

**PRODUCT DESCRIPTION: ECOFIT® HIP
STEM SYSTEM**

PRODUCT-GROUP: PRIMARY ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

DATE: 08.05.2014

ECOFIT® HIP STEM SYSTEM

EcoFit® Hip Stem - Design Description



FIG.1: ECOFIT® **FIG.2: ECOFIT®** **FIG.3: ECOFIT®** **FIG.4: ECOFIT®** **FIG.5: ECOFIT®** **FIG.6: ECOFIT®**
 CEMENTLESS CPTI CEMENTLESS T-HA CEMENTLESS HA CEMENTED CEMENTED HIGH CEMENTED TIN

The EcoFit® hip stems are femoral hip stem components for total hip or hemi-hip arthroplasty. The EcoFit® hip stem are intended either for uncemented, press fit or cemented fixation. It is indicated in cases of:

- severe joint destruction with significant impairment where other therapeutic measures are not more promising,
- severe joint pain due to degenerative or rheumatoid arthritis, joint fractures or bone necrosis,
- post-operative conditions after previous surgery with or without the use of implants,
- arthrosis,
- femoral neck fractures,
- avascular necrosis,
- hip dysplasia.

To ensure firm anchorage and offer full weight bearing of the operated extremity, the implant is usually cemented in the case of elderly patients. In contrast, cementless fixation of the implant is applied in younger patients, who are able to move with partial weight bearing of the operated extremity after surgery.

The EcoFit® hip stem is collarless, straight, monoblock, flat tapered wedge design. The stem has a rectangular cross sectional geometry to provide rotational stability and tapers from proximal to distal, 7° in frontal plane and 3.5° in sagittal plane with a stem – neck angle (CCD angle) of 138°. The stem is designed in both a standard offset and a lateralized offset version to allow lateralization of the patient's femur without increasing leg length.

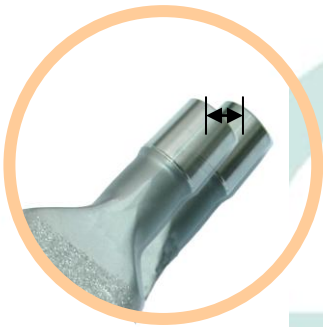


FIG. 7: LATERALISATION OF THE FEMUR STEM

The neck has a Morse type 12/14 taper to mate with a modular femoral head. The taper has an angle of 5.7°, a length 13.5 mm, roundness of 0.008 µm, and straightness of 0.003 µm. The taper has a machine turned surface finish producing circular grooves to provide a roughness of Rz of 6 + 14 µm. A threaded hole for the insertion instrument attachment is provided on the superior lateral surface of the proximal stem body.



FIG.8: THREADED HOLE FOR INSERTION INSTRUMENT

The EcoFit® hip stem is available for cementless and cemented fixation.

Materials

The cementless version is manufactured from Titanium 6 Alumina 4 Vanadium (TiAl₆V₄) alloy acc. to ISO 5832-3 while the cemented version is made of CoCrMo – casting alloy acc. to ISO 5832-4. One version of the cemented stem is available in TiAl₆V₄ alloy as well (*EcoFit® hip stem cemented Titanium standard*).

Coatings / Surfaces

The cementless EcoFit® hip stems are either coated with plasma sprayed cpTi (commercially pure titanium), meeting the specifications of ISO 5832-2, or with a double layer consisting of plasma sprayed cpTi and Hydroxyapatite (HA).

The coating is applied circumferentially on the proximal portion (46 – 47%) of the stem to provide a press fit cementless fixation surface. Also one version is available which is completely coated with HA. The proximal portion of this stem offers a double layered cpTi and HA coating. The hydroxyapatite is synthetic and not of animal origin.

The distal surface of the non-fully coated cementless stem is sandblasted matte.

The cemented EcoFit® stem is available with a titanium nitrite coating which is applied circumferentially throughout the stem.

The non-coated cemented EcoFit® hip stems are either high polished or sandblasted matte.

Coating Specifications

| CHARACTERISTICS | VALUE | | |
|----------------------|---------------|------------|--------------|
| | cpTi | HA | TiN |
| COATING THICKNESS | 250 +/- 50 µm | 90 ± 30 µm | 5,5 ± 1,5 µm |
| POROSITY | 30 +/- 10 % | ≤ 30% | / |
| AVERAGE ROUGHNESS RA | 50 +/- 15 µm | / | < 0,05 µm |
| AVERAGE ROUGHNESS RT | / | 50 ± 20 µm | / |
| TENSILE STRENGTH | > 22 MPa | ≥ 15 MPa | ≥ 22 MPa |
| SHEAR STRENGTH | > 20 MPa | ≥ 20 MPa | / |

TABLE 1: COATING SPECIFICATIONS

Sizes and Dimensions

The EcoFit® hip stem cementless is available in 10 sizes from 132.5 mm – 160 mm in length in both standard and lateralized offset versions. The cemented version is only available in five sizes with a length from 130 mm to 150.5 mm. The sizes and their respective offsets are given in the tables below.

