Instructions for Use

System for Knee Arthroplasty – Rotaflex

Legends of symbology used in Packaging

	Catalogue Number		Batch Code
	Sterile Product - Sterilized by Gamma Radiation		Product certified in accordance with Directive 93/42/EEC). When applicable.
	Date of Manufacture		Valid until
	Consult instructions for use		Single-Use Product
	Do not use if package is damaged		Do not re-sterilize
	Keep out of the sun		Fragile, handle with care.
	Keep Dry		Temperature Limit (40°C);

Features and technical specifications of the product

Technical Name: System for Total Arthroplasty Multi-Compartmental Femoral-Tibial-Patellar

Trade Name: System for Knee Arthroplasty – Rotaflex

System Components:

- Femoral Component;
- Tibial Plateau;
- Tibial Base;
- Anatomic Patella;

Raw Material:

- **Femoral Component / Tibial Base –** Cobalt Chromium Molybdenum Alloy (Co-28Cr-6Mo) – ASTM F75;
- **Tibial Plateau / Anatomic Patella –** Cross-linked Polyethylene (X-UHMWPE) – ASTM F-648

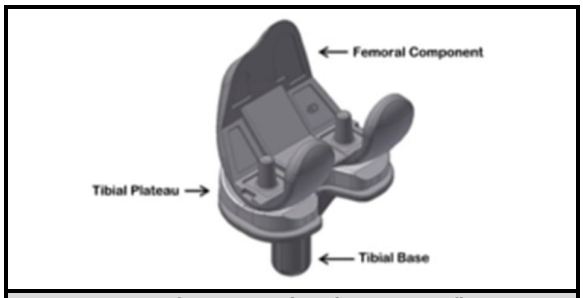
Sterile Product

Sterilization Method: Gamma Radiation (25 kGy)

Validity: 05 years (from sterilization date)

Description

The System for Knee Arthroplasty – Rotaflex is formed by a set of implantable devices, surgically invasive for long term use, developed for Knee articular replacement in primary multi-compartmental total arthroplasty procedures.



System for Knee Arthroplasty – Rotaflex

The knee arthroplasty is a complex surgical procedure which aims to the restoration of the joint function in order to remedy pain, which is obtained by substituting the involved joint by prosthetic components.

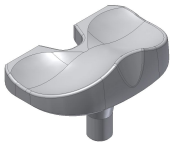
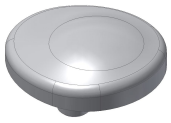
The product is a system of semi-restricted prosthesis, which aims to promote greater joint stability without compromising the medial-lateral movements of the knee, which is designed for the population of patients who have degenerative, traumatic and / or inflammatory diseases for which arthroplasty is indicated.

The system incorporates advances in design, allowing self-stabilization with option of preserving or not the posterior cruciate ligament with the same prosthetic design. The product provides the preservation of bone stock even in arthroplasty procedures with sacrifice of the posterior cruciate ligament. Furthermore, the design of the polyethylene insert allows rotation of the Tibial tray, promoting the stabilization of the prosthesis without compromising the knee medial-lateral movements. The product is intended to promote knee mobility of full extension to a maximum of 120 degrees of flexion.

The femoral and Tibial components that comprise the system are made from cobalt chromium molybdenum alloy (Co-28Cr-6Mo), and the plateau and patellar components are made from cross-linked polyethylene (X UHMWPE). The fixation way to the intramedullary canal of the femur and tibia is through cementation using polymethylmethacrylate bone cement (PMMA).

In order to restore joint and knee movements, the product consists of the following components:

- **Femoral Component:** metal component to replace the articular surface of the distal femur;
- **Tibial Base:** metal component to replace the articular surface of the proximal Tibia;
- **Tibial Plateau:** polymeric component that adapts to the Tibial base and articulates with the femoral component;
- **Anatomic Patella**: optional polymeric component to replace the patella articular surface.

			
Femoral Component	**Tibial Plateau**	**Tibial Base**	**Anatomic Patella**

Composition

The materials selected for the manufacture of the System for Knee Arthroplasty - Rotaflex meet the physical, chemical and mechanical properties required to achieve the desired performance for the product. The selection took into account factors such as the purpose of manufacturing, handling, sterilization, storage, as well as possible reactions of the material with human tissues and body fluids.

