eVoLutiS

HACTIV

HA coated titanium stem

A product from SCANOS

BIOMED. 2 Avenue de KARBEN. 31520 RAMONVILLE. France ☏ : +33.5.61.73.67.16 fax : +33.5.61.73.52.35

eVoLuTiS

Technical specifications

in compliance to standards

Titanium HA coated HACTIV'™ stem

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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.

HACTIV™ stems also comply to different other standards to be found in the various chapters of this technical dossier.

2. MATERIAL

The HACTIV™ stem is manufactured from high strength forged titanium TA6V ELI alloy (Ti 6-Al 4-V. Titanium-aluminium 6-vanadium 4) in compliance to **ISO 5832-3 standard**.

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

Résumé of the principle **ISO 5832-3** specifications:

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

3. MICROSTRUCTURE

The titanium microstructure must comply with the reading of the microphotography of the **ETTC2* standard**. When viewed under a microscope x200 no visible inclusion must be seen.

* ETTC. This is not an international standard. There is no international or European standard for this test. The requirements are those fixed by IMI Titanium, Technical Services Department. Wilton. BIRMINGHAM B6 7UR United Kingdom. This standard will be replaced by an international standard when one will be available.

4. TITANIUM TA6V

Chemical composition of the titanium to meet requirements:

ELEMENTS	UPPER & 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 the best bone-stem match available. Its metal-bone modulus match is twice as favourable than any other available implantable alloy.

5. BASIC MANUFACTURING PROCESS FOR THE HACTIV'™ STEM

High precision machining of high strength forged Ta6V titanium coined stems.
Advantages of forged titanium coining technique compared to cast or simply machined stems: perfect metal homogeneity throughout the implant. No insipient micro-fractures. No potential or incidental fracture point.

6. STEM FATIGUE TESTS

The HACTIV'™ stem undergoes mechanical resistance test in order to resist to over 10 million load cycles with 6 times the average body weight.

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

7. SURFACE PROCESSING

FOR THE HACTIV'™ STEM

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

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

Polished anodized neck. Reduces potential generation of wear debris secondary to prosthetic impingement.

8. HACTIV'™ STEM TAPER

Complies to **NFS 90-443 standard**:

A standard 12/14 micro-grooved taper with a 5°42'30" angle and a proximal minimum diameter of 12.5mm.

Geometry standard:
Angle: angled between 5°42'30" and 5°37'30"
Roundness: ≤8 µm
Straightness: ≤3 µm
Roughness: >6 µm
Diameter: 12.70 to 12.34 at 1.4mm from the proximal part of the cone.

8.1 Ceramtec qualified and approved

Ceramtec Alumina Head Burst tests for HACTIV'™ heads and taper:
Tests carried out in compliance to **ISO 6474 standard**.

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

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

9. COATING

The HACTIV stem is full-length coated with a 155µm 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.

9.1. 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

10. TRACEABILITY

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

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 top of the 12/14 HACTIV stem taper.
Engraving placed as such guarantees easy reading should the stem need be explanted.

MARKS TO BE FOUND:

-Manufacturer's logo: in this case a triangle with an E inside the triangle. (E stands for Evolutis)
-Characteristics of the taper: in this case 5'42
-Material of the implant: in this case T (for titanium)
-Smallest diameter of the taper: in this case 12.5
-Lot n°: in this case the number represented by the year, month and manufacturer's monthly factory work order number.

11. STEM SIZES

The stem size is engraved on the anodised non-coated surface on the side of each stem.
HACTIV stem sizes available are : 7-8-9-10-11-12-13-14-15-16-18-20

12. CE REGISTRATION

The HACTIV™ implant and heads 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.

13. HACTIV'™ STEM HEADS

Three head sizes are available: 22.2mm, 28mm and 32mm. The size, shape and dimensions of these heads are in conformity with **NFS standard 90 443** thereby guaranteeing a size compatibility with the polyethylene inserts where and when applicable, and in the case of use of alumina CeraLock® BIOLOX *forte* inserts with such inserts the corresponding ceramic heads are CERAMTEC approved and comply to ISO ceramic material standards, **ISO standards 6474.**

ISO 6474: see below.