| SIZE (MM) | 6,25 | 7,5 | 8,75 | 10 | 11,25 | 12,5 | 13,75 | 15 | 17,5 | 20 |
|----------------------------|-------|------|-------|------|-------|------|-------|------|------|------|
| LENGTH | 132,5 | 135 | 137,5 | 140 | 142,5 | 145 | 147,5 | 150 | 155 | 160 |
| OFFSET* (MM) - STANDARD | 34,5 | 35,2 | 35,8 | 36,5 | 37,1 | 37,7 | 38,3 | 39 | 40,2 | 41,5 |
| OFFSET* (MM) - LATERALISED | 42,3 | 43 | 43,6 | 44,3 | 44,9 | 45,5 | 46,1 | 46,8 | 48 | 49,3 |

TABLE 2: CEMENTLESS ECOFIT® HIP STEMS

| | | | | | | |
|----------------------------|------|------|------|------|------|-------|
| SIZE (MM) | 6,25 | 7,5 | 10 | 12,5 | 15 | 17,5 |
| LENGTH | 130 | 132 | 137 | 142 | 147 | 150,5 |
| OFFSET* (MM) - STANDARD | 34,5 | 35,2 | 36,5 | 37,7 | 39 | 40,2 |
| OFFSET* (MM) - LATERALISED | 42,3 | 43 | 44,3 | 45,5 | 46,8 | 48 |

TABLE 3 CEMENTED ECOFIT® HIP STEMS

| | | | | | | |
|----------------------------|------|-----|------|------|------|---|
| SIZE (MM) | 6,25 | 7,5 | 10 | 12,5 | 15 | / |
| LENGTH | 130 | 132 | 137 | 142 | 147 | / |
| OFFSET* (MM) - STANDARD | / | / | / | / | / | / |
| OFFSET* (MM) - LATERALISED | 42,3 | 43 | 44,3 | 45,5 | 46,8 | / |

TABLE 4: CEMENTED STEMS (LPP STEMS)

(*) for femoral heads on medium-length (M) necks

The following table summarizes the aforementioned design characteristics.

ECOFIT® HIP STEM CEMENTLESS - ECOFIT® HIP STEM CEMENTED AND LPP STEMS

| | |
|-------------------------------------|---|
| FIXATION / OSSEOUS ANCHORAGE | <ul style="list-style-type: none"> - CEMENTLESS, METAPHYSIARY - CEMENTED, METAPHYSIARY |
| MATERIAL | <ul style="list-style-type: none"> - CEMENTLESS STEMS - CEMENTED STEMS <ul style="list-style-type: none"> - TIAI₆V₄ – WROUGHT ALLOY ACC. TO ISO 5832-3 - COCRM0 –CASTING ALLOY ACC. TO ISO 5832-4 OR TIAI₆V₄ - WROUGHT ALLOY ACC. TO ISO 5832-3 |
| MODULARITY | MONOBLOCK WITH MODULAR FEMORAL HEAD ATTACHMENT (INSERTION TAPER CONNECTION) |
| INSERTION TAPER | 12/14 TAPER, TAPER ANGLE = 5,7° (5°42'30"), TAPER LENGTH = 13,5MM, CIRCULAR GROOVES ON SURFACE |
| STEM FORM | STRAIGHT STEM WITH FLAT, TAPERED WEDGE GEOMETRY: <ul style="list-style-type: none"> - 7° ON FRONTAL PLANE, - 3.5° ON SAGITTAL PLANE |
| SURFACES CEMENTLESS STEMS | |
| FEMORAL NECK SURFACE | MATTE |

