BIARTICULAR HEAD

1. TYPE OF MEDICAL DEVICE.

According to MDD 93/42, it will be classified as *Class III* becuase it is an invasive, implantable, single uso and long term product.

2. GENERAL DESCRIPTION OF THE PRODUCT. DESIGN RATIONALE.

The Biarticular Head is fundamentally designed as a means to reduce the friction that develops, in most cases and early, in the acetabular cartilage upon direct contact of the metallic head of a stent in a classic hemiarthroplasty. These prostheses are designed to allow movement not only between the acetabulum and the prosthesis but also in a joint within the prosthesis itself. The purpose of the second joint is to reduce acetabular wear.

This type of prosthesis must allow the housing inside a spherical metallic femoral head. This head is contained in a polyethylene cover which, in turn, is surrounded by a metallic cup (Figure b.1). There are many different types of prostheses with different stem designs. The solution designed for the Biarticular System will be valid and compatible with all stem designs made by Surgival.

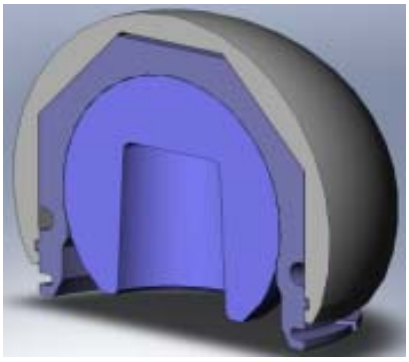

Figure 1. Section of a biarticular head prosthesis

The biarticular concept (existence of two possible centers of rotation) is further developed by the incorporation of a frustoconical joint in which a cavity in the head of the prosthesis fits into a

frustoconical extension of the stem. The modular joint allows the use of different rods with or without cement fixing.

The Biarticular Head consists of three parts:

- A metallic cup that articulates with the acetabulum (not to be confused with the head) (Fig. 2a). The metal cup has an inner geometry that matches the outer geometry of the polyethylene (PE) insert.

- An insert of polyethylene that fits inside the metal cup and inside which the head is fixed in turn (Fig. 2.b).

- Metal or ceramic femoral head that articulates with the inside of the polyethylene insert and houses the femoral stem cone. It would have two sizes available for the Biarticular system; 22 and 28 mm. of diameter (Fig. 2.c).

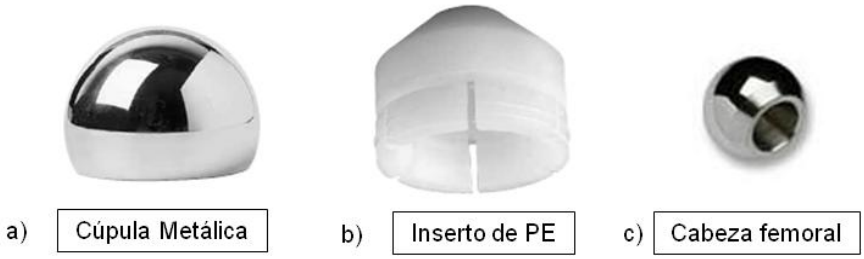

Figure 2. Components of a head endocephalic.

Firstly, the femoral head will be mounted on the polyethylene insert. Thereafter, the insert is mounted inside the metal cup and is trapped under pressure, in its interior. In this way two joints are created, one between acetabulum and cup (center of rotation 1), and another between insert and femoral head attached to the stem (Center of rotation 2) (Figure 3).

Figure 3. Components of a Biarticular head.

2.1 Main features. Design Attributes.

Subcomponent Metal Cup

The design will meet the requirements of ISO 21535, section 5.- Attributes of the Design, and more specifically what is discussed in section 5.2.2.- Tolerances of the diameters of articulating surfaces, which in turn makes Reference to ISO 7206-2 to specify the following design requirements:

- Sphericity of 100µm (0.1 mm); (Section 4.3.2.- Sphericity of ISO 7206-2)

- Surface Roughness of Ra <0,5 µm (Apdo "4.3.3.- Surface Finishing" of ISO 7206-2).

- Dimensional tolerances in spherical heads of ± 0,5 mm. (Apdo "4.3.4.- Dimensional Tolerances" of ISO 7206-2).

- Material Stainless Steel according to ISO Standard 5832-1

Subcomponent UHMWPE Insert

The articulating internal area of the design will comply with ISO 21535, section 5.- Attributes of the Design, and more specifically what is discussed in section 5.2.2.- Tolerances of the articulating surface diameters, which In turn, refers to ISO 7206-2 to specify the following design requirements:

- 100µm (0.1 mm) sphericity; (Apdo. "4.2.1.- Sphericity" of ISO 7206-2.).

