TECHNICAL FILE:

CEMENTLESS QUARTER ACETABULAR SYSTEM (CUP + INSERT)

SURGIVAL Co. S.A.U

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Annex

Parque Tecnológico
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1. PURPOSE AND USE

The Quarter Acetabular System is designed to be part of a total hip replacement system, as an acetabular component.

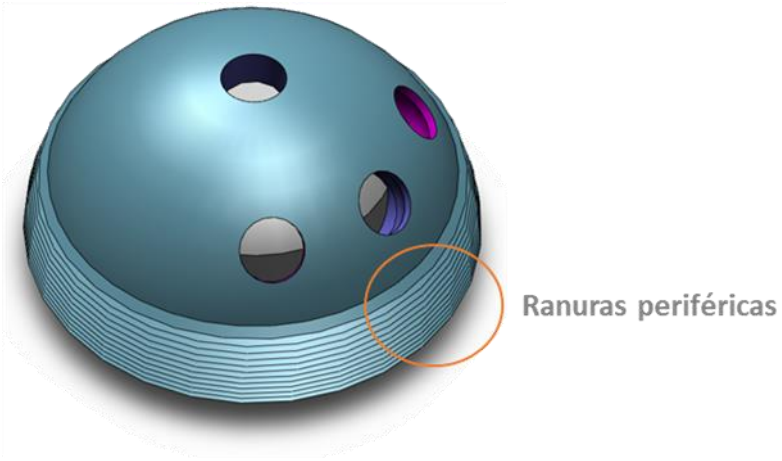
It will be implanted through a surgical intervention called Total Hip Arthroplasty whose objective is to restore the functional state of the hip.

Its specific use makes these products considered single-use, invasive, not reusable. Therefore, applicable both in the sense of "not using the product in more than one patient" and in the sense of "not using 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 (viruses, prions ...).

The surgical technique associated with the Quarter Acetabular System is attached in Annex 1.

2. DESCRIPTION OF THE MEDICAL DEVICE

The Quarter Acetabular System manufactured by SURGIVAL is composed of several subcomponents, the Titanium Cup covered with titanium and hydroxyapatite spray plasma, the Polyethylene Insert (XL-UHMWPE), the cup screws (they are the same as those of the SHY Acetabular System Not Cemented) and screw caps.

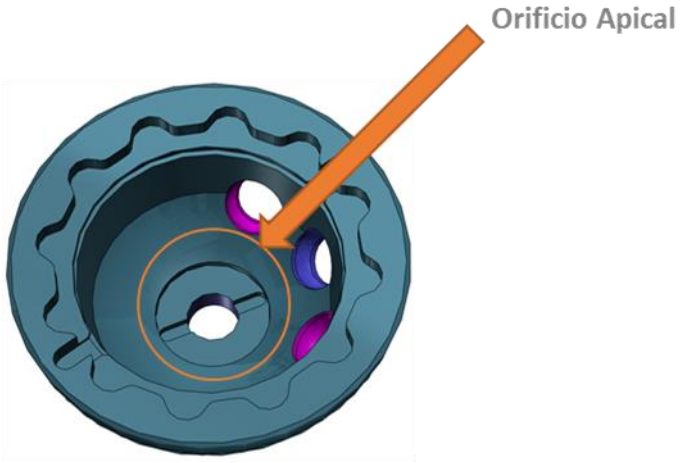


The "Quarter" Cup is a hemispherical cup based on TI6Al4V titanium alloy. It has peripheral relief rings of diametral augmentation to favor anchoring by press-fit. These rings, in addition to providing primary stability by snap fit, provide greater peripheral contact by increasing the contact surface, thereby favoring osteoinduction and osseointegration. In addition, they reduce the micromovements of the implant on the bone surface and achieve an effective peripheral bone seal of the bone-implant interface, reinforced by the hydroxyapatite coating.

The surface of the metal cup is covered by a first layer of titanium spray plasma on which a second hydroxyapatite projection is made. This surface treatment gives the implant a good osseointegration capacity in the pelvic acetabulum.

The hemispheric design allows maximum conservation of bone capital, ensuring a homogeneous distribution of loads to the bone thanks to close contact with the acetabular bone.

A polar hole will allow to check the implant bone contact in addition to threading the cup impactor necessary for the placement of the acetabular dome.



As can be seen in the previous image, the polar or apical hole is located on a cylindrical recess with two notches or grooves.

This designed system has the function of damping and unloading the compression on the thread so as not to jeopardize the durability and functional integrity of this.

The polar hole is threaded and therefore the threaded plugs can be threaded on it, in this way a supplementary and homogeneous surface will be available for secondary fixing.

The main function of the screw caps is to increase the contact interface between the bone and the dome. These screws have a rough surface finish using plasma titanium spray (PST) and Hydroxyapatite (HA) that will increase the contact surface and improve osteoconduction. The cap will be manufactured like the cup in Titanium Alloy (Ti6Al4V).

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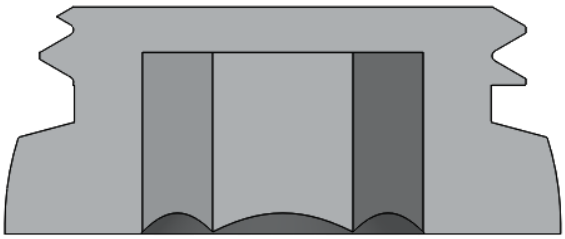
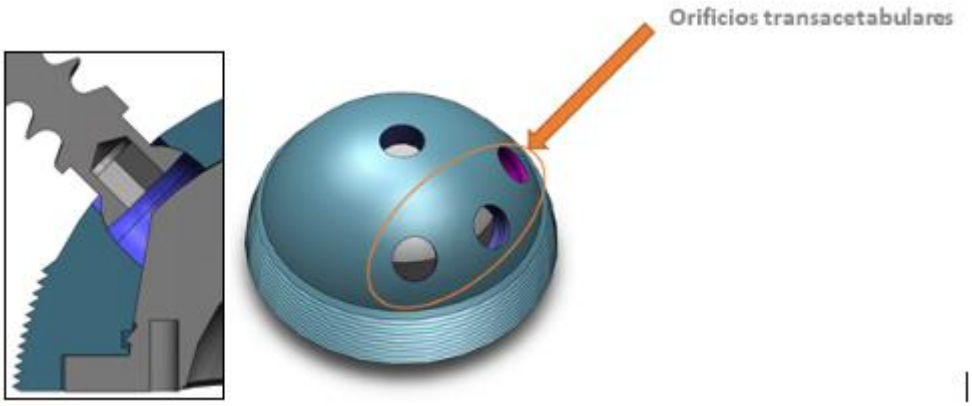


