TECHNICAL FILE FOR:

GENUTECH PRIMARY PROSTHESIS JOINT KNEE

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This Technical file has been developed by Quality Management Area of SURGIVAL Co. S.A.U

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Annexs

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Surgival Co. S.A.U. is an organization where qualified and professional ethics people design, manufacture and control products for orthopedic surgery. In **Surgival Co S.A.U** working in the line of manufacturing durable products, minimizing as far as possible corrective surgery operations and the risks that are associated with these interventions. The safety and functional efficacy of our products is a fundamental aspect, and it is taken into account from the earliest stages of design and manufacturing to the end of product life, identifying, assessing, reducing and eliminating as far as possible, associated risks Therefore, the continued clinical evaluation of products is the main engine that drives new solutions and improved medical technology.

Quality is a priority in the operation and development of the company in order to match the best companies in the sector and to ensure the safety, reliability and compliance of the products with the requirements of European Directive 93/42/EEC on medical devices. For it must established a system of quality management according to the **UNE-EN ISO 13485** which contains recommendations and customization of the **UNE-EN ISO 9001** for manufacturers of medical devices, certifying compliance by O.N. 0318 of the Spanish Agency for Medicines and Health Products. This certification is offered as a guarantee of the products to customers and as a token a strong commitment to fulfilling its requirements as well as regulatory, trying in this way to earn a reputable name in the national and international market.

Surgival Co. S.A.U. Compare our products with existing market multinationals known by name and quality that endorse their products.

Surgival Co. S.A.U. ensures correct operation of all current manufacturing systems and information as well as the incorporation of all necessary means to achieve the outlined objectives and strategies.

Every employee of the company has the duty and the right to suggest the elimination of situations and circumstances preventing the manufacture of perfect quality, without forgetting that the prevention of potential failures is more important than identifying them. Furthermore, it is the responsibility of all staff to the company's compliance with the provisions required in the Quality System.

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Genutech Primary Prosthesis Joint Knee has been designed and developed by Surgival.

That system consist of the following components :

- **Femoral Components** (Cemented – Cementless)
  - NPS (With preservation of Posterior Cruciate Ligament)
  - PS (Without preservation of Posterior Cruciate Ligament)
- **Tibial Insert**
  - NPS
  - PS
- **Cemented Tibial Tray**
  - Cemented Short Cap for Tibial Tray
  - Cemented Long Cap for Tibial Tray
- **Cemented Patella**
- **Augmentation Blocks**
  - Cemented Posterior Femoral Blocks
  - Cemented Distal Femoral Blocks
  - Cemented Tibial Block

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1. Description of Devices, Presentation Form and List of Instruments used to implant the device.

The aim of the knee prosthesis is the substitution of the original knee joint re-establishing its own functions, mainly, the transmission of weight on the inferior member and its mobility, allowing the patient to carry out normal physical activity with relief or absence of pain.

The implantation of this prosthesis is carried out via a surgical procedure known as knee arthroplasty.

This prosthesis is a system of components that interact with each other, with different versions depending on the clinical needs or the surgeon´s criteria at the time of the operation.

The knee prosthesis has three different versions, the three of them in LEFT/RIGHT option. The choice of one or another will depend on the needs and the condition of the patient and also on the surgeon´s criteria before and during the operation :

- **NPS Version (Non posterior stabilised) :** Used in arthroplasty in which it is necessary to keep the posterior cruciate ligament (LCP) and there is good ligamentary stability in the knee joint
- **PS Version (Posterior stabilised) :** Indicated in those cases in which the LCP is substituted and there is good ligamentary stability
- **Revision or Constricted Version :** Used in revision surgery to substitute a previous prosthesis or when the instability of the knee makes greater constriction of movement necessary in the varus / valgus movements and axial rotation

The components used in each version of the system are described as follows :

- NPS Version
  - NPS Femoral Component
  - NPS Tibial Insert
  - Tibial Tray
  - Patella

- PS Version
  - PS Femoral Component
  - PS Tibial Insert
  - Tibial Tray
  - Patella
  - Femoral Blocks : Distal or Posterior
  - Tibial Block

- Revision Version
  - Revision Femoral Component
  - Revision Tibial Insert
  - Tibial Tray
  - Patella
  - Straight Stem

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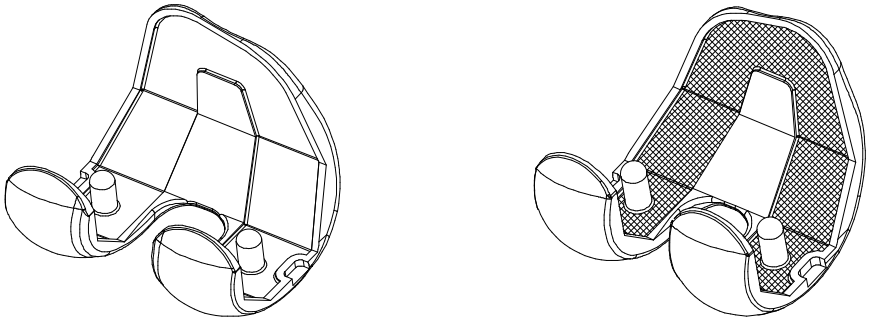
- Femoral Blocks : Distal or Posterior
- Tibial Block

GENUTECH Primary Prosthesis Joint Knee System are inspired in the first evolution of Insall-Burnstein (IB II) prosthesis that have been used successfully during the last 20 years.

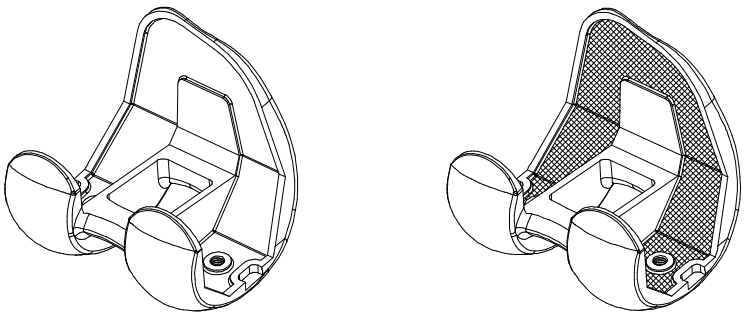
DEVICE DESCRIPTION

The different versions of a component are differentiated by their design but they have common features such as the material and the function they perform :

FEMORAL COMPONENTS



NPS Femoral Component Cemented / Cementless



PS Femoral Component Cemented / Cementless

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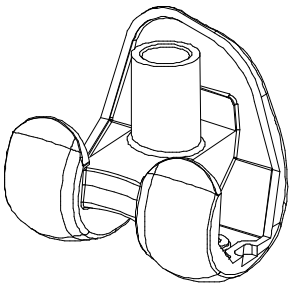


Revision Femoral Component

There are three version of the Femoral Component according to the use : NPS, PS and Revision.

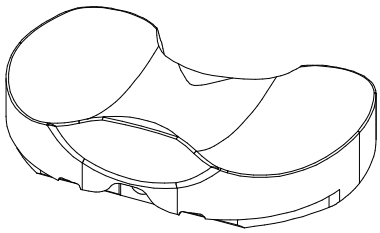
In all cases, the femoral component is made of a CoCrMo alloy casting, material with a higher hardnedd and lower surface roughness for implant applications, and it is fixed in the distal end of the femur through its inner side and it articulates with the tibial component through its external side or articular surface.

There are several sizes of each version of the femoral component. Both the NPS and PS design are available in two possible fixation versions : press-fit and cemented.

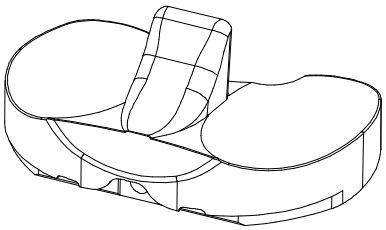
The Revision Component is always cemented.

The press-fit fixation is made through pressure fixation and later bone integration on the porous coating with hydroxyapatite of the fixation surfaces

TIBIAL INSERT



NPS Tibial Insert



PS Tibial Insert

There are also three versions of the Tibial Insert : NPS, PS and Revision. The Tibial Insert is made of polyethylene UHMWPE. It is introduced through its lower face on the tibial tray where it is fixed. Its upper side or articular surface substitutes the tibial plates and articulates with the surfaceof the femoral condyles. There are several sizes each version of tibial inserts.

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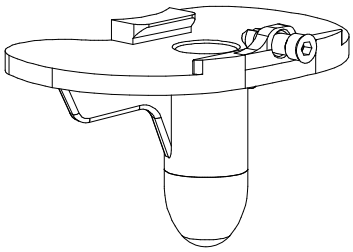
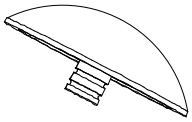
TIBIAL TRAY



The Tibial Tray is made of titanium alloy (Ti6Al4V). It substitutes the proximal extreme of the tibia, where it is fixed with the surgical cement. It helps the tibial insert in support and fixation. It allows adding plugs or stems on its lower side. There is only one version or design of the tibial tray suitable for all versions of the insert and it comes in several sizes

The tibial plugs are made of titanium alloy as is the tray. They are fixed to the extreme of the stem of the tibial tray by means of the same system as the stems (Morse cone and screw). They are used to cover the tibial tray (accessory).

