FEMORAL HEADS

1. MEDICAL DEVICE CLASSIFICATION

According to MDD 93/42/CE and MDR 745/2017 femoral heads are classified as class III, being a long term implantable medical device.

2. GENERAL DESCRIPTION. DESIGN RATIONALE

The Femoral Head is the part of the prosthesis in charge of articulating with the acetabular component. It is usually integrated or fixed to the femoral component on its cone, since internally it has the corresponding housing or female to accommodate the machined cone in the proximal part of the neck of the femoral stem. The interior housing of the Surgival Brand Femoral Heads is compatible with any of the Surgival Femoral Stems. It is a component with a simple and logical design according to the intended function. Spherical geometry, with an excellent polished surface finish, a hard sliding surface with high resistance to scratching and abrasion, with internal housing for the reception of the femoral stem.

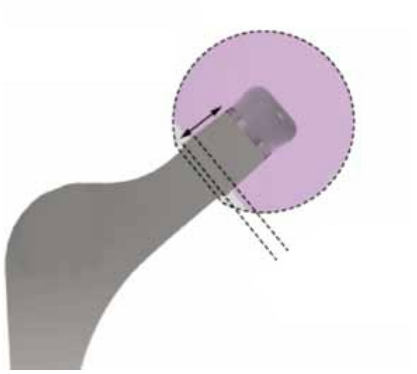
SURGIVAL femoral heads are available in three different materials:

- Stainlees Steel (ISO 5832-1)
- Co-Cr-Mo alloy (ISO 5832-12)
- Reinforced alumina BIOLOX DELTA® (ISO 6474-2)

2.1 Main geometrical features.

- The design meet the requierements of standards ISO 21535, and ISO 7206-2 to specify the following design requirements:
  - Sphericity 10µm (0,01 mm.);
  - Surface roughness Ra < 0,05 µm for metallic surfaces & Ra < 0,02 µm for ceramic surfaces.
  - Taper 12/14
- In order to provide more options for restoring the original anatomical distance between the center of rotation of the femoral head and the axis contained in the intramedullary or diaphyseal canal (anatomical offset), at least 3 neck options are available (short, medium or long neck) and in some variants up to a 4th (extra-long neck). In the table below the value of the offset provided by the femoral head is showed:

CERAMIC	S	M	L	XL
Ø22	-2	0	+2	--
Ø 28	-3,5	0	+3,5	--
Ø 32	-3,5	0	+3,5	+7
Ø 36	-4	0	+4	+8
Ø 40	-4	0	+4	+8
STAINLESS STEEL	**S**	**M**	**L**	**XL**
Ø 22	-2	0	+2	--
Ø 28	-3,5	0	+3,5	+7
Ø 32	-3,5	0	+3,5	+7
Ø 36	-4	0	+4	+8
Ø 40	-4	0	+4	+8
Cr-Co-Mo	**S**	**M**	**L**	**XL**
22	-2	0	2	--
28	-3,5	0	+3,5	+7
32	-3,5	0	+3,5	+7
36	-4	0	+4	+8
40	-4	0	+4	+8



3. LIFE TIME & SHELF LIFE:

The life time of these implants is determined between 10 and 15 years, depending on the interaction of several factors; Some are the responsibility of the manufacturer, others such as the implantation technique, are the responsibility of the surgeon in directing the operation, and some others are related to the patient, such as the biological and physiological response of the implant, the medical condition of the patient, as well as its behavior with regard to their weight gain, carrying heavy loads and adopting a high level of daily physical activity. However, the end of the useful life of an implanted prosthesis deserves a specific treatment for each patient and, therefore, it will be the specialist doctor who determines that the prosthesis does not satisfactorily fulfill the function for which it was implanted in its day. Problems that arise from long-term use are generally due to the aging of the product. The prosthesis over time loses its mechanical integrity due to friction, corrosion, stress, which may cause its loosening Also in accordance with the provisions of the ISO 21535 Standard, the indication or phrase equivalent to the following must be included in the Instructions for Use: "Patients receiving hip joint replacement implants should be aware that the longevity of the implant may depend on the weight and activity level of the patient."

