Models of LARS artificial ligament:
(Please tick the appropriate box)

Knee	
☐ L010605 - PC 60	☐ L021201 - AC 120 2BL
☐ L010805 - PC 80	☐ L021202 - AC 120 2BR
☐ L020205 - AC 20 DB	☐ L021601 - AC 160 2BL
☐ L020305 - AC 30 DB	☐ L021602 - AC 160 2BR
☐ L020306 - AC 30 DB/P	☐ L030205 - IT 20 RA
☐ L020404 - AC 40 DB/AM	☐ L030305 - AC 30 RA
☐ L020405 - AC 40 DB	☐ L030306 - IT 32 RA
☐ L020505 - AC 50 DB	☐ L030307 - ACFAR 32 CK
☐ L020601 - AC 60 L	☐ L030405 - ACTOR 5
☐ L020602 - AC 60 R	☐ L030406 - ACTOR 8
☐ L020605 - AC 60 SC	☐ L030407 - ACTOR 10
☐ L020606 - AC 60 DB	☐ L040805 - PPLY-FP 80
☐ L020801 - AC 80 L	☐ L041005 - PPLY 100
☐ L020802 - AC 80 R	☐ L041006 - PPLY-LCL 100
☐ L020803 - AC 80 C	☐ L041105 - PPLY 110
☐ L021001 - AC 100 2BL	☐ L050305 - PTR 30
☐ L021002 - AC 100 2BR	☐ L060305 - MCL 32
☐ L021003 - AC 100 C	☐ L070605 - ACPCPL 60 CK1
☐ L021005 - AC 100 2BL/S	☐ L130605 - R06x400 (6 mm)
☐ L021006 - AC 100 2BR/S	☐ L130605D - R06x400/V
Shoulder	
☐ L400205 - LAC 20	☐ L410205 - CR 25/SB
☐ L400206 - LAC 20 L	☐ L410205B - CR 25/DB
☐ L400305 - LAC 30 CK	☐ L410305 - CR 30/SB
☐ L410206 - LCR 25	☐ L410305B - CR 30/DB
☐ L410306 - LCR 30	
Ankle - Foot	
☐ L200405 - LLEA 44	☐ L300605 - AT 60
Hand - Finger	
☐ L131005 - R10x10 MPL	☐ ML20200 - FTR 14
Revision & Tumour surgery	
☐ L130605B - R06x400/S	☐ L130605C - R06x400 (6 cm)

Any serious incident that occurs in relation to this device should be reported to the manufacturer and to the Therapeutic Goods Administration.

Australian Government
Department of Health
Therapeutic Goods Administration

https://www.tga.gov.au

Patient Information Leaflet

Made in France by

LARS

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CE 0459

Certification obtained in 1997

FAB-L/IN.201.00
Rev 09/2020
(en/AU)

LARS® ARTIFICIAL LIGAMENTS

DEVICE DESCRIPTION AND INTENDED PURPOSE

In most cases, joint instability and laxity are caused by a traumatic accident. LARS artificial ligaments are used when other techniques (autograft and allograft) are not considered suitable by the surgeon. Indeed, LARS artificial ligaments are intended to replace or repair a damaged or ruptured ligamentous, tendinous or muscular structure in order to restore the natural function. They are indicated for:

- Intra-articular implantation such as anterior and posterior cruciate ligaments reconstruction or reinforcement, reinforcement of the medial collateral ligament, autogenous reinforcement and reconstruction or reinforcement in case of ankle lateral instability.

- Extra-articular implantation such as coraco-clavicular dislocation, Achilles tendon rupture, reconstruction of the knee extensor apparatus, reconstruction or reinforcement in case of a painful patella syndrome, reinforcement of the rotator cuff reconstruction or reinforcement of hand tendon, muscle reconstruction and reinforcement in tumour surgery.

The different types of LARS artificial ligaments are available in the ***"Model of the artificial ligament"*** table. They are supplied sterile.

KIND OF PATIENT

LARS artificial ligaments are intended to be used on patients who need to compensate the damage/loss of natural ligaments, tendons and muscles.

SPECIAL OPERATING INSTRUCTIONS

The use of LARS artificial ligaments does not require any special operating instructions from the patient except the complete follow-up of the rehabilitation program. Rushing the post-operative rehabilitation could have undesirable consequences on the patient's healing. The final result depends equally on the rehabilitation program defined by health care physicians and the patient attendance to the rehabilitation program.

