



**SATURNE CUP
CEMENTED**

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01

General presentation of the product

- ⌋ This product is a sterile medical device Class III according to article first of the directive 2005/50/CE modified annex IX of the directive 93/42/CEE.
- ⌋ The SATURNE cemented cup is the acetabular 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 SATURNE cemented cup is dedicated to an exclusive use with polyethylene SATURNE liners. It is a dual mobility cup, and consequently features two levels of mobility: a first mobility, called «large joint», between the metal-back and the polyethylene liner, and the second mobility, called «small joint», happening more conventionally between the femoral head and the liner.
- ⌋ The SATURNE cemented cup must be fixed with cement. The metal cup, made of implantable stainless steel (M30NW), features a rough outer surface. The presence of grooves allows spreading the cement mantle and stability of the implant within the mantle. The cup features an anatomical shape with a posterior wall above the hemisphere, and anterior cut-out below the hemisphere, and a flat pole at the apex. Excluding the rough outer surface, the internal surface and the rim of the cup are mirror polished. The cup is available in nine sizes, ranging from diameter 44 mm to diameter 60 mm with 2 mm increments. The edges of the cup are curved.
- ⌋ The high density polyethylene is retentive to ensure proper hold of the head. It is available (depending on sizes) for diameter 22,2 mm or 28 mm femoral heads.

02

List of references*

SATURNE CEMENTED CUP

CUP DESIGNATION	REFERENCE
SATURNE tripolar cup - Cemented - Size 44	1-0106244
SATURNE tripolar cup - Cemented - Size 46	1-0106246
SATURNE tripolar cup - Cemented - Size 48	1-0106248
SATURNE tripolar cup - Cemented - Size 50	1-0106250
SATURNE tripolar cup - Cemented - Size 52	1-0106252
SATURNE tripolar cup - Cemented - Size 54	1-0106254
SATURNE tripolar cup - Cemented - Size 56	1-0106256
SATURNE tripolar cup - Cemented - Size 58	1-0106258
SATURNE tripolar cup - Cemented - Size 60	1-0106260



* Check availability depending on countries

02

List of references*

SATURNE LINER

LINER DESIGNATION	REFERENCE Ø22,2 mm	REFERENCE Ø28 mm
SATURNE Liner for tripolar cup - Size 44/xx	1-0103644	
SATURNE Liner for tripolar cup - Size 46/xx	1-0103646	
SATURNE Liner for tripolar cup - Size 48/XX	1-0103648	1-0103748
SATURNE Liner for tripolar cup - Size 50/XX	1-0103650	1-0103750
SATURNE Liner for tripolar cup - Size 52/XX	1-0103652	1-0103752
SATURNE Liner for tripolar cup - Size 54/XX	1-0103654	1-0103754
SATURNE Liner for tripolar cup - Size 56/XX	1-0103656	1-0103756
SATURNE Liner for tripolar cup - Size 58/XX	1-0103658	1-0103758
SATURNE Liner for tripolar cup - Size 60/XX	1-0103660	1-0103760



* Check availability depending on countries

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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:

Machined, Blasted, Polished, Laser engraved, Controlled, Passivated, Cleaned,
Packaged, Labelled and Sterilized by gamma radiation with a minimum dose of 25 kGy

CE mark:

Notified body BSI Group (CE2797)
Date of first CE mark certification: 2002



Product material:

Ultra High Molecular Weight Polyethylene (UHMWPE) according to ISO 5834-1 and ISO 5834-2 standards

Production process:

Machined, Engraved, Controlled, Cleaned,
Packaged, Labelled and Sterilized by gamma radiation with a minimum dose of 25 kGy

CE mark:

Notified body BSI Group (CE2797)
Date of first CE mark certification: 1999



04 Product identification

SATURNE CUP CEMENTED

Implant engraving



Information:

Manufacturer logo
Batch number
Implant size
Stainless Steel (S)

Label



Packaging

Paper box:

Dimensions:

Size 44 mm to 58 mm: 130 mm x 130 mm x 50 mm

Size 60 mm: 160 mm x 160 mm x 60 mm

Color: Sky 80

Internal packaging:

Size 44 mm to 58 mm: Dual blister

Size 60: Dual blister & protection pouch

04

Product identification

SATURNE LINER

Implant engraving



Information:

Manufacturer logo
Batch number
Implant size
Polyethylene (PE)

Label



Packaging

Paper box:

Dimensions: 130 mm x 130 mm x 50 mm

Color: Blue Sky 417

Internal packaging:

Double pouch