Heads are then available in 4 different alloys or materials:

734L stainless steel in conformity with **ISO standard 5832-9**
ISO standard 5832-1
Implants for Surgery. Metallic materials. Part 1.
Wrought stainless steel. 1997-07-15

Cobalt Chrome alloy in conformity to **ISO standard 5832-12**
ISO standard 5832-12
Implants for surgery. Metallic materials. Part 12.
Wrought cobalt-chromium-molybdenum alloy. 1995-01-00

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

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

14. Manufacturing certifications of the Manufacturer of the Scanos Total Hip System

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

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

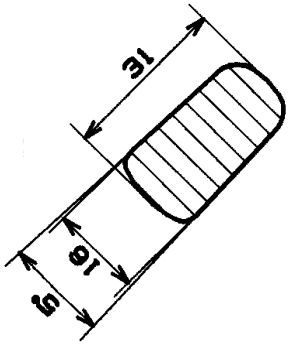
Implants are manufactured in compliance to **EC Guideline EC 42/93**

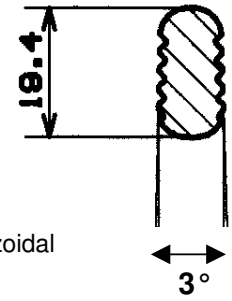
***EN46001 which has now become ISO 13485.**
ISO 13485: Quality systems--Medical devices--Particular requirements for the application of **ISO 9001**.

15. DESIGN SPECIFICATIONS

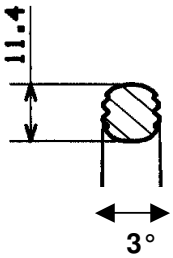
The main design features of the ScanOs HACTIV'™ stem are based on a clinically established low rate stress shielding titanium HA coated tulip flared proximally trapezoidal shaped stem smoothly and gradually tapered down to a rounded off distal quadrangular section.

Trapezoidal proximal cross section: for enhanced rotational stability and optimum metaphysis fill.





Mid section cross cut: fading from a trapezoidal shape to a distal quadrangular rounded tip.



Quadrangular distal cross section: for enhanced rotational stability

16. INTENTED USE OF THE IMPLANT

The HACTIV'™ stem is intended principally for a non-cemented implantation for primary and in some cases for first intention revision surgery.

SCANOS Global Total Hip System :

STEMS

HACTIV'™ titanium HA coated stem
HACTIV'™ titanium HA coated stem with collar.
HACTIV'™ titanium HA coated Dysplasia stem
HACTIV'™ titanium HA coated High Offset Coxa Vara stem
REACTIV'™ titanium HA coated revision stem
REACTIV'™ titanium HA coated revision stem with collar
REACTIV'™ titanium HA coated distally locked revision stem
X-TENSIV'™ titanium HA coated stem 300mm
CEMTIV'™ cemented M30NW stainless steel stem
CEMTIV'™ cemented M30NW stainless steel revision stem
KERATOS™ anatomical stem system

HEADS 12/14 microgroove short Euro taper

Biolox® *forte* alumina ceramic femoral heads
Morgan Matrox alumina ceramic femoral heads
Cobalt Chrome femoral heads
M30NW stainless steel femoral heads

CUPS

CAPTIV'™ SCW titanium HA coated screw cup
CAPTIV'™ PRF titanium HA coated press-fit cup
CAPTIV'™ ELS titanium elastic HA coated press-fit cup
CAPTIV'™ DM double mobility spiked HA coated press-fit cup
CAPTIV'™ DM double mobility HA coated press-fit cup
CAPITOLE™ double mobility HA coated revision cup
CAPTIV™ C double mobility cemented cup

INLAYS

Ceramic alumina Ceramtec CeraLock® Biolox forte inlay
Ceramic alumina Morgan Matrox inlay
Sandwich PE-ceramic double mobility inlay
Anti-luxation peaked Polyethylene insert
Standard flat Polyethylene insert

NB : HACTIV'™ cement free stems and CEMTIV'™ cemented stems require only one rational instrument set for both types of stem. REACTIV and X-TENSIV stems can also be implanted with the same instrument set as the HACTIV and CAMTIV stems. However in this case a separate flexible reamer is required in order to ream the distal part of the canal. All cups, inserts and heads are common to all stems. All stems and cups are Ceramtec approved either for ceramic alumina BIOLOX® *forte* ceramic heads or ceramic CeraLock® alumina conical inlays.