GENUTECH KNEE SYSTEM

1. MEDICAL DEVICE TYPE

According to Directive 93/42/CE, it is classified as class III because it is a long term, implantable, surgical invasive medical device.

2. GENERAL PRODUCT DESCRIPTION. DESIGN RATIONALE

a) Femoral Componentl

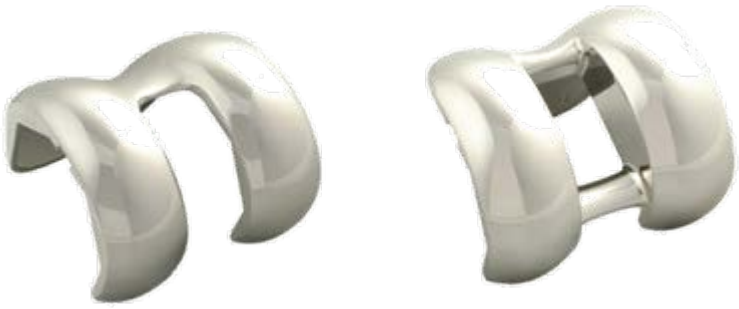
There are 3 types of femoral component available for primary surgery:

- with preservation of the posterior cruciate ligament and that we will call from here on (NPS),
- posterior stabilized for the sacrifice of the posterior cruciate (PS)
- revision constrained component (REV).

	Sizes	Anatomic	USE
PS Femoral Component	1/2/3/4/5	Right /Left	Non-preservation of the Posterior Cruciate Ligament
NPS Femoral Component	1/2/3/4/5	Right /Left	Preservation of the Posterior Cruciate Ligament
REV Femoral Component	1/2/3/4	Right /Left	For primary and revision surgeries

The material used for the femoral component is Co-Cr and it is manufactured by casting. This choice is based on the minimization of wear, since Cr-Co is the metallic material with the highest hardness and lowest roughness applicable to implantable products.

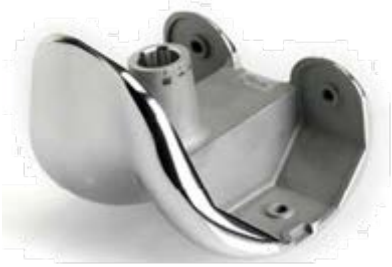
The geometry of the condylar area will be convex in the sagittal and frontal planes. Said geometry articulated against the surface of the concave polyethylene insert in the sagittal and frontal planes constitutes a congruent contact that increases the contact area and minimizes the local stresses that occur when the prosthesis undergoes lateral lifting.



There are 5 sizes available for the different Femoral Components (PS, NPS) (between 55 and 75 mm), while for Revision Femoral Components (REV) 4 sizes are considered (between 55 and 70).

Fixation will be cemented and uncemented. The femoral component is the same, keeping in the cemented components a space for the lodging of the sufficient cement, by means of a recess in the cementation area. Said recess will be filled in the non-cemented components by means of porous or microporous material and coating with hydroxyapatite.

The Revision femoral component also has the incorporation of 2 Ti6Al4V stems that will allow a better anchoring of the component. The selection of this material for the stems lies in the greater elasticity of Titanium compared to cobalt chrome. In this way, the stresses at the tip of the stem that cause the tip effect are minimized.



The stems have a cylindrical geometry (without sharp edges and with longitudinal grooves that reduce the stiffness of the stem). They have three lengths (70, 120, 200 mm).

The femoral components are anatomical, with left and right models available to prevent the prosthesis from being blown off as currently occurs in symmetrical systems and, in the case of Revision Femoral Components, to prevent the femoral component from being blown off in its anterior support, Offset Stems are available that will allow the femoral component to be lowered, seeking support on the anterior cut of the femur.

