SCANOS

CAPTIV®PRF

HA coated titanium press-fit cup

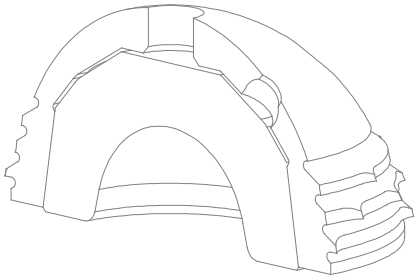
BIOMED sarl 2 avenue de Karben, 31520 RAMONVILLE France
☏ +33.5.61.73.67.16 🖷 : + 33.5.61.73.52.35 e-mail : biomed.biomaterials@wanadoo.fr

SCANOS

Technical specifications

in compliance to standards

Titanium HA coated CAPTIV® PRF press-fit cup.



BIOMED sarl 2 avenue de Karben, 31520 RAMONVILLE France
☏ +33.5.61.73.67.16 🖷 : + 33.5.61.73.52.35 e-mail : biomed.biomaterials@wanadoo.fr

Introduction

The combined ScanOs and Evolutis experience in the designing and developing of titanium HA cups now dates back to well over 15 years.

This dossier will explain the general technical features in correlation to International and EC standards and guidelines of the Scanos CAPTIV® PRF press-fit cup designed specifically on expressed criteria.

The CAPTIV® PRF exact-fit press-fit cup is an integrant part of the ScanOs Total Hip System. The system is designed for use with what is generally referred to as a ceramic option. However in the case of CAPTIV® cups the use of CERAMTEC CeraLock® Biolox® alumina ceramic inlays in conjunction with Biolox® *forte* alumina heads is not an option but the basis of the system. The option in the case of the use of a CAPTIV® cup is then the use of a Cobalt Chrome component or M30NW, nitrogen enriched stainless steel, head with PE inserts.

The CAPTIV® acetabular cup system features a standard conical CERAMTEC inlay housing design that accepts a comprehensive range of ceramic and PE inserts which provide for a full range of femoral head options to choose from thereby giving the surgeon a much greater flexibility in operative choice.

This high primary and secondary stability titanium HA coated CAPTIV® cups therefore offer ideal low friction ceramic-ceramic alumina Biolox® *forte* bearing combination and also the choice between 2 types of conical PE liners, along with the already mentioned CeraLock® Biolox® ceramic alumina liner; a flat standard conical PE liner or a "peaked" anti-luxation PE version.

As an instrument set is nearly as important as the acetabular component itself the CAPTIV® instrument set has been designed so as to be as rational while still offering the same operative quality and ease as only the best currently available systems. Two of the CAPTIV® instrument set innovating features are the availability in the set of a ceramic inlay suction carrier to make ceramic insert positioning easier and thereby enable the surgeon to follow the Ceramtec operative protocol.

BIOMED sarl 2 avenue de Karben, 31520 RAMONVILLE France
☏ +33.5.61.73.67.16 🖷 : + 33.5.61.73.52.35 e-mail : biomed.biomaterials@wanadoo.fr

1. GENERAL

ORTHOPAEDIC IMPLANT MANUFACTURING IS GOVERNED BY **ISO 8828 STANDARDS**. HIP IMPLANTS ARE GOVERNED BY **EN 12563 STANDARDS**. HACTIV™ STEMS AND COMPONENTS COMPLY TO THESE STANDARDS.

ISO 8828 standard: Implants for surgery. Guidance on Care and Handling of orthopaedic implants

EN 12563 standard: Non-active surgical implants-Joint replacement implants. Specific requirements for hip joint replacement implants.

CAPTIV® acetabular components also comply to different other standards to be found in the various chapters of this technical dossier.

2. DESIGN SPECIFICATIONS

The main design features of the ScanOs titanium HA coated CAPTIV® exact-fit press-fit cup are based on a clinically established data and corresponds to general requirements for such a device. These requirements, standard for a press-fit type cup are in the case of sufficient bone stock and bone quality that the cup has a strong primary fixation and a very good long term secondary fixation and stability.