The materials for manufacturing are compatible with biological tissues, cells and bodily tissues which they come in contact with in implantable state, evidenced by a history of use in similar applications available in the worldly scientific and clinical literature. This confirmation also applies to the possible products of wear and degradation of materials at acceptable levels throughout its use.

The Femoral Component and the Tibial Base are made from the cobalt chromium molybdenum (Co-28Cr-6Mo) molten alloy, which complies with the requirements specified by ASTM F75 'Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)'.

The components Tibial Plateau and Anatomic Patella are manufactured from cross-linked polyethylene (X-UHMWPE), in accordance with the requirements specified by ASTM F648 "Standard

Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants'.

The choice of these materials for the manufacturing of the System for Knee Arthroplasty - Rotaflex was based on criteria of similarity (results widely described in the literature) and its biocompatibility and physicochemical and mechanical specification standards proven by the properties of these materials.

Indication and Finality

The System for Knee Arthroplasty - Rotaflex is indicated to replace the articular surface of the distal femur, proximal tibia and patellar surface during surgical procedure of total primary multi-compartmental arthroplasty of the knee, made under the circumstances in which this joint is jeopardized as a consequence of degenerative, traumatic or inflammatory disorders that compromise the function of the knee joint.

The total knee arthroplasty is indicated for skeletally mature patients with severe disabling pain as a result of destruction of the knee joint and which do not respond to conservative treatment, with drugs, with analgesic therapy exercises to maintain range of joint movements and improve the strength of periarticular muscles, weight reduction, activity modification, and so on.

Now, the use of the System for Knee Arthroplasty – Rotaflex is intended to:

- Relieve pain status;
- Correct deformities;
- Re-establish articular mobility;
- Improve overall knee function;

The product described herein is designed for use under the circumstances described above, so that all other uses are considered to be contraindicated or with no scientific support..

Contraindications

Listed below are the relative contraindications for the use of the device. Only the surgeon in charge can indicate the procedures after a thorough study of the case:

- Patients with general active infections or specific ones that may lead to complications;
- Patients in general impaired health status and/or immunosuppressed who are unable to undergo a surgical procedure;
- Patients who have sensitivity to foreign bodies. In these specific cases, testing should be performed;
- Patients with osteoporosis and/ or other bone disorders that may jeopardize the arthroplasty result;
- Patients with rapidly destructive bone disease or post irradiation osteonecrosis;
- Patients who suffer from progressive neurological diseases;
- Patients with cardiovascular diseases and local arterial or venous insufficiencies;
- Patients who use narcotic, alcoholic beverages or tobacco;
- Patients without osseous support needed to the implant proper fixation;
- Patients with absence or paresis of the muscle which controls the knee;

The only absolute contraindication for total knee arthroplasty is the presence of localized or systemic active infection. There are other relative contraindications, such as obesity, cognitive disorders, vascular disorders of the lower limbs, paralysis or severe muscle weakness around the joint.

The decision to use the product in a certain patient with the presence of relative contraindications above must be the result of a careful individual evaluation of the case, by the surgeon, based on their experience and insight.

Form of Presentation

The components that make up the System for Knee Arthroplasty - Rotaflex are packaged unitary in primary packaging blister type system, sealed with surgical grade paper (Tyvek® type) or in surgical wrapping system Tyvek® type, which act as a shield for the sterilization.

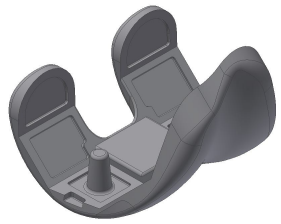
The product is available for commercialization in sterile condition. The adopted sterilization method is by Gamma Radiation (dosage of 25 kGy), which is outsourced by a certified company.

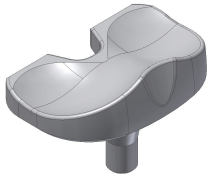
Once sterilized, the components packaged in its primary packaging, properly labeled, are packed in a cardboard carton (secondary packaging), which contains five copies of the traceability label and a pamphlet with instructions for the correct use and handling of the product.