PATELLA



The patella is made of polyethylene UHMWPE. It substitutes the articular part of the natural rotula where it is fixed with surgical cement. It articulates with the trochlear canal of the femoral component. There are several sizes of the rotula that can be used with any version and size of the femoral component.

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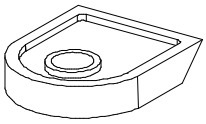
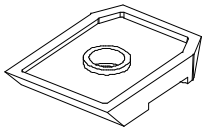
DISTAL AND POSTERIOR FEMORAL BLOCKS

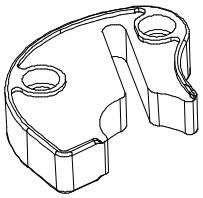




Cemented Posterior And Distal Femoral Blocks

The femoral blocks are made of titanium alloy (Ti6Al4V). There are two versions, each with several sizes : distal and posterior. They are fixed on the inner faces of the femoral component with screws. Their function is to cover the hollows or bone defects that remain in the distal part of the femur after the cuts made in the arthroplasty.

TIBIAL BLOCKS



The Tibial Blocks are made of titanium alloy (Ti6Al4V) like the tray. There are as many blocks as there are trays. Each size combines with the same size of the tibial tray. The blocks are reversible and both can be used in the medial or the lateral side of each tray. They are fixed on the lower

The fixation to the tibial tray is by a little titanium screw supplied together the block.

STRAIGHT STEM

The Straight Stem are made of Titanium alloy (Ti6Al4V). They fit on to the extreme of the stem of the tibial tray or to the revision femoral component. The bonding system is the same in both cases. There are two lengths and several possible diameters of each version.

The reference covered by this technical file are the following :

- **Femoral Components**

REFERENCE	DESCRIPTION
D8011110E	NPS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 1
D8011120E	NPS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 1

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REFERENCE	DESCRIPTION
D8011210E	NPS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 2
D8011220E	NPS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 2
D8011310E	NPS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 3
D8011320E	NPS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 3
D8011410E	NPS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 4
D8011420E	NPS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 4
D8011510E	NPS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 5
D8011520E	NPS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 5
D8021110E	NPS FEMORAL COMPONENT RIGHT CEMENTED SIZE 1
D8021120E	NPS FEMORAL COMPONENT LEFT CEMENTED SIZE 1
D8021210E	NPS FEMORAL COMPONENT RIGHT CEMENTED SIZE 2
D8021220E	NPS FEMORAL COMPONENT LEFT CEMENTED SIZE 2
D8021310E	NPS FEMORAL COMPONENT RIGHT CEMENTED SIZE 3
D8021320E	NPS FEMORAL COMPONENT LEFT CEMENTED SIZE 3
D8021410E	NPS FEMORAL COMPONENT RIGHT CEMENTED SIZE 4
D8021420E	NPS FEMORAL COMPONENT LEFT CEMENTED SIZE 4
D8021510E	NPS FEMORAL COMPONENT RIGHT CEMENTED SIZE 5
D8021520E	NPS FEMORAL COMPONENT LEFT CEMENTED SIZE 5
D8012110E	PS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 1
D8012120E	PS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 1
D8012210E	PS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 2
D8012220E	PS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 2
D8012310E	PS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 3
D8012320E	PS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 3
D8012410E	PS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 4
D8012420E	PS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 4
D8012510E	PS FEMORAL COMPONENT RIGHT CEMENTLESS SIZE 5
D8012520E	PS FEMORAL COMPONENT LEFT CEMENTLESS SIZE 5
D8022110E	PS FEMORAL COMPONENT RIGHT CEMENTED SIZE 1
D8022120E	PS FEMORAL COMPONENT LEFT CEMENTED SIZE 1
D8022210E	PS FEMORAL COMPONENT RIGHT CEMENTED SIZE 2
D8022220E	PS FEMORAL COMPONENT LEFT CEMENTED SIZE 2
D8022310E	PS FEMORAL COMPONENT RIGHT CEMENTED SIZE 3
D8022320E	PS FEMORAL COMPONENT LEFT CEMENTED SIZE 3
D8022410E	PS FEMORAL COMPONENT RIGHT CEMENTED SIZE 4
D8022420E	PS FEMORAL COMPONENT LEFT CEMENTED SIZE 4
D8022510E	PS FEMORAL COMPONENT RIGHT CEMENTED SIZE 5
D8022520E	PS FEMORAL COMPONENT LEFT CEMENTED SIZE 5

- **Tibial Insert**

REFERENCE	DESCRIPTION
D8041100E	NPS TIBIAL INSERT SIZE 1 10MM.
D8041120E	NPS TIBIAL INSERT SIZE 1 12MM.

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REFERENCE	DESCRIPTION
D8041140E	NPS TIBIAL INSERT SIZE 1 14MM.
D8041160E	NPS TIBIAL INSERT SIZE 1 16MM.
D8042100E	NPS TIBIAL INSERT SIZE 2 10MM.
D8042120E	NPS TIBIAL INSERT SIZE 2 12MM.
D8042140E	NPS TIBIAL INSERT SIZE 2 14MM.
D8042160E	NPS TIBIAL INSERT SIZE 2 16MM.
D8043100E	NPS TIBIAL INSERT SIZE 3 10MM.
D8043120E	NPS TIBIAL INSERT SIZE 3 12MM.
D8043140E	NPS TIBIAL INSERT SIZE 3 14MM.
D8043160E	NPS TIBIAL INSERT SIZE 3 16MM.
D8044100E	NPS TIBIAL INSERT SIZE 4 10MM.
D8044120E	NPS TIBIAL INSERT SIZE 4 12MM.
D8044140E	NPS TIBIAL INSERT SIZE 4 14MM.
D8044160E	NPS TIBIAL INSERT SIZE 4 16MM.
D8045100E	NPS TIBIAL INSERT SIZE 5 10MM.
D8045120E	NPS TIBIAL INSERT SIZE 5 12MM.
D8045140E	NPS TIBIAL INSERT SIZE 5 14MM.
D8045160E	NPS TIBIAL INSERT SIZE 5 16MM.
D8051100E	PS TIBIAL INSERT SIZE 1 10MM.
D8051120E	PS TIBIAL INSERT SIZE 1 12MM.
D8051140E	PS TIBIAL INSERT SIZE 1 14MM.
D8051160E	PS TIBIAL INSERT SIZE 1 16MM.
D8051180E	PS TIBIAL INSERT SIZE 1 18MM.
D8051200E	PS TIBIAL INSERT SIZE 1 20MM.
D8052100E	PS TIBIAL INSERT SIZE 2 10MM.
D8052120E	PS TIBIAL INSERT SIZE 2 12MM.
D8052140E	PS TIBIAL INSERT SIZE 2 14MM.
D8052160E	PS TIBIAL INSERT SIZE 2 16MM.
D8052180E	PS TIBIAL INSERT SIZE 2 18MM.
D8052200E	PS TIBIAL INSERT SIZE 2 20MM.
D8053100E	PS TIBIAL INSERT SIZE 3 10MM.
D8053120E	PS TIBIAL INSERT SIZE 3 12MM.
D8053140E	PS TIBIAL INSERT SIZE 3 14MM.
D8053160E	PS TIBIAL INSERT SIZE 3 16MM.
D8053180E	PS TIBIAL INSERT SIZE 3 18MM.
D8053200E	PS TIBIAL INSERT SIZE 3 20MM.
D8054100E	PS TIBIAL INSERT SIZE 4 10MM.
D8054120E	PS TIBIAL INSERT SIZE 4 12MM.
D8054140E	PS TIBIAL INSERT SIZE 4 14MM.
D8054160E	PS TIBIAL INSERT SIZE 4 16MM.
D8054180E	PS TIBIAL INSERT SIZE 4 18MM.
D8054200E	PS TIBIAL INSERT SIZE 4 20MM.
D8055100E	PS TIBIAL INSERT SIZE 5 10MM.

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REFERENCE	DESCRIPTION
D8055120E	PS TIBIAL INSERT SIZE 5 12MM.
D8055140E	PS TIBIAL INSERT SIZE 5 14MM.
D8055160E	PS TIBIAL INSERT SIZE 5 16MM.
D8055180E	PS TIBIAL INSERT SIZE 5 18MM.
D8055200E	PS TIBIAL INSERT SIZE 5 20MM.