- Surface Roughness of Ra <2 µm (Apdo "4.2.2.- Surface Finishing" of ISO 7206-2.).

- Dimensional tolerances in the femoral heads of + 0,1 / + 0,3 mm. (Apdo "4.2.3.- Dimensional Tolerances" of ISO 7206-2).

- Material Polyethylene UHMWPE. According to ISO Standard 5834-1

3. LIFE TIME:

The life time of this System is determined between 10 and 15 years, depending on the interaction of several factors; Some are the responsibility of the manufacturer, others such as implantation technique, are the responsibility of the surgeon to direct the operation, and some others are related to the patient, such as the biological and physiological response of the implant, The conduct of the same in terms of weight gain, transport of heavy loads and adopt a high level of daily physical activity, according to point 4 of ISO 21534.

However, the end of the life time of an implanted prosthesis deserves a specific treatment for each patient and therefore, it will be the medical specialist who determines that the prosthesis does not satisfactorily fulfill the function for which it was implanted in its day.

Problems arising from long-term use are generally due to product aging. The prosthesis over time loses mechanical integrity due to friction, corrosion, stress and can cause it to loosen

Also in accordance with the provisions of ISO 21535, the indication or phrase equivalent to the following must be included in the Instructions for Use:

"Patients receiving hip replacement implants should take into account that implant longevity"

4. PRODUCT RANGE. VARIANTS.

The following diagram presents the different options in terms of materials, necks and coatings

used in Surgival Self-Locking Stems.

REFERENCE	DESCRIPTION
A1519041E	STAINLESS STEEL BIARTICULAR HEAD Ø41mm
A1519042E	STAINLESS STEEL BIARTICULAR HEAD Ø42mm
A1519043E	STAINLESS STEEL BIARTICULAR HEAD Ø43mm
A1519044E	STAINLESS STEEL BIARTICULAR HEAD Ø44mm
A1519045E	STAINLESS STEEL BIARTICULAR HEAD Ø45mm
A1519046E	STAINLESS STEEL BIARTICULAR HEAD Ø46mm
A1519047E	STAINLESS STEEL BIARTICULAR HEAD Ø47mm
A1519048E	STAINLESS STEEL BIARTICULAR HEAD Ø48mm
A1519049E	STAINLESS STEEL BIARTICULAR HEAD Ø49mm
A1519050E	STAINLESS STEEL BIARTICULAR HEAD Ø50mm
A1519051E	STAINLESS STEEL BIARTICULAR HEAD Ø51mm
A1519052E	STAINLESS STEEL BIARTICULAR HEAD Ø52mm
A1519053E	STAINLESS STEEL BIARTICULAR HEAD Ø53mm
A1519054E	STAINLESS STEEL BIARTICULAR HEAD Ø54mm
A1519055E	STAINLESS STEEL BIARTICULAR HEAD Ø55mm
A1519141E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø28mm "A" (Ø41-42-43 mm)
A1519144E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø28mm "B" (Ø44-45-46 mm)
A1519147E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø28mm "C" (Ø47-48-49-50 mm)
A1519151E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø28mm "D" (Ø51-52-53-54-55 mm)
A1519241E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø22mm "A" (Ø41-42-43 mm)
A1519244E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø22mm "B" (Ø 44-45-46 mm)
A1519247E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø22mm "C" (Ø 47-48-49-50 mm)
A1519251E	POLYETHYLENE (UHMWPE) INSERT FOR BIARTICULAR HEAD OF Ø22mm "D" (Ø 51-52-53-54-55 mm)

The Biarticular System has 15 different sizes of external diameter ranging from 41mm to 55mm for the Biarticular Heads. We have 4 sizes of Polyethylene Inserts for each one of the measures: Ø28mm and Ø22mm. The equivalence between the bi-articular head and the polyethylene insert is defined in the table.

5. STERILIZATION:

The sterilization of these products is carried out by Gamma Radiation with controlled dosimetry, thus complying with this Essential Requirement referring to infection and microbial contamination, as well as with all the harmonized regulations in this regard.

6. PACKAGING FOR DELIVERY.

- Packaging.