Vista en sección de tapón roscado hexagonal

Vista perspectiva de tapón roscado hexagonal

The design will have three holes for cup screws to allow a primary anchor reinforcement fixation, by means of titanium screws accessory to the system, to be used in cases where an acceptable "press-fit" primary stability is not achieved as can be achieved. occur with acetabulums with great bone destruction, dysplastic hips and prosthetic reviews.



These 3 holes will be threaded for the introduction of 3 plugs. These plugs will be preassembled on the cup and will be removed in cases where the doctor determines that the use of cup screws will be necessary to give greater strength to the primary fixation..

The screws for the cup can enjoy a freedom of angulation of at least 15º, which will allow the surgeon to make the fixation by directing the anchor towards the area where the bone has a higher structural quality and bone stock.

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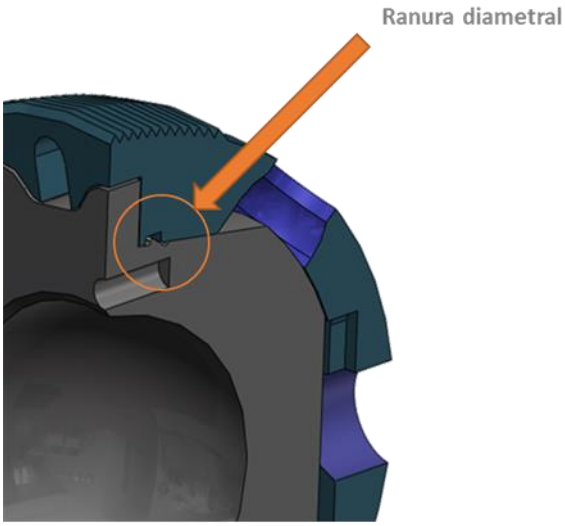
These cup screws will be manufactured in Titanium and their head will be spherical (to allow angular tilting of the screw in any direction) and of low profile (to avoid contacts with the polyethylene insert that can cause friction with this and therefore, release of particles). The fixing of the cup by screws must be done before inserting the insert.

The polyethylene insert (made of Ultra High Molecular Weight Polyethylene), reproduces on its outer surface, the inside of the metal cup. The fixation in the metal cup is made by clipping a diametral flange that it has and which is embedded in a diametral groove practiced in the inner surface of the cup.



It has practiced 12 peripheral tabs separated by 30º that will prevent rotation and resist tilt or dislocation forces.

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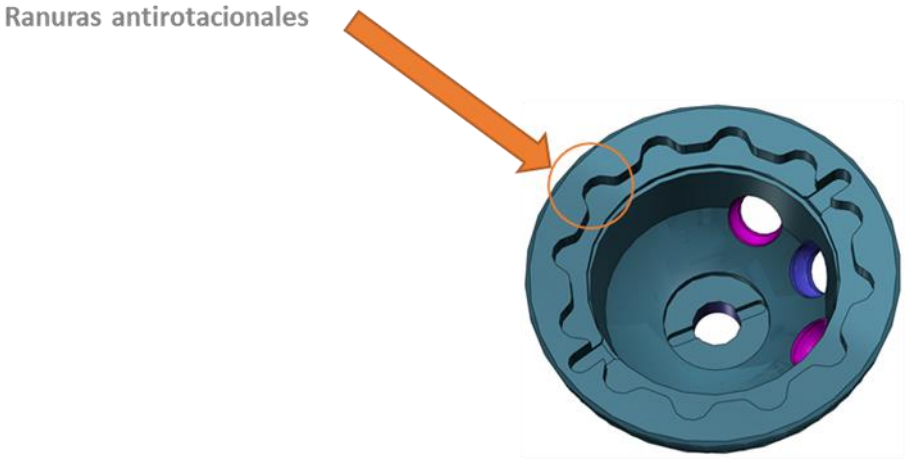
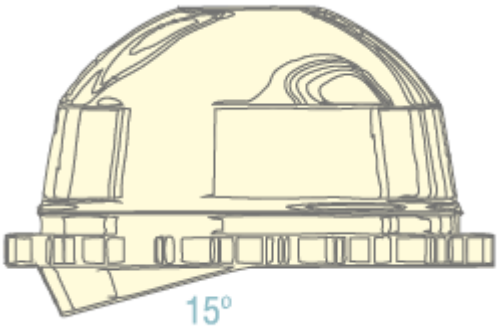


La cúpula e inserto disponen de una superficie cónica de unión entre ambos dispositivos. Esta geometría cónica permite la transferencia de fuerzas desde la cúpula al inserto.

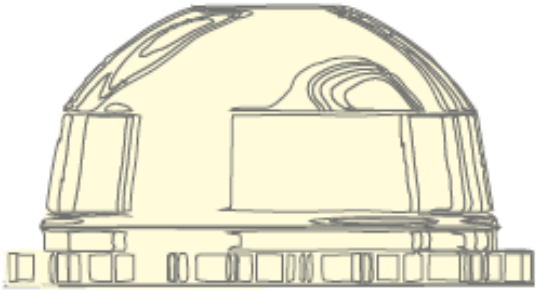
Neutral and antiluxant inserts will be available.