| | |
|---|---|
| <p><u>PROXIMAL SURFACE (AROUND FIXATION)</u></p> <ul style="list-style-type: none"> - ECOFIT® HIP STEM CEMENTLESS CPTI - ECOFIT® HIP STEM CEMENTLESS HA - ECOFIT® HIP STEM CEMENTLESS T-HA | <ul style="list-style-type: none"> - COATED WITH PURE TITANIUM (CPTI) CPTI-COATING THICKNESS = 250 ± 50 µm - COATED WITH PURE TITANIUM (CPTI) + HYDROXYAPATITE (HA) CPTI-COATING THICKNESS = 250 ± 50 µm; HA-COATING THICKNESS = 90 ± 30 µm - COATED WITH PURE TITANIUM (CPTI) + HYDROXYAPATITE (HA) CPTI-COATING THICKNESS = 250 ± 50 µm; HA-COATING THICKNESS = 90 ± 30 µm |
| <p><u>DISTAL SURFACE</u></p> <ul style="list-style-type: none"> - ECOFIT® HIP STEM CEMENTLESS CPTI - ECOFIT® HIP STEM CEMENTLESS HA - ECOFIT® HIP STEM CEMENTLESS T-HA ZEMENTFREI T-HA | <ul style="list-style-type: none"> - MATTE - MATTE - COATED WITH HYDROXYAPATITE (HA) HA-COATING THICKNESS = 90 ± 30 µm |
| <p>SURFACES CEMENTED STEMS</p> | |
| <p><u>FEMORAL NECK SURFACE</u></p> <ul style="list-style-type: none"> - ECOFIT® HIP STEM CEMENTED - ECOFIT® HIP STEM CEMENTED HIGH POLISHED - ECOFIT® HIP STEM CEMENTED. TIN - LPP STEM CEMENTED | <ul style="list-style-type: none"> - MATTE - HIGH POLISHED - COATED WITH TIN, TIN- COATING THICKNESS = 5,5 ± 1,5 MM - MATTE |
| <p><u>PROXIMAL SURFACE</u></p> <ul style="list-style-type: none"> - ECOFIT® HIP STEM CEMENTED - ECOFIT® HIP STEM CEMENTED HIGH POLISHED - ECOFIT® HIP STEM CEMENTED. TIN - LPP STEM CEMENTED | <ul style="list-style-type: none"> - MATTE - HIGH POLISHED - COATED WITH TIN, TIN- COATING THICKNESS = 5,5 ± 1,5 MM - ROUGH |

| | |
|--|--|
| <p>DISTAL SURFACE</p> <ul style="list-style-type: none"> - ECOFIT® HIP STEM CEMENTED - ECOFIT® HIP STEM CEMENTED HIGH POLISHED - ECOFIT® HIP STEM CEMENTED. TIN - LPP STEM CEMENTED | <ul style="list-style-type: none"> - MATTE - HIGH POLISHED - COATED WITH TIN, TIN- COATING THICKNESS = $5,5 \pm 1,5$ MM - HIGH POLISHED |
| <p>CCD – ANGLE</p> | <p>138°</p> |
| <p>VARIETIES</p> | <p>STANDARD AND LATERALISED; LATERALISED ("HIGH OFFSET") STEMS ALLOW LATERALISATION OF THE FEMUR STEM WITHOUT ALTERING LEG LENGTH (SEE FIG. 7).</p> |
| <p>SIZE RANGE</p> <ul style="list-style-type: none"> - CEMENTLESS STEMS - CEMENTED STEMS - LPP STEM CEMENTED | <ul style="list-style-type: none"> - AVAILABLE IN 10 SIZES (SEE. TABLE 1) - AVAILABLE IN 6 SIZES (SEE. TABLE 2) - AVAILABLE IN 5 SIZES (SEE. TABLE 3) |

EcoFit® Hip Stem Revision



FIG.6: ECOFIT® HIP STEM REVISION

| ECOFIT® HIP STEM REVISION | |
|--|---|
| FIXATION / OSSEOUS ANCHORAGE | CEMENTLESS, METAPHYSIARY |
| MATERIAL | COCRM0 –CASTING ALLOY ACC. TO ISO 5832-4 |
| MODULARITY | MONOBLOCK WITH MODULAR FEMORAL HEAD ATTACHMENT (INSERTION TAPER CONNECTION) |
| INSERTION TAPER | 12/14 TAPER, TAPER ANGLE = 5,7° (5°42'30"), TAPER LENGTH = 13,5MM, CIRCULAR GROOVES ON SURFACE |
| STEM FORMS | |
| STEMS OF LENGTH 240MM | STRAIGHT |
| STEMS OF LENGTH 180MM | ANATOMICALLY CURVED |
| CROSS SECTION | ROUND/OVAL |
| SURFACE | |
| <u>FEMORAL NECK SURFACE</u> | MATTE |
| <u>PROXIMAL SURFACE (AROUND FIXATION)</u> | COATED WITH PURE TITANIUM (CPTI) + HYDROXYAPATITE (HA) CPTI-COATING THICKNESS = 250 ± 50 µm; HA-COATING THICKNESS = 90 ± 30 µm |
| <u>DISTAL SURFACE</u> | HIGH POLISHED |
| CCD – ANGLE | 135° |
| SIZE RANGE | |
| - STRAIGHT STEMS | - AVAILABLE IN 4 SIZES (SEE. TABLE 4) |
| - CURVED STEMS | - AVAILABLE IN 3 SIZES (SEE. TABLE 5) |

| | | | | |
|-----------------|-------|-------|-------|-------|
| DIAMETER | 12MM | 14MM | 16MM | 18MM |
| LENGTH | 180MM | 180MM | 180MM | 180MM |

TABLE 5: STRAIGHT STEMS

| | | | |
|-----------------|-------|-------|-------|
| DIAMETER | 14MM | 16MM | 18MM |
| LENGTH | 240MM | 240MM | 240MM |

TABLE 6: ANATOMICALLY CURVED STEMS (RIGHT AND LEFT VERSION)

