MÜLLER CUPS

1. TYPE OF SANITARY PRODUCT.

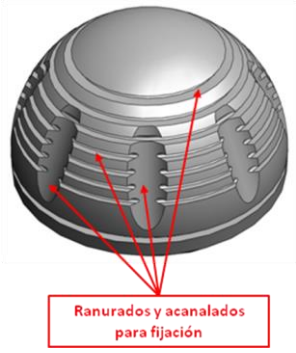
According to RD 1591/2009, it would be classified as **Class III** for being an invasive hip medical device, implantable for single use and prolonged use.

2. GENERAL DESCRIPTION OF THE PRODUCT. DESIGN JUSTIFICATION.

The **Acetabular Components "MÜLLER CUP"** are characterized by being Hemispherical Cup made entirely of ultra high molecular weight polyethylene (UHMWPE).

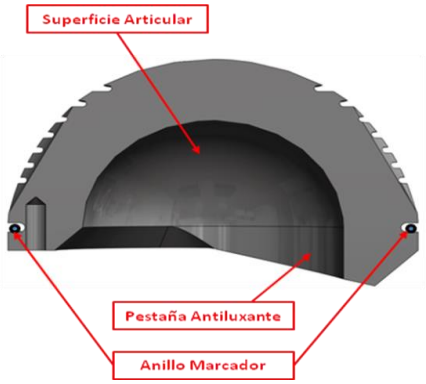
Its hemispheric design allows the maximum preservation of the bone capital, guaranteeing a homogenous distribution of loads to the bone thanks to a close contact with the acetabular bone (Estimated separation between implant and bone inferior to 0.5 mm

They are Cemented Cups, so that on its outer surface (convex surface intended to be housed within the acetabular cavity) has a specially designed grooved design, intended to improve the primary attachment of the cup. This primary fixation takes place upon impacting the sac over the acetabular cavity, which has previously been filled with bone cement. This impaction causes the bone cement to invade the machined grooves in the cup and, once the bone cement has set, they will act as counter-cuts, avoiding the rotation and loosening of the cup. These grooves also have the function of increasing the specific surface in contact with the acetabulum, providing a greater peripheral contact, whereby the adhesion force will be higher as we increase the contact surface at the Cotity-Cement-Bone interface. It is also worth noting its lightness compared to other metallic cups.



Externally all the cups of the Range will have similar finishes in terms of grooves, depending on their number and arrangement, logically, of the size or acetabular diameter of the cup

These Cups have a ring marker whose function will be to assist the surgeon in the correct acetabular placement of the implanted cup. This is necessary because the UHMWPE is a radiolucent material, so we need this radio-opaque marker ring to serve as reference for the surgeon at the time of its placement and for its subsequent postoperative clinical follow-up.



The minimum thickness of Polyethylene (UHMWPE) used in the Surgival Type Müller Type range is well above the minimum value of 6 mm. Which for components without any reinforcement, has been established in point 5.3 of the standard **UNE EN ISO 21535.** This extra thickness will provide a greater dispersion of stresses between insert / cement / bone interfaces and therefore, will result in a longer durability of both the cup and Of its fixation.

2.1. Main features. Design attributes.

- The Hemispherical cup with peripherally machined grooves and grooves, externally distributed according to the diameter of the cup, intended to favor the primary anchorage on bone cement and to limit the occurrence of possible micromovements that may cause prosthetic loosening.
- Arrangement of three external holes intended to house the instruments used for their positioning and impaction.
- The product range of the Antiluxante Variant has an antiluxante flange of 15º.
- Design specifications conforming to UNE EN ISO 21535 and ISO 7206-2 standards.

3. LIFESPAN:

The lifespan 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 the implantation technique, are the responsibility of the surgeon 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, the behavior of the same with regard to their weight gain, carrying heavy loads and adopting a high level of daily physical activity, as stated in point 4 of the ISO 21534 standard.

However, the end of the lifespan 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 at the time.

Problems that arise from long-term use are generally due to the aging of the product. Over time, the prosthesis loses its mechanical integrity due to friction, corrosion, and stress, which 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:

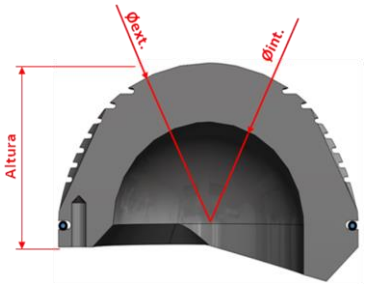
"Patients receiving hip joint replacement implants should be aware that the longevity of the implant may depend on the patient's weight and activity level."