Inserts with Antiluxante Flange. The Insert will not protrude above the metal cup line with the exception of the antiluxante eyebrow (15º). The antiluxante eyebrow is a safety element that helps prevent dislocations in the implanted hips.

Neutral inserts. It will allow a greater range of mobility avoiding “impigement” and therefore problems derived from wear.



Antiluxation Insert



Neutral Insert

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The references covered under this report are the following:

Cementless **QUARTER Cup**:

REFERENCE	*DESIGNATION*	*DIMENSIONS*
A2401640E	*Ti6Al4V QUARTER CUP + Ti PLASMA SPRAY (TPS) + HYDROXYAPATITE (HA). CEMENTLESS*	Ø40mm
A2401642E		Ø42mm
A2401644E		Ø44mm
A2401646E		Ø46mm
A2401648E		Ø48mm
A2401650E		Ø50mm
A2401652E		Ø52mm
A2401654E		Ø54mm
A2401656E		Ø56mm
A2401658E		Ø58mm
A2401660E		Ø60mm
A2401662E		Ø62mm
A2401664E		Ø64mm
A2401666E		Ø66mm
A2401668E		Ø68mm

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Crosslinked polyethylene **Insert** (UHMWPE-XL) for **QUARTER** Cup (neutral and antiluxation):

REFERENCE	*DESIGNATION*	*DIMENSIONS*
A2412240E	*QUARTER CUP CROSSLINKED POLYETHYLENE ANTILUXATION INSERT (UHMWPE-XL)*	Ø40x22mm
A2412242E		Ø42x22mm
A2412244E		Ø44x22mm
A2412246E		Ø46x22mm
A2412844E		Ø44x28mm
A2412846E		Ø46x28mm
A2412848E		Ø48x28mm
A2412850E		Ø50x28mm
A2412852E		Ø52x28mm
A2412854E		Ø54x28mm
A2412856E		Ø56x28mm
A2412858E		Ø58x28mm
A2412860E		Ø60x28mm
A2412862E		Ø62x28mm
A2412864E		Ø64x28mm
A2412866E		Ø66x28mm
A2412868E		Ø68x28mm
A2413248E		Ø48x32mm
A2413250E		Ø50x32mm
A2413252E		Ø52x32mm
A2413254E		Ø54x32mm
A2413256E		Ø56x32mm
A2413258E		Ø58x32mm
A2413260E		Ø60x32mm
A2413262E		Ø62x32mm
A2413264E		Ø64x32mm
A2413266E		Ø66x32mm
A2413268E		Ø68x32mm
A2413652E		Ø52x36mm
A2413654E		Ø54x36mm
A2413656E		Ø56x36mm
A2413658E		Ø58x36mm
A2413660E		Ø60x36mm
A2413662E		Ø62x36mm
A2413664E		Ø64x36mm
A2413666E		Ø66x36mm
A2413668E		Ø68x36mm

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REFERENCE	DESIGNATION	DIMENSIONS
A2402844E	QUARTER CUP CROSSLINKED POLYETHYLENE NEUTRAL INSERT (UHMWPE-XL)	Ø44x28mm
A2402846E		Ø46x28mm
A2402848E		Ø48x28mm
A2402850E		Ø50x28mm
A2402852E		Ø52x28mm
A2402854E		Ø54x28mm
A2402856E		Ø56x28mm
A2402858E		Ø58x28mm
A2402860E		Ø60x28mm
A2402862E		Ø62x28mm
A2402864E		Ø64x28mm
A2402866E		Ø66x28mm
A2402868E		Ø68x28mm
A2403248E		Ø48x32mm
A2403250E		Ø50x32mm
A2403252E		Ø52x32mm
A2403254E		Ø54x32mm
A2403256E		Ø56x32mm
A2403258E		Ø58x32mm
A2403260E		Ø60x32mm
A2403262E		Ø62x32mm
A2403264E		Ø64x32mm
A2403266E		Ø66x32mm
A2403268E		Ø68x32mm
A2403652E		Ø52x36mm
A2403654E		Ø54x36mm
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A2403658E		Ø58x36mm
A2403660E		Ø60x36mm
A2403662E		Ø62x36mm
A2403664E		Ø64x36mm
A2403666E		Ø66x36mm
A2403668E		Ø68x36mm
A2404056E		Ø56x40mm
A2404058E		Ø58x40mm
A2404060E		Ø60x40mm
A2404062E		Ø62x40mm
A2404064E		Ø64x40mm
A2404066E		Ø66x40mm
A2404068E		Ø68x40mm

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Screw for Cup *(Cross-linked polyethylene are the same as those of the Acetabular System S.H.Y. Not Cemented)*

REFERENCE	DESIGNATION	DIMENSIONS
A2400520	SCREW FOR CUP (sterile)	20mm
A2400525		25mm
A2400530		30mm
A2400535		35mm
A2400540		40mm
A2400545		45mm

3. INDICATIONS

A hip arthroplasty can be indicated in the following disorders of the coxofemoral joint:

- Primary and Secondary Arthrosis.
- Arthritic processes, such as Rheumatoid Arthritis.
- Avascular Necrosis of the Femoral Head.
- Post-traumatic disorders such as fractures of the femoral neck.
- Failed Reconstruction Processes: Proximal Femoral Osteotomy, Arthrodesis, Painful Endoprosthesis.

4. CONTRAINDICATIONS

It is contraindicated in the following cases:

- Patients with allergies to the previously described materials. In order to avoid this, if an allergy to these materials is suspected, it is advisable to give patients an allergy test beforehand.
- Presence of an active infection.
- Neuromuscular injury or vascular deficiency in the affected limb.
- Severe osteoporosis.
- Osteomalacia.
- Obesity.
- Serious pathologies such as cardiac, pulmonary, metabolic or autoimmune disorders, which prevent the correct formation of bones or can significantly increase the risk of mortality.
- Progressive neurological disease.

