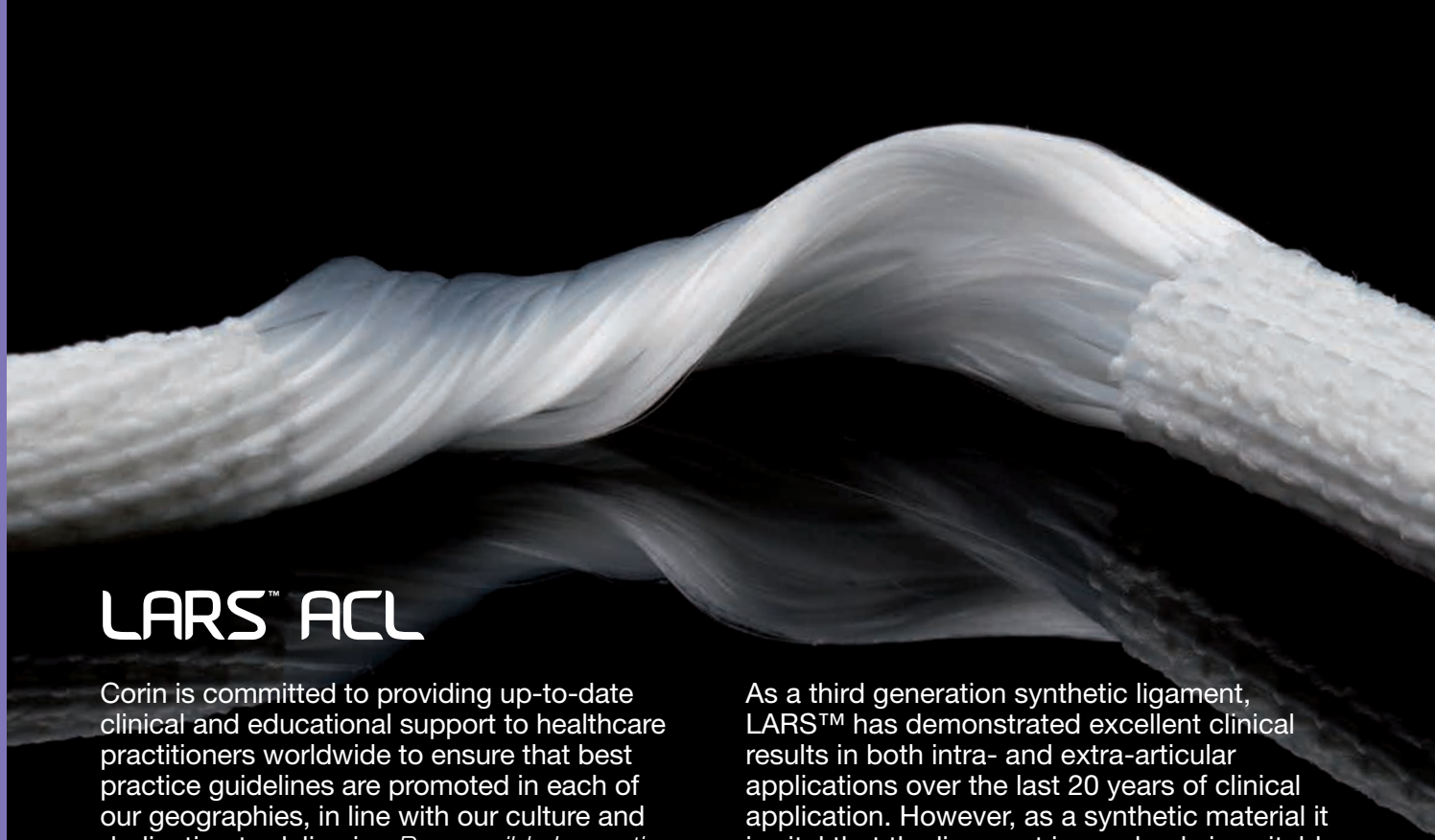
LARS™ ACL

Best practice guidelines

Corin

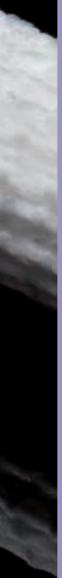
Responsible Innovation



LARS™ ACL

Corin is committed to providing up-to-date clinical and educational support to healthcare practitioners worldwide to ensure that best practice guidelines are promoted in each of our geographies, in line with our culture and dedication to delivering *Responsible Innovation*. The following positioning statement has been produced to identify key indications and surgical criteria necessary for the successful use of LARS™ in ACL applications.