The Tibial Insert is made of ultra-high molecular weight polyethylene (UHMWPE) that will constitute the joint surface (metal back type since it will rest on the tibial tray). Will articulate on the femoral component

In turn, the tibial insert is mounted on the tibial tray by means of a pressure union. The anchoring system is the same for all sizes so that there will be interchangeability between all sizes of the plastic insert (which will always coincide with those of the femoral component) and all sizes of the metal tray

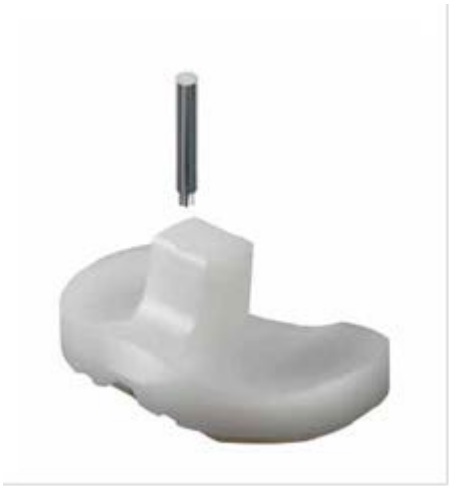
b) Tibial Insert

There are 3 models of polyethylene inserts (for PS, NPS, REV). In turn, each size has a certain number of thicknesses.

	Sizes	Thickness (mm)	Use
UHMWPE Tibial Insert PS	1/2/3/4/5	10/12/14/16/18/20	Non-preservation of the Posterior Cruciate Ligament
UHMWPE Tibial Insert NPS	1/2/3/4/5	10/12/14/16	Preservation of the Posterior Cruciate Ligament
UHMWPE Tibial Insert REV	1/2/3/4	10/12/14/16/18/20/22/24	For primary and revision surgeries

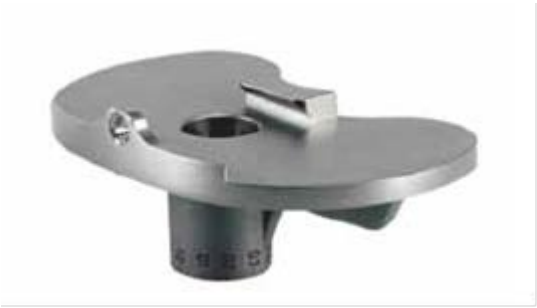
The geometry of the condylar area is convex in the sagittal and frontal planes. Said geometry articulated against the surface of the convex femoral component in the sagittal and frontal planes constitutes a congruent contact that increases the contact area and minimizes the local stresses that occur when the prosthesis undergoes lateral lifting.

5 sizes will be considered for the different Tibial Inserts (PS, NPS) (between 55 and 75 mm), while for the Revision Tibial Inserts (REV) 4 sizes (between 55 and 70) will be considered.



c) Tibial tray

The Tibial tray is made of Titanium alloy (Ti6Al4V) and will support the Tibial Insert. Its function will be to provide a stable settlement on the tibia in order to transmit the compressive forces to the lower extremities.



The tibial tray has a lodging and pressure capture system for the tibial insert. It also has a locking bolt that will prevent any possible detachment of the insert from the tray.

The tibial tray will come in its standard format with a 15mm plug. long anchored on its post. This stem can be replaced in primary by another 25 mm plug. if the surgeon deems it appropriate.

For the revision tray, instead of plugs, straight or offset stems will be used.

5 sizes of the metal tray will be considered for PS, NPS and Revision models

These 5 sizes will be used for the different Tibial Inserts (PS, NPS and Revision) with dimensions

between 60 and 80 mm. mid-lateral distance and 43 to 53 mm. anterior-posterior distance.

	Sizes	Use
Bandeja Tibial Metálica	1/2/3/4/5	For PS, NPS or Revisión surgery

d) Patella

The patella is made of ultra-high molecular weight polyethylene (UHMWPE) which will constitute the femoro-patellar joint surface. Will articulate on the femoral component

This component has the function of replacing part of the patella that articulates on the patellar canal carved on the femoral component. The purpose will be to provide stability on the rodilla originada por las estructuras tendinosas y ligamentosas del tensor rotuliano.
Dispone de un único poste para su anclaje y con el fin de evitar la rotación del mismo se le practicarán 2 fresadas laterales al mismo.