However a cup, be it a Press-Fit cup or a screw cup is composed of two parts, the metal cup and the insert . Besides the cup fixation itself the insert has a major function as a bearing. The quality of such a bearing is dependent of: the quality of the inlay, the perfect fitting of the same inlay and then the quality of the surface of the inlay itself. In turn these high quality aspects will not function correctly if the heads accepted by such inserts are not of the same standard and quality.

The CAPTIV® cup range accepts the following standard conical inserts: Ceramtec ceramic or PE.

3. INTENDED USE FOR THE IMPLANT

The CAPTIV® cup is intended for a non-cemented implantation for primary and in some cases for first intention revision surgery.

This quality is governed by two ISO and/or EN standards: ISO 7206-2 for the bearing surfaces, both the heads and the inserts and EN 12563 in so far as thickness are concerned.

EN 12563 standard: Non-active surgical implants Joint replacement implants. Specific requirements for hip joint implants.

4. MATERIAL OF THE METAL CUP

The CAPTIV® press-fit cup is manufactured from high strength non wrought titanium TA6V ELI alloy (Titanium-aluminium 6-vanadium 4.Ti 6-Al 4V) in compliance to **ISO 5832-3 standard** even though the TA6V alloy in the case of use as an orthopaedic cup does not undergo a forging process. For this reason the mechanical properties of the metal differ from those of the same wrought alloy from which the Scanos HACTIV HA coated titanium is manufactured with. The differences are shown below.

ISO 5832-3 Implants for surgery. Metallic materials.
Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
1996-07-01

WROUGHT TA6V
Resistance to traction : minimum 860 Mpa
Elasticity limit : minimum 780 Mpa
Reciprocal value of modulus of elasticity : minimum 10%
Contraction coefficient : minimum 25%

NON-WROUGHT TA6V
Resistance to traction : minimum 900 Mpa
Elasticity limit : minimum 820 Mpa
Reciprocal value of modulus of elasticity : minimum 15%

5. METAL MICROSTRUCTURE

The titanium microstructure must comply with the reading of the microphotography **standard**.

6. TITANIUM TA6V

Chemical composition for both wrought and non-wrought titanium to meet requirements:

Elements	Upper and lower limits in %
Aluminium	5.5 to 6.75
Vanadium	3.5 to 4.5
Iron	0.3 maximum
Oxygen	0.2 maximum
Carbon	0.08 maximum
Nitrogen	0.05 maximum
Hydrogen	0.015 maximum
Titanium	Balance

TA6V ELI titanium alloy is currently one of the best bone-cup matches available. Its metal-bone modulus match is twice as favourable than any other available implantable alloy.

BIOMED sarl 2 avenue de Karben, 31520 RAMONVILLE France
☏ +33.5.61.73.67.16 🖷 : + 33.5.61.73.52.35 e-mail : biomed.biomaterials@wanadoo.fr

7. BASIC MANUFACTURING PROCESS FOR THE CAPTIV'™ CUP

Metallic back

High precision machining of high strength non-forged barTa6V titanium alloy. Specific manufacturing processes concern the inner part of the cup and the outer part. The inside of each cup is shot-pinned (surface hardening) while the external part of the cup corundum blasted before receiving an HA coating. (see HA coating paragraph 9 and surface processing paragraph 7)

Polyethylene inserts

The polyethylene used is an UHMW PE, (commercial denomination GUR 1020). The polyethylene is compressed before being lathe worked into a bar which is then machined into the appropriate shape and size. The inserts are then vacuum packed and undergo gamma ray sterilization at a minimal dosage of 25Kgray and maximum of 35kGray. This process not only sterilizes the implant but also cross-links the PE (cross-linking: transformation of a linear polymer into a three-dimensional polymer by creating 3D molecular transversal liaisons, then referred to as being cross-linked).