- **Tibial Tray**

REFERENCE	DESCRIPTION
D8032100E	CEMENTED TIBIAL TRAY SIZE 1
D8032200E	CEMENTED TIBIAL TRAY SIZE 2
D8032300E	CEMENTED TIBIAL TRAY SIZE 3
D8032400E	CEMENTED TIBIAL TRAY SIZE 4
D8032500E	CEMENTED TIBIAL TRAY SIZE 5
D8032610E	CEMENTED SHORT CAP FOR TIBIAL TRAY
D8032620E	CEMENTED LONG CAP FOR TIBIAL TRAY

- **Patella**

REFERENCE	DESCRIPTION
D8030140E	CEMENTED PATELA Ø32
D8030150E	CEMENTED PATELA Ø34
D8030160E	CEMENTED PATELA Ø36
D8030170E	CEMENTED PATELA Ø38
D8030180E	CEMENTED PATELA Ø40

- **Femoral Blocks**

REFERENCE	DESCRIPTION
D8026010E	CEMENTED POSTERIOR FEMORAL BLOCK SIZE 1
D8026020E	CEMENTED POSTERIOR FEMORAL BLOCK SIZE 2
D8026030E	CEMENTED POSTERIOR FEMORAL BLOCK SIZE 3
D8026040E	CEMENTED POSTERIOR FEMORAL BLOCK SIZE 4
D8026050E	CEMENTED POSTERIOR FEMORAL BLOCK SIZE 5
D8026150E	CEMENTED DISTAL FEMORAL BLOCK SIZE 1 4MM
D8026190E	CEMENTED DISTAL FEMORAL BLOCK SIZE 1 8MM
D8026250E	CEMENTED DISTAL FEMORAL BLOCK SIZE 2 4MM
D8026290E	CEMENTED DISTAL FEMORAL BLOCK SIZE 2 8MM
D8026350E	CEMENTED DISTAL FEMORAL BLOCK SIZE 3 4MM
D8026390E	CEMENTED DISTAL FEMORAL BLOCK SIZE 3 8MM
D8026450E	CEMENTED DISTAL FEMORAL BLOCK SIZE 4 4MM

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REFERENCE	DESCRIPTION
D8026490E	CEMENTED DISTAL FEMORAL BLOCK SIZE 4 8MM
D8026550E	CEMENTED DISTAL FEMORAL BLOCK SIZE 5 4MM
D8026590E	CEMENTED DISTAL FEMORAL BLOCK SIZE 5 8MM

- **Tibial Blocks**

REFERENCE	DESCRIPTION
D8032710E	CEMENTED TIBIAL BLOCK SIZE 1
D8032720E	CEMENTED TIBIAL BLOCK SIZE 2
D8032730E	CEMENTED TIBIAL BLOCK SIZE 3
D8032740E	CEMENTED TIBIAL BLOCK SIZE 4
D8032750E	CEMENTED TIBIAL BLOCK SIZE 5

The knee prosthesis is for use in clinical cases where the substitution of the knee joint or arthroplasty is needed. Given the high magnitude of the intra-articulated stress to which the knee joint is subjected and the great mobility it must have, this knee joint is very prone to suffering pathologies of a degenerative type such as arthritis and arthrosis.

The main reason for substituting a natural knee for a prosthesis is pain, associated to a sever degradation of the articulation that is normally accompanied by disability or serious loss of function. Therefore, the main objective of a knee prosthesis is relieve or avoid pain and secondly to recover the mobility of the articulation. If these two purposes are achieved, it will be possible to recover the knee function and carry out a normal life without any need of support or another kind of technical help. The knee arthroplasty is used only when the symptoms and the incapacity are serious. The alternative techniques, such as the tibial osteotomy, are preferable if they are feasible

Knee replacement are used in :

- Gonarthosis (taking into account factors such as age, activity level and weight)
- Arthroplasty should be avoided in young patient (under 60 years), overweight patients, even though the patient together with the surgeon makes the final decision.
- Serious imflammatory or rheumatoid arthritis
- Post-traumatic arthrosis (except in young patients)
- Failure of a tibial osteotomy that did not relieve the symptoms or when they appear after certain time as a consequence of progressive arthrosis
- Revision of a previous arthroplasty

It is contraindicated in the following cases :

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- Presence of an active infection in any region
- Stable and painless arthrosis in good position
- Genu recurvatum with weakness and muscle paralysis has many probabilities of reappearing after the joint reemplacement
- Quadricep weakness
- Processes of quick bone mass destruction (general progressive osteopenia, focused osteoporosis…) at least when the progression of the process cannot be controlled
- Obesity, because it may produce loads on the prosthesis causing the failure of the implant
- Knee arthroplasty is not advised in cases of : other disorders (cardiac, pulmonary, metabolic, etc.), patients that are unable to walk after the arthroplasty due to other problems, skeletally immature patients.
- Allergy to any of the material that make up the components of the prosthesis

The possible undesired side effects :

- Deformation or breakage of the implant due to wear or fatigue
- Local infection. This is the most usual complication
- Loosening and/or migration of the implant with loss of the initial correction causing pain to the patient. Pain can be caused by mechanical overload, by osteoporosis or by an immunological reaction, either specific or non-specific to alien bodies
- Wear :
  Loss of mechanical resistance and functionality
  Release of particles : immunological reaction
- The prosthesis does not achieve the predicted mobility ;
  Rigidity due to intraarticular adherence
  Instability which may cause patellar luxation or luxation between the femur and the tibia
- Failure because of luxation due to a sudden movement provoked by excessive or inappropriate stress

On some occasions, additional surgical intervention can be necessary because of the incapacity to return to normal daily life, either by correcting some of these adverse reactions or by substituting the prosthesis worn down due to use.

The physician shall establish the end of the useful life of the total knee prosthesis, which could range from 10 to 15 years, when it does not satisfactorily carry out its function. Nevertheless, if the implants breaks or weakens during its useful life, the involved components must be extracted to avoid their causing damage from the presence of sharp edges or migration of the components. In this situation, a new knee prosthesis shall be implanted.

In order to implant this product, the physician must know the associated surgical technique (See Annex 1)

According to the Principles of Medical Devices Classification of the **Global Harmonization Task Force (GHTF),** the components of **Genutech Primary Prosthesis Joint Knee** are Risk Class D, that is High Hazard. Is an Invasive Device that under Rule 8 : Surgically invasive, long term use > 30 days, implant , unless they are intended to be life supporting or life sustaining, in which case the are

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in Class D.

Life supporting or life sustaining is a device that is essential to, or that yield information that is essential to, the restoration or continuation of a bodily function important to continuation of human life.

The components produced by SURGIVAL for total knee arthroplasties have been designed to ensure interchangeability. Therefore, SURGIVAL shall not be held responsible for the combination of its products with those of a different brand or manufacturer.

Only the instruments and prosthetic components for trials, specially designed by **SURGIVAL** for this implant, may be used. Consult our catalogue and surgical technique (Annex 1)

To implement the **Genutech Primary Prosthesis joint knee,** Surgival has a specific set for this product, Genutech reduced primary knee instrumental complete set, that comprises 6 sets in turn :

- **Tibial Instrumental Set**

Upper Tray

- **Trial Spacer 10mm**
- **Trial Spacer 12mm**
- **Trial Spacer 14mm**
- **Trial Spacer 16mm**
- **Trial Spacer 18mm**
- **Trial Spacer 20mm**
- **Pin with Head Ø3.4x55mm**
- **Headless Pin Ø3.4x55mm**
- **Headless Pin Ø3.4x80mm**
- **Tibial Guide Support (3 pieces)**
- **Simple Tibial Guide**
- **Distal Forceps for Tibial Guide**
- **Extramedullar fixation system**

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- **Tibial Probe**

Lower Tray

- **Right Tibial Cutting Guide**
- **Left Tibial Cutting Guide**
- **Trial Tibial Templates Size 1**
- **Trial Tibial Templates Size 2**
- **Trial Tibial Templates Size 3**
- **Trial Tibial Templates Size 4**
- **Trial Tibial Templates Size 5**
- **Keel Impactor Handle**
- **Keel Chisels Size 1**
- **Keel Chisels Size 2**
- **Keel Chisels Size 3**
- **Keel Chisels Size 4**
- **Keel Chisels Size 5**
- **Tibial Template Handle**
- **Fixation Bolt Handle**
- **Tibial Impactor**
- **Tibial Tray Impactor**
- **Inserts Extractor**
- **2.5mm Screwdriver**
- **Intramedullar Chisel**

- **NPS Set**

- **Trial Tibial Insert NPS 10mm Size 1**
- **Trial Tibial Insert NPS 12mm Size 1**
- **Trial Tibial Insert NPS 14mm Size 1**
- **Trial Tibial Insert NPS 16mm Size 1**
- **Trial Tibial Insert NPS 10mm Size 2**
- **Trial Tibial Insert NPS 12mm Size 2**
- **Trial Tibial Insert NPS 14mm Size 2**
- **Trial Tibial Insert NPS 16mm Size 2**
- **Trial Tibial Insert NPS 10mm Size 3**
- **Trial Tibial Insert NPS 12mm Size 3**
- **Trial Tibial Insert NPS 14mm Size 3**
- **Trial Tibial Insert NPS 16mm Size 3**

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- **Trial Tibial Insert NPS 10mm Size 4**
- **Trial Tibial Insert NPS 12mm Size 4**
- **Trial Tibial Insert NPS 14mm Size 4**
- **Trial Tibial Insert NPS 16mm Size 4**
- **Trial Tibial Insert NPS 10mm Size 5**
- **Trial Tibial Insert NPS 12mm Size 5**
- **Trial Tibial Insert NPS 14mm Size 5**
- **Trial Tibial Insert NPS 16mm Size 5**