There is 1 model of polyethylene PATELA (for PS, NPS, REV), with various thicknesses

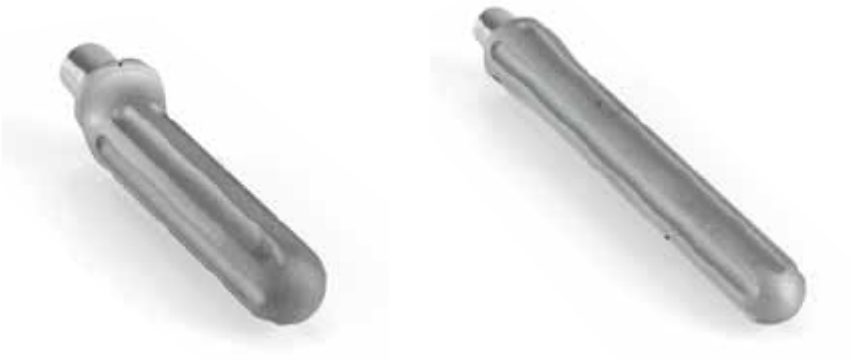
	Sizes (Ø)	Espesores (mm)
PATELLA	32/34/36/38/40	7/8/9/10/11

e) Stems

The stem design is common for tibial trays and revision femoral components.

There are two types of stem: straight stems and offset stems.

Offset stems offer greater intraoperative flexibility in revision surgeries, since they allow a better adaptation to the anthropometric needs of the patient. These offset stems allow us a shaft offset of 4.5 mm. on the position of the diaphyseal axis of the femoral component by rotating it. Therefore, in cases in which the anterior surface of the femoral component does not provide adequate support or is totally or partially cantilevered, we can ensure its support.



This point is of special relevance in comparison with other knee replacement systems, since, being adaptive, it allows us to perform anterior bone resections to clean up a possible unstable bone, ensuring that the anterior support of the femoral component is carried out on “healthy” bone. It also allows us to adapt the component to any bone defect created during the extraction of a primary prosthesis, and even to vary medio-laterally the position of the femoral component by ±4.5 mm. to center it on the joint.

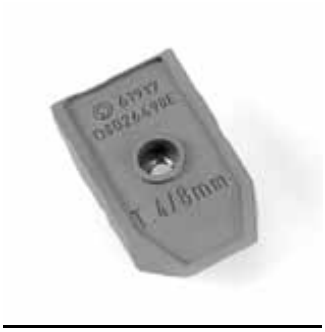
These two stem designs come in three possible lengths: 70, 120 and 200mm. and with 6 possible diameters: 10, 12, 14, 16, 18 and 20 mm. They will be manufactured in Ti6Al4V.

The stems are fixed on the components by means of a Morse-type taper and a screw that threads the end of the stem, inside the cone.

f) Augmentation blocks

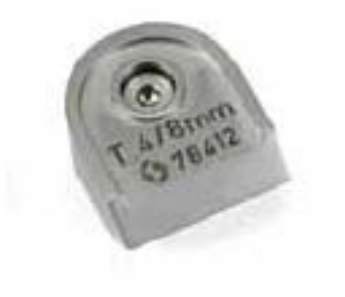
Femoral distal:

There are 5 different sizes for PS femoral components and 4 sizes for REV components, each one corresponding to the corresponding femoral component size. The design is symmetrical and serves the medial and lateral condyles indifferently. There are 3 possible thicknesses: 4, 8 and 12 mm. Manufactured in Ti6Al4V.



Femoral posterior:

As in the distal ones, there are 5 sizes for the PS femoral components and 4 sizes for the REV components, each one being combined with the same size of femoral component. The design is symmetrical and the thicknesses are 4mm. and 8 mm Made of Ti6Al4V.

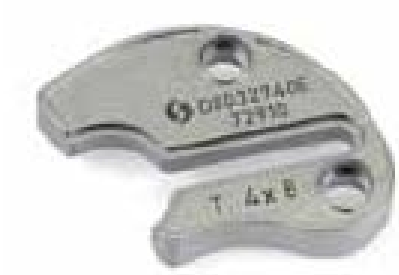


Only the REV and PS versions of the femoral components can be fitted with augmentation blocks. Both the distal and posterior augmentation blocks are fixed to the femoral component using a Titanium screw.

Tibial:

There are 5 sizes of tibial augmentation blocks with thicknesses of 8 mm and 12 mm. Each size matches the same size of tibial tray. The blocks are reversible and can be used on both the medial and lateral sides of each endplate.

They are fixed to the tray using M4 mm screws. normal pitch and thread length 7 mm. The head has the same characteristics as the screws used in femoral augmentation blocks. Made of Ti6Al4V.