A label containing information needed for the product identification is pasted on the product primary package as well as on its carton.

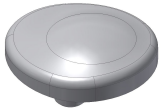
The System for Knee Arthroplasty - Rotaflex is made up by the following components, and each of them is available for commercialization in these dimensions:

List of the components of the System for Knee Arthroplasty – Rotaflex

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packed Quantity
	04.15.10.00000	Femoral Component Right Nº 00	**Sizes:** 00, 01, 02, 02 Plus, 03, 03 Plus, 04, 04 Plus, 05, 05 Plus, 06, 06 Plus, 07, 08.	Cobalt Chromium Molybdenum Alloy (Co-28Cr-6Mo) ASTM F75	01
	04.15.10.00001	Femoral Component Right Nº 01			
	04.15.10.00002	Femoral Component Right Nº 02			
	04.15.10.10002	Femoral Component Right Nº 02 Plus			
	04.15.10.00003	Femoral Component Right Nº 03			
	04.15.10.10003	Femoral Component Right Nº 03 Plus			
	04.15.10.00004	Femoral Component Right Nº 04			
	04.15.10.10004	Femoral Component Right Nº 04 Plus			
	04.15.10.00005	Femoral Component Right Nº 05			
	04.15.10.10005	Femoral Component Right Nº 05 Plus			
	04.15.10.00006	Femoral Component Right Nº 06			
	04.15.10.10006	Femoral Component Right Nº 06 Plus			
	04.15.10.00007	Femoral Component Right Nº 07			
	04.15.10.00008	Femoral Component Right Nº 08			
	04.15.11.00000	Femoral Component Left Nº 00	**Sizes:** 00, 01, 02, 02 Plus, 03, 03 Plus, 04, 04 Plus, 05, 05 Plus, 06, 06 Plus, 07, 08.	Cobalt Chromium Molybdenum Alloy (Co-28Cr-6Mo) ASTM F75	01
	04.15.11.00001	Femoral Component Left Nº 01			
	04.15.11.00002	Femoral Component Left Nº 02			
	04.15.11.10002	Femoral Component Left Nº 02 Plus			
	04.15.11.00003	Femoral Component Left Nº 03			
	04.15.11.10003	Femoral Component Left Nº 03 Plus			
	04.15.11.00004	Femoral Component Left Nº 04			
	04.15.11.10004	Femoral Component Left Nº 04 Plus			
	04.15.11.00005	Femoral Component Left Nº 05			
	04.15.11.10005	Femoral Component Left Nº 05 Plus			
	04.15.11.00006	Femoral Component Left Nº 06			
	04.15.11.10006	Femoral Component Left Nº 06 Plus			
	04.15.11.00007	Femoral Component Left Nº 07			
	04.15.11.00008	Femoral Component Left Nº 08			

