

# EXACTA RS - Cementless stem

MANUFACTURING - DISTRIBUTION:

**permedica S.p.a.**  
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REGISTERED TRADEMARK:



QUALITY CERTIFICATION:



## INTENDED PURPOSE

EXACTA RS is a straight femoral stem intended for use in Total or partial Hip Replacement procedures, combined with a femoral ball head (or a bi-articular head) and an acetabular cup. Fixation of the device to the bone is obtained by means of a primary cementless press-fit stabilization and a long term biological integration.

Indicated for primary hip arthroplasties in cases where the bone structure of the metaphyseal region is suitable enough to guarantee a correct and enduring mechanical fixation by means of press-fit technique.

## TECHNICAL INFORMATION

DESIGN:

The particular shape of the stem avoids excessive bone sacrifice in the trochanteric region. The reduced length allows anchoring in the metaphyseal region with limited involving of the diaphysis. The medial curvature guarantees optimal support on the calcar. The tapered distal end reduces the loads on the cortex. The trapezoidal section neck presents a reduced diameter to increase the Range Of Motion.

TAPER:

12/14 standard taper (angle at the top 5°42'30"). Optimal Morse-type locking with metallic as well as ceramic articular heads.

CERVICAL-DIAPHYSEAL ANGLE:

Standard stem: CCD angle 132°

Lateralized stem: CCD angle 132° High off-set (+6mm size 1 to 5; +7mm size 6 to 12).

MATERIALS:

Titanium Aluminium Niobium alloy Ti6Al7Nb in compliance with ISO5832/11.

The device DOES NOT CONTAIN ferromagnetic materials.

SURFACE FINISHING - COATINGS:

- HaX-Pore: double coating 300µm pure Titanium + 50µm Hydroxyapatite Ca<sub>10</sub>(OH)<sub>2</sub>(PO<sub>4</sub>)<sub>6</sub> plasma sprayed.

- X-Pore: single coating 300µm pure Titanium plasma sprayed.

STERILIZATION:

Method: Irradiation (Beta or Gamma rays - minimum dose 25 kGy) or vaporized Hydrogen Peroxide (VH2O2).

Validity: 5 years (Beta sterilized products) - 10 years (Gamma-VH2O2 sterilized products).

PACKAGING:

Outer: rigid carton box, with polypropylene protection film;

Inner: double plastic bi-laminated envelopes polyamide / PE, vacuum-packed (Beta /Gamma sterilized products).

Double Tyvek envelopes and bi-laminated BOPET / PE (VH2O2 sterilized products).

Identification labels reporting all necessary information regarding the product can be found both on the outer or inner package; extra detachable labels for application to the clinical chart and patient Implant Card are enclosed.

CLASSIFICATION:

**Class III** as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendements.

# PRODUCT TECHNICAL INFORMATION SHEET

## FURTHER INFORMATION

The availability of 12 sizes with proportional growth, in Standard and Lateralized version allows fitting to a variety of anatomical conditions. The Lateralized version maintains the same 132° CCD angle with offset increased by 6mm in the sizes from 1 to 5 and 7mm in sizes from 6 to 12 which allows lateralization without affecting the length of the limb.

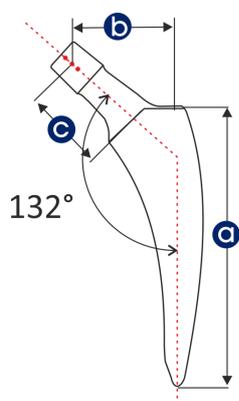
The stem is designed to provide optimal initial stability, thanks to its triple tapered shape in all planes and the properties of the materials utilized, as well as optimal long term stability thanks to the characteristics of the bioactive coatings applied to the bone contact surface. The horizontal grooves on the proximal region of the stem are projected to reinforce axial stability; the distal portion and the neck have a glossy finishing.

The reduced length, more than making this device particularly indicated for use with minimally invasive techniques (also including those foreseeing anterior approaches) allows centering of the stem without involving excessively the femoral canal, thus preserving the diaphysis for eventual future revision surgeries. The tapered distal end reduces the loads on the cortex. The trapezoidal section neck presents a reduced diameter to increase the Range Of Motion, avoiding any impingement on the inner edge of the acetabular cup.

The housing of the stem introducer on the top of the stem is inclined to facilitate the insertion even with direct anterior approach (DAA), for the correct alignment and positioning of the stem. A threaded hole allows coupling with the Extraction End (optional). The threaded hole also permits the connection of the extraction device.

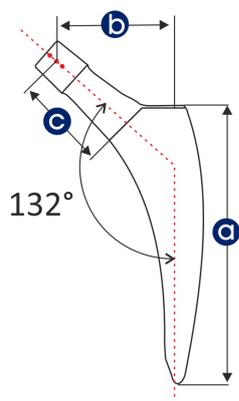
## AVAILABLE SIZES \*Articles with asterisk are available on special request

### EXACTA RS femoral stem



SIZE	a mm	b mm	c mm	HaX-Pore	X-Pore
				reference	reference
1	90	35,0	26,2	13211	13251
2	93	37,0	28,3	13212	13252
3	96	37,5	28,3	13213	13253
4	99	39,5	30,3	13214	13254
5	102	40,0	30,3	13215	13255
6	105	41,6	31,6	13216	13256
7	108	42,2	31,6	13217	13257
8	111	43,9	33,0	13218	13258
9	114	44,5	33,0	13219	13259
10	117	46,2	34,3	13220	13260
11	120	47,0	34,3	13221	13261
12	123	47,8	34,3	13222	13262

### EXACTA RS LATERAL femoral stem



SIZE	a mm	b mm	c mm	HaX-Pore	X-Pore
				reference	reference
1	90	41,0	30,5	13231	13271
2	93	43,0	32,5	13232	13272
3	96	43,5	32,5	13233	13273
4	99	45,5	34,5	13234	13274
5	102	46,0	34,5	13235	13275
6	105	48,6	36,6	13236	13276
7	108	49,2	36,6	13237	13277
8	111	50,9	37,9	13238	13278
9	114	51,5	37,9	13239	13279
10	117	53,2	39,3	13240	13280
11	120	54,0	39,3	13241	13281
12	123	54,7	39,3	13242	13282

**WARNING: do not use with ball heads longer than L**

## RELATED DOCUMENTS \* downloadable from our website (registration required)

Product Information Sheet: **SI030EN\***

Surgical Technique: **TC094EN\***

Instruments Technical Information Sheet: **SSP062EN**