2.1 Main features. Design attributes.

2.1.1 Femoral Component

El componente femoral esta diseñado para proporcionar unas características articulares óptimas mostrando una máxima congruencia con el Inserto Tibial. Las tolerancias geométricas establecidas para este componente se establecerá en 0,05 mm. siendo esta una característica muy restrictiva y compleja de obtener en componentes articulares condilares. No existe recomendación en la ISO 7207-2.

La rugosidad recomendada para este tipo de componentes en las zonas articulantes, según la ISO 7207-2 no deberá ser superior a 0,1 µm, Nuestro componente dispone de una rugosidad Ra no mayor de 0,05 µm.

La rugosidad de estos componentes en las zonas no articulantes está establecida según ISO 21536:2007 en Ra 1,5 µm,

La selección del Cr-Co (acorde a ISO 5832-4) un material de una alta dureza y unas prestaciones mecánicas muy elevadas garantizan un comportamiento dentro de lo esperado para este tipo de articulaciones. Este material se encuentra encontrado adecuado según la norma ISO 21534. como material para superficies articulantes de implantes “Aleaciones para moldeo de Cobalto-Cromo-molibdeno (ISO 5832-4)/UHMWPE (ISO 5834-1, ISO5834-2).

El componente femoral dispone de unas características geométricas para la fijación sobre el hueso, que facilitarán su anclaje de manera permanente.

Dispone de componentes cementados y no cementados. Los cementados disponen de una geometría rebajada en el interior que permita la deposición del cemento al implante y genere una interfase apropiada. Los no cementados disponen de este mismo rebaje pero será recubierto con plasma spray de Titanio e Hidroxiapatita.

2.1.2 Tibial Insert

The Tibial Insert is designed to provide optimal joint characteristics showing maximum congruence with the Tibial Insert. The geometric tolerances set for this component are set to 0.1mm. this being a very restrictive and complex characteristic to obtain in polyethylene condylar joint components. There is no recommendation in ISO 7207-2.

• The recommended roughness for this type of components in the articulating areas, according to ISO 7207-2, should not be greater than 2 µm. Our component has a roughness Ra of no greater than 1.5 µm.

• UHWMPE Polyethylene 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. This material is found suitable according to the ISO 21534 standard as a material for articulating surfaces of implants with Cobalt-Chromium-molybdenum (ISO 5832-4) / UHMWPE (ISO 5834-1, ISO5834-2) molding alloys.

• The Tibial Insert has some geometric characteristics for fixation on the tibial tray, which will facilitate its permanent anchoring.

• The femoral component has a finish obtained after machining with a very low roughness in order to minimize the surface wear that originates between the femur and tibia.

• UHMWPE Tibial Inserts have a minimum thickness of 6 mm. since our system mounts on a tibial tray, in compliance with the ISO 21536 standard.

2.1.3 Tibial tray

• It has a clipping fixation system between the tibial tray and the tibial insert. This system provides a reliable anchorage to the system.

• According to the nomenclature identified in the ISO 7207-1 standard. Antero-posterior (m) and mid-lateral (n) dimensions are defined to define the range of products, in addition, the height of the post-keel (lt), its diameter (Kt) and the thickness of the tray (h).

• Titanium (ISO 5832-3) is a biocompatible metal, because the body's tissues tolerate its presence without allergic reactions of the immune system have been observed. This material is found suitable according to ISO 21534 for use with UHMWPE Polyethylene (ISO 5834-2).

2.1.4 Patella

• The Patella is designed to provide optimal joint characteristics showing maximum congruence with the femoral component. The geometric tolerances set for this component will be set to 0.1mm. this being a very restrictive and complex characteristic to obtain in polyethylene condylar joint components. There is no recommendation in ISO 7207-2.

• The recommended roughness for this type of components in the articulating areas, according to ISO 7207-2, should not be greater than 2 µm. Our component has a roughness Ra of no greater than 1.5 µm.

• UHWMPE Polyethylene 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. This material is suitable according to ISO 21534. as a material for articulating surfaces of implants with Cobalt-Chromium-molybdenum (ISO 5832-4) / UHMWPE (ISO 5834-1, ISO5834-2) molding alloys.

2.1.5 Stems

• The system has a morse taper for fixation with the tibial and femoral tray, its angulation is 6º.

• Offset stems have an offset of 4.5 mm with respect to the diaphyseal axis.

