Patient information leaflet

Reference of the LARS artificial ligament used:
(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)

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(en)

LARS ® ARTIFICIAL LIGAMENTS

DEVICE DESCRIPTION AND USE

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.

The different types of LARS artificial ligaments are listed in the "Reference of the LARS artificial ligament used" table. They are delivered in a sterile state.

INTENDED PERFORMANCES

The use of LARS artificial ligaments allows an earlier resumption of daily activity, even sport, than the other techniques do not allow.

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.

MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE

LARS artificial ligaments are made of polyester material (PET – Polyethylene terephthalate). They do not 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.

SPECIAL OPERATING INSTRUCTIONS

Two fixation techniques of LARS artificial ligaments can be used:
- fixation by screws, possibly reinforced by staples
- fixation by sutures

LARS ligament screws are made from titanium alloy.
LARS ligament staples are made from cobalt-chromium alloy.

LARS artificial ligaments are fixed, depending of the site of lesion, by 1 or 2 screws and possible 1 staple.
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 responsibility.
The use of LARS artificial ligaments does not require any special operating instructions except that the result of the intervention depends on the patient's motivation and the received information regarding postoperative rehabilitation. Poorly followed or poorly directed rehabilitation can have undesirable consequences for the patient.

UNDESIRABLE SIDE EFFECTS

As in any surgical intervention, the use of artificial ligaments involves a minor risk of infection (less than 1% in published studies) as well as some cases of chronic synovitis.
A postoperative hematoma can occur and requires special cares.
Limitation of joint mobility is often the result of insufficient or untimely postoperative rehabilitation.
If such side effects occur, see paragraph "**When to contact healthcare professionals**".

RESIDUAL RISKS

The LARS artificial ligament does not protect the patient from further trauma.

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 requirement other than following the rehabilitation program.

SYMPTOMS, SIGNS OF MALFUNCTION AND ASSOCIATED PRECAUTIONS

Any symptoms or signs of dysfunction deemed abnormal (instability, pain ….) must be reported to a health professional.

The patient who has undergone an intervention with a LARS artificial ligament must be careful in the exercise of a sporting activity and a fortiori at a high level of sporting practice.

WHEN TO CONTACT HEALTH PROFESSIONALS

If the patient experiences any of the symptoms described in the paragraph "**Symptoms, signs of dysfunction and associated precautions**" and/or if the patient is the victim of a new accident, a healthcare professional must be consulted.

Only the healthcare professional is able to establish the cause of the experienced disorders and treat them

MANUFACTURING RESIDUALS

The manufacturing and cleaning processes of LARS artificial ligaments are controlled in particular by biological test which allow to reduce the risk of complications to a very low level.

Glossary:

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

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.

Infection: 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