (Neoligaments) and two generic small spiked staples. Alternatively, a single Fastlok™ (Neoligaments) can be used for anatomic single tunnel tibial fixation.

**INDICATION**
The Hybrid System is a group of single use implants intended to be used for ACL reconstruction.

Contraindications to surgery include:

- infections or any structural or pathological condition of the bone or soft tissue that would be expected to impair healing or secure fixation;
- the patient’s inability or unwillingness to restrict activities to prescribed levels or follow the rehabilitation programme during the healing period.
IMPLANTS
The Hybrid System uses a 10 x 500 mm Poly-Tape in conjunction with a 6 mm Fastlok fixation device or 2 generic small spiked staples for tibial fixation. Femoral fixation is provided by an LK2-H, or the EndoButton CL Ultra or EndoButton CL BTB, which may be sourced from Smith & Nephew.

INSTRUMENTATION
The Hybrid graft can be implanted using modern ACL guidewire systems that are utilized for hamstring grafts. Please note that these instruments are not provided and should be sourced by the surgeon prior to performing the operation.

If utilizing the Fastlok for fixation with the anatomic single tunnel technique, the user can also order the following standard items:
- Fastlok impactor/extractor;
- Fastlok sliding hammer.

NOTE: The LK2-H is not available for sale in the United States.

FEATURES & BENEFITS
The LK2-H comprises a 10 x 500 mm Poly-Tape and a titanium alloy SurfButton. It therefore provides all the advantages of the Poly-Tape (as described below) while also having several additional structural features intended to facilitate the surgery and improve its outcome:
- the transverse yarns are removed to provide parallel fibres where the Poly-Tape is threaded through the SurfButton. This facilitates a low profile when the button is seated on the lateral femoral cortex;
- the LK2-H can be attached to a closed loop of tendon which allows the reconstruction of the Hybrid graft to occur concurrently with the preparation of the bone tunnels and so minimizes the operating time;
- continuous longitudinal yarns provide a high strength to allow early mobilization.

The Poly-Tape is a flexible textile device, which has the following general advantages:
- it is manufactured from polyester, a biocompatible material that has been in use for the reconstruction of ligaments and tendons for over 25 years;
- the flat, open weave section of the Poly-Tape acts as a scaffold that encourages tissue ingrowth.

The Poly-Tape also has the following advantages over sutures used for fixation of ACL grafts:
- the wide tape does not cut through the graft tissue;
- its mesh structure provides good grip with the staple or Fastlok so reducing slippage past the staple or Fastlok;
- there is a reduced chance of cutting the mesh compared to sutures when impacting the staple or Fastlok.

The Fastlok is made from titanium alloy and consists of a staple and buckle. It has several structural features intended to facilitate the surgery and improve its outcome:
- the buckle provides a unique triple clamping action to minimize slippage under repeated loading;
- the bridge of the staple is shaped to allow the instrumentation to be securely clamped, so it is easy to implant and remove.
ANATOMIC DOUBLE-BUNDLE PROCEDURE
Since the procedure for ACL reconstruction is well known, the following text is primarily concerned with the ways in which the Hybrid System differs from a standard ACL technique.

Patient Preparation
The procedure is performed with the patient in the supine position with the femur horizontal and the tibia flexed at 90°, in the “Hanging leg position”. This opens the knee joint during surgery due to gravity and the tibia is easily positioned at 90°. This position also enables the femoral PL bundle to be easily recognized.

Approach
Standard medial and lateral infrapatellar portals are established together with a 3 cm long transverse incision in the anteromedial aspect of the proximal tibia. An arthroscope is inserted through the lateral infrapatellar portal. The ACL remnant is resected, leaving a 1 mm long ligament stump at the femoral and tibial insertions to obtain landmarks for inserting guide wires. Notchplasty is performed in chronic cases when an osteophyte has formed at the notch.

Graft harvesting and preparation
The leg is flexed to approximately 100° with the lateral surface of the leg lying on the table. A semitendinosus (ST) tendon is harvested using standard techniques and instruments (not provided). When this tendon is longer than 24 cm and when doubled is thicker than 6 mm, the following preparation is used.

The ST tendon is transversely cut in half.

To form the anteromedial (AM) bundle, the distal half of the ST tendon is doubled over to produce a loop. Both the free ends are firmly sutured side by side at 3 different positions, using the circumferential ligation technique (see step 3) with No 2-0 polyester suture.

NOTE: If using the EndoButton CL Ultra, this device needs to be linked to the tendon loop before the ends of the tendon are sutured. Its length is matched to the femoral tunnel measured during surgery.

To form the posterolateral (PL) bundle, the proximal half of the ST tendon is doubled, and the ends secured using the same circumferential ligation technique.

Alternative graft harvesting and preparation
When the ST is short or thin, the gracilis (GR) tendon is also harvested.

The ST tendon is transversely cut in half. The thickest portion of the GR tendon is resected so that the length is matched to one half of the ST tendon.

To form the anteromedial (AM) bundle, one half of the ST tendon and the resected GR tendon are doubled over to produce a loop. Both the free ends are firmly sutured side by side at 3 different positions, using the circumferential ligation technique (see step 3) with No 2-0 polyester suture.