Ceramic Biolox® *forte* CERALOCK inserts

These inlays are manufactured by Ceramtec (see paragraph 13 on inserts)

8. CAPTIV® CUP INSERTS

The CAPTIV® press-fit inlays are available in two diameters: 28mm and 32mm. Two types of polyethylene inserts, a flat insert and a 20° angled peak anti-luxation insert. But the principal bearing for which the cup was specifically designed for is the alumina CeraLock® Biolox *forte* insert with a Biolox *forte* alumina heads that comply to ISO ceramic material standards, **ISO standards 6474. This bearing is available for cups sizes 48-50-52 with 28mm inlays and in cup sizes 52-54-56-58-60-63-66-69 with 32mm inlays.**

NB: PE inserts accept 28mm heads for cup sizes 48 to 66 and 22.2 heads for cups sizes 44-46.

Acetabular orthopaedic cups comply to EN 12563 concerning thickness standards and ISO 7206-2 standards for the articular surfacing.

EN 12563: Non-active surgical implants. Joint replacement implants. Specific requirements for hip joint replacement implants.

EN 12563 establishes a minima for PE thickness for acetabular components. A minimum of 5mm of PE thickness is required for a PE insert and 6mm for a complete PE cup (Muller type).

ISO 7206-2: Implants for surgery. Partial and total hip joint prostheses. Part 2. Articulating surfaces made of metallic, ceramic and plastic materials.

PE inserts:

Material: Polyethylene in compliance to ISO 5834 parts 1&2
ISO 5834-1: implants for surgery. Ultra High Molecular Weight Polyethylene. Part 1. Powder form.

ISO 5834-2: implants for surgery. Ultra High Molecular Weight Polyethylene. Part 2. Moulded forms.

UHWM PE

A general description of UHMW PE rarely to be found in medical technical dossiers: A semi-crystalline, whitish opaque engineered thermoplastic which chemically has an extremely high molecular weight (3-6 million) HDPE. UHMW PE can only be processed by powder sintering methods. UHMW PE has outstanding strength, a very high cut and wear resistance plus a very high chemical resistance.
UHMW PE evidences very high tensile properties broadly similar to KEVLAR on a volume basis and even higher on a weight basis. However neither UHMWPE nor KEVLAR match carbon fibre properties on either basis.

For medical use UHMW PE is sterilized, and as mentioned above this process not only sterilizes the implant but also cross-links the PE. (cross-linking: transformation of a linear polymer into a three-dimensional polymer by creating 3D molecular transversal liaisons, then referred to as being cross-linked).

Mechanical properties of UHMW PE:

Coefficient of friction	0.1-0.2
Elongation at break (%)	500
Hardness (Rockwell)	R50-70
Izod impact strength (j m^{-1})	>1000
Tensile modulus (gpa)	0.2-1.2
Tensile strength (mpa)	20-40

Physical properties:

Density (g cm^3)	0.94
Water absorption over 24hrs (%)	<0.01

Ceramic inserts:

Alumina ceramic **Biolox**® *forte* from CERAMTEC in conformity to **ISO standard 6474**
Implants for surgery-Ceramic materials based on high purity alumina. 1994-02-00

BIOMED sarl 2 avenue de Karben, 31520 RAMONVILLE France
☏ +33.5.61.73.67.16 🖷 : + 33.5.61.73.52.35 e-mail : biomed.biomaterials@wanadoo.fr

9. SURFACE PROCESSING

Outer surface of the cup: Grit alumina corundum blasted. Provides a rough secondary surface for bone on-growth after initial bone in-growth into the hydroxyapatite surface coating. (see paragraph 'coating')

Corundum surface specifications: **[Ra5. Porosity 30µm]**.

In the design specifications we have mentioned that one the main elements concerned in an acetabular cup is the quality of the bearing. This means the mechanical precision with which such elements are manufactured.

