

QUARTER ACETABULAR SYSTEM

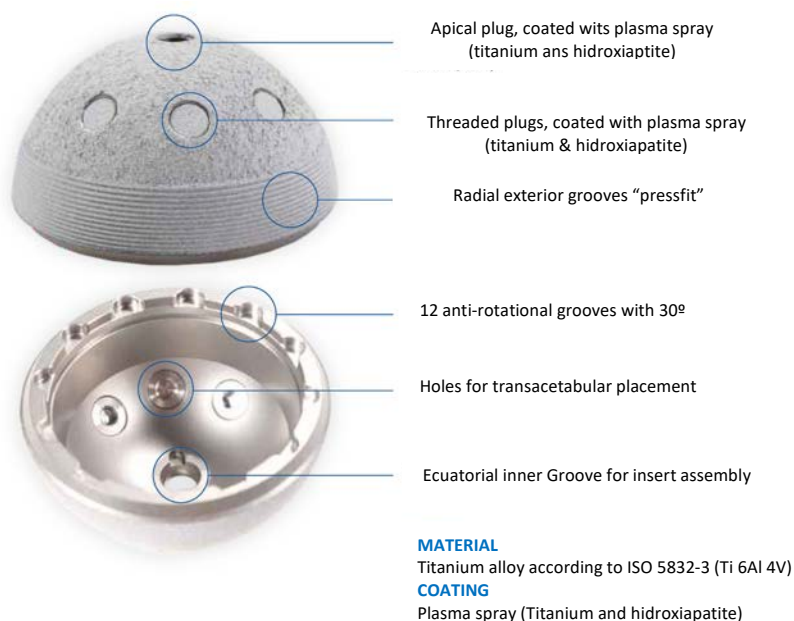
1. MEDICAL DEVICE CLASSIFICATION

According to Regulation 745/2017 CE, Directive 93/42/CE and transposition to RD 1591/2009, it is classified as Class III because it is an invasive, surgical, implantable and long term medical device.

2. GENERAL PRODUCT DESCRIPTION. DESIGN RATIONALE.

QUARTER acetabular system it is composed by several different items:

- The QUARTER Titanium Cup that has diameters from Ø 40 mm. up to Ø 68 mm., it is coated with a layer of Titanium and Hydroxyapatite plasma spray and has equatorial grooves to optimize the press-fit of the system.
- The Cup will have plugs for: the Transacetabular Screw holes, as well as for the apical hole.
- The QUARTER Polyethylene Insert will have Neutral and Antiluxant devices, and will allow the accommodation of Femoral Heads with diameters of: Ø 22 mm., Ø 28 mm., Ø 32 mm., Ø 36 mm., Ø 40 mm.
- Transacetabular screws for an improved fixation.



2.1 Main features. Design attributes

a) QUARTER cup

- Cup with 15 different acetabular diameters, that allow to have sizes from Ø40 mm to Ø68 mm., with increments of 2 mm.

QUARTER™ CUP

Diameter (Ø)	Reference
Ø 40 mm	A2407640E
Ø 42 mm	A2407642E
Ø 44 mm	A2407644E
Ø 46 mm	A2407646E
Ø 48 mm	A2407648E
Ø 50 mm	A2407650E
Ø 52 mm	A2407652E
Ø 54 mm	A2407654E
Ø 56 mm	A2407656E
Ø 58 mm	A2407658E
Ø 60 mm	A2407660E
Ø 62 mm	A2407662E
Ø 64 mm	A2407664E
Ø 66 mm	A2407666E
Ø 68 mm	A2407668E



- Hemispherical cup with 12 anti-rotational grooves machined peripherally and equally distributed each 30°, which allows a wide range of rotation for the positioning of the antiluxation insert in the proper position.



- Peripheral grooves in relief to favor the "Pressfit". This device allows an "efficient and effective" pressfit due to the excess thickness created in the equatorial zone by the grooves.



Ø52 REAMER
Ø 52 mm



Ø52 CUP
Ø 53,3 mm (1,3 mm pressfit)

- It has 3 perforations spaced 45° apart and at 45° elevation with respect to the center of the sphere. These holes allow fixing with Ø 6.5 mm screws. as well as a tilting of the screw of at least 15°. These perforations are sealed by the PLUGS.



- It has a threaded hole in the apical part of the cup in order to be able to carry out its impaction and allow visualization during the achievement of the acetabulum-cup cavity contact. This hole will be closed with the Apical Plug provided with the cup.
- Both the QUATER Cup and the available plugs will be made of Titanium Alloy (Ti6Al4V) and coated by $150 \pm 30\mu$ porous Titanium plasma spray, which will be subsequently coated with a $90 \pm 30\mu$ layer of Hydroxyapatite (HA).
- The supply will be individual and in sterile condition.