	04.17.08.00009	Tibial Plateau Nº 0 Thickness 09 mm	**Size:** Nº 0 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.00011	Tibial Plateau Nº 0 Thickness 11 mm			
	04.17.08.00013	Tibial Plateau Nº 0 Thickness 13 mm			
	04.17.08.00015	Tibial Plateau Nº 0 Thickness 15 mm			
	04.17.08.00017	Tibial Plateau Nº 0 Thickness 17 mm			
	04.17.08.00019	Tibial Plateau Nº 0 Thickness 19 mm			
	04.17.08.00021	Tibial Plateau Nº 0 Thickness 21 mm			
	04.17.08.01009	Tibial Plateau Nº 01 Thickness 09 mm	**Size:** Nº 02 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.01011	Tibial Plateau Nº 01 Thickness 11 mm			
	04.17.08.01013	Tibial Plateau Nº 01 Thickness 13 mm			
	04.17.08.01015	Tibial Plateau Nº 01 Thickness 15 mm			
	04.17.08.01017	Tibial Plateau Nº 01 Thickness 17 mm			
	04.17.08.01019	Tibial Plateau Nº 01 Thickness 19 mm			
	04.17.08.01021	Tibial Plateau Nº 01 Thickness 21 mm			
	04.17.08.02009	Tibial Plateau Nº 02 Thickness 09 mm	**Size:** Nº 02 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.02011	Tibial Plateau Nº 02 Thickness 11 mm			
	04.17.08.02013	Tibial Plateau Nº 02 Thickness 13 mm			
	04.17.08.02015	Tibial Plateau Nº 02 Thickness 15 mm			
	04.17.08.02017	Tibial Plateau Nº 02 Thickness 17 mm			
	04.17.08.02019	Tibial Plateau Nº 02 Thickness 19 mm			
	04.17.08.02021	Tibial Plateau Nº 02 Thickness 21 mm			
	04.17.08.03009	Tibial Plateau Nº 03 Thickness 09 mm	**Size:** Nº 03 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.03011	Tibial Plateau Nº 03 Thickness 11 mm			
	04.17.08.03013	Tibial Plateau Nº 03 Thickness 13 mm			
	04.17.08.03015	Tibial Plateau Nº 03 Thickness 15 mm			
	04.17.08.03017	Tibial Plateau Nº 03 Thickness 17 mm			
	04.17.08.03019	Tibial Plateau Nº 03 Thickness 19 mm			
	04.17.08.03021	Tibial Plateau Nº 03 Thickness 21 mm			
	04.17.08.04009	Tibial Plateau Nº 04 Thickness 09 mm	**Size:** Nº 04 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.04011	Tibial Plateau Nº 04 Thickness 11 mm			
	04.17.08.04013	Tibial Plateau Nº 04 Thickness 13 mm			
	04.17.08.04015	Tibial Plateau Nº 04 Thickness 15 mm			
	04.17.08.04017	Tibial Plateau Nº 04 Thickness 17 mm			
	04.17.08.04019	Tibial Plateau Nº 04 Thickness 19 mm			
	04.17.08.04021	Tibial Plateau Nº 04 Thickness 21 mm			

	04.17.08.05009	Tibial Plateau Nº 05 Thickness 09 mm	**Size:** Nº 05 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.05011	Tibial Plateau Nº 05 Thickness 11 mm			
	04.17.08.05013	Tibial Plateau Nº 05 Thickness 13 mm			
	04.17.08.05015	Tibial Plateau Nº 05 Thickness 15 mm			
	04.17.08.05017	Tibial Plateau Nº 05 Thickness 17 mm			
	04.17.08.05019	Tibial Plateau Nº 05 Thickness 19 mm			
	04.17.08.05021	Tibial Plateau Nº 05 Thickness 21 mm			
	04.17.08.06009	Tibial Plateau Nº 06 Thickness 09 mm	**Size:** Nº 06 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.06011	Tibial Plateau Nº 06 Thickness 11 mm			
	04.17.08.06013	Tibial Plateau Nº 06 Thickness 13 mm			
	04.17.08.06015	Tibial Plateau Nº 06 Thickness 15 mm			
	04.17.08.06017	Tibial Plateau Nº 06 Thickness 17 mm			
	04.17.08.06019	Tibial Plateau Nº 06 Thickness 19 mm			
	04.17.08.06021	Tibial Plateau Nº 06 Thickness 21 mm			
	04.17.08.07009	Tibial Plateau Nº 07 Thickness 09 mm	**Size:** Nº 07 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.07011	Tibial Plateau Nº 07 Thickness 11 mm			
	04.17.08.07013	Tibial Plateau Nº 07 Thickness 13 mm			
	04.17.08.07015	Tibial Plateau Nº 07 Thickness 15 mm			
	04.17.08.07017	Tibial Plateau Nº 07 Thickness 17 mm			
	04.17.08.07019	Tibial Plateau Nº 07 Thickness 19 mm			
	04.17.08.07021	Tibial Plateau Nº 07 Thickness 21 mm			
	04.17.08.08009	Tibial Plateau Nº 08 Thickness 09 mm	**Size:** Nº 08 **Thickness:** 09, 11, 13, 15, 17, 19, 21 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.17.08.08011	Tibial Plateau Nº 08 Thickness 11 mm			
	04.17.08.08013	Tibial Plateau Nº 08 Thickness 13 mm			
	04.17.08.08015	Tibial Plateau Nº 08 Thickness 15 mm			
	04.17.08.08017	Tibial Plateau Nº 08 Thickness 17 mm			
	04.17.08.08019	Tibial Plateau Nº 08 Thickness 19 mm			
	04.17.08.08021	Tibial Plateau Nº 08 Thickness 21 mm			
	04.14.08.00000	Tibial Base Nº 00	**Sizes:** 00, 01, 02, 03, 04, 05, 06, 07, 08	Cobalt Chromium Molybdenum Alloy (Co-28Cr-6Mo) ASTM F75	01
	04.14.08.00001	Tibial Base Nº 01			
	04.14.08.00002	Tibial Base Nº 02			
	04.14.08.00003	Tibial Base Nº 03			
	04.14.08.00004	Tibial Base Nº 04			
	04.14.08.00005	Tibial Base Nº 05			
	04.14.08.00006	Tibial Base Nº 06			
	04.14.08.00007	Tibial Base Nº 07			
	04.14.08.00008	Tibial Base Nº 08			

