



E² CEMENTED STEM

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01 General presentation of the product

- ∅ The product presented hereafter is a sterile medical device of class III according to rule 8 annex VIII of regulation (UE) 2017/745.
- ∅ The E² cemented stem is the femoral component of a total hip prosthesis. A total hip prosthesis is composed of several implants dedicated to replacing the joint. Two distinctive parts, the femoral stem and the cup, are respectively fixed into the femoral bone and into the acetabulum of the natural joint. The prosthetic femoral head, in metal or ceramic, ensures the functional link of these two components.
- ∅ The E² cemented stem is intended to be implanted exclusively with Amplitude femoral heads, either ceramic or metallic, with a 12/14 taper (see Product ID femoral head taper 12/14). It is also usually paired with a distal centralizer, either winged (for standard femurs) or narrow (for narrow femurs). All surfaces of the stem apart from the Morse taper are highly polished with a 0.1 Ra.
- ∅ The E² cemented stem must be implanted with acrylic orthopaedic cement. Its straight, quadrangular, dual tapered shape and surface finish ensure uniform load distribution on the cement mantle and transform shear forces into compression forces. Proximal depth markings help the surgeon to reproduce the same insertion level as the broaches, for leg length preservation and control.
- ∅ The stem is made up of M30NW stainless steel. It is available in 5 sizes (0, 1, 2, 3, 4) and up to 4 offsets (35.5, 37.5, 44 and 50 mm) depending on size. The stem length is constant throughout the range, as well as the neck-shaft angle (125°)

STEM DESIGNATION	REFERENCE
E2 Femoral Stem - 35.5mm Offset – Cemented - Taper 12/14 - Size 1	111-042-002
E2 Femoral Stem - 37.5mm Offset - Cemented - Taper 12/14 - Size 0	111-042-005
E2 Femoral Stem - 37.5mm Offset - Cemented - Taper 12/14 - Size 1	111-042-006
E2 Femoral Stem - 37.5mm Offset - Cemented - Taper 12/14 - Size 2	111-042-007
E2 Femoral Stem - 37.5mm Offset - Cemented - Taper 12/14 - Size 3	111-042-008
E2 Femoral Stem - 44 mm Offset - Cemented - Taper 12/14 - Size 0	111-042-009
E2 Femoral Stem - 44 mm Offset - Cemented - Taper 12/14 - Size 1	111-042-010
E2 Femoral Stem - 44 mm Offset - Cemented - Taper 12/14 - Size 2	111-042-011
E2 Femoral Stem - 44 mm Offset - Cemented - Taper 12/14 - Size 3	111-042-012
E2 Femoral Stem - 44 mm Offset - Cemented - Taper 12/14 - Size 4	111-042-013
E2 Femoral Stem - 50 mm Offset - Cemented - Taper 12/14 - Size 1	111-042-014
E2 Femoral Stem - 50 mm Offset - Cemented - Taper 12/14 - Size 2	111-042-015
E2 Femoral Stem - 50 mm Offset - Cemented - Taper 12/14 - Size 3	111-042-016



03 Technical informations

Name of legal manufacturer:
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, Controlled, Polished, LASER engraved, Controlled, Passived, Cleaned
Packaged, Labelled and Sterilized by gamma radiation with a minimum dose of 25 kGy

CE mark:

Notified body BSI (CE2797)
Date of first CE mark certification: May 2021



04 Product identification

E² STEM


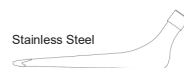


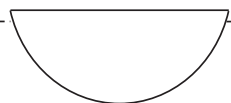






D Implant engraving



Information:

- Manufacturer logo
- Batch number
- Implant size
- Stainless Steel (S)

D Label

 Stainless Steel 	E² Femoral Stem - 35.5 mm Offset Tige fémorale E ² - <u>Offset 35.5 mm</u> Cemented / À cimenter For cemented use only / Pour usage cimenté uniquement	Size 1 Taille 1 Taper / Cône 12/14 5° 42' 30"
	REF 111-042-002 LOT 123456 2026-10-01 2021-11-02 QTY 1   UDI (01)03701089502399(17)261001(11)211112(10)123456	
		
eifu.amplitude-ortho.com 164C		
STERILE R LATEX Rx only       MD CE 2797		
AMPLITUDE - 11 cours Jacques Offenbach – ZA Mozart 2 – 26000 VALENCE - FRANCE		

D Packaging

Paper box:

Dimensions: 300 mm x 150 mm x 55 mm

Color: Lead 5415C

Internal packaging: Dual blister

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