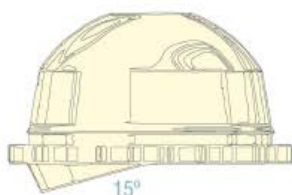
b) QUARTER UHMWPE crosslinked insert

- The QUARTER range of Inserts allows the use of "Neutral" or "Antiluxant" Inserts and the use of Femoral Heads with diameters: Ø 22 mm., Ø 28 mm., Ø 32 mm., Ø 36 mm., Ø 40 mm. combined according to the following table:

QUARTER™ INSERTS

ANTILUXATION (15°)

Cup diameter	Head diameter	Reference
Ø 40 mm	Ø 22 mm	A2412240E
Ø 42 mm	Ø 22 mm	A2412242E
Ø 44 mm	Ø 22 mm	A2412244E
Ø 46 mm	Ø 22 mm	A2412246E
Ø 44 mm	Ø 28 mm	A2412844E
Ø 46 mm	Ø 28 mm	A2412846E
Ø 48 mm	Ø 28 mm	A2412848E
Ø 50 mm	Ø 28 mm	A2412850E
Ø 52 mm	Ø 28 mm	A2412852E
Ø 54 mm	Ø 28 mm	A2412854E
Ø 56 mm	Ø 28 mm	A2412856E
Ø 58 mm	Ø 28 mm	A2412858E
Ø 60 mm	Ø 28 mm	A2412860E
Ø 62 mm	Ø 28 mm	A2412862E
Ø 64 mm	Ø 28 mm	A2412864E
Ø 66 mm	Ø 28 mm	A2412866E
Ø 68 mm	Ø 28 mm	A2412868E
Ø 48 mm	Ø 32 mm	A2413248E
Ø 50 mm	Ø 32 mm	A2413250E
Ø 52 mm	Ø 32 mm	A2413252E
Ø 54 mm	Ø 32 mm	A2413254E
Ø 56 mm	Ø 32 mm	A2413256E
Ø 58 mm	Ø 32 mm	A2413258E
Ø 60 mm	Ø 32 mm	A2413260E
Ø 62 mm	Ø 32 mm	A2413262E
Ø 64 mm	Ø 32 mm	A2413264E
Ø 66 mm	Ø 32 mm	A2413266E
Ø 68 mm	Ø 32 mm	A2413268E
Ø 52 mm	Ø 36 mm	A2413652E
Ø 54 mm	Ø 36 mm	A2413654E
Ø 56 mm	Ø 36 mm	A2413656E
Ø 58 mm	Ø 36 mm	A2413658E
Ø 60 mm	Ø 36 mm	A2413660E
Ø 62 mm	Ø 36 mm	A2413662E
Ø 64 mm	Ø 36 mm	A2413664E
Ø 66 mm	Ø 36 mm	A2413666E
Ø 68 mm	Ø 36 mm	A2413668E



QUARTER™ INSERTS

NEUTRAL

Cup diameter	Head diameter	Reference
Ø 44 mm	Ø 28 mm	A2402844E
Ø 46 mm	Ø 28 mm	A2402846E
Ø 48 mm	Ø 28 mm	A2402848E
Ø 50 mm	Ø 28 mm	A2402850E
Ø 52 mm	Ø 28 mm	A2402852E
Ø 54 mm	Ø 28 mm	A2402854E
Ø 56 mm	Ø 28 mm	A2402856E
Ø 58 mm	Ø 28 mm	A2402858E
Ø 60 mm	Ø 28 mm	A2402860E
Ø 62 mm	Ø 28 mm	A2402862E
Ø 64 mm	Ø 28 mm	A2402864E
Ø 66 mm	Ø 28 mm	A2402866E
Ø 68 mm	Ø 28 mm	A2402868E
Ø 48 mm	Ø 32 mm	A2403248E
Ø 50 mm	Ø 32 mm	A2403250E
Ø 52 mm	Ø 32 mm	A2403252E
Ø 54 mm	Ø 32 mm	A2403254E
Ø 56 mm	Ø 32 mm	A2403256E
Ø 58 mm	Ø 32 mm	A2403258E
Ø 60 mm	Ø 32 mm	A2403260E
Ø 62 mm	Ø 32 mm	A2403262E
Ø 64 mm	Ø 32 mm	A2403264E
Ø 66 mm	Ø 32 mm	A2403266E
Ø 68 mm	Ø 32 mm	A2403268E
Ø 52 mm	Ø 36 mm	A2403652E
Ø 54 mm	Ø 36 mm	A2403654E
Ø 56 mm	Ø 36 mm	A2403656E
Ø 58 mm	Ø 36 mm	A2403658E
Ø 60 mm	Ø 36 mm	A2403660E
Ø 62 mm	Ø 36 mm	A2403662E
Ø 64 mm	Ø 36 mm	A2403664E
Ø 66 mm	Ø 36 mm	A2403666E
Ø 68 mm	Ø 36 mm	A2403668E
Ø 56 mm	Ø 40 mm	A2404056E
Ø 58 mm	Ø 40 mm	A2404058E
Ø 60 mm	Ø 40 mm	A2404060E
Ø 62 mm	Ø 40 mm	A2404062E
Ø 64 mm	Ø 40 mm	A2404064E
Ø 66 mm	Ø 40 mm	A2404066E
Ø 68 mm	Ø 40 mm	A2404068E