	04.16.04.00027	Anatomic Patella Ø 27 mm	**Diameters:** 27, 30, 33, 36 mm	Cross-linked Polyethylene (X-UHMWPE) ASTM F-648	01
	04.16.04.00030	Anatomic Patella Ø 30 mm			
	04.16.04.00033	Anatomic Patella Ø 33 mm			
	04.16.04.00036	Anatomic Patella Ø 36 mm			

The surgeon in charge is responsible for the correct selection of components, dimensions, combinations and the surgical technique for implanting the System for Knee Arthroplasty - Rotaflex and must be familiar with the material, the application method and the surgical procedure adopted.

The procedure success depends upon the surgeon in charge and the correct selection, combination, positioning and fixation of the devices, after evaluating the patient and deciding which implant has to be used. It is also linked to the strict compliance with postoperative care recommended by the surgeon.

Supporting Materials

The supporting materials are the instruments designated solely for implanting the System for Knee Arthroplasty – Rotaflex.

These instruments are made of stainless steel for meeting the requirements specified by ASTM F-899 - Standard Specification for Stainless Steel for Surgical Instruments, which provides greater strength and durability.

The instruments below are not objects of this registration process and should therefore be purchased separately and always from the same implant manufacturer or their indication.

See below, list of instruments available from the manufacturer or their indication for implanting the product:

- Instruments – Knee - Rotaflex

The instruments are provided decontaminated, but not sterilized. Inappropriate sterilization of the surgical instrument might cause infection.

Surgical instruments are subject to wear and tear during their regular use. Therefore breaking may occur. The instruments should only be used for the purpose they were designed to and should be inspected regularly for possible wear and damage.

For further information concerning the instruments, please consult the dealer.

Warnings and Precautions

The team in charge of the procedure must consider the following warnings and precautions to use the product:

- The product must only be used after a thorough analysis of the surgical procedure to be adopted and complete reading of these instructions for use;
- The product should only be handled by specialized surgical teams with specific knowledge and capacity building concerning arthroplasty techniques. The choice and dominance of the adopted technique to be applied are under the responsibility of the surgeon in charge;
- Inappropriate choice and selection of the implants to be used, as well as mistakes concerning the indication, handling and application technique might cause excessive stress and tractions on the implant leading to failure due to fatigue, fracture and even looseness;
- Clinical results and the durability of the implants are totally dependent upon a precise surgical technique;
- The deployment under improper bone bed can cause early looseness and progressive loss of bone stock;
- The product must be used together with acrylic bone cement;
- A greater risk of the implant failure is its use in patients who are predisposed to disobey medical guidelines and postoperative restrictions, such as children, elderly, individuals with neurological changes, or addicted;
- Implant failure risks are greater in patients who practice physical exertion activities or those who practice sports during the postoperative period, contradicting the medical restrictions;
- The postoperative complications represent a greater risk in patients with functional expectations beyond the articular replacement load capacity; patients with morbid obesity and patients with small bone structure;
- The Product should not be used whether there is not an appropriate osseous support that might guarantee the implant stability;
- The patient must be submitted to periodic medical monitoring to check the implant, the bone and the adjacent tissues conditions;
- The pre and perioperative prophylactic antibiotic therapy as well as antibiotic therapy - in cases there is a local and/or systemic predisposition or infections occur – are under medical criteria;
- The product should not be used with components from other manufacturers or purpose. The combination of implants from different manufacturers or purposes can result incongruity among the components;
- The product identification must be strictly observed and are not permitted combinations with components from other manufacturers or purpose;