4. PRODUCT RANGE. VARIANTS.

REFERENCES	DESCRIPTION
A1512244E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø44X28mm
A1512246E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø46X28mm
A1512248E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø48X28mm
A1512250E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø50X28mm
A1512252E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø52X28mm
A1512254E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø54X28mm
A1512256E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø56X28mm
A1512258E	POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED Ø58X28mm

These variants differ mainly by the internal and external spherical diameter of the Cup, that is, for this reason, with the Assigned Description we can distinguish:

"POLYETHYLENE (UHMWPE) ANTILUXATION ACETABULAR CUP TYPE MÜLLER CEMENTED ***Ø_{Int.} X Ø_{Ext.}***"



5. STERILIZATION:

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

6. CONDITIONING AND PACKAGING FOR SUPPLY.

- **Conditioning and 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. MÜLLER CUP MANUFACTURING MATERIALS..

- ***Polyethylene (UHMWPE).***

The UHMWPE used in the Müller Cup is a low-friction thermoplastic, with excellent chemical resistance and very high resistance to scratching and abrasion, characteristics that, if combined with an implantable medical grade, justify its wide prosthetic use in articulating elements subject to relative movements between components. For this reason, the MULLER Cup has been selected as the ideal material to be used in the prosthetic solution of the complete prosthetic replacement system.

Other characteristics that have favored the use of UHMWPE is its low degree of internal stresses, which allows complex parts to be machined with minimal deformations, which supports its use in parts subject to critical and complex dimensional and geometric restrictions.

The use of this material is not only justified by the aforementioned, but also by a huge number of studies and examples of use that can be found, for many years now, in the prosthetic market with excellent demonstrated results, which has led to confirm its suitability in Annex A "List of Materials found acceptable for the manufacture of implants" of the ISO 21534 standard.-"Non-Active Surgical Implants. Joint replacement implants. Particular Requirements", recommending that this material contemplate (depending on its processing form) the ISO 5834-1 standard "Surgical implants manufactured with UHMWPE from powder" or ISO 5834-1 "Surgical implants manufactured with UHMWPE from forms previously molded".

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

PROPERTIES	REQUIREMENT
Density (Kg/m^3)	927-944
Maximum Ash Content	Maximum150
Minimum Tensile Strength	Minimum21
Minimum Yield Limit	Minimum40
Minimum Elongation	Minimum380
Izod impact resistance	Minimum180
Charpy Impact Strength	Minimum126

- ***Stainless Steel :***

Material used in the Müller Cup to manufacture the marker ring.

It is a version of AISI 316 type steel with a low carbon content (0.07% compared to 0.03% for LVM). It is the steel used in medical applications par excellence, it is melted and remixed under vacuum to achieve the extremely high degree of purity that is required for temporary and definitive surgical implants. It offers excellent resistance to tissues and physiological fluids, to intergranular corrosion and to corrosion in general. Thanks to its excellent surface finish, its applications also include high-precision electronics.

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

Chemical composition

Element	Content (%Weight)
Carbon (C)	0,030 max.
Silicon (Si)	1,0 max.
Manganese (Mn)	2,0 max.
Phosphorus (P)	0,025 max.
Sulfur (S)	0,010 max.
Nitrogen (N)	0,10 max.
Chromium (Cr)	17,0-19,0
Molybdenum (Mo)	2,25-3,00.
Nickel (Ni)	13,0-15,0
Cooper (Cu)	0,50 max.
Iron (Fe)	Balance

Mechanical properties

Tensile Strength	Elastic Limit	% Elongation
Between 490 and 690 MPa	190 MPa	40%

8. PURPOSE AND USE

The Antiluxation Cup Type Müller Cemented is designed to act as the acetabular component in a total hip replacement system. It is implanted through a surgical intervention, referred to as a Total Hip Arthroplasty, with the purpose of restoring the natural biomechanics of the hip.

Due to its particular use, these products are considered single use, invasive, no reusable. Hence, applicable both in the sense of “not using the device in more than one patient” and in the sense of “not using the device several times in the same patient.” Reusing this device carries the risk of possible

implant failure due to fatigue, giving rise to the need for another intervention, and the possible transmission of pathogenic agents by cross infection (virus, prions...).

9. INDICATIONS

A hip arthroplasty is recommended for the following hip joint disorders:

- Primary and Secondary Coxarthrosis
- Arthritic processes such as rheumatoid arthritis.
- Atraumatic avascular necrosis.
- Post-traumatic disorders such as femoral neck fractures
- Unsuccessful reconstruction processes : Proximal femoral osteotomy, arthrodesis, painful stent.

10. CONTRAINDICACIONES

- 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.
- 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.
- Arthritis associated with Paget syndrome
- Acetabular Fracture
- Patients with disabilities in the opposite joint
- Mass of proximal acetabulum bone compromised by disease or previous implant preventing proper fixation and cup support

11. POSSIBLE ADVERSE OR SIDE EFFECTS

Possible side effects that may occur are:

- 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.
- Acetabular fracture or perforation
- Dislocation or subluxation.
- Lengthening or shortening of the limb.
- Allergic Reactions
- Immunological 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.
- Periarticular calcification or ossification, with or without impairment of joint mobility.