NOTE: If using the EndoButton CL Ultra, this device needs to be linked to the tendon loop before the ends of the tendon are sutured. Its length is matched to the femoral tunnel measured during surgery.

To form the posterolateral (PL) bundle, the remaining half of the ST tendon is doubled, and the ends secured using the same circumferential ligation technique.
Circumferential ligation technique
A. A polyester No 2-0 suture is passed through the tendon ends using a standard technique. The ends of the suture are knotted.
B. The same suture is wrapped around the tendon ends.
C. The ends of the suture are tensioned to pull the suture tight around the tendon ends.
D. The ends of the suture are knotted to firmly secure the tendon ends side by side and excess suture is trimmed.

By means of a guide, in a Japanese patient series using the alternative graft harvesting and preparation technique described in point 2, the autogenous tendon portion of the graft ranged from 55 to 65 mm. The intra-articular portion of the AM bundle graft was 30 to 35 mm, and that of the PL bundle graft was 25 to 30 mm. The minimum length of the graft placed within the tunnel was 15 to 20 mm².

Creation of the Hybrid graft
A Hybrid graft for the AM bundle is constructed. A 10 x 500 mm Poly-Tape is passed through the tendon loop and placed at the sutured end. The tape is firmly sutured to the tendon using a circumferential ligation technique in 3 positions. This tape will be used for tibial fixation.

The femoral component of the Hybrid graft is created after the femoral bone tunnel is drilled and its length measured so that the corresponding length of the fixation device is thereby determined.

When using the LK2-H for femoral fixation, both ends of the tape component of the LK2-H device are passed through the opposite end of the tendon loop. The tape ends are sutured side-by-side using the circumferential ligation technique in 3 positions.

A Hybrid graft for the PL bundle is constructed in the same manner as the AM bundle.
When using the EndoButton CL BTB for femoral fixation, the long CL loop of the device is passed through the tendon loop and then through the short CL loop. The long loop is then slipped over the EndoButton and the resulting knot tightened.

**PL tibial tunnel**

An appropriate tibial guide (not supplied) is used to create the two bone tunnels in the tibia.

First a tibial tunnel for the PL bundle is created. The aimer portion of the guide is introduced into the joint cavity through the medial infrapatellar portal. The knee is flexed at 90° keeping the femur horizontal ("Hanging leg position"). The tip of the aimer is placed at the centre of the PL bundle footprint on the tibia. This is located at the most posterior aspect of the area between the tibial eminences and 6 to 7 mm anterior to the posterior cruciate ligament (the "over the back ridge" distance). The bullet of the guide is fixed on the anteromedial aspect of the tibia at approximately 45° from vertical and 5 to 10 mm anterior to the medial collateral ligament. A guidewire is drilled into the tibia.

The tibial tunnel is made with a cannulated drill corresponding to the measured diameter of the prepared PL Hybrid graft.

**AM tibial tunnel**

The tibial aimer of the guide is placed at the centre of the tibial footprint of the AM bundle. This is located at a point approximately 8 mm anterior to the guidewire for the PL bundle and 5 mm lateral from the medial tibial spine. The bullet of the guide is fixed on the anteromedial aspect of the tibia at approximately 20° from vertical which is approximately 20 mm medial to the centre of the PL tunnel.

The knee is extended to ensure the tip of the guidewire is located at the point 5 mm posterior to the anterior edge of the roof in the intercondylar notch.

A guidewire is drilled in the tibia. The tibial tunnel is made with a cannulated drill corresponding to the measured diameter of the prepared AM Hybrid graft.
AM femoral tunnel

The arthroscope is located in the lateral infrapatellar portal. A standard transtibial offset femoral ACL drill guide (not supplied) is used to locate the tunnel at the most appropriate point on the femur.

A guidewire is drilled at the centre of the femoral footprint of the AM bundle through the second (AM) tibial tunnel, using a standard transtibial offset femoral ACL drill guide. The offset guide is typically 5 mm or 6 mm. The guide is orientated in the 10:30 o’clock (right knee) or 1:30 o’clock (left knee) position. The guidewire is over-drilled with a 4.5 mm diameter cannulated bone tunnel drill, through the lateral cortex. The length of the tunnel is measured with a depth gauge.

The construction of the AM Hybrid graft is completed by setting the LK2-H to the correct length and securing it with sutures (shown in Figures 4 and 5). Alternatively, the correct length of EndoButton CL BTB is chosen (shown in Figure 6).

PL femoral tunnel

The arthroscope is moved to the medial infrapatellar portal as it is difficult to precisely identify the attachment of the PL bundle through the lateral infrapatellar portal. The tibia is held at 90° of knee flexion, keeping the axis of the femoral shaft (AFS) horizontal (“Hanging leg position”).

A guidewire is drilled at the centre of the PL bundle attachment on the femur through the first (PL) tibial tunnel. A zero offset aimer is used or the guidewire is manually aimed. If manually aimed, the tip of the guidewire is lightly tapped into the bone before drilling to prevent the point from wandering. Alternatively, a pilot hole is created with a suitable bone awl.