- Care of this material is of responsibility of skilled staff, who should follow the normalization and/or any applicable local regulations;
- Falls or crushing on hard surfaces might damage the product. So, it is necessary the handler to perform inspection of the product to check its integrity while it is unpacked and if there is any abnormality, the product should not be used;
- Only skilled staff for the surgical procedure may open the package;
- Do not use the product whether the validity period is expired or the package damaged;
- Handle with care;
- Single use product – Do not reuse;
- The implants must NEVER be reused. Although they may seem undamaged, prior tensions they have been submitted may cause imperfections that would reduce the lifetime of the product in a re-implantation;
- REPROCESSING PROHIBITED;
- Sterile Product – Do Not Re-Sterilize;
- Manufacturing date, validity term and batch number: see label;

Adverse Effects

Every surgical procedure presents some common risks and complication possibilities such as infections, bleeding, allergic drug reactions and anesthetic risks, among others. The following complications and adverse effects can still be associated with the implantation of the product:

- Loosening, dislocation, deformation, break of the implant or osteolysis;
- Pains, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Inflammatory reactions, associated or not to the loosening or releasing of the implant;
- Bone necrosis or adjacent soft tissues;
- Device breaking may make removal difficult or impossible;

Use Instructions

For the correct use of product, the following instructions should be adopted:

- The care of this material is responsibility of the skilled staff, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (materials center and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for arthroplasty, and the surgeon in charge is responsible for the choice and dominance of the surgical technique to be performed;
- The useful life established for the System for Knee Arthroplasty – Rotaflex is 10 (ten) years, once the devices are implanted by adopting an appropriate surgical technique and observing the details of the topics "Indication and Purpose", "Contraindication", "Warnings and Precautions" and “Instructions for Use”;
- The realization of revision surgery after the useful life period may be required, under medical criterion, if the wear and / or looseness of components is observed;
- For applying the product, specific instruments – indicated in the “Supporting Material” - are necessary. Due to the possibility of dimensional and/or functional incompatibility it MUST NOT be used with any other instruments different from the ones indicated by the manufacturer
- It is necessary washing and drying the channel of the Tibial base component prior to implantation of other components to ensure that there is no residual bone or tissue in the joint between the components;
- Antes Before starting the insertion of the polymeric components, the surface of other prosthetic components must be free of waste as tissue fragments, or particles of bone cement.

Guidance to the Patient and/or Legal Representative

The responsible surgical team should guide the patient or his legal representative about:

- The suitable care and restrictions during the postoperative period. The capacity and willingness of patient to follow these guidelines are one of the most important aspects in a surgical procedure;
- The fact that the risks are greater when using in patients with predisposition to disobey the medical guidelines, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or addicted;
- The fact that the product does not substitute nor does have the same performance of normal bone and therefore can break, deform or loosening due to excessive effort or activities of early load and other situations;
- All postoperative restrictions, overall those ones related to sport and occupational activities.
- The fact that postoperative complications represent a greater risk when it is used in patients with functional expectations beyond the articular replacement load capacity, patients with morbid obesity and patients with small bone structure;
- The necessity of use of external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load is under exclusive medical criteria;
- The necessity of periodic medical monitoring to check the conditions of the implant, the bone and the adjacent tissues;
- The fact that the non-performing of the revision surgery when there is component releasing can lead to progressive bone stock loss.
- The fact that implants can interfere with results of imaging examinations. So, implant users should report this fact when submitted to such examinations;
- The complications related to the knee arthroplasty procedures, as well as the listed information in this topic “Guidance to the patient and/or the Legal Representative” and in the topic “Adverse Effects;

Sterilization

The product is available in sterile condition. It is adopted the Gamma Radiation (dosage of 25 kGy) Sterilization method.

The product manufacturing process is done with great care, in order to meet the intended performance for it. So, the surgical team and all the other who are involved with the procedure should handle the devices properly in order to minimize the infection risks.