- 15° antiluxation flap.
- The Polyethylene Insert is an Ultra High Molecular Weight (UHMWPE) crosslinked, with a congruent profile for its assembly with the Titanium cup. The fixation of the UHMWPE Insert will be carried out by clipping a diametral flange on a groove arranged in the metallic Cup.
- The PE insert has 12 tabs for rotation control.
- It has a diametral ring for clipping and fixing the PE insert on the Ti Cup.
- External surface concordant with the internal surface of the cup. Good surface finish of concordant surfaces.
- Its supply is individual, packed in sterile format.
- Design according to requirements of ISO 21535, section 5 Design attributes
 - **5mm.** of UHMWPE thickness minimum in all the inserts range. The acetabular system consists of a polyethylene insert and an external titanium cup which forms the metallic reinforcement. According to ISO 21535, section 5.3.1.
- The design complies with what is indicated in the ISO 21535 standard, in its section 5.- Design Attributes, and more specifically what is commented in point 5.2.2.- Tolerances of the diameters of articulating surfaces, which in turn instead, it refers to ISO 7206-2 to specify the following design requirements:
 - Sphericity of 100µm (0,1 mm.); (Section. "4.2.2.- Sphericity" of standard **ISO 7206-2**.)
 - Surface roughness of $R_a < 2 \mu m$ (Section "4.2.3.- Surface finish" of standard **ISO 7206-2**.)
 - Dimensional tolerances between +0,1mm and +0,3mm. (Section "4.2.4.- Dimensional tolerances" of standard **ISO 7206-2**.)

c) Titanium transacetabular screws

- Titanium alloy screws
- Self tapping tip
- Low profile spherical head
- 3.5 mm hexagonal housing for screwing

**3. LIFE TIME:**

The service life of this cup is estimated 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, the behavior of the same with regard to their weight gain, carrying heavy loads and adopting a high level of daily physical activity, according to point 4 of the ISO 21534 standard.

"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."

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.

4. PRODUCT RANGE. VARIANTS.

- **QUARTER CUP**. Range composed of the following 15 variants (models / sizes):

QUARTER™ CUP

Diameter (Ø)	Reference
Ø 40 mm	A2407640E
Ø 42 mm	A2407642E
Ø 44 mm	A2407644E
Ø 46 mm	A2407646E
Ø 48 mm	A2407648E
Ø 50 mm	A2407650E
Ø 52 mm	A2407652E
Ø 54 mm	A2407654E
Ø 56 mm	A2407656E
Ø 58 mm	A2407658E
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Ø 64 mm	A2407664E
Ø 66 mm	A2407666E
Ø 68 mm	A2407668E

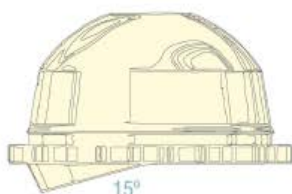


- QUARTER polyethylene insert. Range made up of the following 77 variants (models / sizes):

QUARTER™ INSERTS

ANTILUXATION (15°)