As a third generation synthetic ligament, LARS™ has demonstrated excellent clinical results in both intra- and extra-articular applications over the last 20 years of clinical application. However, as a synthetic material it is vital that the ligament is used only in suitable indications and following a well-defined surgical technique to ensure that optimal patient function, long-term outcomes and satisfaction are achieved.



Indications for use

LARS™ is a synthetic scaffold designed to provide initial stability, facilitating the potential of the original ligament to heal whilst eliminating post-operative elongation.

In the context of Anterior Cruciate Ligament (ACL) repair, LARS™ should be utilised only after non-synthetic alternatives (allografts and autografts) have been considered as possible treatment options by the treating clinician and patient.

LARS™ ACL repair should only be used in the presence of viable tissue remnants. In the absence of viable tissue remnants LARS™ should be used as an augmentation or reinforcement alongside an autograft or allograft.

Regardless of treatment method, acute phase post ACL injuries should be treated with caution.

Contraindications for use

The LARS™ ligament provides a conservative choice of graft for ACL reconstructions but is contraindicated for use in the following circumstances:

- If the ACL remnants have fully degraded or are not vascularised and autologous tissue is not available.
- In revision and multi-ligament cases where no remnants are available, previous tunnel placements are not through the original attachment sites of the native ACL and autogenous tissue is not available.

Best practice guidelines

The following best practice guidelines should be adhered to when conducting a LARS™ ACL ligament repair:

Ligament positioning

- The LARS™ fibres should be placed as close to the centre of the remnants of the native ligament as possible. This allows tissue encapsulation and micro-separation of the ligament fibres providing strong fixation and minimising the potential for long-term wear of the material due to fibre abrasions. If possible the remnants should be sutured together with the LARS™ positioned in the centre of the stump.
- It is important to avoid placing the intra-articular 'free parallel fibres' portion of the LARS™ ligament within the tunnels or at the tunnel edges as these fibres are more prone to damage due to abrasion against sharp bony tunnel edges. A 2mm length of the extra-articular woven portion of the LARS™ ligament should be visible outside the tunnel entrance, particularly on the femoral side, to minimise risk of long-term wear of the ligament.
- During positioning of the LARS™ ligament, it is essential to avoid any abrasion of the ligament in the joint such as roof/wall impingement or contact with other tissues as this may ultimately lead to premature wear/potential rupture of the ligament fibres. A notchplasty should be conducted if risk of impingement is noticed during surgery.
- Aim to align the femoral and tibial tunnels as closely as possible in the longitudinal plane in mid flexion (45-50°) during tunnel drilling. This allows the optimal positioning of the synthetic fibres, minimising the extent of torsion and flexion experienced by the individual fibres through the range of motion.

Tunnel diameter

- The diameter of the bony tunnels must correspond to the specific reference for each type of LARS™ ACL ligament and as a general rule, should be as small as possible to encourage bony tissue in-growth. This will also minimise micro-motion of the ligament and migration of synovial fluid into the tunnel, which may impede bony in-growth.

Fixation

- LARS™ ACL ligaments tolerate a maximum stretch of approximately 9%, which equates to 3mm. To ensure that minimum elastic demand is placed on the ligament during normal range of motion, the ligament should be fixed isometrically or at its longest length necessary to permit full range of motion. To this effect LARS™ ligaments should not be over-tensioned during fixation and the range of motion must be verified before final fixation is completed.

LARS™ ligaments must always be positioned in such a way as to avoid extensive strain or elongation of the synthetic material. LARS™ has less elasticity than native structures or autologous graft material.

