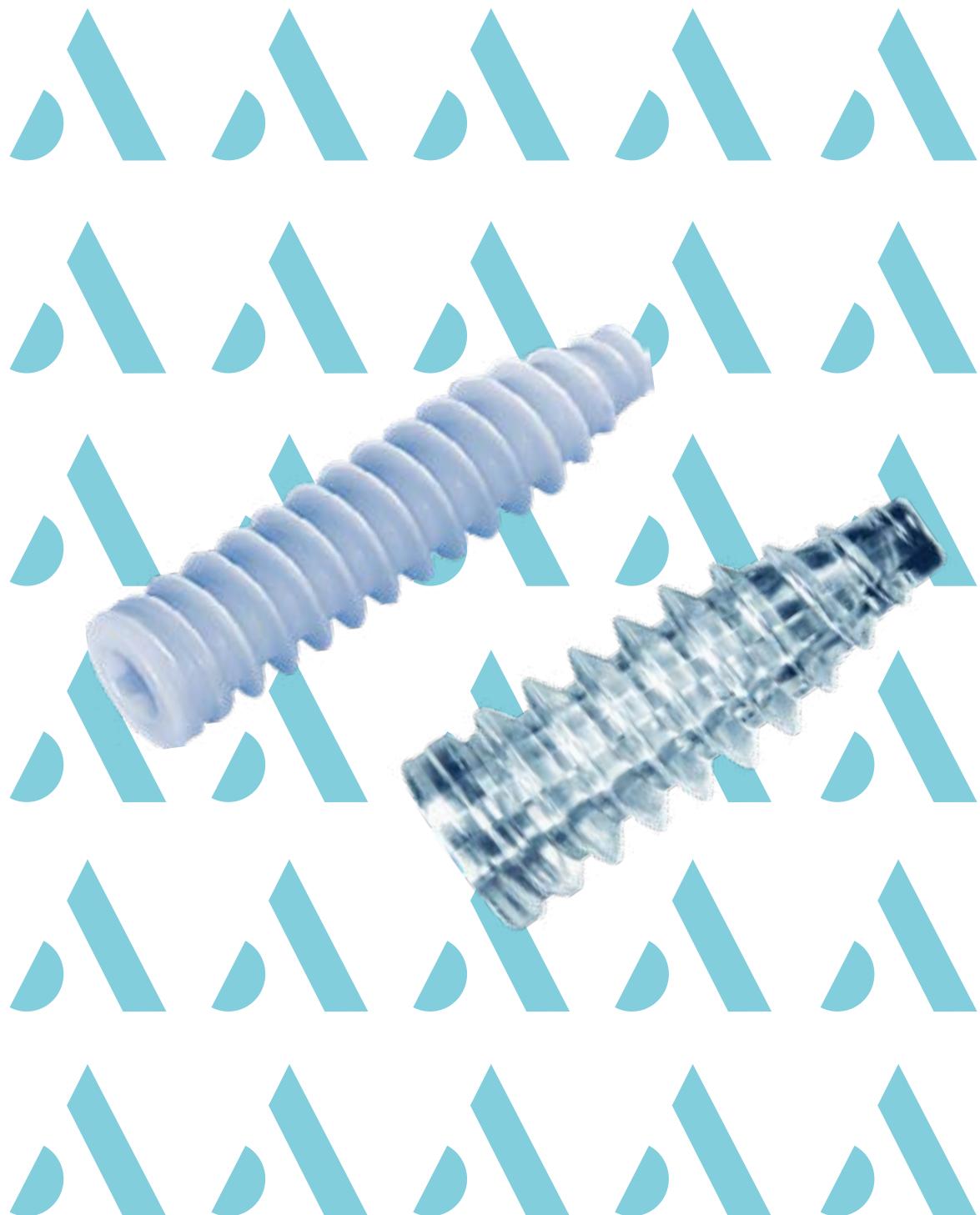


eclipse
BCP

eclipse
profil

Product
ID



Interference screws
polylactic eclipse Profil and composite eclipse BCP

amplitude

01

General presentation

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Technical information

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Product Identification

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01

General presentation

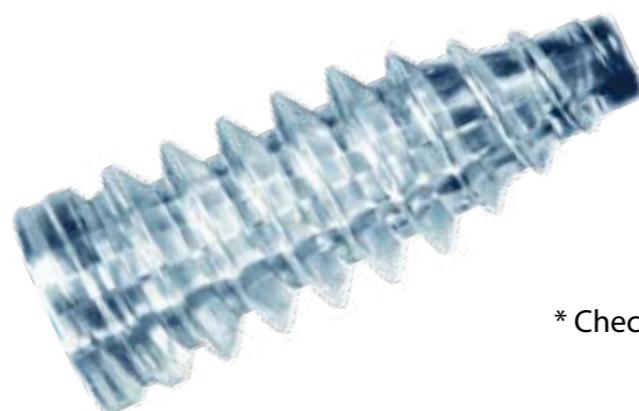
Interference screws Polylactic
eclipse Profil and Composite
eclipse BCP

