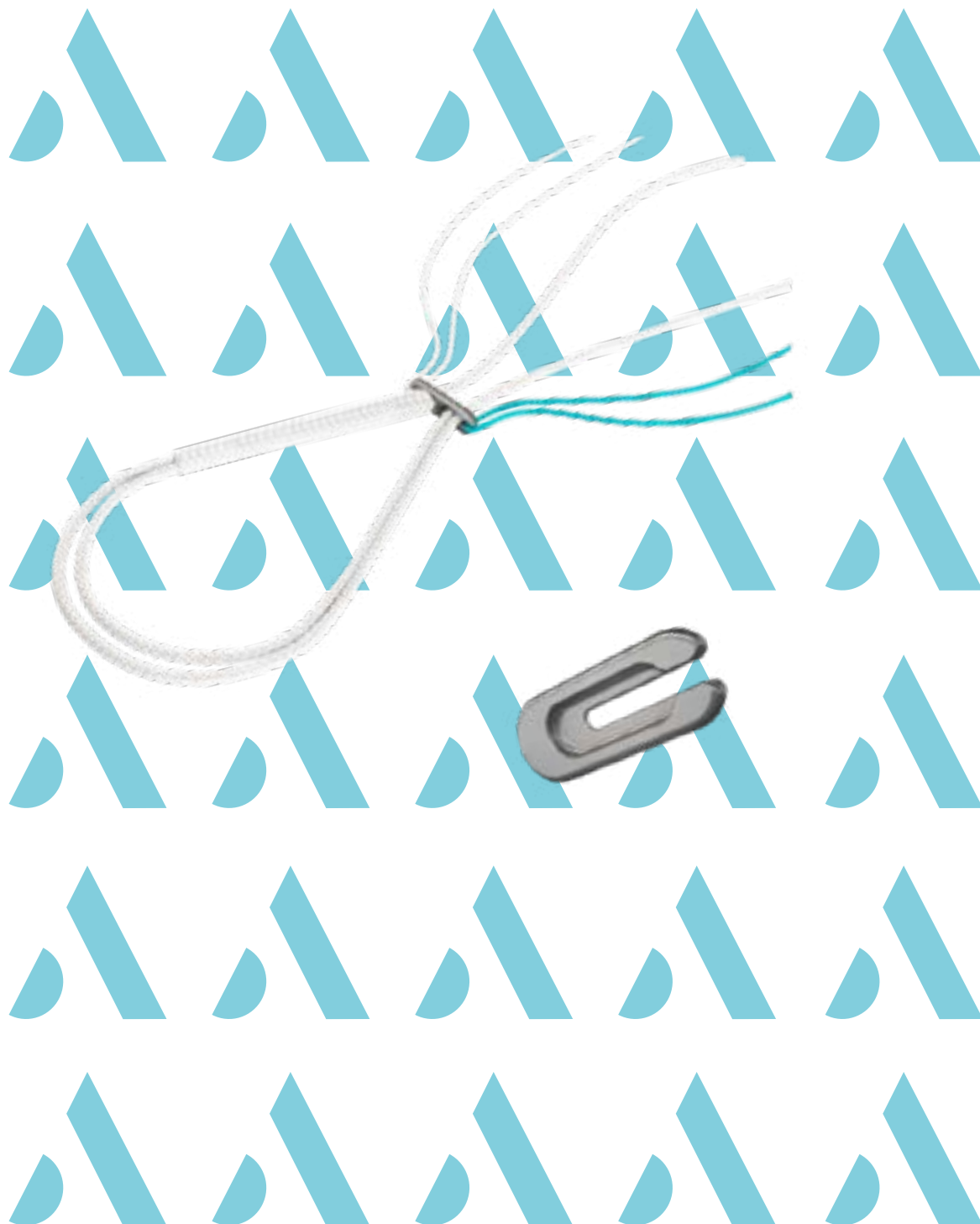


Adjustable cortical fixation and Extended plate for cortical fixation



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Product identification

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01

General presentation

Cortical fixation system:
comete control
comete extra plate

- ∅ The product presented hereafter is a sterile medical device of IIb according to the first article of the Directive 2005/50/CE modifying the annex IX of the Directive 93/42/CEE.
- ∅ The cortical fixation systems are used for fixation of tendons and ligaments during orthopaedic reconstruction procedures for the anterior cruciate ligament (ACL) reconstruction.
- ∅ For the anterior cruciate ligament reconstruction case using soft tissue (semi tendinosus and gracilis or Semitendinosus quadrupled) graft.
A tendinous tissue graft is harvested from the patient and implanted into the knee to replace the damaged ligament. This graft is positioned into the joint through bone tunnels performed into the tibial and femoral epiphyses.
COMETE Control graft fixation. The graft is carried out by an anchorage of the titanium plate of the cortical (with a 4,5 mm cortical tunnel). The titanium plate is linked to the tendons through a round polyethylene UHMWPE adjustable loop into which the tendons are passed in loops. The cortical attachment is 1844N* and avoids tendon sliding phenomena.
The COMETE Extra plate is used for the cortical tunnel up to 5 mm to Allows a larger surface of contact with the cortical bone.

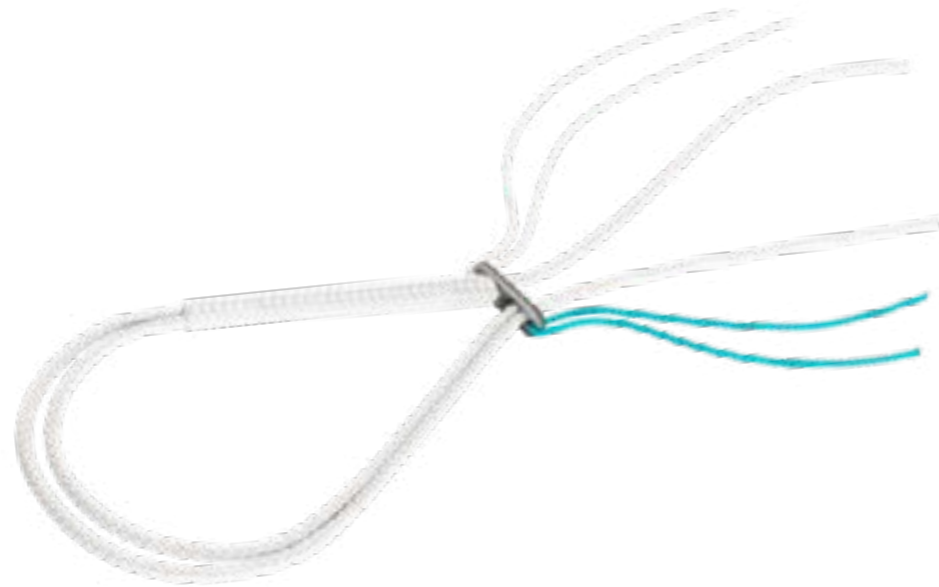
* Result obtained after dynamic test (device only) carried out as part of the CE marking of the product.

02

Liste of references*

Adjustable cortical fixation comete control

