LIGAMENT ADVANCED REINFORCEMENT SYSTEM LARS ® (Patented)

DEVICE DESCPIPTION

The **LARS** artificial ligament is made of industrial strength polyester fibers (polyéthylène téréphtalate). There are several types of **LARS** ligaments, each one containing a specific number and length of fibers, depending on their intended use. Each ligament has a specific reference. These ligaments also provide leaders to facilitate passage through the bony tunnels. All ligaments are delivered sterile. Resistance to traction varies with the number of the longitudinal fibers. These resistances are approximately 1 500 N for 30 fibers, 2 500 N for 60 fibers, 3 600 N for 80 fibers, 4 700 N for 100 fibers. The active intra-articular portion of the LARS ligament is made of longitudinal fibers without transversal nor crossing components. The fibers are oriented according to the ligament they are made for, to mimic the anatomic fibers. This patented structure allows a high resistance to fatigue specially to flexion - torsion stresses and a negligeable secondary elongation, as well as its porosity favorizes the fibrobastic ingrowth which isolates the synthetic fibers. In their extra-articular portion, as well as for extra-articular ligaments, same longitudinal fibers are maintained united and parallel by the mean of a warp knitting. This knitting process minimizes secondary elongation as opposed to abraided or woven structure.

INDICATION FOR USE

The **LARS** ligament is intended for the intra or extra articular reconstruction of ruptured ligaments. It can be used in association with :

- A suturing to the remnant of the ruptured ligament, in fresh laxities, thereby allowing the original to heal in the absence of traction and providing an earlier return to normal function,
- An autogenous reconstruction, with all of the advantages listed above,
- Or by itself in extra articular reconstructions or, posterior cruciale ligament, and in tendon repair, such as Achilles tendon, patellar tendon, biceps tendon, rotator cuff etc...

IMPLANTATION METHOD

These ligaments must always be placed in the joint in an anatomical and isometric position. The diameter of the bony tunnels must correspond to the specific reference for each type of ligament and as a general rule, should always be as small as possible. The fixation of the ligament extremities must always be extra articular, using either a ligament staple and/or an interference fit screw. In the case of fresh laxity, the artificial ligament must be placed at the center of the autogenous remnant. Tibial anchorage must be secured by double fixation. Ligaments extremities must be cut flush with the fixation.

CONTRAINDICATIONS

The use of artificial ligaments is contraindicated in all cases of septic arthritis, infected tissue, or where there is a risk of secondary infection (i.e. open wound of the joint).

WARNINGS

Biological and mechanical testing on resistance, fatigue, creep have shown that the **LARS** ligaments are probably the best available on the market. Nevertheless, the use of the **LARS** artificial ligament requires a precise surgical technique for which the **LARS** specific Instruments are highly recommanded. A certain number of rules must be strictly respected :

- isometry,
- acute angles must be avoided in the drilling of bony tunnels,
- No impingement or abrasion of the ligament in the joint,
- Absence of tension : the tension should not be more than that of anatomical ligament being repaired,
- Solid extra articular fixation, using only the **LARS** interference fit screws, or the **LARS** Staples designed specifically for artificial ligament fixation. The diameter of the screw must be generally 1 mm above the diameter of the tunnel,
- Coverage by fibrous tissue : in particular, when placing the ligament under arthroscopy, it is contraindicated to remove all remnants in the intercondylar notch. The ligament must pass through this tissue,
- Small incisions to maintain propioception,
- The mechanical fixation does not normally have to be removed. If however, for particular reasons the surgeon wants to remove the extra articular fixation, it is recommended to wait at least one and half years after the intervention, For futher Information, contact your local distributor or **LARS**.

PRECAUTIONS

Only surgeons who have received the proper training are invited to use the **LARS** artificial ligaments. A careful study of the technical brochures provided by **LARS**, as well as articles published in the orthopaedic journals*, is highly recommended. The final result depends equally on the motivation of the patients and the quality of the post operative physiotherapy. The patient must be properly informed and the rehabilitation strictly adhered to. (* References are available upon request)

COMPLICATIONS

As in all surgery, there exists an inherent risk of infection in the use of artificial implants (less than 1% in published studies). If an infection occurs, it will be necessary to remove the artificial ligament. The use of an artificial ligament also has a certain risk of failure, which usually exhibits itself as instability. Using an artificial ligament permits a non disruptive intervention, which allows for a successful revision, since none of the normal anatomical structures have been compromised.
These polyester fibers have been in use for over 10 years, in thousands of cases. Due to the special cleaning process they undergo, no acute synovitis has been encountered. These have always been related to technical errors involving some type of intra articular impingement. Should such a complication arise, the necessary surgical technique open or arthroscopic must first be used to correct the source of impingement, followed by a proper lavage of the joint, to eliminate any possible microparticles. The percentage of secondary failures, exhibited as instability, is less than 15 % after 5 years. This is very comparable to the results seen in autogenous repairs. When these failures have occurred, in 50 % of the cases they were due to a technical error during implantation, principally :

- Insertion on the tibial plateau too anterior,
- Lack of isometry,
- Angle of bony tunnels too acute,
- Missed combined instabilities such as antero lateral or postero lateral. The users of this ligament are invited therefore to follow scrupulously the rules laid out in the WARNINGS section. The surgeons and patients must be aware that the use of an artificial ligament allows a return to the previous level of activity in about 90 % of the cases, however it will not prevent further trauma, despite the fact that the strength of the artificial ligament is obviously superior to that of the natural one.

STERILITY

The **LARS** ligaments are supplied sterile (β radiations) and must not be opened until the moment of use. Resterilization is not advised.

ATTENTION

The law restricts the sa/e, *distribution or use of these implants by or under the order of a licensed physician.*

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