Sterile Product – Do Not Re-sterilize.

Do not use the product if the package is damaged.

Contamination Risk

As this is an implantable product, there are risks of biologic contamination and viral disease transmission in cases in which it has to be explanted.

For minimizing these risks, the explanted product should be treated as potentially contaminant material and the standardization and/or other local regulations applied should be adopted.

Product Discard

The components which were explanted or regarded as inappropriate for use must be discarded. It’s highly recommended that before discarding, the product is mischaracterized, and so its parts can be cut, bent or sanded.

The implants should be discarded in proper locals, to avoid the environmental contamination and other individuals. It is recommended adoption of local legal regulations for potentially contaminant products.

Single use product – DO NOT REUSE.

REPROCESSING PROHIBITED

Traceability

To ensure the traceability of the implanted product, and comply with the requirements for sanitary surveillance, the surgeon or his team must register in the patient's medical record the information about the product. Furthermore, such information must also be passed to the distributor of the product and to the patient in order to complete the cycle of the product traceability established. The information necessary for traceability are relatives to the product used, surgery and patient, as below:

- Name of patient who received the implant;
- Surgeon's name;
- Hospital's name;
- Manufacturer's name;
- Supplier's name;
- Surgery date;
- Code of product;
- Number of batch of the product;
- Quantity used;
- Registration product at ANVISA.

The surgeon in charge and his team must use the traceability labels provided in five copies inside the product package. The labels are to be pasted onto the patient medical records for keeping the implanted product traceability. Besides that, one of those labels must have given the patient in order he or she can get information about the implanted product in his/her surgical procedure.

The following measures necessary for product traceability information are printed on the labels:

- Manufacturer Identification;
- Component code;
- Component Batch Number;
- Component Description (in three languages – Portuguese, English and Spanish);
- Quantity;
- Nº. of ANVISA Registration;
- Technical Name;
- Product Trade Name;

Traceability information is required for notifying the Sanitary Surveillance Agency ANVISA, either by the health service or by the patient him/herself, when serious adverse events occur, so that it helps to drive appropriate investigations.

Storage and Transport

For the storage it is recommended dry and airy place, without exposure to light incidence, humidity or contaminants substances.

For this is a Sterile Product the storage place humidity and temperature must be monitored and kept below 40ºC.

The implants cannot be stored directly on the floor. It is recommended the use of shelves with minimal height of 20 cm.

The product should be kept in its original packaging until the moment of its use, being that the surgical packaging opening and handling should be done by trained personal for this procedure.

The product should be transported properly, avoiding falls and friction that can damage the structure and surface of the part.

For information about manufacturing date and batch number: see label.

Further Information

Manufactured and distributed by:
MDT – Indústria Comércio Importação e Exportação de Implantes SA
Address: Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP – Brasil
CEP: 13505-600
Phone/ Fax: (55-19) 2111-6500
CNPJ: 01.025.974/0001-92
Technician Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

ANVISA Registration Nº: 10417940093
Review: 00
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ALERT
INSTRUCTIONS FOR USE

These INSTRUCTIONS FOR USE are not available in printed form, they are available at the website of the manufacturer www.mdt.com.br**.**

The INSTRUCTIONS FOR USE on the website are indexed by REGISTRATION/ CADASTRE ANVISA´s NUMBER and its TRADE NAME of the product, informed at the label of the product purchased.

All the INSTRUCTIONS FOR USE provided on the website have the identification of the revision and date of emission of the document. The user must pay attention to the correct version (revision and date of emission) of the document regarding the MANUFACTURING DATE informed at the label of the product purchased.

If it is interest to the user, the INSTRUCTIONS FOR USE may be provided in printed form, with no extra cost and the request of the same shall be held by the CAP (Customer Service Department) manufacturer, as following:

Customer Service Department – CAP:
Telephone: +55 19 2111.6500
FAX: +55 19 2111.6500
http://www.mdt.com.br/contato
Avenida Brasil, 2983 – Distrito Industrial CEP: 13505-600 | Rio Claro – São Paulo – Brasil

Opening Hours: 8 AM to 5 PM, from Monday to Friday, except holidays.