DESIGNATION	REFERENCE
comete control : Adjustable cortical fixation system	OAMGEFCR1U



* Check availability in your country

02

Liste of references*

Extended plate for cortical fixation comete extra plate

DESIGNATION	REFERENCE
comete extra plate : Extended plate for cortical fixation	OAMGEPLA1U



* Check availability in your country

Adjustable cortical fixation comete control

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 product's composition: No

CE mark:

Notified body SGS Belgium (CE1639)
Date of first CE mark certification: 2017

Product material

Titanium plate Ti6Al4V selon ISO 5832-3
Adjustable loop polyethylene UHMWPE (ultra high molecular weight polyethylene)
Traction threads siliconized polyethylene terephthalate and colorant DC Green n°6

Production process:

Titanium plate: machined
Polyethylene adjustable loop: braided
Polyethylene terephthalate traction wire: braided
Dimensional control
Packaging and labelling
Sterilised by gamma irradiation with a minimum dose of 25 kGy

Extended plate for corticale fixation comete extra plate

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 product's composition: No

CE mark:

Notified body SGS Belgium (CE1639)
Date of first CE mark certification: 2017

Product material

Titanium plate Ti6Al4V selon ISO 5832-3

Production process:

Titanium plate: machined
Dimensional control
Packaging and labelling
Sterilised by gamma irradiation with a minimum dose of 25 kGy

Adjustable cortical fixation
comete control



Paper box:

Dimensions : 250 mm x 120 mm x 20 mm
Color : White printed blue
Primary packaging: Double bag

Extended plate for corticale fixation
comete extra plate



Paper box:

Dimensions : 250 mm x 120 mm x 20 mm
Color : White printed blue
Primary packaging: Double bag