Cup diameter	Head diameter	Reference
Ø 40 mm	Ø 22 mm	A2412240E
Ø 42 mm	Ø 22 mm	A2412242E
Ø 44 mm	Ø 22 mm	A2412244E
Ø 46 mm	Ø 22 mm	A2412246E
Ø 44 mm	Ø 28 mm	A2412844E
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Ø 52 mm	Ø 28 mm	A2412852E
Ø 54 mm	Ø 28 mm	A2412854E
Ø 56 mm	Ø 28 mm	A2412856E
Ø 58 mm	Ø 28 mm	A2412858E
Ø 60 mm	Ø 28 mm	A2412860E
Ø 62 mm	Ø 28 mm	A2412862E
Ø 64 mm	Ø 28 mm	A2412864E
Ø 66 mm	Ø 28 mm	A2412866E
Ø 68 mm	Ø 28 mm	A2412868E
Ø 48 mm	Ø 32 mm	A2413248E
Ø 50 mm	Ø 32 mm	A2413250E
Ø 52 mm	Ø 32 mm	A2413252E
Ø 54 mm	Ø 32 mm	A2413254E
Ø 56 mm	Ø 32 mm	A2413256E
Ø 58 mm	Ø 32 mm	A2413258E
Ø 60 mm	Ø 32 mm	A2413260E
Ø 62 mm	Ø 32 mm	A2413262E
Ø 64 mm	Ø 32 mm	A2413264E
Ø 66 mm	Ø 32 mm	A2413266E
Ø 68 mm	Ø 32 mm	A2413268E
Ø 52 mm	Ø 36 mm	A2413652E
Ø 54 mm	Ø 36 mm	A2413654E
Ø 56 mm	Ø 36 mm	A2413656E
Ø 58 mm	Ø 36 mm	A2413658E
Ø 60 mm	Ø 36 mm	A2413660E
Ø 62 mm	Ø 36 mm	A2413662E
Ø 64 mm	Ø 36 mm	A2413664E
Ø 66 mm	Ø 36 mm	A2413666E
Ø 68 mm	Ø 36 mm	A2413668E



QUARTER™ INSERTS

NEUTRAL

Cup diameter	Head diameter	Reference
Ø 44 mm	Ø 28 mm	A2402844E
Ø 46 mm	Ø 28 mm	A2402846E
Ø 48 mm	Ø 28 mm	A2402848E
Ø 50 mm	Ø 28 mm	A2402850E
Ø 52 mm	Ø 28 mm	A2402852E
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Ø 58 mm	Ø 28 mm	A2402858E
Ø 60 mm	Ø 28 mm	A2402860E
Ø 62 mm	Ø 28 mm	A2402862E
Ø 64 mm	Ø 28 mm	A2402864E
Ø 66 mm	Ø 28 mm	A2402866E
Ø 68 mm	Ø 28 mm	A2402868E
Ø 48 mm	Ø 32 mm	A2403248E
Ø 50 mm	Ø 32 mm	A2403250E
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Ø 62 mm	Ø 32 mm	A2403262E
Ø 64 mm	Ø 32 mm	A2403264E
Ø 66 mm	Ø 32 mm	A2403266E
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Ø 62 mm	Ø 36 mm	A2403662E
Ø 64 mm	Ø 36 mm	A2403664E
Ø 66 mm	Ø 36 mm	A2403666E
Ø 68 mm	Ø 36 mm	A2403668E
Ø 56 mm	Ø 40 mm	A2404056E
Ø 58 mm	Ø 40 mm	A2404058E
Ø 60 mm	Ø 40 mm	A2404060E
Ø 62 mm	Ø 40 mm	A2404062E
Ø 64 mm	Ø 40 mm	A2404064E
Ø 66 mm	Ø 40 mm	A2404066E
Ø 68 mm	Ø 40 mm	A2404068E



- Titanium transacetabular screws. System accessories range, composed by the following 6 screw lengths:

QUARTER TRANSACETABULAR SCREWS

Length	Reference
20 mm	A2400520E
25 mm	A2400525E
30 mm	A2400530E
35 mm	A2400535E
40 mm	A2400540E
45 mm	A2400545E



5. STERILIZATION:

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

6. PACKAGING.

The Packaging System, consisting of a Preformed Sterile Barrier System and a Protective Container, of this terminally sterilized medical device, satisfies the following points:

1. Provides physical protection and maintain the integrity of the sterile barrier system.
2. Allows sterilization and be compatible with the indicated sterilization process.
3. Maintains sterility until point of use or expiration date.
4. Proper assembly of the Packaging System.
5. Allows aseptic presentation.
6. Provides an adequate 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 the packaging do not contain or release toxic products.

7. QUARTER ACETABULAR CUP SYSTEM MANUFACTURING MATERIALS

□ Ti6Al4V titanium alloy:

It is the "grade 5" titanium alloy, the most widely used in the medical field (it contains aluminum and vanadium depending on the composition: [[Ti6Al4V]]. Aluminum increases the temperature of the transformation between the alpha and beta phases. Vanadium lowers that temperature. The alloy can be well welded. It has high toughness.