All femoral head variants are supplied in STERILE condition. Sterility is guaranteed at least until 5 years since the manufacturing date. Expiry date is indicated in the product label.

4. PRODUCT RANGE. VARIANTS

REFERENCIA	DESCRIPCIÓN
A1506040E	Cr-Co-Mo femoral head Ø28, 12/14 short neck
A1506041E	Cr-Co-Mo femoral head Ø28, 12/14 medium neck
A1506042E	Cr-Co-Mo femoral head Ø28, 12/14 long neck
A1506043E	Cr-Co-Mo femoral head Ø28, 12/14 cuello extra-long neck
A1506060E	Cr-Co-Mo femoral head Ø22, 12/14 short neck
A1506061E	Cr-Co-Mo femoral head Ø22, 12/14 medium neck
A1506062E	Cr-Co-Mo femoral head Ø22, 12/14 long neck
A1506013E	Cr-Co-Mo femoral head Ø32, 12/14 short neck
A1506014E	Cr-Co-Mo femoral head Ø32, 12/14 medium neck
A1506015E	Cr-Co-Mo femoral head Ø32, 12/14 long neck
A1506016E	Cr-Co-Mo femoral head Ø32, 12/14 extra-long neck
A1506070E	Cr-Co-Mo femoral head Ø36, 12/14 short neck
A1506071E	Cr-Co-Mo femoral head Ø36, 12/14 medium neck
A1506072E	Cr-Co-Mo femoral head Ø36, 12/14 long neck
A1506073E	Cr-Co-Mo femoral head Ø36, 12/14 extra-long neck

REFERENCIA	DESCRIPCIÓN
A1506080E	Cr-Co-Mo femoral head Ø40, 12/14 short neck
A1506081E	Cr-Co-Mo femoral head Ø40, 12/14 medium neck
A1506082E	Cr-Co-Mo femoral head Ø40, 12/14 long neck
A1506083E	Cr-Co-Mo femoral head Ø40, 12/14 extra-long neck
A1509080E	Stainless Steel femoral head Ø40, 12/14 short neck
A1509081E	Stainless Steel femoral head Ø40, 12/14 medium neck
A1509082E	Stainless Steel femoral head Ø40, 12/14 long neck
A1509083E	Stainless Steel femoral head Ø40, 12/14 extra-long neck
A1509070E	Stainless Steel femoral head Ø36, 12/14 short neck
A1509071E	Stainless Steel femoral head Ø36, 12/14 medium neck
A1509072E	Stainless Steel femoral head Ø36, 12/14 long neck
A1509073E	Stainless Steel femoral head Ø36, 12/14 extra-long neck
A1509013E	Stainless Steel femoral head Ø32, 12/14 short neck
A1509014E	Stainless Steel femoral head Ø32, 12/14 medium neck
A1509015E	Stainless Steel femoral head Ø32, 12/14 long neck
A1509016E	Stainless Steel femoral head Ø32, 12/14 extra-long neck
A1509040E	Stainless Steel femoral head Ø28, 12/14 short neck
A1509041E	Stainless Steel femoral head Ø28, 12/14 medium neck
A1509042E	Stainless Steel femoral head Ø28, 12/14 long neck
A1509043E	Stainless Steel femoral head Ø28, 12/14 extra-long neck
A1509060E	Stainless Steel femoral head Ø22, 12/14 short neck
A1509061E	Stainless Steel femoral head Ø22, 12/14 medium neck
A1509062E	Stainless Steel femoral head Ø22, 12/14 long neck
A1507113E	Ceramic Biolox Delta femoral head Ø32mm 12/14, short neck
A1507114E	Ceramic Biolox Delta femoral head Ø32mm 12/14, medium neck
A1507115E	Ceramic Biolox Delta femoral head Ø32mm 12/14, long neck
A1507116E	Ceramic Biolox Delta femoral head Ø32mm 12/14, extra-long neck
A1507140E	Ceramic Biolox Delta femoral head Ø28mm 12/14, short neck
A1507141E	Ceramic Biolox Delta femoral head Ø28mm 12/14, medium neck
A1507142E	Ceramic Biolox Delta femoral head Ø28mm 12/14, long neck
A1507160E	Ceramic Biolox Delta femoral head Ø22mm 12/14, short neck
A1507161E	Ceramic Biolox Delta femoral head Ø22mm 12/14, medium neck
A1507162E	Ceramic Biolox Delta femoral head Ø22mm 12/14, long neck
A1507170E	Ceramic Biolox Delta femoral head Ø36mm 12/14, short neck
A1507171E	Ceramic Biolox Delta femoral head Ø36mm 12/14, medium neck
A1507172E	Ceramic Biolox Delta femoral head Ø36mm 12/14, long neck
A1507173E	Ceramic Biolox Delta femoral head Ø36mm 12/14, extra-long neck
A1507180E	Ceramic Biolox Delta femoral head Ø40mm 12/14, short neck
A1507181E	Ceramic Biolox Delta femoral head Ø40mm 12/14, medium neck
A1507182E	Ceramic Biolox Delta femoral head Ø40mm 12/14, long neck
A1507183E	Ceramic Biolox Delta femoral head Ø40mm 12/14, extra-long neck