• Titanium (ISO 5832-3) is a biocompatible metal, because the body's tissues tolerate its presence without allergic reactions of the immune system have been observed. This material is found suitable according to the ISO 21534 standard for use as a surgical implant, and can also be combined with Co-Cr (ISO 5832-4) in non-articulating conditions.

2.1.6 Augmentation blocks

• Titanium (ISO 5832-3) is a biocompatible metal, because the body's tissues tolerate its presence without allergic reactions of the immune system have been observed. This material is found suitable according to ISO 21534 for use in surgical implants.

• The femoral supplements have a geometry adaptable to the PS and Revision femoral components. They also have various thicknesses (Distal: 4mm. 8mm. and 12mm and Posterior: 4mm. and 8mm)

• The tibial supplements have a geometry adaptable to the tibial trays. They have thicknesses of 8 mm. and 12mm

• The metallic reinforcement for polyethylene Tibial Inserts in Review, has various lengths, adapting to the increase in thickness in polyethylene, which will vary from 34 mm. up to 48mm.

3. LIFESPAN:

The lifespan of this prosthesis 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 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.

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

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 at the time.

4. PRODUCT RANGE. VARIANTS.

4.1. Femoral Components

Implantes Implants

Componentes femorales NPS sin cemento NPS cementless femoral components			Componentes femorales PS sin cemento* PS cementless femoral components*			Componentes femorales NPS con cemento NPS cemented femoral components			Componentes femorales PS con cemento PS cemented femoral components		
Izquierdo Left	Talla Size	Derecho Right	Izquierdo Left	Talla Size	Derecho Right	Izquierdo Left	Talla Size	Derecho Right	Izquierdo Left	Talla Size	Derecho Right
Ref. D8011120E	1	Ref. D8011110E	Ref. D8012120E	1	Ref. D8012110E	Ref. D8021120E	1	Ref. D8021110E	Ref. D8022120E	1	Ref. D8022110E
Ref. D8011220E	2	Ref. D8011210E	Ref. D8012220E	2	Ref. D8012210E	Ref. D8021220E	2	Ref. D8021210E	Ref. D8022220E	2	Ref. D8022210E
Ref. D8011320E	3	Ref. D8011310E	Ref. D8012320E	3	Ref. D8012310E	Ref. D8021320E	3	Ref. D8021310E	Ref. D8022320E	3	Ref. D8022310E
Ref. D8011420E	4	Ref. D8011410E	Ref. D8012420E	4	Ref. D8012410E	Ref. D8021420E	4	Ref. D8021410E	Ref. D8022420E	4	Ref. D8022410E
Ref. D8011520E	5	Ref. D8011510E	Ref. D8012520E	5	Ref. D8012510E	Ref. D8021520E	5	Ref. D8021510E	Ref. D8022520E	5	Ref. D8022510E

(*) Estos componentes se fabrican bajo solicitud. Consultar con **Surgival**.
(*) These components are manufactured on order. Contact **Surgival**.

Componente femoral de revisión cementado	
Ref. D8023110E	Derecho Talla 1
Ref. D8023210E	Derecho Talla 2
Ref. D8023310E	Derecho Talla 3
Ref. D8023410E	Derecho Talla 4
Ref. D8023120E	Izquierdo Talla 1
Ref. D8023220E	Izquierdo Talla 2
Ref. D8023320E	Izquierdo Talla 3
Ref. D8023420E	Izquierdo Talla 4