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5. POSSIBLE ADVERSE OR SIDE EFFECTS

Possible side effects are as follows:

- Deformation or break of the implant due to wear or fatigue.
- Superficial or periprosthetic infection.
- Relaxation 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.
- Acetabular 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 to a forced intraoperative positioning.
- Periarticular calcification or ossification, with or without a reduction in joint mobility.
- If screws are used, perforation of the pelvis or damage of tissues or organs.

6. MAIN FEATURES

- The design will have the diameters: Ø 40 mm. Up to Ø 68 mm. (in steps of 2 mm in 2 mm.). It is maintained the same Screw Cup as in the Acetabular S.H.Y. Cementless.
- The cup will be hemispherical with anti-rotational grooves, it will have peripheral grooves in relief to favor the “Press-fit” and three perforations at 45º to allow the fixation by screws of Ø 6.5 mm, these perforations must allow a screw tilt of at least 15º.
- The holes for the Cotilo screws and the apical hole will be threaded for plug placement.
- The Cup will be covered by a porous plasma of Titanium Spray which in turn will be subsequently coated with a layer of Hydroxyapatite (HA) in order to favor its osseointegration.
- The Inserts will allow the incorporation of Femoral Heads with diameters: Ø 22mm, Ø 28mm, Ø 32mm, Ø36mm, Ø 40mm.
- Neutral and antiluxant inserts will be available. The antiluxante inserts will have an eyebrow of 15º to avoid possible dislocations mainly in the smaller sizes. Larger sizes will later justify the possibility of not using eyebrow antiluxante.

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- The Insert will be made of Ultra High Molecular Polyethylene and highly crosslinked (XL-UHMWPE), with a congruent profile for its assembly with the Titanium cup. The fixation of the Insert will be done by clipping a diametral flange over a slot arranged in the metal Cup.

- The insert will have projections for rotation control.

- Useful life of 10 to 15 years.

- Manufacturing using biocompatible materials.

- The supply of the Cotilo Quarter must be sterile and the container must maintain sterility.

- The Quarter insert will be conditioned with a container that will minimize the oxidation of cross-linked polyethylene and guarantee the sterility of the product until the moment of use.

- The Quarter system (cup and insert) WILL NOT BE REUSABLE.

7. DESCRIPTION OF PRODUCT / MATERIAL COMPOSITION AND REFERENCE TO RELEVANT RULES

The materials used in the manufacture of implants are selected considering the precise properties to achieve the intended purpose, also taking into account the effects of manufacturing, handling, sterilization and storage, as well as any treatment (chemical, electrochemical, thermal, mechanical, etc. .) applied to the surface or to a part of the surface of the implant material to modify its properties. Possible reactions of implant materials with tissues and body fluids, with other materials, other implants, substances and gases should be considered. The possible effects of radiation and magnetic and electromagnetic fields on the material should also be considered.

The materials used for implants, including biological materials, must be acceptably compatible with biological tissues, cells and body fluids with which they come into contact in their implantable state. The compatibility of the products with the possible result of wear and degradation of the implant must also be acceptable. Acceptability of any product resulting from wear and degradation of the implant must also be acceptable. Acceptability for the particular application to which the implant is intended will be demonstrated in any of the following ways:

a) documental evaluation

b) selection of materials that have proven to be suitable for clinical use in similar applications where they have been tested

The base material used in the manufacture of the Cotilo Quarter, as well as that of the screws, is a Ti6Al4V titanium alloy. This material has historically been used in human implants to meet the requirements of international standards ISO 5832-3 and ASTM F136, in the case of titanium alloy.

As for the materials used in the Cotilo Quarter coatings, on the one hand, porous non-alloyed titanium is used according to ASTM F-1580, applied in the form of plasma spray. On the other hand, Hydroxyapatite (Ca5 (PO4) 3OH) is used according to ISO 13779 and ASTM F-1185.

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On the other hand, the inserts are manufactured in Ultra High Molecular Weight Polyethylene (UHMWPE), being an acceptable material for use in humans.

Ti6Al4V alloy properties (according to ASTM F-136 and ISO 5832-3)

Chemical Composition of Ti6Al4V Alloy

Element	Content (% bulk)
Aluminum (Al)	between 5.5 y 6.5 %
Vanadium (V)	between 3.5 y 4.5 %
Iron (Fe)	Max. 0.25 %
Oxygen (O)	Max. 0.13 %
Carbon (C)	Max. 0.08 %
Nitrogen (N)	Max. 0.05 %
Hydrogen (H)	Max. 0.012 %
Titanium (Ti)	Balance

Ti6Al4V alloy mechanical properties

Tensile strength	Elastic limit	% Elongation
Minimum 825 MPa	Minimum 760 MPa	8.00%

Properties of Hydroxyapatite (Ca5 (PO4) 3OH) for coatings (according to ASTM F-1185)

CHEMICAL COMPOSITION	
Minimum Hydroxyapatite Content	95% (% bulk)
Maximum Arsenic Content (As)	3 ppm
Maximum Cadmium Content (Cd)	5 ppm
Maximum Mercury Content (Hg)	5 ppm
Maximum Lead Content (Pb)	30 ppm
Maximum Content Heavy Metals	50 ppm

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Properties of pure titanium powder for coatings (according to ASTM F1580)

CHEMICAL COMPOSITION	
Maximum Oxygen Content (O)	0.4%
Maximum Iron Content (Fe)	0.5%
Maximum Carbon Content (C)	0.08%
Maximum Hydrogen Content (H)	0.05%
Maximum Nitrogen Content (N)	0.05%
Titanium content	Balance

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

PROPERTIES	REQUIREMENT
Density (Kg/m^3)	927-944
Maximum Ash Content	Maximum 125
Minimum tensile strength	Minimum 21
Minimum Elastic Limit	Minimum 40
Mínima Elongación	Minimum 380
Izod impact resistance	Minimum 126

All raw materials used in the manufacture of Surgival products are inspected before entering the warehouse. These inspections consist of the review of the documentation provided by the supplier, with special attention to the mechanical properties and chemical composition of the batch of raw material. On the other hand, the operators check the dimensions of the raw materials and the visual aspect.