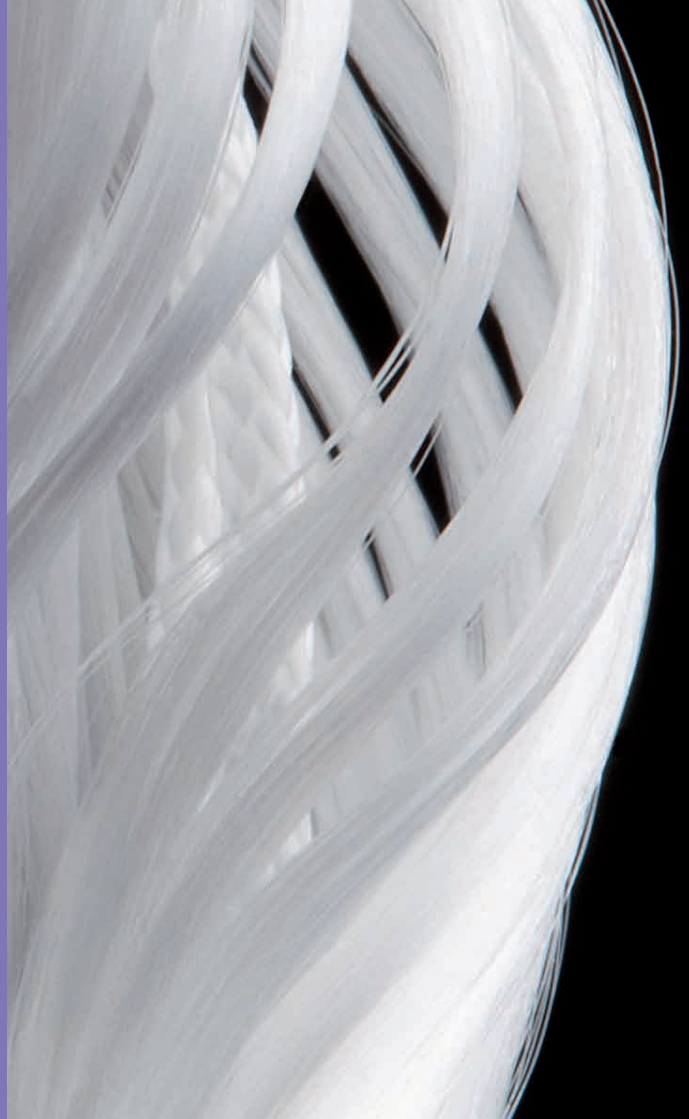
- Fixation of the ligament must always be conducted using blunt threaded non-resorbable LARS™ interference screws, which should be at least 1mm bigger than the tunnel size, with the longest length permissible, dependent on tunnel length. Secondary fixation with an additional screw or staple is recommended for the tibia.
- The interference screws must be positioned from outside-in, with the head of the screw resting against the cortex. It is crucial that the screw is not embedded beyond the cortex to ensure optimal cortical fixation is achieved. The ligament extremities must be cut flush with the fixation to avoid soft tissue irritation.

Rehabilitation

- The pace of rehabilitation is individual to the patient and should be tailored to their demands, response to therapy and their wound healing. Return to full sporting activity should only be recommended when both objective and subjective outcomes are satisfactory

LARS™ is strong immediately after implantation, therefore there is a temptation for a patient to be less diligent with physiotherapy. Tissue integration may take some time, leaving the LARS™ ligament more susceptible to wear if aggressive rehabilitation is undertaken.

- LARS™ recommends the following post-operative care and physiotherapy for ACL reconstruction:
  - Isokinetic closed chain rehabilitation with no post-op bracing or immobilisation
  - Full weight bearing and mobilisation with isometric quadriceps exercises to be started the next day to recover full extension
  - 90° of flexion should be obtained after 7-10 days
  - Return to sports (jogging) approximately 2-3 weeks
  - Return to full contact sports once proprioception has returned
  - Competitive training after approximately 5 weeks



Soft tissue internal fixation with LARS™

Corin educational support

As part of Corin's responsible approach to the promotion and ethical use of LARS™ ligaments, a number of educational and training initiatives have been developed to ensure best practice guidelines are observed. It is highly recommended, and a Corin requirement, that surgeons review and utilise these materials prior to conducting LARS™ ACL reconstructions.

Surgeon support

- Corin Surgeon e-Learning website

  An educational tool to guide potential and existing customers through the LARS™ philosophy and critical surgical considerations.

  www.coringroup.com/lars_training

- LARS™ instructional courses

  Provide surgeons with an introductory overview entailing presentations, dry bone workshops and live surgery links, aimed at promoting a greater understanding of soft tissue implantation techniques.

- LARS™ experts forum/user groups

  Offer an ideal opportunity for distinguished surgeons to share best practice and debate key topics surrounding non-biological soft tissue constructs and implantation techniques.

- Cadaveric workshops

  Allow surgeons to fully appreciate the adaptations required for the surgical techniques with LARS™.

- LARS™ website

  A comprehensive LARS™ website dedicated to delivering essential up-to-date information regarding the effective use of LARS™ ligaments.

In line with these initiatives and our commitment to improving long-term outcomes through *Responsible Innovation*, Corin will also be launching a 'no train, no use' policy for LARS™ throughout 2013. The aim of this programme is to provide a comprehensive educational platform for new and existing surgeons on the various LARS™ applications. Training will comprise of online educational tools and webinars, beginner and advanced instructional courses, sawbone and cadaveric workshops, as well as in-theatre surgical skills training.

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