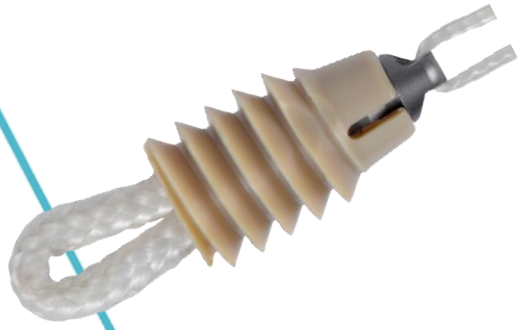
IMPLANTS

For Tendon and ligament anchorage

IMPORTANT PATIENT LEAFLET

ACLip



READ CAREFULLY THIS LEAFLET BEFORE SURGERY. IT CONTAINS IMPORTANT INFORMATION FOR YOU.

WHAT IS IN THIS LEAFLET

INTENDED USE

The implant is designed to fix the graft that replaces the ligament. The implant is effective during the graft healing process.
Patients with a mature skeleton may be implanted with an ACLip implant during an anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction when other treatments have failed.
Please ask your surgeon for details. The decision to perform an ACL or PCL reconstruction and implant an ACLip fixation is left to the surgeon after assessment of the risk/benefit balance and discussion with you.

SURGEY REVISION RATE

The revision rate for knee ligament reconstruction is around 3% two years after surgery. However, patient's factors such as weight, bone quality, activity level, and other medical condition and comorbidities may increase or decrease the revision rate. **Please attend regular check-ups according to your surgeon's advice.**

CONTRAINDICATIONS

At the time of the surgery, these conditions are not recommended:

- Pregnancy.
- Allergy to the implant materials.
- Infections.
- Severe mental, muscular, neurological or vascular deficiencies affecting the limb in question.
- Destruction of bone or poor bone quality which may affect stability of the implant;
- Highly localized arthrosis requiring osteotomy or unicompartmental arthroplasty.

These conditions should be discussed with your surgeon. Any pathology (even if not listed above) must be mentioned to your surgeon beforehand as well.

MATERIALS COMPOSITIONS AND DISTRIBUTIONS FOR ACL RECONSTRUCTION IMPLANT

Mass-to-mass ratio %

Polyetheretherketone (PEEK) 100% homopolymer of PEEK with possible traces of: Argent (Ag), Molybdenum (Mo), Copper (Cu), Lead (Pb), Mercury (Hg), Cadmium (Cd), Arsenic (As), Bismuth (Bi), Antimony (Sb) and Tin (Sn). Trace elements must be <100 ppm	**ACLip Cage**
Titanium Alloy (Ti6Al4V) Titanium (Ti): Balance / Aluminum (AI): 5.5 - 6.75% / Vanadium (V): 3.5 - 4.5% / Iron Fe): 0.3% max / Oxygen (O): 0.2% max / Carbon (C): 0.08% max / Nitrogen (N): 0.05% max / Hydrogen (H): 0.015% max	**ACLip Button**
Polyethylene Terephthalate (PET) Polyethylene Terephthalate (PET): 96.5 - 99.5%; Fiber finish: 0.5 - 1.5 % / Titanium Dioxide (TiO2) ≤ 1%	**ACLip Button (loop)**

IMPLANTS YOU HAVE BEEN IMPLANTED WITH:

Associations with other devices have to be validated by Amplitude.

COMPONENTS

ACLIP

☑ **ACLip Button**

☑ **ACLip Cage**

SPECIFIC WARNINGS & MRI INFORMATION

The materials used in your implant may trigger security gates/scanners.

Please inform personnel about your implanted device.

The following technical information is intended for medical staff, to ensure that MRI equipment is used in the best possible conditions.

Non-clinical testing demonstrated that the implants are MR Conditional. A patient with these devices can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5T or 3T for a 15 min-procedure
- Maximum spatial gradient field of 38T/m (=3800 G/cm) for a 1.5T MRI system and 19 T/m (=1900 G/cm) for a 3.0T MRI system.
- Normal operating mode only.
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning.

MAXIMUM MEASURED TEMPERATURE RISE

With 3T MRI, for a 1-hour-Procedure

ACLip	2°C (calorimetry WB-SAR of 2 W/kg)

POSSIBLE SIDE EFFECTS

You must be informed about the side effects in relation to the device that might occur. Those recorded by Amplitude are rare (inferior to 1 for 1000 cases).

Please consult your surgeon if any doubt.

- Allergy to implanted materials.
- Instability
- Bone degeneration.
- Bone fracture.
- Damage to soft tissues (muscle, tendon).
- Difficult recovery after major surgery
- Graft failure
- Implant breakage
- Implant dislocation
- Implant displacement
- Implant loosening.
- Inadequate graft.
- Infection.
- Injury to a major artery or nerve in the lower limb.
- Pain.
- Stiffness.
- Tissue reactions to prosthetic debris and wear particles

Other events linked to the surgery or current knowledge can also occur:

- Phlebitis, fat or pulmonary embolism.
- Complex regional pain syndrome.
- Bruise.
- Bone ossification abnormalities.
- Poor bone healing.

You must also be aware of the risks and possible side effects of surgery - please ask your surgeon for further information.

After ligament reconstruction, you should pay attention during the ligament healing period: any blow, fall or accident may jeopardise your recovery or your implant lifetime. Please ask your surgeon for further information.

WARNINGS AND PRECAUTIONS

You must be informed about the factors that could compromise the success of the surgery and post operative results:

- Overweight
- Case history detailing infections and/or falls.
- Metabolic disorders that reduce your resistance or induce progressive bone deterioration.
- Local bone tumours.
- Severe bone deformities.
- Osteoporosis.
- Playing risky sports or engaging in risky activities.
- Addictive behaviour.

KEEP THIS LEAFLET

You may need to read it again. If you have any further questions, ask your surgeon. If you experience any side effect, including **side effects not listed** in this leaflet, talk to your doctor or pharmacist. See page 6.

This leaflet has been written assuming the person receiving the implants will read it.

REPORTING ADVERSE EVENTS

Any incident in relation to the device shall be reported to your surgeon, healthcare facilities or family doctor.

AMPLITUDE
11 cours Jacques Offenbach – ZA Mozart 2 – 26000 VALENCE – France
https://implantcard.amplitude-ortho.com

PL-EU-EN-008.01 – 2026-02-10