PATIENT INFORMATION LEAFLET

MOVMEDIX
5 rue de la Fontaine
21560 Arc sur Tille FRANCE
☏ : 33 (0)3 80 37 26 60
@ : contact@movmedix.com
💻 : www.movmedix.com

CE 0459

Certification obtained in 1997

LARS™ artificial ligaments:

Name	Model
LARS – Anterior Cruciate	AC 60 SC
	AC 80 C
	AC 100 C
	AC 30 RA
	AC 60 L
	AC 60 R
	AC 80 L
	AC 80 R
	AC 100 2BL
	AC 100 2BR
	AC 120 2BL
	AC 120 2BR
	AC 160 2BL
	AC 160 2BR
	AC 100 2BL/S
	AC 100 2BR/S
LARS – Anterior Cruciate (DB)	AC 30 DB
	AC 20 DB
	AC 40 DB
	AC 50 DB
	AC 60 DB
	AC 30 DB/P
LARS – Posterior cruciate	PC 60
	PC 80
LARS – Cruciate ligament reinforcement	ACTOR 8
	ACTOR 10
LARS – Knee Lateral Ligaments (straight)	MCL 32

Name	Model
LARS – Knee Lateral Ligaments (straight)	MCL 32
LARS – Knee Lateral Ligaments (Y)	PPLY-FP 80
	PPLY 100
	PPLY-LCL 100
LARS – Patellar tendon	AC 40 DB/AM
	PTR 30
LARS – Achilles tendon	AT 60
LARS – Ankle ligaments	LLEA 44
LARS – Soft tissues – tendons and ligaments	ACPCPL 60 CK1
	R06x400 (6 mm)
	R06x400/V
	LAC 20
	LAC 20 L
	LAC 30 CK
LARS – Soft tissues – muscles, tendons, and ligaments	IT 32 RA
	ACFAR 32 CK
	IT 20 RA
	ACTOR 5
LARS – Soft tissues – muscles and tendons	R06x400/S
	R06x400 (6 cm)
	R06x400
	CR 25/SB
	CR 30/SB
	CR 25/DB
	CR 30/DB
	LCR 25
	LCR 30

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LARS® ARTIFICIAL LIGAMENTS

INTENDED PURPOSE

The purpose of LARS devices is to reconstruct the native ruptured soft tissue or reinforce damaged native soft tissue or a graft (autograft or allograft) to restore physiological function.

LARS devices are intended for use in patients with a mature and healthy bone structure to reinforce and/or reconstruct soft tissues as detailed for each device name below:

- **LARS – Anterior Cruciate** devices are intended for reconstruction of the anterior cruciate ligament of the knee.
- **LARS – Anterior cruciate (DB)** devices are intended for reconstruction and reinforcement of the anterior cruciate ligament of the knee.
- **LARS – Posterior cruciate** devices are intended for the reconstruction of the posterior cruciate ligament of the knee.
- **LARS – Cruciate ligament reinforcement** devices are intended for the reinforcement of anterior and posterior cruciate ligaments.
- **LARS – Knee Lateral Ligaments (straight)** devices are intended for the reconstruction and reinforcement of the lateral ligaments of the knee.
- **LARS – Knee Lateral Ligaments (Y)** are intended for the reconstruction and reinforcement of the lateral ligaments of the knee.
- **LARS – Patellar tendon** devices are intended for the reinforcement of the patellar tendon of the knee.
- **LARS – Achilles tendon** devices are intended for the reinforcement of the Achilles tendon of the ankle.
- **LARS – Ankle ligaments** devices are intended for the reconstruction and the reinforcement of the ligaments of the ankle.
- **LARS – Soft tissues – tendons and ligaments** devices are intended for the reconstruction and reinforcement of tendons and ligaments.
- **LARS – Soft tissues – muscles, tendons and ligaments** are intended for the reconstruction and reinforcement of muscles, tendons, and ligaments.
- **LARS – Soft tissues – muscles and tendons** are intended for the reconstruction and reinforcement of muscles and tendons

KIND OF PATIENT

If you have damaged and or loss of natural ligaments, tendons and muscles that restricts regular activities, then you are likely a good candidate for a LARS™ artificial ligament. As always, it is best to discuss possible treatments with your surgeon.

SPECIAL OPERATING INSTRUCTIONS

The use of LARS artificial ligaments requires a complete follow-up of the rehabilitation program. Rushing the post-operative rehabilitation could have undesirable consequences on your healing. The result depends equally on the rehabilitation program defined by your health care physicians and your attendance to the rehabilitation program.

INTENDED PERFORMANCE

LARS artificial ligaments implantation allows you to return to normal daily and sport activities as an equivalent level as before the injury.

LARS artificial ligaments enable you to shorten the rehabilitation period compared to autograft technique and enable you to avoid disease transmission compared to allograft technique.

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.

POTENTIAL UNDESIRABLE SIDE EFFECTS

Side effects and possible complications related to the placement of the LARS™ artificial ligament:

- infection
- chronic synovitis
- hematoma in case of intra-articular implantation
- joint stiffness

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 OF DEVICE INTERACTION WITH OTHER EQUIPMENT

LARS artificial ligaments, associated to LARS fixations (screws and staples), are compatible with Magnetic Resonance environment.

EXAMINATION, MONITORING OR MAINTENANCE OF THE DEVICE

No requirements other than rehabilitation program follow-up established by your surgeon.

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.

EXPECTED DEVICE LIFETIME

Thanks to many scientific studies and publications[1], the expected device lifetime is 20 years.
There are some things that can influence the product lifetime including, but not limited to, surgical indication, surgical technique, patient weight, activity level and comorbidities. You should talk to a registered healthcare professional about your specific situation.
Nonetheless, without any complications, the ligament is not intended to be removed and/or replaced. LARS artificial ligaments remain implanted during all your life. 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 you feel any symptoms described in paragraph ***"Symptoms, signs and associated precautions"*** and/or if you have experienced a new trauma/accident linked the implanted LARS artificial ligament, a health professional must be consulted.

Only the health professional can determine the cause of the possible complications and, if needed, 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.
LARS artificial ligament L050305 - PTR 30 also contains a 316L stainless-steel bar.
There are no medicinal substances, materials of microbial origin, stable derivatives of human blood, human plasma and animal origin materials, carcinogenic substances, latex or phthalates included with any of the components of the LARS artificial ligaments.

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

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 that is performed on a joint to examine, diagnose, and/or treat joint abnormalities
- *Autograft*: transplant from one part of the body to another in the same person
- *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

[1] *Smolle MA, Fischerauer SF, Zötsch S, et al. Long-term outcomes of surgery using the Ligament Advanced Reinforcement System as treatment for anterior cruciate ligament tears. Bone Joint J. 2022;104-B(2):242-248. doi:10.1302/0301-620X.104B2.BJJ-2021-0798.R2. Available on https://boneandjoint.org.uk/article/10.1302/0301-620X.104B2.BJJ-2021-0798.R2*

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

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Corin
Connected Orthopaedic Insight

Australian Sponsor
17 Bridge Street
Pymble
NSW 2073 AUSTRALIA

Explanation of the symbols used in the Patient Implant Card:

MD	Device Name
REF	Order number
CODE	Model code
LOT	Lot Number
UDI	Unique Device Identifier
	Patient Name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
CE 0459	CE marking of conformity