- **PS Set**

Upper Tray

- **Trial Tibial Insert PS 10mm Size 1**
- **Trial Tibial Insert PS 12mm Size 1**
- **Trial Tibial Insert PS 14mm Size 1**
- **Trial Tibial Insert PS 16mm Size 1**
- **Trial Tibial Insert PS 18mm Size 1**
- **Trial Tibial Insert PS 20mm Size 1**
- **Trial Tibial Insert PS 10mm Size 2**
- **Trial Tibial Insert PS 12mm Size 2**
- **Trial Tibial Insert PS 14mm Size 2**
- **Trial Tibial Insert PS 16mm Size 2**
- **Trial Tibial Insert PS 18mm Size 2**
- **Trial Tibial Insert PS 20mm Size 2**
- **Trial Tibial Insert PS 10mm Size 3**
- **Trial Tibial Insert PS 12mm Size 3**
- **Trial Tibial Insert PS 14mm Size 3**
- **Trial Tibial Insert PS 16mm Size 3**
- **Trial Tibial Insert PS 18mm Size 3**
- **Trial Tibial Insert PS 20mm Size 3**
- **Trial Tibial Insert PS 10mm Size 4**
- **Trial Tibial Insert PS 12mm Size 4**
- **Trial Tibial Insert PS 14mm Size 4**
- **Trial Tibial Insert PS 16mm Size 4**
- **Trial Tibial Insert PS 18mm Size 4**
- **Trial Tibial Insert PS 20mm Size 4**
- **Trial Tibial Insert PS 10mm Size 5**
- **Trial Tibial Insert PS 12mm Size 5**
- **Trial Tibial Insert PS 14mm Size 5**
- **Trial Tibial Insert PS 16mm Size 5**

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- **Trial Tibial Insert PS 18mm Size 5**
- **Trial Tibial Insert PS 20mm Size 5**

Patellar Instrumental Set

- **Trial Patella Ø32mm**
- **Trial Patella Ø34mm**
- **Trial Patella Ø36mm**
- **Trial Patella Ø38mm**
- **Trial Patella Ø40mm**
- **Clamp for Patella Resection**
- **Patellar Drill**
- **Patellar Clamp**

Femoral Instrumental Set 1 DCF

Upper Tray

- **Starter Awl**
- **Starter Drill**
- **Distal Cut Guide**
- **Alignment Rod**
- **Alignment Femoral Guide**
- **DCF Cutting Guide Positioner**
- **Pin Impactor / Extractor Auxiliar Bar**
- **Adapter Helical Pin Ø3.4mm to Hudson**
- **Pin Extractor Terminal Ø3.4mm**
- **Pin Extractor Forceps**
- **Helical Pin Ø3.4x50mm**
- **Helical Pin Ø3.4x75mm**
- **Helical Pin Ø3.4x35mm Hexagonal Head**
- **Helical Pin Ø3.4x50mm Hexagonal Head**

Lower Tray

- **Femoral Gauge**
- **Drill Ø3.4mm**
- **Cutting Block Inserter / Extractor**
- **Cutting Femoral Blocks Size 1**
- **Cutting Femoral Blocks Size 2**
- **Cutting Femoral Blocks Size 3**
- **Cutting Femoral Blocks Size 4**
- **Cutting Femoral Blocks Size 5**

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- **Protector Tibial Plate**
- **Resection Checker**

Femoral Instrumental Set 2 DCF

Upper Tray

- **Trial Femoral Component Size 1 Right**
- **Trial Femoral Component Size 1 Left**
- **Trial Femoral Component Size 2 Right**
- **Trial Femoral Component Size 2 Left**
- **Trial Femoral Component Size 3 Right**
- **Trial Femoral Component Size 3 Left**
- **Trial Femoral Component Size 4 Right**
- **Trial Femoral Component Size 4 Left**
- **Trial Femoral Component Size 5 Right**
- **Trial Femoral Component Size 5 Left**
- **NPS Drill Bit**
- **Pin with Head Ø3.4x40mm**
- **Intercondilar Cutting Guide**
- **PS Trial Intercondylar Size 1**
- **PS Trial Intercondylar Size 2**
- **PS Trial Intercondylar Size 3**
- **PS Trial Intercondylar Size 4**
- **PS Trial Intercondylar Size 5**
- **Chisel**
- **Axle Alignment 400mm**

Lower Tray

- **Inserter / Extractor of Femoral Components**
- **Ø4.5mm Screwdriver**
- **Posterior Recur Block + 4mm**
- **Reduced Distal Recutting Mask**
- **Femoral Component Impactor**
- **Axle Alignment 400mm**
- **Chisel**

2. Description of device´s composition / material and relevant reference standards

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The materials used to manufacturer **Genutech Primary Prosthesis joint knee** are :

- **Femoral Component → CoCrMo Alloy**
- **Tibial Insert → Polyethylene UHMWPE**
- **Tibial Tray →Titanium alloy**
- **Patela → Polyethylene UHMWPE**
- **Distal and Posterior Femoral Blocks → Titanium alloy**
- **Tibial Blocks → Titanium alloy**

Properties of UHMWPE (according to ASTM F648 and ISO 5834-1)

PROPERTY	REQUIREMENT
Density (Kg/m^3)	927-944
Max. Ash content (mg/Kg)	Max. 150
Min. Ultimate Tensile Strength (MPa)	Min. 21
Min. Yield Strength (MPa)	Min. 40
Min. Elongation (%)	Min. 380
Izod impact strength Kj/m^2	Min. 180
Charpy impact strength Kj/m^2	Min 126

Properties of Ti6Al4V alloy for human implant applications (according to ASTM F136 and ISO 5832-3)

Chemical composition for Ti6Al4V implant alloy

Element	Content (mass %)
Alumium	Between 5,5 and 6,5%
Vanadium	Between 3,5 and 4,5%
Nitrogen	Max. 0,05%
Carbon	Max. 0,08%
Hydrogen	Max. 0,012%
Iron	Max. 0,25%
Oxygen	Max. 0,13%
Titanium	balance

Mechanical properties of Ti6Al4V alloy

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Ultimate Tensile Strength	Yield strength	%Elongation
Min, 825 Mpa	Min. 760 Mpa	8,00%

Properties of Chromium-Cobalt-Molybdenum alloy casting for human implant applications (according to ASTM F75 and ISO 5832-4)

ELEMENT	COMPOSITION (mass %)
Chromium	Between 27 and 30
Molybdenum	Between 5 and 7
Nickel	Max. 0.5
Iron	Max. 0.75
Carbon	Max. 0.35
Silicon	Max. 1.00
Manganese	Max. 1.00
Tungsten	Max. 0.20
Phosphorous	Max. 0.020
Sulfur	Max. 0.010
Nitrogen	Max. 0.25
Aluminum	Max. 0.10
Titanium	Max. 0.10
Boron	Max. 0.010
Cobalt	balance

BIOCOMPATIBILITY

Wrought Cr-Co-Mo alloy

As we can read at point X2.1 of ASTM F75: "*The alloy composition covered by this standard has been used successfully in human implant applications in contact with soft tissue and bone for over a decade. Because of the well characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.*

No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of the use of the material referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications."

UHMWPE (Ultra High Molecular Weight Polyethylene)

As we can read at point 8 of ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and fabricated form for Surgical Implants:

"This material has been shown to produce a well characterized level of biological response following long term clinical use in laboratory animals. The results of these studies and the clinical history indicate an acceptable level of biological response in the applications in which the

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material has been utilized. When new applications of the material, or modification to the material or physical forms of the materials are being contemplated, the recommendations of Practice F 748 should be considered and testing as described in Practices F 619, F 749, F 756, F 763, F 813, and F 981 as well as Test Method F 895."

Ti6Al4V alloy

As we can read at point X.2 of ASTM F136 standard "*The alloy composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.*

No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications."

All the raw materials used in the manufacturing of SURGIVAL products are inspected before the entry to the warehouse. These inspections consist in a supplier's documents revision, with special attention to the Mechanical properties and chemical composition of the batch. By the other side the operators check the raw materials dimensions and the visual aspect.

