

**SATURNE CUP
CEMENTLESS**

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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 cementless 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 cementless 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 cementless cup must be fixed without cement through press-fit effect. The metal cup, made of implantable stainless steel (M30NW), features a dual coating made of titanium spray and hydroxyapatite (HA) that promotes bone ongrowth and osteointegration. The press-fit is located in the equatorial zone of the cup in «inverted chevron» shape. 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 coated areas, the internal surface and the rim of the cup are mirror polished. The cup is available in eleven sizes, ranging from diameter 44 mm to diameter 64 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 CEMENTLESS

CUP DESIGNATION	REFERENCE
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 44	1-0103444
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 46	1-0103446
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 48	1-0103448
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 50	1-0103450
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 52	1-0103452
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 54	1-0103454
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 56	1-0103456
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 58	1-0103458
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 60	1-0103460
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 62	1-0103462
SATURNE tripolar cup - Press-Fit HA coated - cementless - Size 64	1-0103464



* Check availability depending on countries

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List of references*

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
SATURNE Liner for tripolar cup - Size 62/XX	1-0103662	1-0103762
SATURNE Liner for tripolar cup - Size 64/XX	1-0103664	1-0103764



* Check availability depending on countries

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:

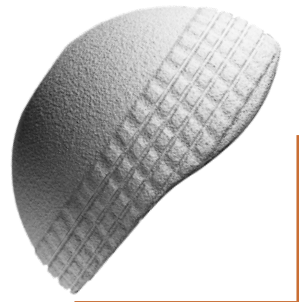
Stainless steel (M30NW) implantable according to ISO 5832-9 standard
Hydroxyapatite coating (HA) and Titanium according to ASTM F1580, ASTM F1185, ISO 13779-2,
13779-6 and ISO 13179-1 standards

Production process:

Machined, Polished, Laser engraved, Controlled, Passivated, Cleaned,
Projection of Titanium and Hydroxyapatite (HA) with plasma torch, Cleaned, Controlled, Final cleaning
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



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 CEMENTLESS

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 to 64 mm: 160 mm x 160 mm x 60 mm

Color: Blue /400/74

Internal packaging:

Size 44 mm to 58 mm: Dual blister

Size 60 mm to 64 mm: Dual blister & protection pouch

04 Product identification

SATURNE LINER

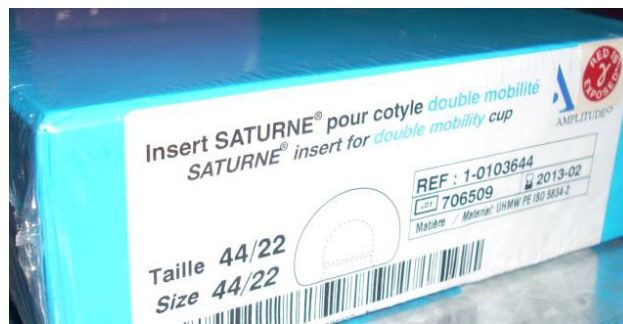
Implant engraving



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