5. STERILIZATION:

Femoral heads are sterilized by means of a validated Co-60 gamma irradiation process.

6. PACKAGING

Packaging system for femoral heads consist of a preformed sterile barrier system and a protective package. The sterile barrier system is compossed by a double PET-G blíster which is thermally sealed to a Tyvek 1073B lid. Once the sterile barrier system has been formed, it is inserted into a protective cardboard box. This packaging system:

1. Provides physical protection and keeps the integrity of the sterile barrier system.
2. Is compatible with the gamma irradiation process.
3. Maintains sterility until point of use or expiry date (5 years after manufacturing date).
4. Allows aseptic handling.
5. Provides an adequate sterile barrier.
6. Is compatible with the labeling system.
7. Is free from toxic compunds.

7. INTENDED USE

This product is intended to be used as a component of a partial or total hip joint, restoring the functions of the hip. It is an invasive medical device which requires a surgery to be implanted. It is a single use product, understanding not to use the implant several times in the same patient as well as not to use the implant in different patients.

8. INDICATIONS

A Hip Arthroplasty is recommended for the following hip joint disorders :

- Primary and Secondary Arthrosis
- Arthritic Processes such as Rheumatoid Arthritis.
- Atraumatic Avascular Necrosis of the Femoral Head
- Post-traumatic disorders such as Femoral Neck Fractures, Trochanteric Fractures of the Proximal Femur

- Unsuccessful Reconstruction Processes: Proximal Femoral Osteotomy, Arthrodesis, Painful Stent.

9. CONTRAINDICATIONS

- Patients with allergies to any of the materials that make up the implant. To avoid this situation, patients should be given an allergy test previously.
- Presence of an active infection.
- Mass of proximal femur bone compromised by disease or previous implant preventingproper fixation and stem support.
- Neuromuscular injury or Vascular deficiency in affected limb.
- Severe osteoporosis.
- Osteomalacia.
- Obesity.
- Severe pathologies such as cardiac, pulmonary, metabolic or autoimmune disorders, which prevent the correct formation of bone or increase the risk of mortality.
- Progressive neurological disease.
- Patients with disabilities in the opposite joint
- In a revision surgeries of a Ceramic Femoral Head rupture, it is contraindicated to combine a Polyethylene Insert with Metallic Heads.

10. POSSIBLE ADVERSE OR SIDE EFFECTS

- Deformation or breakage of the implant due to wear or fatigue.
- Superficial or periprosthetic infection.
- Loosening and migration of the implant.
- Extra-articular pathology: phlebothrombosis, pulmonary embolism.
- Vascular or tissue injuries, temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as a possible result of surgical trauma, which cause pain.
- Femoral fracture.
- Dislocation or subluxation.
- Problems associated with the recovery of joint geometry such as elongation or shortening of the limb, or limited range of joint movement.
- Allergic reactions to materials.
- Adverse reactions to wear particles or products from corrosion.
- Lesions in other joints associated with a forced intraoperative position.
- Periarticular calcification or heterotopic ossification, with or without a reduction in joint mobility.
- Release of metallic particles generating metallosis.