- ▷ The products presented hereafter are class III sterile medical devices in accordance to rule 8 annex VIII of regulation (UE) 2017/745.
- ▷ The absorbable interference screws eclipse Profil and eclipse BCP are intended to insure a fixation by interference between ligament/graft and the bone tunnel's during the consolidation time. They are intended to be used for knee anterior ligaments reconstructions.
- ▷ The polylactic interference screws eclipse Profil:
Are fully composed of PLDLLA (amorphous) a polymer of lactic acid from the family of the poly (α -hydroxyacids) intended to be completely absorbed by the organism.
- ▷ The composite interference screws BCP:
Are composed of PLDLLA associated to pellets of BCP itself composed of 20% hydroxyapatite (HA) and 80% of tri-calcic phosphate β (β -TCP) intended to be completely absorbed by the organism. In aqueous environment, the combination of HA and β TCP lead to a phenomenon of TCP dissolution precipitation by forming microcrystals of biologicalapatite just as an interface contributing to the proliferation of osteoblasts.
This bioactivity associated with the PLDLLA resorption time allows to control the resorption ratio and the bone remodelling.*
- ▷ The surgical procedure for cruciate knee ligaments reconstruction involves the substitution of the torn ligament with an autograft.
This graft is routed in the knee joint through bone tunnels realised in the femoral and tibial epiphyses.
Graft fixation can be performed inside the bone tunnels using interference screw inserted between the graft and the tunnel wall.
Interference screws have a temporary role, once the graft has healed in the bone tunnel, these medical devices become useless. Moreover, in the long term, the presence of these screws can be problematic in the cases of iterative surgery. The use of absorbable screws eclipse Profil and eclipse BCP avoids these potential pitfalls. These medical devices will progressively resorb through hydrolysis in order to eventually leave an implant free area.

* Bart & Al 2016 the orthopedics journal of sports medicine

**Polylactic interference screws
eclipse Profil**

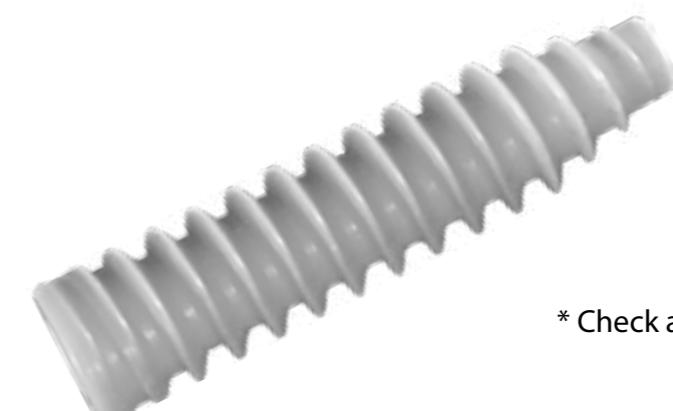
DESIGNATION	REFERENCE
Polylactic interference screw ECLIPSE Profil D 7 Lg 20mm	1-0402771
Polylactic interference screw ECLIPSE Profil D 7 Lg 25mm	1-0402772
Polylactic interference screw ECLIPSE Profil D 7 Lg 30mm	1-0402773
Polylactic interference screw ECLIPSE Profil D 8 Lg 20mm	1-0402781
Polylactic interference screw ECLIPSE Profil D 8 Lg 25mm	1-0402782
Polylactic interference screw ECLIPSE Profil D 8 Lg 30mm	1-0402783
Polylactic interference screw ECLIPSE Profil D 9 Lg 20mm	1-0402791
Polylactic interference screw ECLIPSE Profil D 9 Lg 25mm	1-0402792
Polylactic interference screw ECLIPSE Profil D 9 Lg 30mm	1-0402793
Polylactic interference screw ECLIPSE Profil D 10 Lg 25mm	1-0402702
Polylactic interference screw ECLIPSE Profil D 10 Lg 30mm	1-0402703