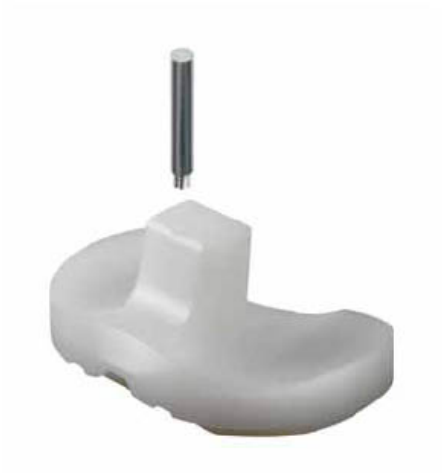
4.2. Tibial Inserts

Insertos tibiales NPS
NPS tibial inserts

Ref. D8041100E	T.S. 1 x 10 mm	Ref. D8043140E	T.S. 3 x 14 mm	Ref. D8051100E	T.S. 1 x 10 mm	Ref. D8052180E	T.S. 2 x 18 mm
Ref. D8041120E	T.S. 1 x 12 mm	Ref. D8043160E	T.S. 3 x 16 mm	Ref. D8051120E	T.S. 1 x 12 mm	Ref. D8052200E	T.S. 2 x 20 mm
Ref. D8041140E	T.S. 1 x 14 mm	Ref. D8044100E	T.S. 4 x 10 mm	Ref. D8051140E	T.S. 1 x 14 mm	Ref. D8053100E	T.S. 3 x 10 mm
Ref. D8041160E	T.S. 1 x 16 mm	Ref. D8044120E	T.S. 4 x 12 mm	Ref. D8051160E	T.S. 1 x 16 mm	Ref. D8053120E	T.S. 3 x 12 mm
Ref. D8042100E	T.S. 2 x 10 mm	Ref. D8044140E	T.S. 4 x 14 mm	Ref. D8051180E	T.S. 1 x 18 mm	Ref. D8053140E	T.S. 3 x 14 mm
Ref. D8042120E	T.S. 2 x 12 mm	Ref. D8044160E	T.S. 4 x 16 mm	Ref. D8051200E	T.S. 1 x 20 mm	Ref. D8053160E	T.S. 3 x 16 mm
Ref. D8042140E	T.S. 2 x 14 mm	Ref. D8045100E	T.S. 5 x 10 mm	Ref. D8052100E	T.S. 2 x 10 mm	Ref. D8053180E	T.S. 3 x 18 mm
Ref. D8042160E	T.S. 2 x 16 mm	Ref. D8045120E	T.S. 5 x 12 mm	Ref. D8052120E	T.S. 2 x 12 mm	Ref. D8053200E	T.S. 3 x 20 mm
Ref. D8043100E	T.S. 3 x 10 mm	Ref. D8045140E	T.S. 5 x 14 mm	Ref. D8052140E	T.S. 2 x 14 mm	Ref. D8054100E	T.S. 4 x 10 mm
Ref. D8043120E	T.S. 3 x 12 mm	Ref. D8045160E	T.S. 5 x 16 mm	Ref. D8052160E	T.S. 2 x 16 mm	Ref. D8054120E	T.S. 4 x 12 mm

Insertos tibiales PS
PS tibial inserts

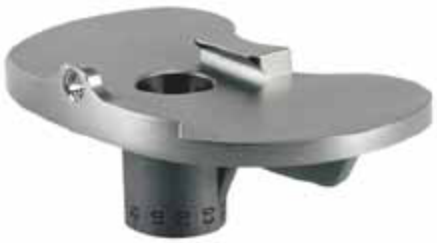
Ref. D8054140E	T.S. 4 x 14 mm		
Ref. D8054160E	T.S. 4 x 16 mm		
Ref. D8054180E	T.S. 4 x 18 mm		
Ref. D8054200E	T.S. 4 x 20 mm		
Ref. D8055100E	T.S. 5 x 10 mm		
Ref. D8055120E	T.S. 5 x 12 mm		
Ref. D8055140E	T.S. 5 x 14 mm		
Ref. D8055160E	T.S. 5 x 16 mm		
Ref. D8055180E	T.S. 5 x 18 mm		
Ref. D8055200E	T.S. 5 x 20 mm		



Inserto tibial implante de revisión		Longitud			Longitud
Ref. D8061100E	Talla 1	10 mm	Ref. D8063180E	Talla 3	18 mm
Ref. D8061120E	Talla 1	12 mm	Ref. D8063200E	Talla 3	20 mm
Ref. D8061140E	Talla 1	14 mm	Ref. D8063220E	Talla 3	22 mm
Ref. D8061160E	Talla 1	16 mm	Ref. D8063240E	Talla 3	24 mm
Ref. D8061180E	Talla 1	18 mm	Ref. D8064100E	Talla 4	10 mm
Ref. D8061200E	Talla 1	20 mm	Ref. D8064120E	Talla 4	12 mm
Ref. D8061220E	Talla 1	22 mm	Ref. D8064140E	Talla 4	14 mm
Ref. D8061240E	Talla 1	24 mm	Ref. D8064160E	Talla 4	16 mm
Ref. D8062100E	Talla 2	10 mm	Ref. D8064180E	Talla 4	18 mm
Ref. D8062120E	Talla 2	12 mm	Ref. D8064200E	Talla 4	20 mm
Ref. D8062140E	Talla 2	14 mm	Ref. D8064220E	Talla 4	22 mm
Ref. D8062160E	Talla 2	16 mm	Ref. D8064240E	Talla 4	24 mm
Ref. D8062180E	Talla 2	18 mm			
Ref. D8062200E	Talla 2	20 mm			
Ref. D8062220E	Talla 2	22 mm			
Ref. D8062240E	Talla 2	24 mm			
Ref. D8063100E	Talla 3	10 mm			
Ref. D8063120E	Talla 3	12 mm			
Ref. D8063140E	Talla 3	14 mm			
Ref. D8063160E	Talla 3	16 mm			