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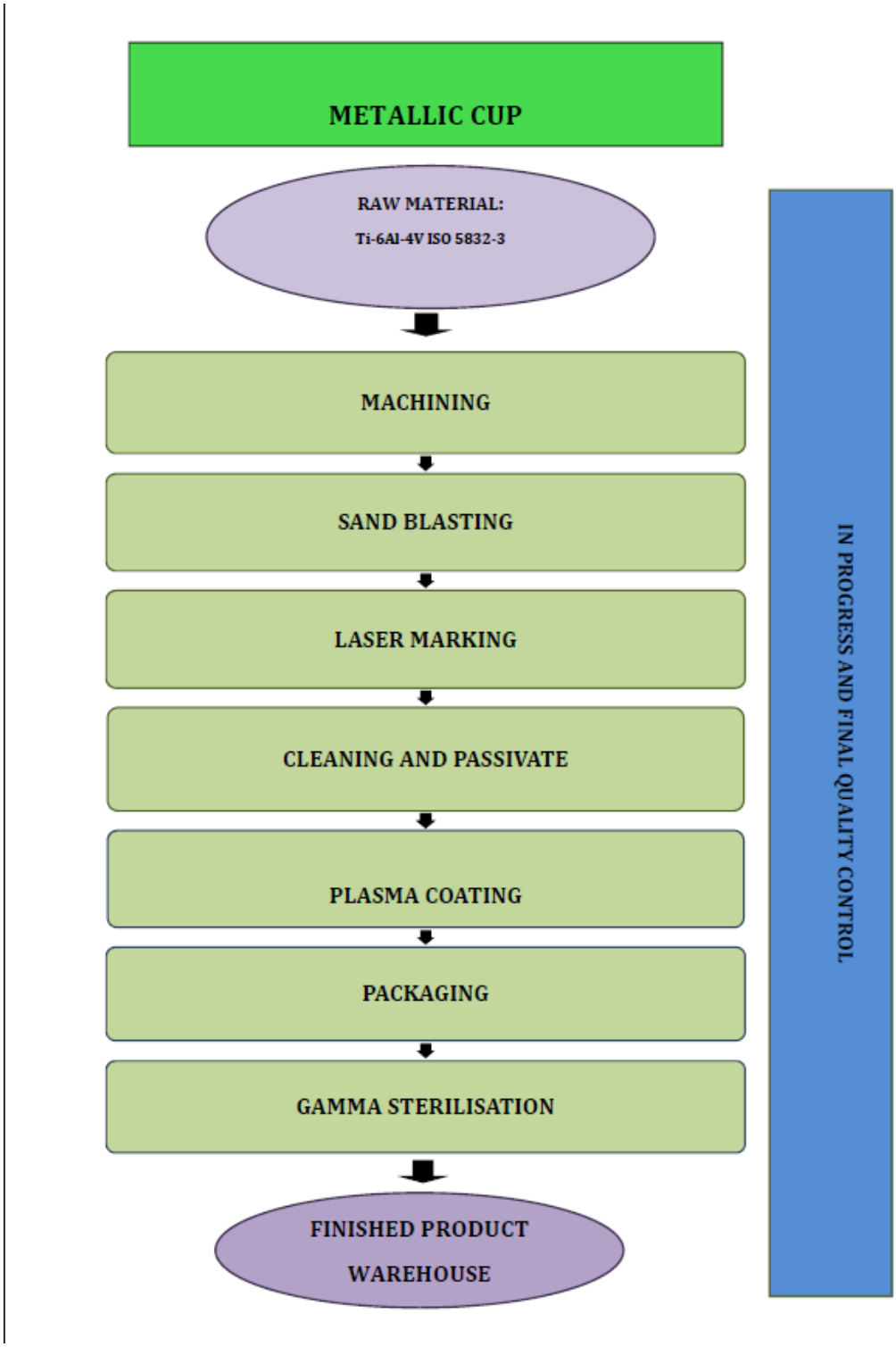
7. MANUFACTURING FLOWCHART