* Check availability in your country

**Composite interference screws
eclipse BCP**

DESIGNATION	REFERENCE
Composite interference screw ECLIPSE BCP D 7 Lg 20mm	1-0401071
Composite interference screw ECLIPSE BCP D 7 Lg 25mm	1-0401072
Composite interference screw ECLIPSE BCP D 7 Lg 30mm	1-0401073
Composite interference screw ECLIPSE BCP D 8 Lg 20mm	1-0401081
Composite interference screw ECLIPSE BCP D 8 Lg 25mm	1-0401082
Composite interference screw ECLIPSE BCP D 8 Lg 30mm	1-0401083
Composite interference screw ECLIPSE BCP D 9 Lg 20mm	1-0401091
Composite interference screw ECLIPSE BCP D 9 Lg 25mm	1-0401092
Composite interference screw ECLIPSE BCP D 9 Lg 30mm	1-0401093
Composite interference screw ECLIPSE BCP D 10 Lg 25mm	1-0401012
Composite interference screw ECLIPSE BCP D 10 Lg 30mm	1-0401013
Composite interference screw ECLIPSE BCP D 11 Lg 35mm	1-0401004
Composite interference screw ECLIPSE BCP D 12 Lg 35mm	1-0401024



* Check availability in your country

**Polylactic interference screws
eclipse Profil**

D Manufacturer name and place:

BIOMATLANTE, ZA les Quatre Nations, 5 rue Edouard Belin,
44360 Vigneux de Bretagne, France.

D Supplier name and place:

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

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

D CE marking:

TÜV SÜD Product Service GmbH (notified body n°0123)
Date EC marking first applied: 2013

D Material's product:

PLDLLA, poly (L/DL-lactide) 70/30

D Manufacturing process:

Injection moulding
Dimensional control
Packaging and labelling
Sterilised by beta irradiation with a minimum dose of 25 kGy

**Composite interference screws
eclipse BCP**

D Manufacturer name and place:

BIOMATLANTE, ZA les Quatre Nations, 5 rue Edouard Belin,
44360 Vigneux de Bretagne, France.

D Supplier name and place:

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

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

D CE marking:

TÜV SÜD Product Service GmbH (notified body n°0123)
Date EC marking first applied: 2011

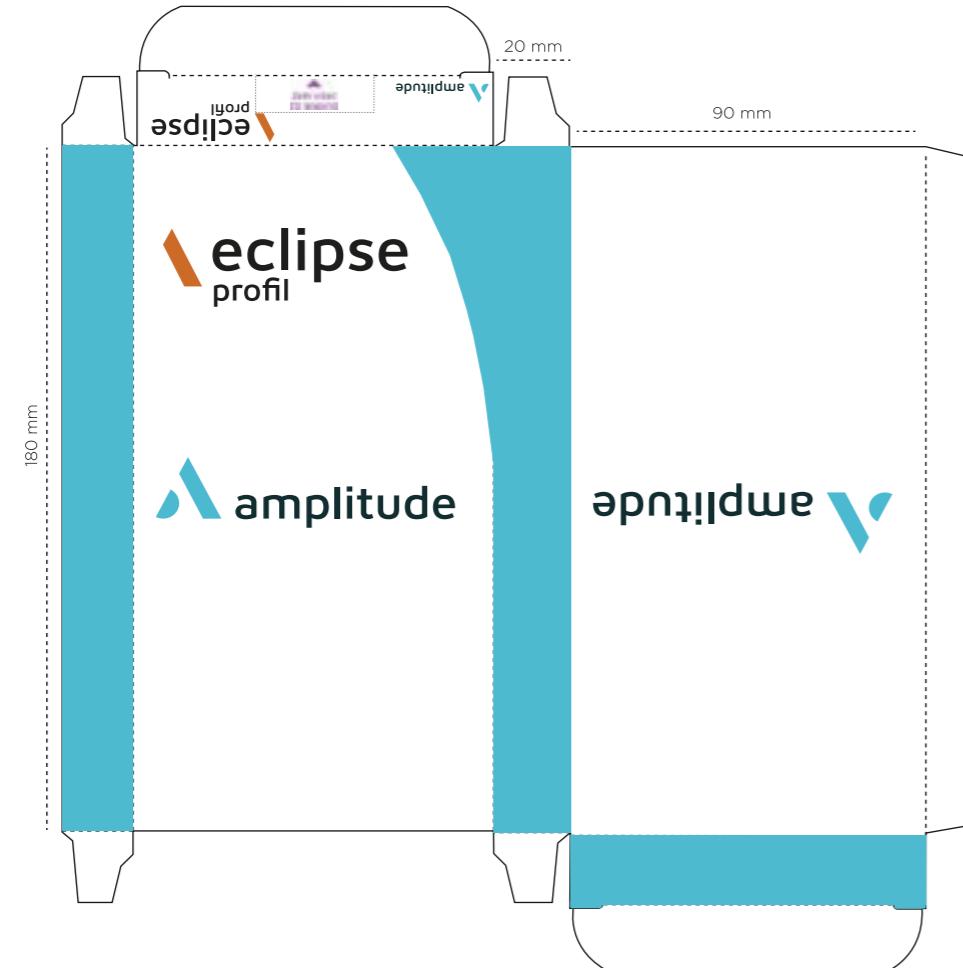
D Material's product:

Stereo-copolymer of lactic acid, poly (L/DL-lactide) 70/30
Mineral filler, BCP granule (20% HA / 80% TCP)

D Manufacturing process:

Injection moulding
Dimensional control
Packaging and labelling
Sterilised by beta irradiation with a minimum dose of 25 kGy

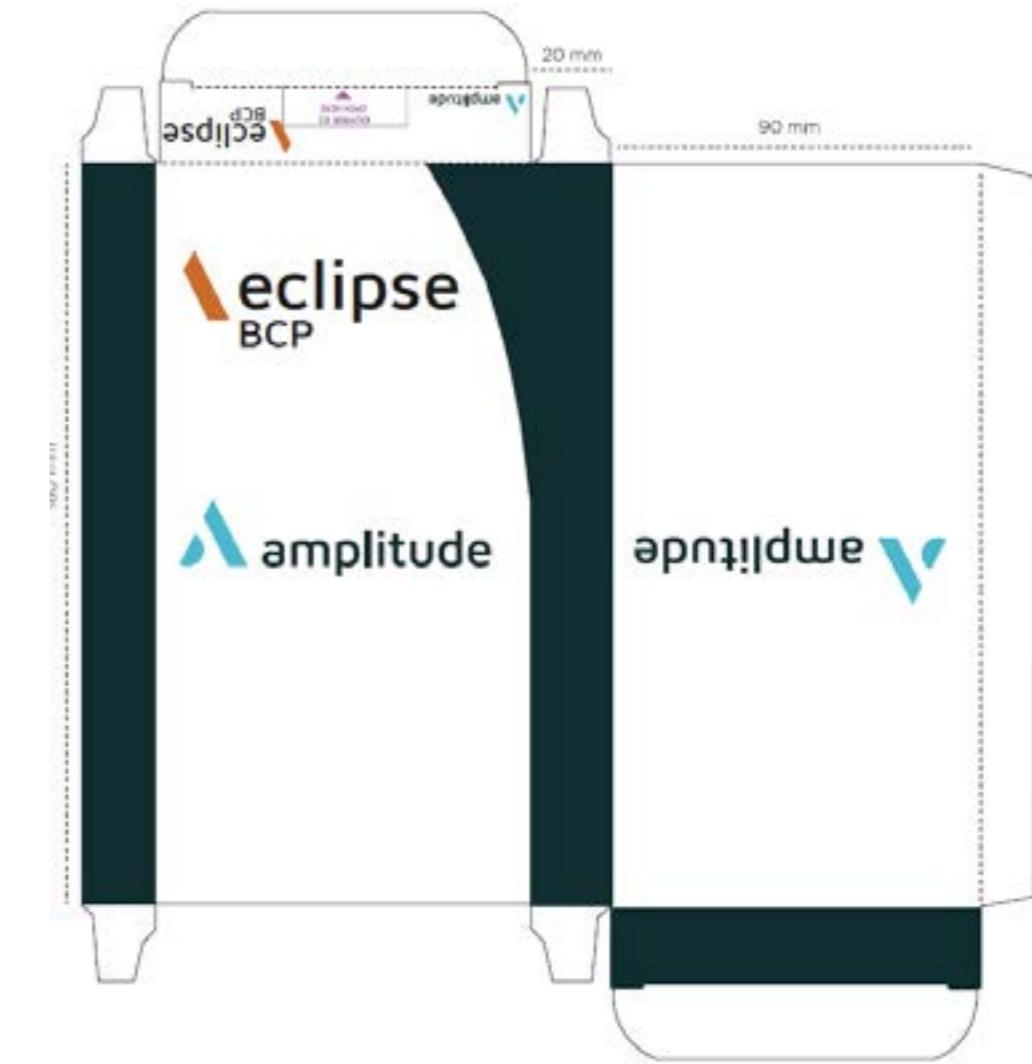
Polylactic interference screws
eclipse Profil



Cardboard box:

Dimensions: 180 mm x 90 mm x 20 mm
Color: White and blue
Packaging: Double pouch

Composite interference screws
eclipse BCP



Cardboard box:

Dimensions: 180 mm x 90 mm x 20 mm
Color: White and grey
Packaging: Double pouch