A sample of a raw material certificated are attached in **Annex 2.**

3. Labelling and Instructions for Use

Labels are distribuited as follows :

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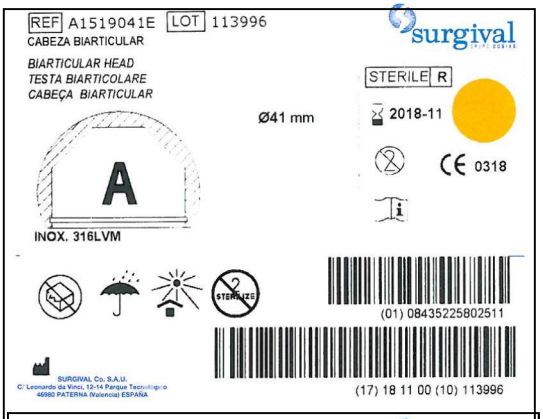
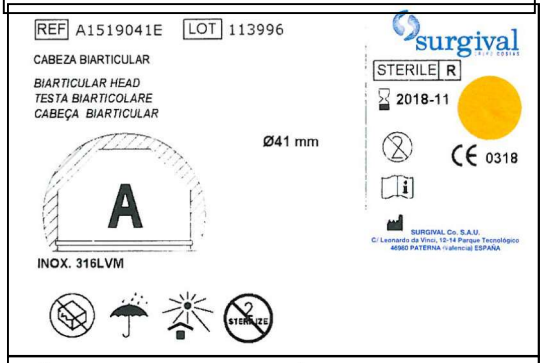
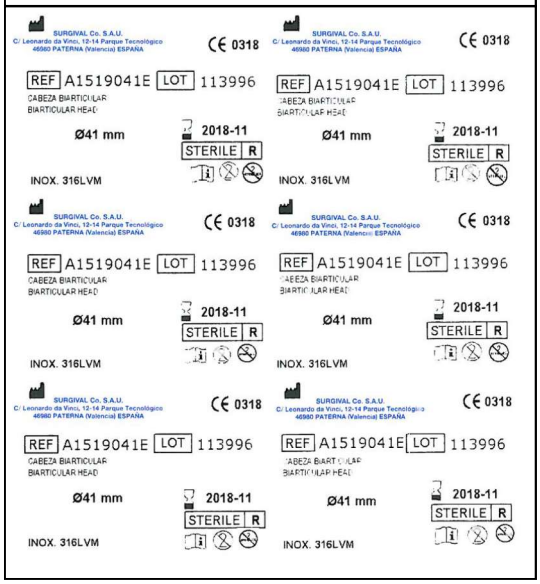


Labels attached to the outside packaging or secondary packaging



Label attached to the primary container or second bag/blister



Labels for hospital use

Labels contains the following information :

- **Reference**
- **Lot / batch number**
- **Name of the product in four languages (spain,english, portuguese, italian)**

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- **Product Image**
- **Dimensions**
- **Material**
- **Manufacturer : Name, address…**
- **Expiration date**
- **CE Market and number of notifícate body**
- **Sterilization method**
- **Symbology of storage and conservation according to ISO 15223-1 Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements**
- **Symbology safe use according to ISO 15223-1 Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements**

In **Annex 3** we attached original labels of all reference from **Genutech Primary Prosthesis Joint Knee**

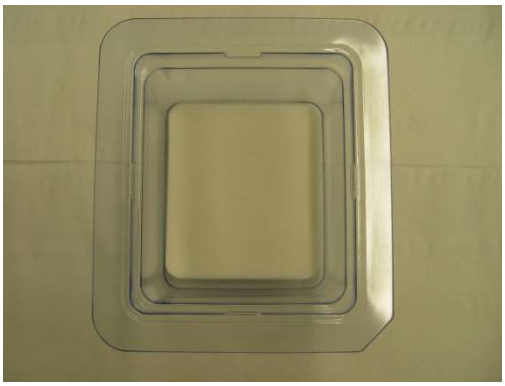
The instructions for use are included in **Annex 4**

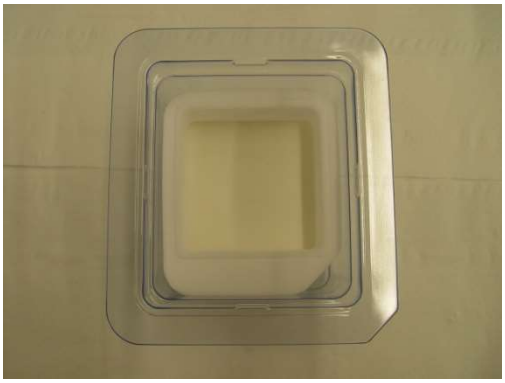
4. Packaging

PACKAGING DESCRIPTION : FEMORAL COMPONENT

Primary packaging

The primary packaging is formed by a double blister barrier made from PET-G (Polyethylene terphtalate Glicol). For the protection of the prosthesis, we place on the bottom of the internal blister a sponge made from low density polyethylene and one more around the internal sides of the blister.





(Image 2 & 3: sponges for protection)

Then the femoral component is placed inside the internal blister, over the sponge.

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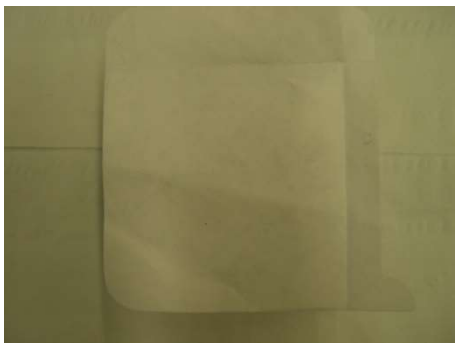
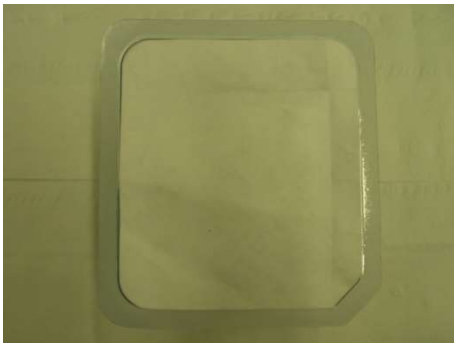
(Image 4: prosthesis placement inside internal blister)

Then we put a sponge over the prosthesis and we close the internal blister with a PET-G cover with a protection sponge.

(Images 5 & 6: internal blister closing)

The internal blister is thermally sealed with a Tyvek® cover made from high density polyethylene fibers. Then the internal blister is placed inside the external blister which is thermally sealed too.





(Images 7 & 8: blisters sealing)

The identification label is attached over the external Tyvek® cover.

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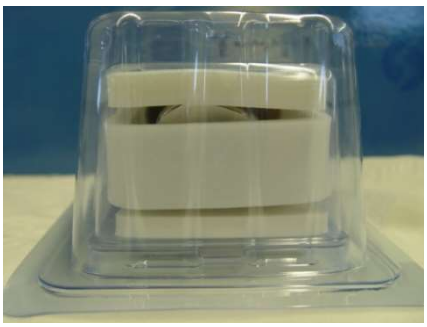

(Image 9&10: final disposition of the prosthesis in the primary package)

Secondary packaging

(Image 7: SURGIVAL cardboard box)

Finally the cardboard box is protected by a shrink film made from polypropylene.

All packaging process is made in a cleanroom that meets the requirement of standard ISO 14644 "*Cleanrooms and associated controlled environments*" and controlled according to standard ISO 14698 "*Cleanrooms and associated controlled environments. Biocontamination control.*".

PACKAGING DESCRIPTION : TIBIAL INSERT

Primary packaging

The primary packaging is formed by a double sterilization pouch barrier made from polyethylene and polyamide where the stem is vacuum sealed.

First, we put the stem inside the internal bag. This bag is vacuum sealed.

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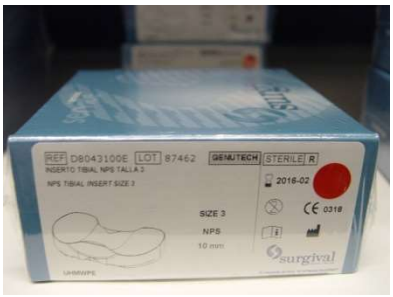
(Image 2: tibial insert inside internal pouch)

Finally the internal pouch is placed inside the external pouch which is vacuum sealed too. The identification label is attached on the external pouch.

(Image 3: final disposition of the insert, inside the double pouch barrier)

Secondary packaging

When external blister has been sealed and identified with the corresponding label, we put the blister inside SURGIVAL cardboard.



(Image 8: SURGIVAL cardboard box)

Finally the cardboard box is protected by a shrink film made from polypropylene.

All packaging process is made in a cleanroom that meets the requirement of standard ISO 14644 "*Cleanrooms and associated controlled environments*" and controlled according to standard ISO 14698 "*Cleanrooms and associated controlled environments. Biocontamination control.*".

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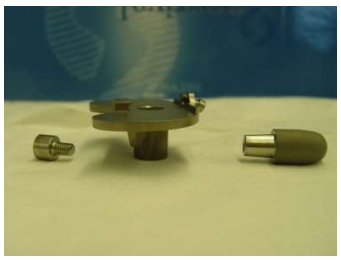
PACKAGING DESCRIPTION : TIBIAL TRAY

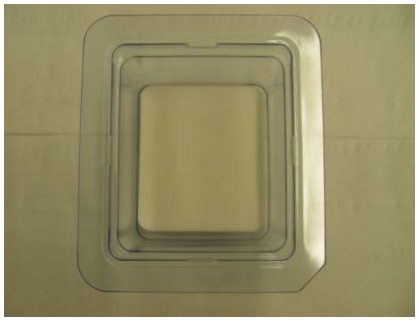
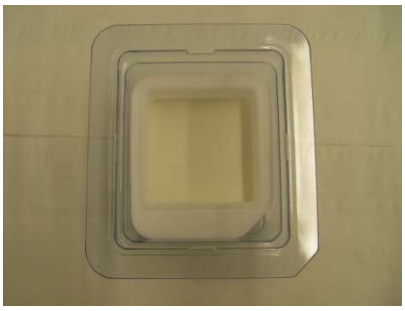
Primary packaging

First step in packaging process of cemented tibial trays is to assemble all components of the system.




(Image 2 & 3: preassembly of tibial tray components)

The primary packaging is formed by a double blister barrier made from PET-G (Polyethylene terphtalate Glicol). For the protection of the prosthesis, we place on the bottom of the internal blister a sponge made from low density polyethylene and one more around the internal sides of the blister.

