

01

General presentation

- p.3 -

02

List of references

- p.4 -

03

Technical informations

- p.5 -

04

Product identification

- p.6 -

01

General presentation of the product

ACLip

- ▷ The product presented hereafter is a sterile medical device of IIb according to rule 8 annex VIII of regulation (UE) 2017/745.
- ▷ The ACLip allows tendon attachment into a bone tunnel especially for knee ligament reconstruction with graft.
- ▷ ACLip system is constituted of two components :
 - The ACLip cage** is a cancellous fixation screw with retentive strips aiming to anchor the graft holding system in the bone. the cage is made of PEEK (Polyether Ether Ketone) according to the ASTM F2026 standard.
 - The ACLip button** is composed of:
 - A titanium plate made of Titanium Alloy (Ti6Al4V ; according to ISO 5832-3 standard and ASTM F136 standard), aiming to be locked into the ACLip Cage,
 - A traction wire, made of Polyethylene terephthalate, used to pull the titanium button into the ACLip Cage.
 - A loop, made of Polyethylene terephthalate, aiming to hold tight the graft.
- ▷ The ACLip is used for femoral graft fixation in Anterior and posterior cruciate ligament reconstruction using Inside-Out technique.

The graft is harvested from the patient and implanted to replace the damaged ligament. This graft is positioned through bone tunnels performed into the tibial and femoral epiphyses.
- ▷ For the ACLip fixation, the graft fixation is performed in two stages :
 - Screwing the ACLip cage in the 5 mm diameter tunnel
 - Locking the ACLip button in the ACLip cage.

02

List of references*

ACLip

DESIGNATION	REFERENCE
ACLip - ACLip cage / ACLip button	1-0402300



* Check availability of product in

▷ Name of legal manufacturer:

AMPLITUDE, 11 Cours Jacques OFFENBACH
ZA MOZART 2, 26000 VALENCE, France.

▷ Presence of Latex in the product's composition: None

▷ CE mark:

Notified body BSI Group (CE2797)

Date of the first CE mark certification: 2016

▷ Product material:

Cage : PEEK Polyether Ether Ketone (ASTM F2026 standard)

Titanium plate : Titanium Ti6Al4V ((ISO 5832-3 standard and ASTM F136 standards))

Traction wires : Polyethylene terephthalate (PET)

Loop : Polyethylene terephthalate (PET)

▷ Production process:

PEEK Cage : Machined

Titanium Plate : Machined

Polyethylene terephthalate Loop : braided

Polyethylene terephthalate traction wires : Braided

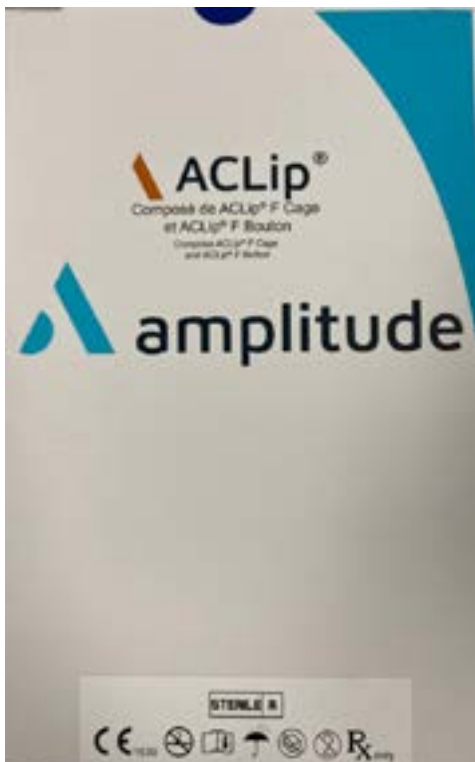
Dimensional control

Packaging and labelling

Sterilised by gamma irradiation with a minimum dose of 25 kGy.

04 Product identification

ACLip



Paper box:

Dimension: 155 mm x 100 mm x 20 mm

Color: white and blue

Primary packaging: Double bag PA/PE