As approximate and characteristic mechanical values of this material we can give the following values:

It has a tensile strength of 845-896 MPa, an elastic limit of 775-830 MPa, a ductility of 10%, a hardness of 33 HRB, a very good weldability and an electrical resistivity of 1.67 ($\mu\Omega\text{m}$). Its application is common wherever high mechanical resistance and high temperatures of use and lightness of material are required. This Material is considered as Acceptable for the manufacture of Implants by the UNE-EN ISO 21534, Annex A.

□ Crosslinked Polyethylene (UHMWPE).

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

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

The Reticulated or Crosslinked process allows this material to offer optimal friction conditions in order to minimize wear and the release of particles that has become one of the main causes of loosening.

In the case of cross-linked polyethylene, Surgival has been subjected to the wear tests established in the international standard ISO 14242. "Implants for surgery - Wear of total hip-joint prostheses". Both "pre-clinical" and "clinical" results show OPTIMAL wear behavior.

a) "In Vitro" results

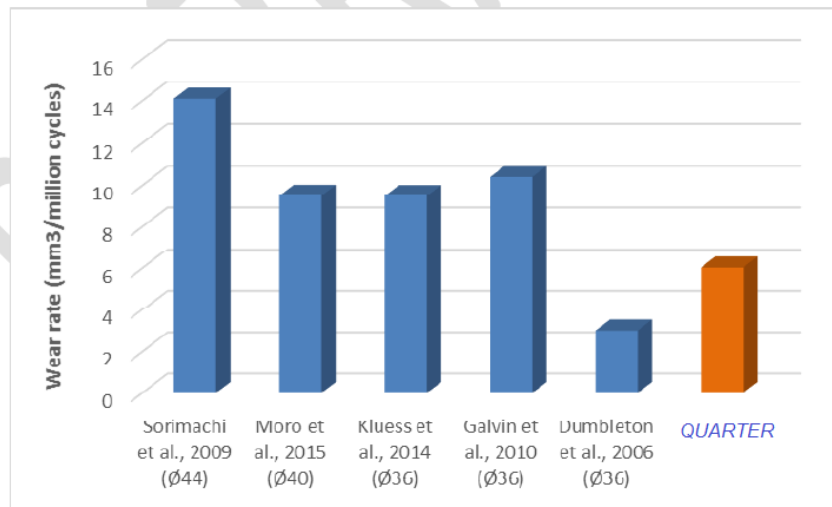


Figure 4. Comparison of the wear rate obtained for QUARTER with several studies published related to "in vitro" wear in total hip prostheses with metal on crosslinked polyethylene. The graph shows the values for diameters of the femoral heads close to the tested QUARTER head. Diameters are shown in parenthesis.

b) "In Vivo" results

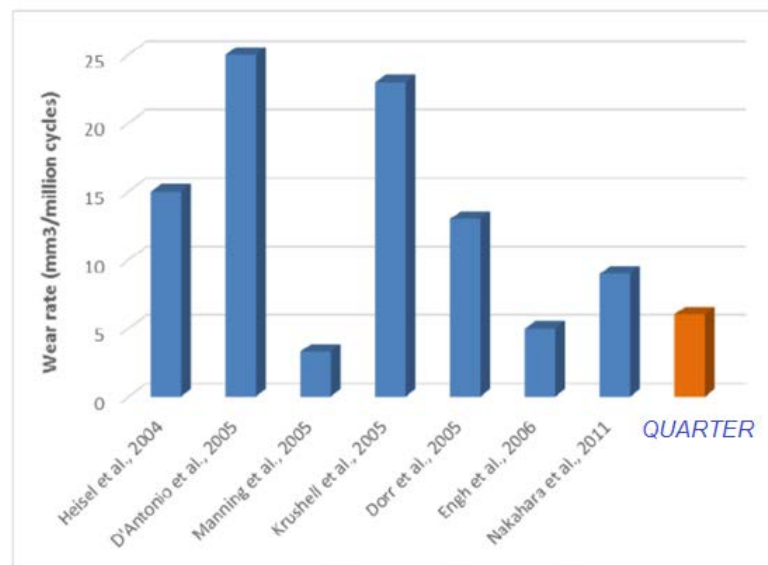


Figure 10. Comparison of the wear rate for the QUARTER with annual rates from several studies published about "in vivo" wear of total hip prostheses with metal on crosslinked polyethylene.

The use of this material is not only supported by the aforementioned, but a large number of studies and examples of use can be found, for many years now, in the prosthetic market with excellent demonstrated results, which has led to the verification of its aptitude 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 the way it is processed) the ISO 5834-1 standard" Surgical implants manufactured with UHMWPE from powder "or ISO 5834-1" Surgical implants manufactured with UHMWPE from previously forms. molded ".