(Image 4 & 5: sponges for protection)

Then the tibial tray is placed inside the internal blister, over the sponge.

(Image 6: prosthesis placement inside internal blister)

Then we put a sponge over the prosthesis and we close the internal blister with a PET-G cover with a protection sponge.

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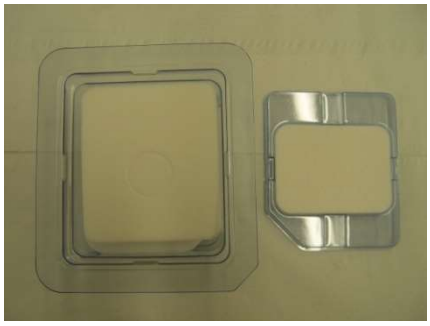
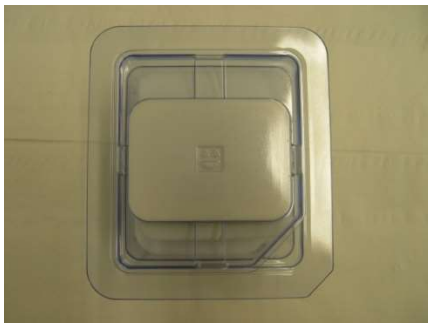
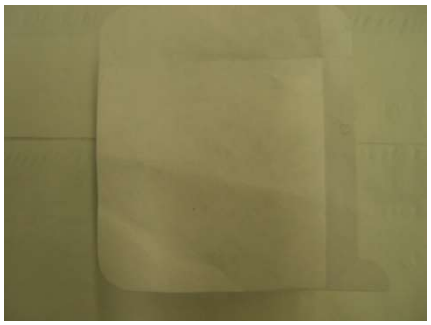
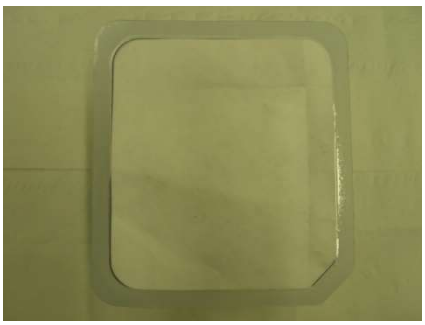




(Images 7 & 8: internal blister closing)

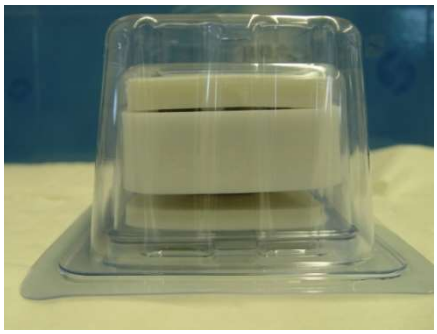
The internal blister is thermally sealed with a Tyvek® cover made from high density polyethylene fibers. Then the internal blister is placed inside the external blister which is thermally sealed too.





(Images 9 & 10: blisters sealing)

The identification label is attached over the external Tyvek® cover.



(Image 11 &12: final disposition of the prosthesis in the primary package)

Secondary packaging

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(Image 7: SURGIVAL cardboard box)

Finally the cardboard box is protected by a shrink film made from polypropylene.

All packaging process is made in a cleanroom that meets the requirement of standard ISO 14644 "*Cleanrooms and associated controlled environments*" and controlled according to standard ISO 14698 "*Cleanrooms and associated controlled environments. Biocontamination control.*".

PACKAGING DESCRIPTION : PATELLA

Primary packaging


(Image 2: packaging components for cemented patella)

The primary packaging is formed by a sterilization pouch barrier made from polyamide and polyethylene where the insert is vacuum sealed.


(Image 3: patella inside the pouch)

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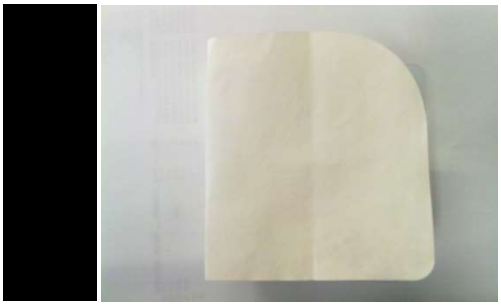
(Image 4&5: product placement inside external blister)




(Image 6&7: blister sealing and internal identification)

Secondary packaging

When external blister has been sealed and identified with the corresponding label, we put the blister inside SURGIVAL cardboard.

(Image 8: SURGIVAL cardboard box)

Finally the cardboard box is protected by a shrink film made from polypropylene.

All packaging process is made in a cleanroom that meets the requirement of standard ISO 14644 "*Cleanrooms and associated controlled environments*" and controlled according to standard ISO 14698 "*Cleanrooms and associated controlled environments. Biocontamination control.*".

PACKAGING DESCRIPTION : FEMORAL BLOCKS

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4.1 Primary packaging

(Image 2: packaging components for femoral augmentation blocks)

The primary packaging is formed by a sterilization pouch barrier made from polyamide and polyethylene where the insert is vacuum sealed.

(Image 3: blocks inside the pouch)

(Image 4&5: sponge positioning and final disposition inside the blister)

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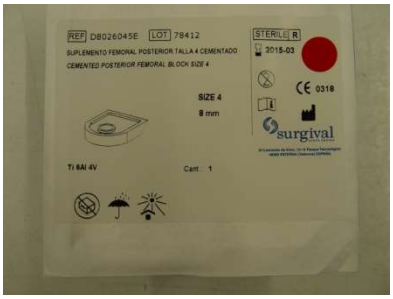
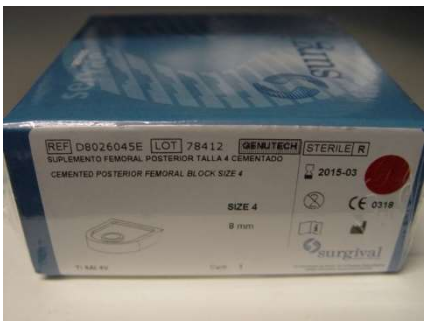
(Image 6: blister sealed)



(Image 7&8: internal identification)

Secondary packaging

When external blister has been sealed and identified with the corresponding label, we put the blister inside SURGIVAL cardboard.



(Image 8: SURGIVAL cardboard box)

Finally the cardboard box is protected by a shrink film made from polypropylene.

All packaging process is made in a cleanroom that meets the requirement of standard ISO 14644 "*Cleanrooms and associated controlled environments*" and controlled according to standard ISO 14698 "*Cleanrooms and associated controlled environments. Biocontamination control.*".

PACKAGING DESCRIPTION : DISTAL BLOCKS

Primary packaging

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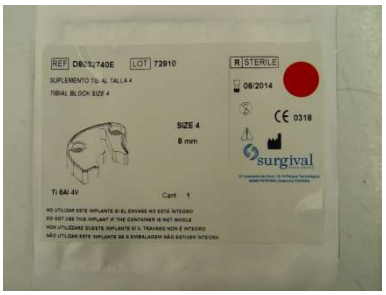
(Image 2: packaging components for tibial augmentation blocks)

The primary packaging is formed by a sterilization pouch barrier made from polyamide and polyethylene where the insert is vacuum sealed.

(Image 3: block inside the internal pouch)

(Image 4&5: sponge positioning and final disposition inside the blister)



(Image 6&7: blister sealed and internal labeling)

Secondary packaging

When external blister has been sealed and identified with the corresponding label, we put the blister inside SURGIVAL cardboard.

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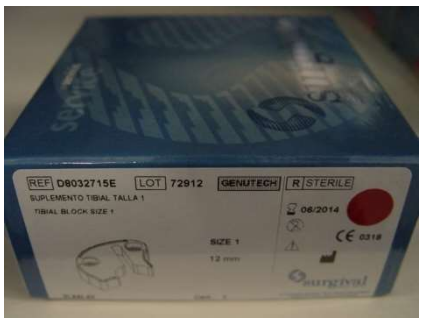

(Image 8: SURGIVAL cardboard box)

Finally the cardboard box is protected by a shrink film made from polypropylene.

All packaging process is made in a cleanroom that meets the requirement of standard ISO 14644 "*Cleanrooms and associated controlled environments*" and controlled according to standard ISO 14698 "*Cleanrooms and associated controlled environments. Biocontamination control.*".

In **Annex 5** we attached the packaging system verification. Here also you can see stability study report for the sterile barrier system, as a guarantee to maintain sterility up to the point of use or expiry date.