The centre of the PL bundle is approximately located at the crossing point of two imaginary lines. The first is a vertical line (VL) through the contact point (CP) between the femoral condyle and the tibial plateau at 90° of knee flexion. The second is the long axis of the ACL attachment site (AX). This crossing point is also about 5 to 8 mm anterior to the edge of the joint cartilage, a distance which can be used when the ACL attachment footprint on the femur cannot be identified.

The guidewire is over-drilled with a 4.5 mm diameter cannulated drill. The length of the tunnel is measured with a depth gauge and the femoral component of the Hybrid PL graft completed.

Two sockets are created for the AM bundle (typically 35 to 40 mm deep) and PL bundle (typically 30 to 35 mm deep), with cannulated drills matched to the diameter of the two Hybrid grafts.

NOTE: Care should be taken to ensure the drills used to create these sockets do not breach the lateral femoral cortex, otherwise fixation with the button cannot be performed.
Fixation
A passing pin is used to pull the Hybrid graft for the PL bundle through the tibial tunnel and into the femoral tunnel. The button component is flipped on the femoral cortical surface. The graft for the AM bundle is then placed using the same technique.

NOTE: The knee is cycled through a full range of motion while examining the graft arthroscopically to ensure that it allows a full range of motion with no graft impingement on the lateral femoral condyle.

The thigh is manually fixed on a sterilized hard pillow placed on the operating table. The heel is kept in contact with the operating table and the knee is flexed to 10°.

NOTE: Graft tension in the PL and AM bundles is highest in full extension, so such a knee position is required for graft tensioning and fixation to avoid post-operative graft failure as a result of over-stretching when the knee is in extension.

A spring tensiometer is attached to the two ends of each Poly-Tape. A tension of 30 N is applied to each graft for 2 minutes using the tensiometer.

While under tension, the 2 ends of the Poly-Tapes are secured onto the AM aspect of the tibia using 2 spiked staples (not supplied) in the turn-buckle technique (Figure 13a to c).

A Lachman test is performed, which should result in a negative outcome to confirm a stable knee.

Surplus Poly-Tape is cut with scissors at right angles to its length to minimize the generation of loose fibres (Figure 13d).

Before wound closure
Bone debris can accumulate in the lateral popliteal space and must be washed out through the medial portal.

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.
POST-OPERATIVE MANAGEMENT
The rehabilitation programme (below) provides only an outline of the prescribed regime. For a full description refer to the document entitled "Hybrid System, Rehabilitation for ACL repair".

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

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

The rehabilitation regime 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.

Day 1
The leg is placed in a Continuous Passive Motion (CPM) machine and subjected to passive flexion of between 20º to 60º for as many hours as possible.

Day 2-7
CPM between 20º and 90º flexion is continued but the range should be reduced to 20º to 60º if the patient complains of any pain.

Week 2
Active Range of Motion (ROM), allowing flexion and extension, is initiated with the patient wearing a brace limiting the range of motion flexion/extension to 20º to 90º of knee flexion.

Week 3
Continue with week 2 activities. In addition, passive full extension is allowed twice per day as the patient tolerates. Partial weight-bearing is commenced with two handed support, e.g. crutches.

Weeks 4-5
Active ROM exercise, with unblocked brace, is allowed to the patient’s maximum flexion/extension capability (this is usually between 90º to 110º). Partial weightbearing is continued with one-handed support, e.g. a cane.

Weeks 6-10
Limitation on both flexion and extension is no longer imposed but wearing an unblocked brace is continued. Full weight-bearing may be commenced at this stage. Extension training for muscles is begun, aiming at full development of ROM.

Weeks 10-12
Light sports activities such as jogging or swimming may be commenced.

Weeks 12-24
Gradual return to sporting activities is permitted. However, it must be noted that the speed of return to full pre-injury sporting activities should be governed by the state of the muscles of the injured leg. If they are inadequate it is recommended that the patient rehabilitates them to an adequate degree before engaging in any strenuous activities that might jeopardize the reconstructed ligament. It should also be noted that, on the occurrence of any significant discomfort, it may be necessary to extend the rehabilitation programme accordingly.

REFERENCES
Hybrid System Implants for Anatomical Single and Double Tunnel repair, include:

102-1010 10 mm x 500 mm Poly-Tape (supplied sterile)
(order 2 for double-tunnel repair)

Optional Tibial Fixation device for single tunnel repair:
102-1380 6 mm x 23 mm Fastlok (supplied sterile)

Optional Femoral Fixation device:
102-1067 LK2-H, 10 mm x 500 mm Poly-Tape with SurfButton (supplied sterile)
(order 2 for double-tunnel repair)

Please note that the LK2-H is not available for sale in the USA

Fastlok Instruments

202-1137 Impactor/Extractor
202-1118 Sliding hammer

Please refer to the Instructions for Use leaflet packed with the Poly-Tape, LK2-H and Fastlok for further essential information including Use, Sterility, Indications, Contraindications, Warnings and Precautions, Potential Adverse Effects and Storage. Additional copies may be obtained from Neoligaments™ sales department, or downloaded from http://www.neoligaments.com/doclib/