QUARTER CUP



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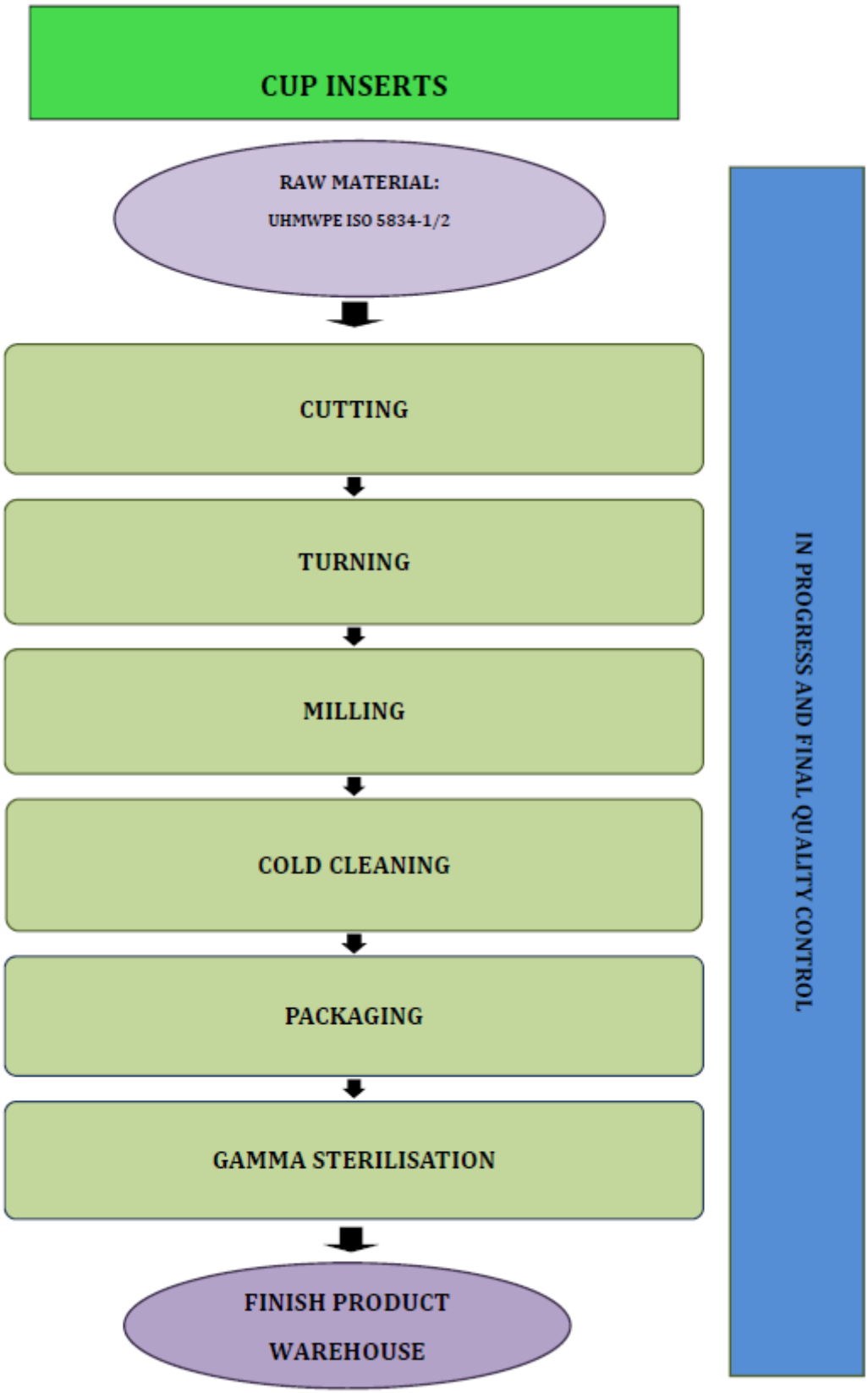
INSERT FOR QUARTER CUP



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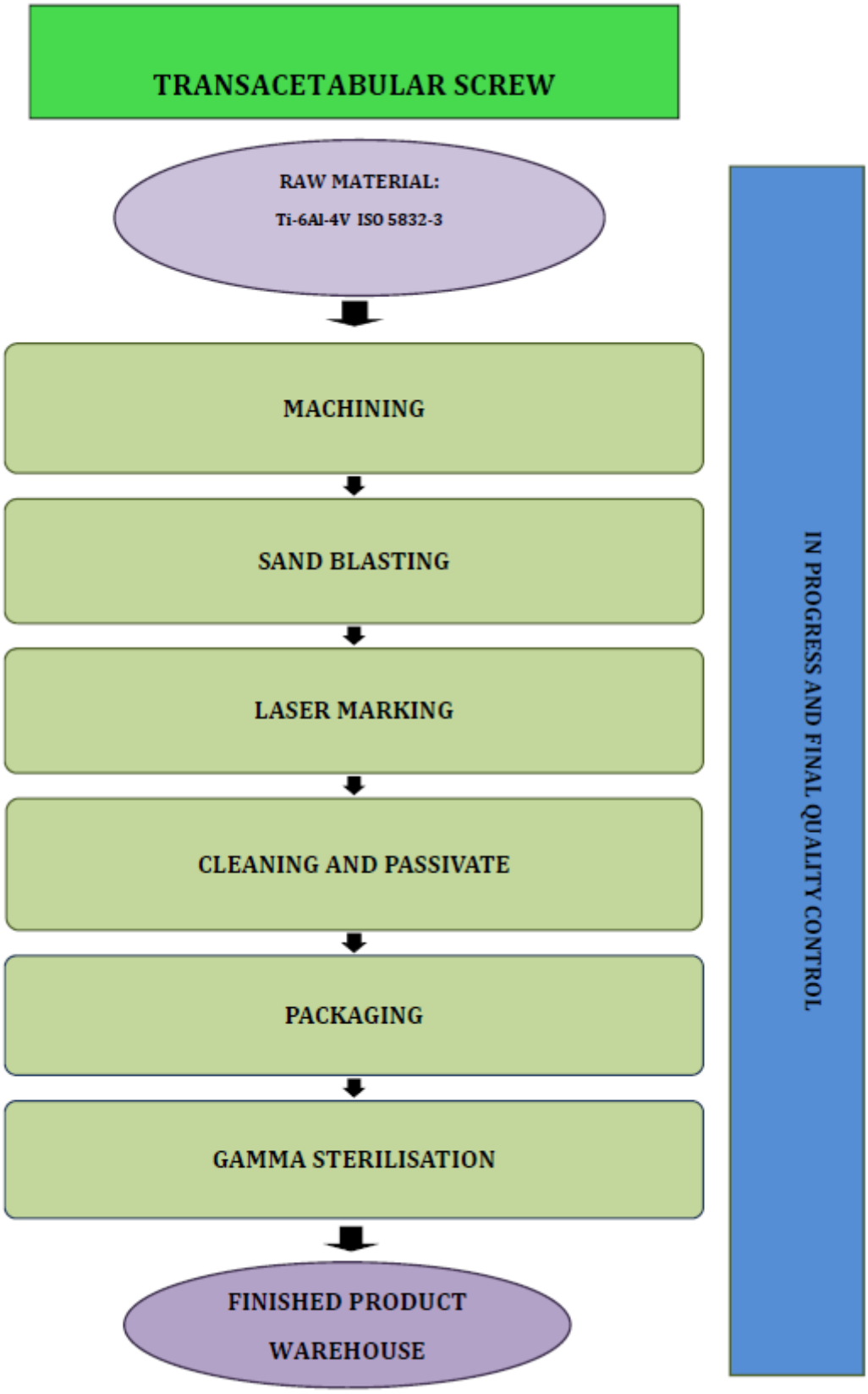
TRANSACETABULAR SCREW FOR QUARTER CUP



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During the production process, operators verify the parts they are manufacturing according to the specific manufacturing control guidelines (PR-SU-IE-06).