5. Manufacturing Flowchart

MANUFACTURING PROCESSES

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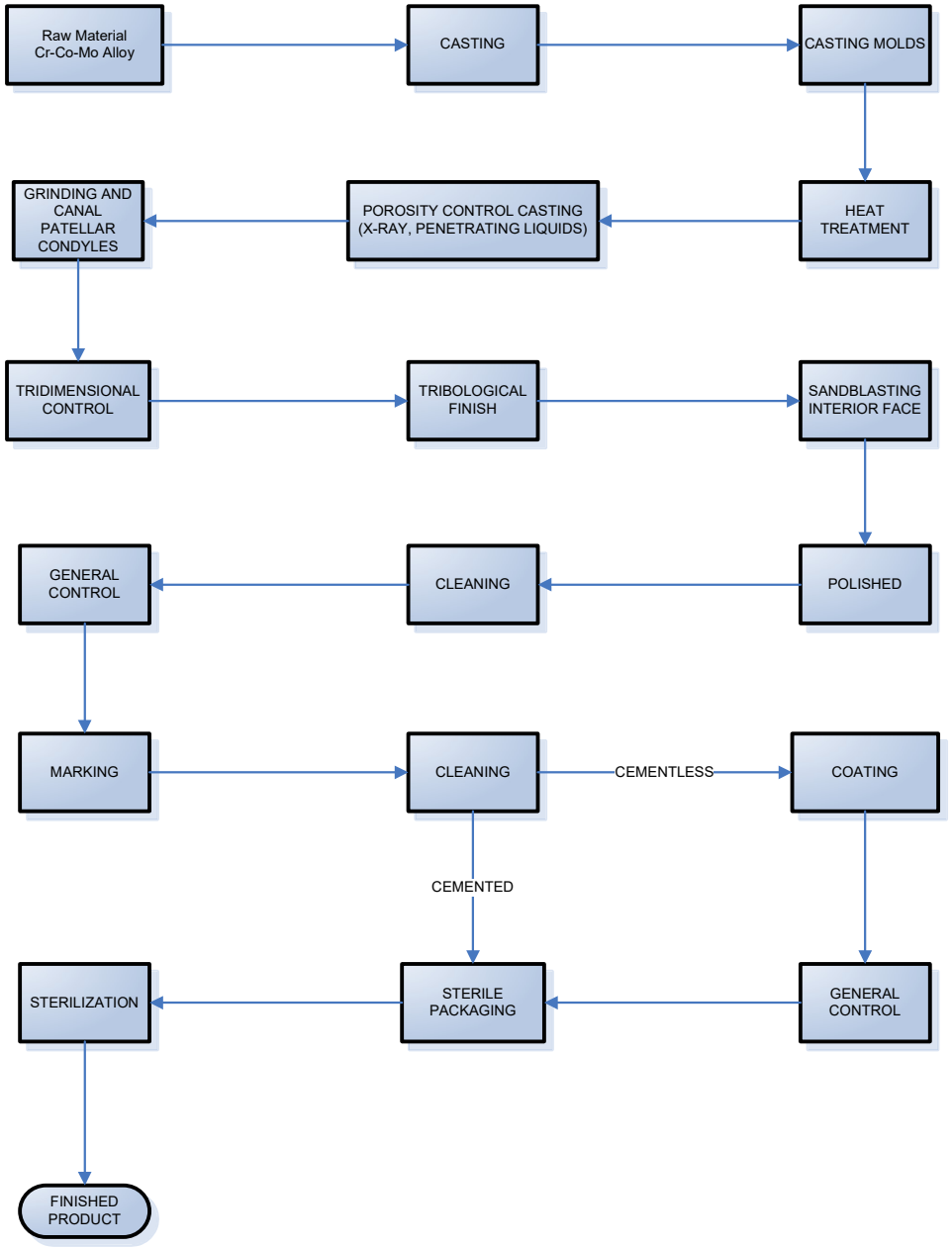
Flow Chart
Femoral Component



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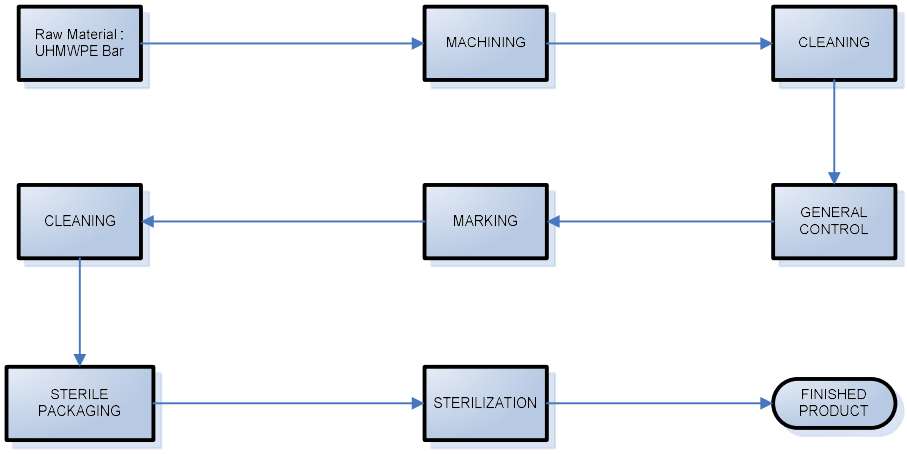
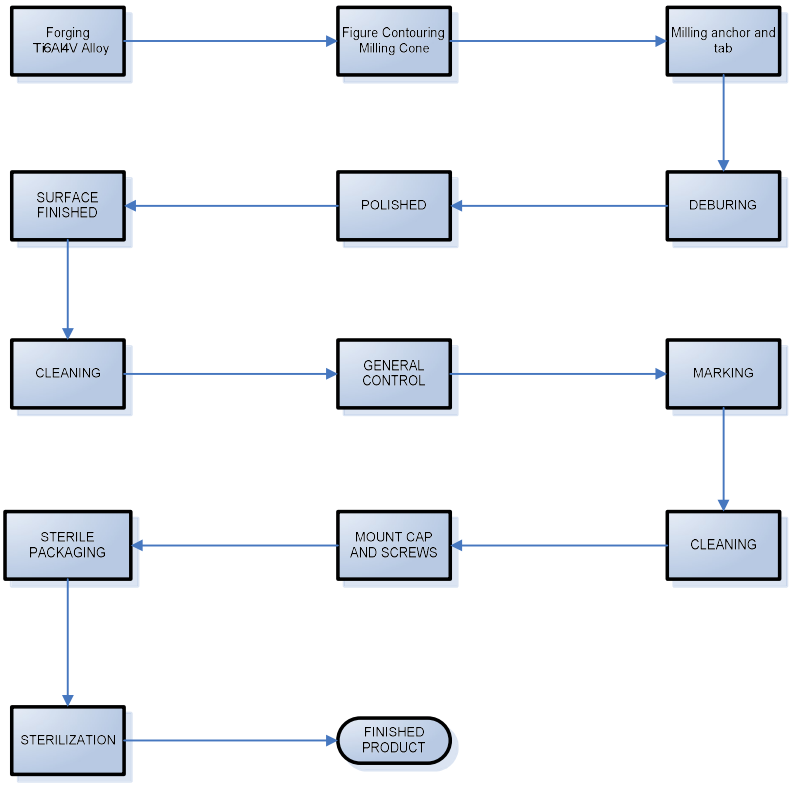
Flow Chart
Tibial Inserts and Patellas



Flow chart
Tibial Tray



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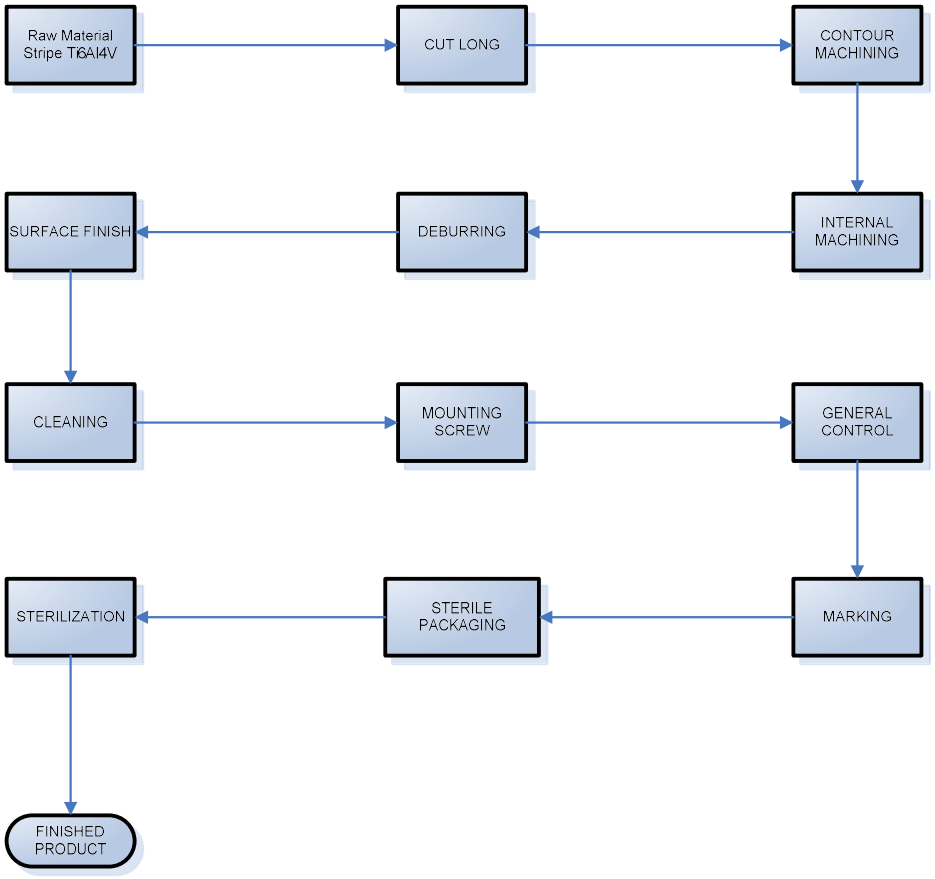
Flow chart
Femoral and Tibial Blocks



During the production, the operators check the parts that they are manufacturing according to specific procedure for process control.