These mechanical specifications are governed by a certain number of ISO and/or EN standards mentioned above. The inner surface of the CAPTIV cup is hardened by means of shot-pinning which greatly reduces potential generation of wear debris between the inlay and the metal back. In order to obtain an ideal bearing two elements have to be taken into account:, the sphericity of both the insert and the femoral head and the roughness of both the same elements.

UHMW PE inserts: the sphericity precision:

is lower than 100µm from nominal value and the inside diameter precision of the insert is between +0.1mm and +0.3mm of the nominal value at a room temperature of 20°C.

UHMW PE roughness: (peak-to-valley height variation)

Less than Ra 2µm

CeraLock insert sphericity precision:

Less than 7µm from nominal value and inside diameter tolerance for the CeraLock insert is between +0.02mm and +0.07mm respectively for heads of 28 and 32mm.

CeraLock insert roughness: (peak-to-valley height variation)

Ra 0.02µm

Such mechanical precision for the different inserts require similar properties for the femoral heads accepted by such components. **NB: Ceramic roughness is therefore 100 times lower than PE roughness and sphericity 15 times better.**

Femoral Head precision:

Metal femoral heads:

Sphericity less than -10µm of nominal diameter and a roughness less than Ra 0.05µm.

Ceramic femoral heads:

Sphericity must be within the limits of the nominal diameter and -0.2µm. Roughness, less than 0.02µm.

10. INSERT FATIGUE TESTS

The CAPTIV® cup inserts undergo mechanical resistance tests (crash tests) in order to resist to over 20 million load cycles [max force=14kN, min force = 0.5kN, frequency = 10 Hz, fluid test: Ringer solution RT]

The results obtained with the CAPTIV cup are as follows:
Average 78kN (required value:>46kN)

Standard deviation: 20kN
Minimum value: 4kN (required value:>25kN)
N) of pieces tested: 7

These tests comply to stem fatigue test governed by **ISO 7206-4 and 8 standards**.

ISO 7206-4: Implants for surgery. Partial and total hip joint prostheses. Part 4.
Determination of endurance properties of stemmed femoral components with application of torsion.

ISO 7206-8: Implants for surgery. Partial and total hip joint prostheses. Part 8:
Endurance performance of stemmed femoral components with application of torsion

Ceramtec qualified and approved

Ceramtec Biolox® Forte Alumina Burst tests for the CeraLock inlay:

Tests carried out in compliance to **ISO 6474 standard** with CAPTIV® acetabular components.

ISO 6474: Implants for surgery --Ceramic materials based on high purity alumina.

Minimum standard required: 46kN
Maximum difference tolerance above or below average readings: 25%
i.e. 16kN maximum

CAPTIV® Burst test results: 63kN
Maximum difference registered on 7 tests and readings: [6.35%]
i.e. only 4kN

BIOMED sarl 2 avenue de Karben, 31520 RAMONVILLE France
☏ +33.5.61.73.67.16 🖷 : + 33.5.61.73.52.35 e-mail : biomed.biomaterials@wanadoo.fr

11. COATING

The CAPTIV® PRF titanium press-fit cup is fully coated externally with a 80µm plasma sprayed hydroxyapatite coating on a pre-prepared alumina corundum surface. [APS coating. Atmospheric Plasma Spray]

Coating specifications :

Coating is in compliance with the following standards: **ISO 13779-1 and ISO 13779-4** and with **NFS 94-065 and 072 (French standards)** and with ASTMF 1185-88 (American standards). These two standards are explicated in the paragraph Hydroxyapatite below.

ISO 13779-1: Implants for surgery--hydroxyapatite--Part 1: Ceramic hydroxyapatite.
ISO 13779-4: Implants for surgery--hydroxyapatite--Part 4: Determination of coating adhesion strength.

Technology used for spraying: APS [Atmospheric Plasma Spray]
Resistance to traction: 20Mpa.
Surface roughness: 50µm.