4.3. Tibial tray

Bandejas tibiales Tibial trays	
Ref. D8032100E	Talla Size 1
Ref. D8032200E	Talla Size 2
Ref. D8032300E	Talla Size 3
Ref. D8032400E	Talla Size 4
Ref. D8032500E	Talla Size 5
Ref. D8220540E	Perno de fijación Fixation bolt

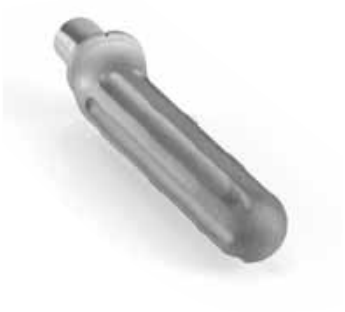


Bandejas tibiales de revisión	
Ref. D8033100E	Talla 1
Ref. D8033200E	Talla 2
Ref. D8033300E	Talla 3
Ref. D8033400E	Talla 4
Ref. D8033500E	Talla 5

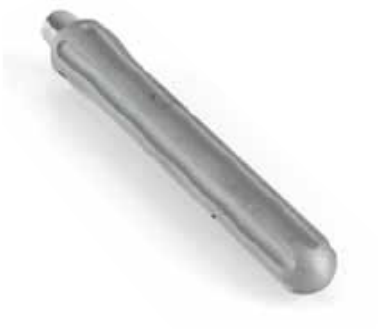
4.4. Patella

Patela	Diámetro
Ref. D8030140	∅ 32 mm
Ref. D8030150	∅ 34 mm
Ref. D8030160	∅ 36 mm
Ref. D8030170	∅ 38 mm
Ref. D8030180	∅ 40mm

4.5. Stems



Vástagos offset 4,5 mm de revisión	Diámetro	Longitud		Diámetro	Longitud
Ref. D8024101E	Ø 10 mm	70 mm	Ref. D8024401E	Ø 16 mm	70 mm
Ref. D8024102E	Ø 10 mm	120 mm	Ref. D8024402E	Ø 16 mm	120 mm
Ref. D8024103E	Ø 10 mm	200 mm	Ref. D8024403E	Ø 16 mm	200 mm
Ref. D8024201E	Ø 12 mm	70 mm	Ref. D8024501E	Ø 18 mm	70 mm
Ref. D8024202E	Ø 12 mm	120 mm	Ref. D8024502E	Ø 18 mm	120 mm
Ref. D8024203E	Ø 12 mm	200 mm	Ref. D8024503E	Ø 18 mm	200 mm
Ref. D8024301E	Ø 14 mm	70 mm	Ref. D8024601E	Ø 20 mm	70 mm
Ref. D8024302E	Ø 14 mm	120 mm	Ref. D8024602E	Ø 20 mm	120 mm
Ref. D8024303E	Ø 14 mm	200 mm			



