comete

Product ID

ACL femoral cortical fixation

amplitude

sommary

01 General presentation

ACL femoral cortical fixation: comete

- The product presented hereafter is a class IIb sterile medical device according to the first article of directive 2005/50/CE changing the annex IX of Directive 93/42/EEC.

- The cortical fixation systems are used for fixation of tendons and ligaments during orthopaedic reconstruction procedures for the anterior cruciate liament (ACL) reconstruction.

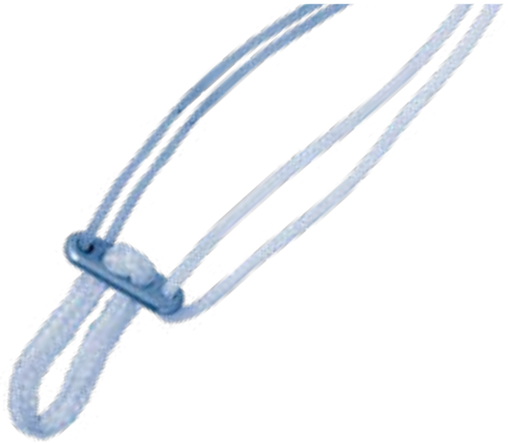
- Within the framework of anterior cruciate ligament reconstruction by Inside-Out technique with soft tissues, a tendinous tissue graft is harvested from the patient and implanted in the knee to replace the damaged ligament. This graft is positionned into the joint through bone tunnels performed into the tibial and femoral epiphyses.
The femoral secure of the graft is done by an anchorage of the titanium plate on the external cortical. The titanium plate is linked to the tendons by a round polyethylene terephtalate loop into which the tendons are passed. The cortical attachment enables a high mechanical holding and avoid tendon sliding phenomena.
COMETE device also enables to get a maximum bone/graft contact area and so facilite the graft integration.

* Result obtained after dynamic test (device only) carried out as part of the CE marking of the product.

02 List of references*

ACL femoral cortical fixation: comete

DESIGNATION	REFERENCE
comete : ACL femoral cortical fixation - Lg 15 mm	OAMGEFX15U
comete : ACL femoral cortical fixation - Lg 20 mm	OAMGEFX20U
comete : ACL femoral cortical fixation - Lg 25 mm	OAMGEFX25U
comete : ACL femoral cortical fixation - Lg 30 mm	OAMGEFX30U
comete : ACL femoral cortical fixation - Lg 35 mm	OAMGEFX35U



* Check availability in your country

03 Technical information

ACL femoral cortical fixation: comete

- **Manufacturer name and place:**
  COUSIN BIOTECH s.a.s, Allée des Roses,
  59117 Wervicq-Sud, France.

- **Supplier name and place:**
  AMPLITUDE, 11 Cours Jacques OFFENBACH,
  ZA MOZART 2, 26000 VALENCE, France.

- **Presence of latex in the composition of the product:** None

- **CE mark:**
  Notified body SGS Belgium (CE1639)
  Date of the first CE mark certification: 2005

- **Product material:**
  Titanium plate Ti6Al4V according to ISO 5832-3
  Loop made up polyethylene terephtalate (polyester)
  Traction wire made up polyethylene terephtalate and colorant DC Green n°6

- **Production process:**
  Titanium plate: machined
  Round polyethylene terephtalate loop is braided
  Stiffening and joining of the traction wire by thermic welding + tinting
  Dimensional control
  Packaging and labelling
  Sterilised by gamma irradiation with a minimum dose of 25 kGy

04 Product identification

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Paper box:

Dimension: 230 mm x 120 mm x 25 mm
Color: White printed blue
Packaging: Double bag