The processes used to manufacture the products are controlled according to the specific process control procedure (PE-SU-CP-01).

Before the product is cleaned, packaged and sterilized, 100% of the parts of the batch are subject to final inspection according to the specific inspection and test procedure (PE-SU-IE-01).

The facilities and controls used for the manufacture, processing, packaging, labeling and storage of the device are defined in the corresponding manufacturing routes according to the production planning procedure (PE-SU-PP-01).

During the different manufacturing processes, the environment must be kept clean to reduce contamination of the components according to the Hygiene Requirements procedure. Maintenance and use of the Clean Room. (PE-SU-RH-01).

8. VALIDATION OF THE STERILIZATION PROCESS

SURGIVAL Cotilo Quarter components are supplied separately in the condition of STERILE. The method of sterilization is by Gamma Radiation using a source of Cobalt 60. This method radiates a dose between 28.60-37.99 kGy for Ultra High Molecular Weight Polyethylene (UHMWPE) and between 29.16-36.99 kGy for metal implants, to ensure a level of sterility of 10-6. The sterilization deadline for each product is indicated on the label.

The gamma radiation sterilization process applied by Surgival Co S.A.U follows the guidelines of the UNE-EN ISO 11137-1 standard “Sterilization of products for healthcare. Radiation. Part 1. Requirements for the development, validation and routine control of a sterilization process for medical devices” and 11137-2 “Sterilization of products for healthcare. Radiation. Part 2. Establishment of the sterilization dose”. In addition, it is periodically reviewed and revalidated, in accordance with the specific procedure PE-SU-VD-01 “Verification of the sterilizing dose and validation of the Gamma radiation sterilization process”.

9. DESCRIPTION OF THE PACKING SYSTEM

The Packaging System, formed by a Preformed Sterile Barrier System (Blister PET G + Tyvek foil) and a Protective Container (cardboard), of this terminal 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 the point of use or until the expiration date.
4. Proper Assembly of the Packaging System.

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5. Allows aseptic presentation.

6. Provides a suitable microbial barrier.

7. Its compatibility with the labeling system.

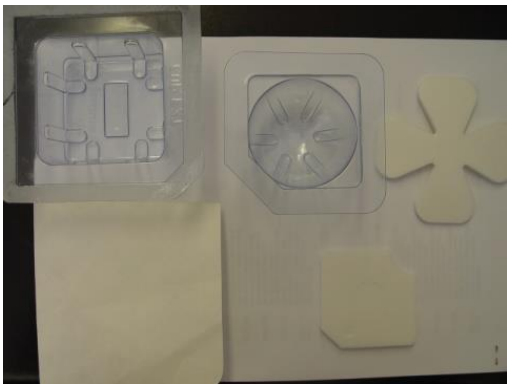
8. Its Labeling facilitates the identification of the product, its traceability, manufacturing material.

9. Its Labeling facilitates the identification of the product, its traceability, manufacturing material.

The components of the Quarter Acetabular System are supplied separately.

PACKAGING DESCRIPTION: QUARTER CUP

Primary container



Components of the primary container of the Quarter cup

It is composed of a sterile barrier system formed by a set of double blister thermoforming made from PET G sheets, which fit inside each other, each of them heat sealed to a Tyvek® sheet. For greater protection and support of the prosthesis inside the blister, low density polyethylene sponges are introduced. For the protection of the polar hole plug that is supplied disassembled with the cup, a PAPE peeling bag is also used.

Secondary container

Once the outer blister has been sealed and identified with the corresponding label, the blister is inserted into the Surgival box.

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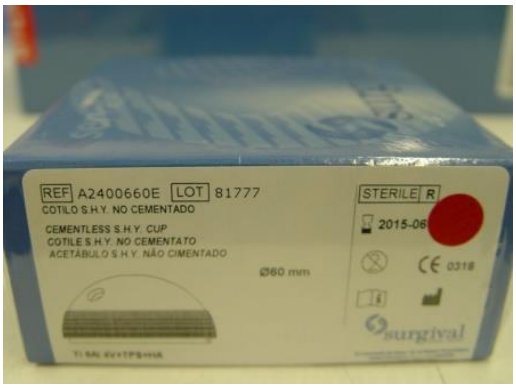

Surgival cardboard box

Finally, the cardboard box is protected with a retractable polypropylene film whose function will be to protect the sterile barrier system from possible mechanical damage caused during normal handling, storage and transfer of the product.

PACKAGING DESCRIPTION: INSERT FOR QUARTER CUP

Primary container

Components of the primary container of the Quarter Cup Insert

It is composed of a sterile barrier system with a double peeling bag, one made of polyamide and another made of polyethylene which is heat sealed and vacuum is made.

Quarter cup insert inside the bag

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Secondary container

The secondary packaging provided will be a cardboard box and shrink film whose function will be to protect the sterile barrier system from possible mechanical damage caused during normal handling, storage and transfer of the producto.

Surgival cardboard box

PACKAGING DESCRIPTION: SCREWS

Primary container

It is composed of a sterile barrier system with a double peeling bag, one made of polyamide and another made of polyethylene which is heat sealed and vacuum is made.

Each of these bags is considered as a preformed, partially assembled sterile barrier system, since the bags are received sealed at all ends except for one that will serve to introduce the product and that once done this will be sealed until the moment of its use. This sterile barrier system is commonly known as a peeling bag.