Before the product is going to be cleaned, packaged and sterilized, the 100% of the lot parts are subject to final inspection according to procedure of inspection and testing.

6. Sterilization Validation

Description of the sterilization process

The sterilization of our products is made by gamma radiation. We outsource this process to a company CE certified by the certified body 0318 and whose Quality System meets the requirements established by the Directive 93/42/CEE, Annex V and it is also conform to the standard ISO 11137-1 "*Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*" and ISO 11137-2 "*Sterilization of health care products -- Radiation -- Part 2: Establishing the*

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sterilization dose".

Given the features of this product, Surgival uses this physical process of sterilization by exposure to ionizing radiations. Ionization can be achieved by bombing the atoms with particles, electrons, or by electromagnetic radiation through a radioactive source of the radionuclide Cobalt-60 which is the method used by Surgival to sterilize its products. The ionized atom when losing its stability due to the absence of the electrons of the last orbits, is chemically very reactive and tries to react with the surrounding atoms to steal the electrons from them to complete its last phase becoming stable atoms.

This phenomenon produces Biological effects, the ionization of the DNA molecule atoms produces its degradation and this will explain its use at the medical field sterilization devices. Before being sterilized, the product is conditioned and labeled under a controlled atmosphere at the Clean Room class 10.000. Then, the material is located in cartoon boxes of maximum external dimensions of 300x300x300mm which will be at conveyor belt inside the irradiation box to be treated.

The selected dose is a minimum doze of 25KGy which is subject to modification after being audited in a systematic way following Surgival´s planning. This appears in our inner procedure PE-SU-VD-01 or Specific Procedure of Verification sterilized dose and Process Validation of sterilization Gamma radiation of our Quality Manual System.

Validation tests of the sterilization cycles and clean room conditioning: goals

The goals followed with these tests are:

- To make controls over the microclimate created at the Clean Room with the aim of ratifying the class or degree of the Room and, at the same time, to determine the microbiological state of the Room *validating so the Clean Room*.
- To *Validate the Sterilization Cycle*, it is that we have an exhaustive control of the microbial levels at the products packed as sterile to make sure the irradiation dose we have to apply. At the same time, we have to check that the irradiation dose given is absorbed by the implants. Finally, we have to verify the products are sterile.

Validation tests of the Clean Room

The job procedure we have developed to continuously control the ambience conditions of the White Room is PE-SU-SB-01 or Specific Procedure for Validation Clean Room of our Quality Manual System, conformed to the standard ISO 14.644 "Clea*n Rooms and Annex Places. Classification of cleanliness in the air*" and the Annex I of the G*uide of Standards of Correctly Production at the European Union*.

Validation tests of the sterilization cycles

The job procedure we have defined to continuously control the sterility of our products is PE-SU-VD-01 or Specific Procedure of Verification sterilized dose and Process Validation

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of sterilization Gamma radiation is conformed to the ISO 11.137 "Requirements to Validate and Control the Sterilization by Irradiation" for which the probability of finding a viable microorganism in a product is under $1x10^{-6}$, value indicated at the standard UNE-EN 556.

The monitoring of the sterilization process consists in annual sterility tests (according to ISO 11737-2, *Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*) over a representative product from each product family (ceramics, metallics, polyethylene and hidroxyapatite). If the test results are negative (microorganisms growth), the irradiation process is re-validated and all the products irradiated under this procedure can be considered as STERILE. An example for metallic materials and plastics materials are attached in **Annex 6**.

In **Annex 4** we attached the packaging system verification

7. Mechanical Test

In **Annex 7** is attached **"Preclinical test report for Genutech Primary Prosthesis Joint Knee".**

8. Risk Analysis and Control Summary

See attached in **Annex 8**

9. Clinical Studies and Scientific Articles proving product´s effectivenes

POST MARKETING SURVEILLANCE DATA

The following **Clinical Monitoring Plan Post-Marketing** is established :

Monitoring Plan Post-Marketing	Procedures applied	Frecuency of revision
Customer complaints and claims for adverse events	PE-SU-NC-01 PE-SU-AS-01 PE-SU-MAM-01	Annual
The review of the indications, contraindications, side effects and affirmed by follow-up studies of patients in reference hospital based on the average life expectancy or life of the product	PE-SU-ECL-01 PE-SU-CD-01 PE-SU-GR-01	Annual
The results of the surveys of customer	PE-SU-MAM-01	Annual

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satisfaction	PE-SU-SC-01	

- **Customer complaints and claims for adverse events**

To treat this point, Surgival proceed as is defined in our specific procedure of **Treatment of non-conformities (PE-SU-NC-01)** and the corresponding registration **Non-Conformance Report (PR-SU-NC-01).** If it is considered a serious adverse effect attributable to medical device, following as assessment, proceed as is defined in our specific procedure of **Health Alert (PE-SU-AS-01).** The rates of serious adverse adverse effects that must communicate are :

- Leading to death
- Those lead to a serious deterioration of the health status of the patient, user or other person :
  - Illness or lesion with life threatering
  - Permanent impairment of a body function or permanent damage to a body structure
  - Process thar requires medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
  - -Potential incidents, those that could have led to death or serious deterioration of health, but they were no good due to fortunate circumstances or intervention of medical personnel.

In order to strengthen the health guarantees, establishing the use of the Health Card Implementation for all implants for spine and hip and knee. In addition, annually review and analyze all complaints or claims in the **Report of Management Review** as defined by specific procedure of **Measurement, Analysis and Improvement (PE-SU-MAM-01)** procedure, also in fulfillment of the plan at this point Postmarketing Monitoring.

- **The results of the surveys of customer satisfaction**

This section of the Plan is reviewed annually by the Report of Management Review, as defined by **PE-SU-MAM-01** procedure. Treatment of these surveys owns the procedure Evaluation Customer Satisfaction **PE-SU-SC-01**.

- **The review of the indications, contraindications, side effects and affirmed by follow-up studies of patients in reference hospital**

Annually, the top management of Surgival establish or review the referral hospitals in which clinical data will be extracted.

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

Risk	Product subcategories	Strategy for clinical Monitoring
Risk III	Joint replacements	Monitoring by each of the products

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Risk IIb	Osteosynthesis	Follow by product type each of the groups of generic products
Risk IIa	Trial Instrumental Motor Instrumental	Indirect implant on which its function is exercised
Risk I	General Instruments	

Yearly registration of clinical data relevant to this monitoring may be conducted through a questionnaire or report.

a) Registration of Clinical Data by Questionnaire

With the data collected in the questionnaire were checked or reviewed the potential adverse effects (residual risks of risk analysis) and their causes**.,** inmediate or long term, addition to the indications for which the products are prescribed. Thus, it is checked whether the products are safe, and if they get the operation or performance under normal conditions of use.

You must be signed and dated by a responsible Optional Specialist Clinical Data.

b) Registration of clinical Data by Report

With the findings of this report you can review the potential adverse effects and causes, immediate or long term, in addition to the indications for which the products are prescribed. Thus, it is checked whether the products are safe, and if they get the operation and performance under normal conditions of use.

This report must be signed and dated by a responsible Optional Specialist Clinical Data.

- **Treatment of results and conclusions obtained by Postmarketing Clinical Monitoring.**

Information obtained will serve as input to the revision of the Risk Analysis of the corresponding product, namely the residual risks that resulted. Thus, the management of the Risk Analysis of the products is performed continuously while it is marketed.

Therefore, it is important to note that if after this fix the residual risks, they are modified, must be analyzed the scope of the situation from these perspectives:

1. Must generate a new prospect or instructions.
2. You have to change any manufacturing process.
3. You have to modify product design.

In addition, such actions shall be reported to the Notified Body.

CLINICAL EVIDENCE

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Annex 11 includes reports of clinical control

- ***"Artroplastia de rodilla infectada. Revisión del tratamiento y valoración de resultados".*** 10 Vol. 37 – Nº209 enero – marzo 2002. J. Tomás Gil, J.L Rodrigo Pérez, J. Chismol Abad, J. Fenollosa Gomez. Servicio de COI Hospital Dr. Peset, Valencia.
- ***"The results at ten years of the Insall-***Burstein II total knee replacement". The journal of bone ¬ Joint Surgery (Br) Vol 81-B, Nº 7,July 1999. P. L. S. Li, J. Zamora, G. Bentley. From the Royal National Orthopaedic Hospital, Stanmore, England.
- ***"Artroplastia total de rodilla en pacientes con artritis reumatoide".*** Rev Méd Chile 2004; 132 : 337-345. Pedro Pablo Amenábar E. Departamento de Ortopedia y Traumatología, Pontificia Universidad Católica de Chile, Marco Carrión M. Residente de Ortopedia y Traumatología, Pontificia Universidad Católica de Chile. Jaime Paulos A. Departamento de Ortopedia y Traumatología, Pontificia Universidad Católica de Chile.

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