Different fixation techniques of LARS artificial ligaments can be used:

- fixation by screws which can be strengthened with staples
- fixation by sutures

It is highly recommended to fix LARS artificial ligaments with LARS screws and staples but the choice of another fixation supplier is under the surgeon's responsibility.

Note 1: LARS ligament screws are made from titanium alloy and LARS ligament staples are made from cobalt-chromium alloy.
Note 2: there is no assurance that products manufactured by other companies can be safely used with LARS ligaments.

INTENDED PERFORMANCE

LARS artificial ligaments implantation allows to return to normal daily and sport activities as an equivalent level as before the injury.
LARS artificial ligaments enable to shorten the rehabilitation period compared to autograft technique and enable to avoid disease transmission compared to allograft technique.

UNDESIRABLE SIDE EFFECTS

As in all surgery, an inherent risk of infection exists in the use of artificial ligaments (less than 1% in published studies).
Some cases of chronic synovitis have been observed.
These two side effects rarely occur and are generally due to a technical error during implantation. If such complication arises, see paragraph **"*When to contact health professionals".***

Other undesirable side effects may exist:

- in case of intra-articular implantation, a hematoma can form due to intra-articular bleeding, which may require special care

- joint stiffness may develop if postoperative rehabilitation is not well followed

RESIDUAL RISKS

LARS artificial ligaments should not be considered better than the natural elements (ligament, tendon, muscle) so a new damage or rupture can occur again.

RISKS DUE TO INTERACTIONS OF THE DEVICE WITH OTHER EQUIPMENT AND ASSOCIATED PRECAUTIONS

There are no specific precautions or measures to be taken by the patient or a health professional regarding the interaction of the device with other equipment as no specific risks have been identified.

LARS artificial ligaments and LARS fixations (screws and staples) are compatible with Magnetic Resonance Imaging (MRI).

EXAMINATION, MONITORING OR MAINTENANCE OF THE DEVICE

No requirements other than the rehabilitation program follow-up.

SYMPTOMS, SIGNS OF MALFUNCTION AND ASSOCIATED PRECAUTIONS

The following symptoms may be a sign of the device malfunction:

- instability
- pain
- swelling of the implantation site associated with fever

If the above symptoms are estimated by the patient at an abnormal level, a health professional must be contacted.

Note: The patient should be aware that the risk of new damage/rupture is higher when practicing contact pivot sports such as team sports, combat sports, tennis or others.

EXPECTED DEVICE LIFETIME

Thanks to many scientific studies and publications, the expected device lifetime is 20 years.
Nonetheless, without any complications, the ligament is not intended to be removed and/or replaced. LARS artificial ligaments remain implanted during all the patient lifetime. There are thus no specific precautions to be taken regarding the end of the expected device lifetime.

The device lifetime may be shortened by a new trauma/accident or an incorrect follow-up of the rehabilitation program.

WHEN TO CONTACT HEALTH PROFESSIONALS

If the patient feels any symptoms described in paragraph ***"Symptoms, signs and associated precautions"*** and/or if the patient has experienced a new trauma/accident linked the implanted LARS artificial ligament, a health professional must be consulted.

Only the health professional is able to determine the cause of the possible complications and, if applicable, will treat them by any surgical technique (open surgery or arthroscopic surgery) or medical technique.

MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE

LARS artificial ligaments are made of polyester material. It doesn't contain any carcinogenic substances, latex or phthalates.
LARS artificial ligaments are biocompatible which means that the ligaments have been tested and found compliant according to the applicable standards and regulations.

MANUFACTURING RESIDUALS

The manufacturing and cleaning processes of the ligament are monitored, validated and approved. Therefore, no manufacturing residuals may pose a risk to the patient.

Glossary:

Allograft: transplant from a genetically non-identical donor of the same species

Arthroscopy: minimally invasive surgical procedure to perform a number of surgical procedures on the knee

Autograft: transplant from one part of the body to another in the same person

Biocompatible: material that has the ability to be tolerated by a living organism, especially when the material is present in the body (such as a prosthesis)

Hematoma: accumulation of blood under the skin or in an organ

Infections: body immunological reaction caused by infectious agents (pathogens)

Synovitis: inflammation of the synovial membrane, located in the inner part of the joints and which secretes a liquid called the synovium, whose purpose is to facilitate sliding