12. HYDROXYAPATITE

Hydroxyapatite coating complies to NFS standards **NFS 94-065** and **072** and to US standard **ASTM F1185-88**

Crystallinity: 50%
Ca/P ratio: between 1.63 and 1.77 [stoichiometric 1.667]
CaO: less than 5%
Metal contents: below readable level.(undetectable).

NFS standard: Hydroxyapatite powder: 2(Ca5(PO4)3, OH, plasma spray.

ASTM F1185-88 (R1993) Standard: Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants.

Notice: FDA Modernization Act of 1997: Modification to the List of Recognized Standards.
Recognition List Number :007
Federal Register: October 2, 2002 (Volume 67, Number 191) Pages 61893-61910.
Docket No.: 97D-0530

AGENCY: FDA. Food and Drug Administration. HHS

13. TRACEABILITY

Traceability is ensured in compliance to **EN 1041 standard** governed by the general **ISO 8828 standard.**

EN 1041: Information supplied by the manufacturer with medical devices.
ISO 8828: Implants for Surgery. Guidance on Care and Handling of Orthopaedic Implants.

The required information is to be found engraved on the cup rim.
Engraving placed as such guarantees easy reading should the cup have be explanted.

MARKS TO BE FOUND:

On the metallic titanium cup itself:
-Manufacturer's name or logo. In the case of the CAPTIV® cups the logo a triangle with an E inside the triangle (the E stands for Evolutis)
-Material of the implant: in this case T (for titanium)
-Lot n°: two numbers represent the year, two for the month and three numbers for the lot n°

On the PE inserts:
The same as for the above metallic cup excepting that the T for titanium is here replaced by the engraving ISO 5834 for UHMWPE

On the ceramic inlays:
These implants are engraved by Ceramtec AG with the Ceramtec logo, the type of cone, the year of production and their own incremental lot n°.

14. CAPTIV® CUP SIZES

The CAPTIV® PRF pres-fit cup is available in 12 sizes: 44-46-48-50-52-54-56-58-60-63-66-69

15. CE REGISTRATION

The CAPTIV® PRF press-fit cup and inserts are CE registered and certified by the SEE, now SNCH, in Luxemburg **(CE 0499)**

SNCH Luxemburg
Société Nationale de Certification et Homologation.
11, Route de Sandweiler
L-5230 SANDWEILER

Phone: + 352.3.57.21.42.50.
Fax: + 352.3.57.21.42.44.

16. Manufacturers certifications

Manufacturer's name: **EVOLUTIS S.A.**
Avenue de La Libération
42720 BRIENNON

Manufacturing certifications: **ISO 9001** / **EN46001***

Implants are manufactured in compliance to **EC Guideline EC 42/93**

***(EN46001 which has now become ISO 13485).ISO 13485:** Quality systems--Medical devices--Particular requirements for the application of **ISO 9001**.

17. Specific aspects of the CAPTIV'PRF press-fit cup

-The CAPTIV® PRF press-fit cup is a classical rigid impacted cup. It differs from existing press-fit cups in the fact that it was initially designed to accept a complete range of inserts either of ceramic or PE. It was not modified like most cups in order to be able to accept ceramic inlays.

-The press-fit is a peripherical press-fit rim type on which the primary fixation claws are placed on 3 rim levels in a unique alternated 'quincuncial' pattern (zigzag) in such a manner to obtain enhanced press-fit.

-The housing of the CAPTIV® PRF is identical to the CAPTIV® SCW screw cup i.e. a micro grooved conical housing designed to accept a CeraLock ceramic Biolox forte inlay or two types of PE inserts.

-In the roof of the CAPTIV® PRF are to be found three screw holes for further fixation and two holes are available in the cup floor either for screws or studs should the cup require further stabilization.

-The cups are delivered with the screw holes unplugged. However should the surgeon prefer to plug all or certain holes a separate sterile pack of porous titanium screw hole plugs is available.

-The cup is supplied with a porous titanium plugged apical dome hole.