Secondary container

The secondary packaging provided will be a cardboard box and shrink film, whose function will be to protect the sterile barrier system from possible mechanical damage caused during normal handling, storage and transfer of the product.

The entire packaging process of SURGIVAL products is carried out in a clean room in accordance with ISO 14644 “Clean rooms and attached rooms”.

All necessary precautions, restrictions and warnings on the use of this product, have been reflected in its Instructions for Use, which are included inside the box of each prosthesis.

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10. LABELING AND INSTRUCTIONS FOR USE

Below is an example of labeling:

Labels attached to the outer packaging or secondary packaging.

Label attached to the primary container or double bag / blister

Tags for hospital use

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Labels attached to the outer packaging or secondary packaging.

Label attached to the primary container or double bag / blister

Tags for hospital use

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Labels attached to the outer packaging or secondary packaging.

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Tags for hospital use

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The labeling contains the following information:

- Reference
- Lot / lot number
- Product name in four languages (Spanish, English, Portuguese, Italian)
- Product image
- Dimensions
- Material
- Manufacturer: Name, address ...
- Date of Expiry
- CE marking and notified body number.
- Sterilization method.
- Symbology of storage and conservation according to ISO 15223-1 Medical devices. Symbols that will be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements.
- Safe use of the symbology according to ISO 15223-1 Medical devices. Symbols that will be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements.

Annex 2 includes the labels of all references to which of the Quarter cup and the inserts of the cup (antiluxante and neutral).

Instructions for use are included in **Annex 3.**

11. POSTMARKET CLINICAL FOLLOW UP: PMS AND PMCF

To address this point, Surgival carries out the PMS and PMCF, specific to the product and aims to actively and continuously update its corresponding clinical evaluation, by obtaining new clinical information while using the device.

PMS SURVEILLANCE PLAN

The treatment and implementation of the information that must be collected, managed and analyzed in the Plan, as well as the responsibilities implicit in it, are addressed with the following internal procedures:

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Post-Marketing Monitoring Plan	Applied Procedures
Product incidents.	PE-SU-AS-01
Claims or Customer Complaints.	PE-SU-NC-01
Comments from unsolicited users not managed as complaints.	PE-SU-NC-01
Sales reports.	PE-SU-MAM-01
Results of customer satisfaction surveys.	PE-SU-SC-01
Implementation records. Implementation Cards.	PE-SU-IT-01
Incident database reviews (MAUDE).	Search Protocol
Post-marketing clinical follow-up.	PE-SU-ECL-01

Once all the points have been analyzed, an annual results report is prepared that is part of the Annual Review by the Management and contains a favorable or unfavorable opinion of the product.

The **favorable report** confirms that the results of these Clinical Data obtained are consistent and within the provisions of the Risk Analysis, residual risks, leaflet or instructions for use and labeling of the corresponding product.

Likewise, the **unfavorable report** confirms that the results of these Clinical Data obtained are not consistent or within the provisions of the Risk Analysis of the corresponding product. Therefore, it will be capable of being modified, so that the Risk Analysis management is carried out continuously while said product is marketed.

Therefore, it is important to bear in mind that if after this review the residual risks, these are modified, it should be analyzed and recorded in this report the scope of the situation and the decisions taken regarding:

1. A new leaflet or instructions for use must be generated.
2. You have to modify some manufacturing process.
3. The product design has to be modified.
4. The product certifying Notified Body must be notified.

PMCF SURVEILLANCE PLAN

Surgival carries out a post-marketing clinical follow-up plan (PMCF) to evaluate the safety and efficacy of its products.

This surveillance plan has defined the following aspects:

1. Objective

2. Design: Design of a study appropriate to the objectives to be met -

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The plan must address and justify these aspects as a minimum:

- The purpose of the study.
- The study population.
- Inclusion / exclusion criteria in the study
- Justification for the design of the chosen study.
- Selection of sites and researchers.
- Clinical protocol to be reviewed in patients taking into account residual risks.
- The number of subjects involved.
- Statistical study sales and number of cases.
- The duration of patient follow-up taking into account the minimum life span.
- The specific data to be collected, CRD data collection notebook.
- Quality control methods of the data collected.

3. Implementation of the PMCF Plan: It will be defined how said plan will be executed to obtain the clinical data and its interpretation

Below is a table that specifies the strategy at this point in the plan based on product risk:

Risk	Product Subcategories	Clinical follow-up strategy
Risk III	Joint replacements	Seguimiento por cada uno de los productos. CRD específico/Base Datos
Risk IIb	Partial Prosthesis	Seguimiento por cada uno de los productos. CRD específico/Base Datos
	Osteosynthesis	Seguimiento por producto Tipo de cada uno de los grupos de productos genéricos. CRD
Risk IIa	Reusable test instrument	Implante indirecto sobre el que se ejerce su función
	Motor instrumental	
Risk I	General instrumental	

The review, analysis and conclusions of the clinical data collected, in effectiveness and safety, through the different data collection notebooks will be reflected in a report by each of the reference centers defined in the plan and must be signed and dated by the researcher assigned in said specific plan.

With the conclusions of this report, possible adverse effects and their causes, immediate or long-term, may be reviewed, in addition to the indications for which the products are prescribed and their effectiveness. This way, it is verified whether the products are safe, and whether they get the operation and the benefits provided in the normal conditions of use.

The information obtained should serve as input to the review of the Risk Analysis of the corresponding product, specifically of the residual risks that resulted. In this way, the management of the Risk Analysis of the products is carried out continuously while said product is marketed.

Therefore, it is important to keep in mind that if after this review the residual risks are modified, the scope of the situation should be analyzed from these perspectives:

- A new leaflet or instructions for use must be generated.

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- You have to modify some manufacturing process.
- The product design has to be modified.

In addition, such actions must be communicated to the Notified Body.

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