Vástagos rectos de revisión	Diámetro	Longitud		Diámetro	Longitud
Ref. D8025101E	Ø 10 mm	70 mm	Ref. D8025401E	Ø 16 mm	70 mm
Ref. D8025102E	Ø 10 mm	120 mm	Ref. D8025402E	Ø 16 mm	120 mm
Ref. D8025103E	Ø 10 mm	200 mm	Ref. D8025403E	Ø 16 mm	200 mm
Ref. D8025201E	Ø 12 mm	70 mm	Ref. D8025501E	Ø 18 mm	70 mm
Ref. D8025202E	Ø 12 mm	120 mm	Ref. D8025502E	Ø 18 mm	120 mm
Ref. D8025203E	Ø 12 mm	200 mm	Ref. D8025503E	Ø 18 mm	200 mm
Ref. D8025301E	Ø 14 mm	70 mm	Ref. D8025601E	Ø 20 mm	70 mm
Ref. D8025302E	Ø 14 mm	120 mm	Ref. D8025602E	Ø 20 mm	120 mm
Ref. D8025303E	Ø 14 mm	200 mm			

4.6. Augments

Suplemento femoral posterior		Longitud
Ref. D8026010E	Talla 1	4 mm
Ref. D8026015E	Talla 1	8 mm
Ref. D8026020E	Talla 2	4 mm
Ref. D8026025E	Talla 2	8 mm
Ref. D8026030E	Talla 3	4 mm
Ref. D8026035E	Talla 3	8 mm
Ref. D8026040E	Talla 4	4 mm
Ref. D8026045E	Talla 4	8 mm

Suplemento femoral distal		Longitud
Ref. D8026150E	Talla 1	4 mm
Ref. D8026190E	Talla 1	8 mm
Ref. D8026195E	Talla 1	12 mm
Ref. D8026250E	Talla 2	4 mm
Ref. D8026290E	Talla 2	8 mm
Ref. D8026295E	Talla 2	12 mm
Ref. D8026350E	Talla 3	4 mm
Ref. D8026390E	Talla 3	8 mm
Ref. D8026395E	Talla 3	12 mm
Ref. D8026450E	Talla 4	4 mm
Ref. D8026490E	Talla 4	8 mm
Ref. D8026495E	Talla 4	12 mm

Suplemento tibial		Longitud
Ref. D8032710E	Talla 1	8 mm
Ref. D8032715E	Talla 1	12 mm
Ref. D8032720E	Talla 2	8 mm
Ref. D8032725E	Talla 2	12 mm
Ref. D8032730E	Talla 3	8 mm
Ref. D8032735E	Talla 3	12 mm
Ref. D8032740E	Talla 4	8 mm
Ref. D8032745E	Talla 4	12 mm
Ref. D8032750E	Talla 5	8 mm
Ref. D8032755E	Talla 5	12 mm

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. PACKAGING

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

1. Provide physical protection and maintain the integrity of the sterile barrier system.
2. Allows sterilization and is 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.
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. 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 according to its composition: [Ti6Al4V]. Aluminum increases the transformation temperature between the alpha and beta phases. Vanadium decreases that temperature.In addition, it has high tenacity.

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, very good weldability and an electrical resistivity of 1.67 (μΩm). Its application is common wherever high mechanical resistance and high temperatures of use and lightness of material are required. This Material is considered Acceptable for the manufacture of Implants by the UNE-EN ISO 21534 standard, Annex A.

- *Poliethylene (UHMWPE) .*

UHMWPE 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.

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.

A material that allows smooth and easy machining, it also offers excellent thermal resistance, with glass transition points that allow it to easily withstand thermal sterilization processes such as Autoclave.

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".

- *Chromium-Cobalt-Molybdenum casting alloy*

Chromium-Cobalt-Molybdenum Alloy (ISO 5832-4/ ASTM F 1586-95) identified as an approved material by ISO 21534, as a Biocompatible material found suitable for joint replacements in particular with UHMWPE (ISO 5834-1, ISO5834-2).

Thanks to its high mechanical-chemical resistance performance, it has been successfully used for years in the manufacture of this type of implant, being one of the most widely used materials considered to be biocompatible and long-term implantable to date, so its functionality is sufficiently endorsed by a huge number of clinical cases of a very diverse category.

Cobalt Chrome is used in medical applications in those circumstances in which a low-friction joint contact is desired. This is melted down and remixed under vacuum to achieve the extremely high degree of purity required for temporary and permanent surgical implants. It offers excellent

resistance to tissues and physiological fluids, to intergranular corrosion and to corrosion in general.

Cr-Co has a very high resistance to corrosion due to its high Chromium content (19 - 21), hardness HRc (Rockwell) 35, Elastic Modulus of 230 GPa; Elastic limit 650 MPa; Tensile strength: 1000 MPa. 20% elongation at break.