



INITIALE FEMORAL STEM
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01

General Presentation of the Product

- ∩ The product presented below is a class III sterile medical device in accordance with rule 8 annex VIII of regulation (UE) 2017/745.
- ∩ INITIALE femoral stem is the femoral component of a total hip prosthesis. It is a Charnley-Kerboull type stem. A total hip prosthesis is composed of several components. This total hip prosthesis consists of different components intended to replace the hip joint. Two separate parts, the femoral stem and the cup, are implanted in the femur and the acetabulum of the natural joint respectively. The prosthetic femoral head, made of metal or ceramic, ensures the functional connection.
- ∩ INITIALE femoral stem is designed to be implanted exclusively with Amplitude ceramic or metallic femoral heads, with a 10/12 taper, angle 5°42'30'' (see Product ID of 10/12 Femoral Heads).
- ∩ The INITIALE femoral stem is designed to be fixed with orthopaedic cement. It is available in several versions and sizes: Primary Standard (13 sizes), Dysplasia (5 sizes) and Revision (11 sizes).
- ∩ It is a straight stem. The stem is made of M30NW stainless steel.
- ∩ All the surfaces, except for the Morse taper (10/12), are bright polished with a Ra of 0.05. The metaphyseal part has no grooves.

STANDARD STEM DESCRIPTION	REFERENCE
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 102 S	1-0180102
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 201 S	1-0180201
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 202 S	1-0180202
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 203 S	1-0180203
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 301 S	1-0180301
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 302 S	1-0180302
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 303 S	1-0180303
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 401 S	1-0180401
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 402 S	1-0180402
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 403 S	1-0180403
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 501 S	1-0180501
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 502 S	1-0180502
INITIALE Femoral Stem - Standard - Cemented - 10/12 Taper - Size 601 S	1-0180601





DYSPLASIA STEM DESCRIPTION	REFERENCE
INITIALE Femoral Stem - Dysplasia - Cemented - 10/12 Taper - Size 121 D	1-0140121
INITIALE Femoral Stem - Dysplasia - Cemented - 10/12 Taper - Size 221 D	1-0140221
INITIALE Femoral Stem - Dysplasia - Cemented - 10/12 Taper - Size 321 D	1-0140321
INITIALE Femoral Stem - Dysplasia - Cemented - 10/12 Taper - Size 421 D	1-0140421
INITIALE Femoral Stem - Dysplasia - Cemented - 10/12 Taper - Size 521 D	1-0140521

REVISION STEM DESCRIPTION	REFERENCE
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 202 R - Lg 200 mm	1-0160220
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 202 R - Lg 250 mm	1-0160225
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 302 R - Lg 200 mm	1-0160320
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 302 R - Lg 250 mm	1-0160325
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 302 R - Lg 300 mm	1-0160330
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 402 R - Lg 200 mm	1-0160420
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 402 R - Lg 250 mm	1-0160425
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 402 R - Lg 300 mm	1-0160430
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 501 R - Lg 200 mm	1-0160520
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 501 R - Lg 250 mm	1-0160525
INITIALE Femoral Stem - Revision - Cemented - 10/12 Taper - Size 501 R - Lg 300 mm	1-0160530



03

Technical Information

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

Presence of Latex in the product's composition: None

Product Material:

Stainless Steel (M30NW) implantable according to ISO 5832-9 standard

Production Process:

Forged, Machined, Three-dimensional inspection, Polished, Laser marked, Cleaned and Decontaminated, Packaged, Labelled and Sterilized by gamma irradiation with a minimum dose of 25 kGy.

CE Mark:

Notified body BSI Group (CE2797)
Date of the 1st CE Mark certification: 2000



04 Product Identification

INITIALE FEMORAL STEM

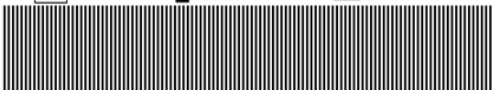
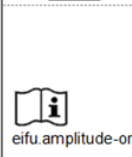
Implant Marking



Information:

Implant size
Batch number
Stainless Steel
Manufacturer logo

Label

  Stainless Steel	INITIALE Femoral Stem - Standard <i>Tige fémorale INITIALE - Standard</i> Cemented <i>A cimenter</i>	Taper / Cône 10/12 5° 42' 30" Size / Taille 102S
REF 1-0180102	LOT 123456	2027-10-01
 UDI	 (01)03701089507776(17)271001(11)221205(10)123456	2022-12-05 QTY 1
 eifu.amplitude-ortho.com		1/2 F
STERILE R	LATEX Rx only	
	AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 26000 VALENCE - FRANCE	CE 2797

Non-contractual image

Packaging

Standard and Dysplasia Stems:

Paper box:

Dimensions : 330 mm x 130 mm x 55 mm
Color : Fuschia / 351

Internal packaging: Double blister and Tyvek lid

Revision Stems:

Paper box:

Dimensions : 490 mm x 140 mm x 55 mm
Color: Fuschia / 351 - Ciel / 80

Internal packaging: Double bag