The packaging system, consisting of a Preformed Sterile Barrier System (PET G Blister + Tyvek cap) and a Protective Container (carton), of this sanitary product, terminally sterilized, satisfies the following points:

1. Provides physical protection and maintains the integrity of the sterile barrier system.
2. It allows sterilization and is compatible with the indicated sterilization process.
3. Maintains sterility up to the point of use or until the expiration date.
4. Proper Assembly of the Packaging System.
5. Allows for aseptic presentation.
6. Provides a suitable microbial barrier.
7. Its compatibility with the labeling system.
8. Its Labeling facilitates the identification of the product, its traceability, manufacturing material.
9. The materials used in packaging do not contain or release toxic products.

7. RAW MATERIALS FOR SELF-LOCKING STEMS

Surgival selects the materials for the manufacture of its implants considering the precise properties to achieve the intended purpose, also taking into account the effects of the manufacture, manipulation, sterilization and storage, as well as any treatment applied to the surface of the implant material to modify His properties.

Possible reactions of implant materials with body tissues and fluids, other materials, other implants, substances and gases have been considered. The requirements of ISO 21534 "Non-active surgical implants - Joint replacement implants - Particular requirements" have been taken into account. The annexes to this Standard describe materials or pairs of materials found to be acceptable through proven use for the manufacture of implants, for use in association with implants or for the articulating surface of the implants.

The Metallic Heads are manufactured in Stainless Steel, while the inserts are manufactured in Ultra High Molecular Weight Polyethylene (UHMWPE)

Properties of Stainless Steel (according to ISO Standard 5832-1)

Chemical Composition of Stainless Steel

Element	Content (% Mass)
Carbon (C)	Max 0.03
Silicon (Si)	Max 1
Manganese (Mn)	Max 2
Phosphorus (P)	Max 0.025
Sulfur (S)	Max 0.01
Nitrogen (N)	Max 0.1
Chromium (Cr)	Between 17 y 19
Molibdenum (Mo)	Between 2.25 y 3.0
Niquel (Ni)	Between 13 y 15
Chromium (Cr)	Between 19.5 y 22
Copper (Cu)	Max 0.5
Iron (Fe)	Balance

Mechanical Properties of High Nitrogen Stainless Steel alloy

Tensile Strength	Yield Strength	%Elongation
Between 490 and 690 MPa.	Mínimo 190 MPa.	40%

Properties of Ultra High Molecular Weight Polyethylene (UHMWPE) (according to ASTM F-648)

PROPERTIES	REQUIREMENT
Density (Kg/m3)	927-944
Maximum Ash Content	Max 150
Minimum Tensile Strength	Min 21
Minimum Elastic Limit	Mín 40
Mínimum Elongation	Mín 380
Izod impact strength	Mín 180
Impact resistance Charpy	Mín 126

8. INTENDED USE

This product allows the total or partial replacement of the hip joint, so that the proper functions of the hip joint are restored, ie, transfer of load, mechanical energy resulting from the patient's own activity, between the pelvis and the femur. Orienting the lower limb in all directions and allowing you to develop

normal physical activity with relief or absence of pain. Therefore, it is an invasive product, ie requires surgical intervention for implantation in the patient and is a single use, not reusable. Therefore, applicable both in the sense of "do not use the product in more than one patient" as in the sense of "do not use the product several times in the same patient." The risks associated with the reuse of this product are the possible failure of the implant due to fatigue resulting in a new intervention and the possible transmission of pathogens by cross infection (virus, prions, ...)

9. 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.
- Effects of subluxation or congenital luxation.
- Post-traumatic disorders such as femoral neck or acetabular fractures.
- Unsuccessful reconstruction processes : proximal femoral osteotomy, arthrodesis, painful stent.

10. CONTRAINDICATIONS

- Patients with allergies to any of the materials that make up the implant. To avoid this situation, patiens should be given an allergy test previously.
- Presence of an active infection.
- Mass of proximal femur bone compromised by disease or previous implant preventing proper fixation and stem support.
- Vascular deficiency in affected limb.
- Severe Osteoporosis.
- Obesity.
- Severe pathologies such as cardiac, pulmonary, metabolic disorders… which can increase the risk of mortality.
- Progressive neurological disease.
- Patients with metabolic disorders that may prevent proper bone formation.

11. 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 lesions, temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as the possible consequences of surgical trauma that cause pain.
- Femoral fracture.
- Dislocation or subluxation.
- Lengthening or shortening of the limb.
- Allergic reactions.
- Bone resorption as a result of reaction to foreign body.
- Traumatic arthrosis of the knee caused by a forced intraoperative position of the limb.
- Heterotopic ossification.