Instructions Use

Bipolar Cup

Symbols used in packaging

REF	Number on the brochure	LOT	Lot code
STERILE R	Sterile Product – Sterilized by Gama Radiation		Manufacturing date
	Valid until		Consult instructions for use
	Fragile, handling with care		Keep away from the sun
	Keep dry		Single use product
	Do no Re-Sterilize		Temperature Limit (40°C)
	Do not use if the package is damaged		

Product technical specifications and Characteristics

Technical Name: Hip Prosthesis

Commercial Name: Bipolar Cup

Commercial Model:

- Bipolar Cup with Lock

Row Material: Polythene (UHMWPE) / Steel Stainless Alloy (18Cr-14Ni-2.5Mo)

Sterile Product

Sterilization Method: Gamma Radiation (Dose 25 kGy)

Validity: 05 years (from sterilization date)

Description

The product is an implantable device, surgically invasive of long term use, used in hip articular substitution procedures at acetabular portion.

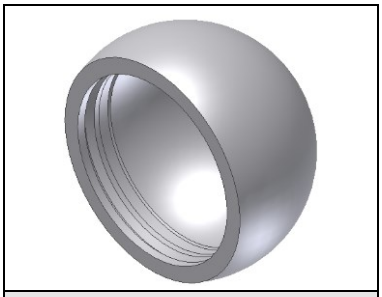
The hip articular substitution procedure is performed in circumstances in that acetabular portion in this articulation in mature skeletally individuals has presented itself compromised in consequence of pathologies as disease degenerative articular (osteoarthrosis) no inflammatory, femoral head vascular necrosis, acetabular protrusion, traumatic arthritis, slipped epiphysis proximal of femur, ankylosis of origin no infectious, hip arthrodesis and in patients with malignant bone tumors.

The bipolar cup articulates itself with acetabular cavity, restoring the femoral-thigh articulation of partial form. The fixation form of the acetabular cavity is made by impaction, not is necessary cementation.

The bipolar cup has two movement poles, being first in femoral head interface with the polyethylene acetabular nucleus, and the second at bipolar cup interface with the natural acetabular cavity of the patient.

It has a lock with the finality of locking the interchangeable head. It has as principal characteristic: low acetabular friction, due to the internal movement between the femoral head and the polyethylene acetabular, preventing the cartilage wear, prolonging this way the life of the prosthetic component.

Below illustrative image of the commercial models that composes the family of the Bipolar Cup:



Bipolar Cup with Lock

Composition

The selected material to the composition of the product presents the required properties to achieve the desired performance. This selection considers factors as: the biocompatibility and mechanics, chemicals, physicals properties required for the product.

The commercial models that compose the family of the Bipolar Cup are made from stainless steel Alloy (18Chromium-14Nickel-2,5Molybdenum). The internal part and the lock are made from Ultra-High-Molecular-Weight (UHMWPE) Polyethylene.

The polyethylene (UHMWPE) and the stainless steel Alloy (18Chromium-14Nickel-2,5Molybdenum) used to manufacturing of the commercial models that compose the family of the Bipolar Cup respectively meet the specified requirements by standards: ASTM F-138 - Standard Specification for Wrought 18 Chromium -14 Nickel - 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) and ASTM F- 648 – Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form, for Surgical Implants.

These materials studied exhaustively have shown satisfactory results in long term segments. Characterized by its mechanics, chemicals and physicals properties for this aim, presents proven biocompatibility for a clinical historic vast largely described in the worldwide literature.

Indication and Purpose

The finality of the Bipolar Cup is substitute the wear natural cup or traumatized allowing the movement of the interchangeable head.

Its use is indicate for mature skeletally patients like part of the acetabular portion reconstruction of, in totals arthroplasty of hip and indication for procedures of non conventional arthroplasty, in patients with malign bone tumors.

The application of product must consider the damage, the pathology, the bone characteristics, the charges and muscular forces (tension and traction) over the segment to be treated.

The products described here were developed for use in the above described circumstances; such that any other using are considered contra indicated or without scientific substrate.

Contra Indication

Below are listed the contra indications related to the device using, being the responsibility of the surgeon the procedure indication, after a thorough case study:

- Patients with specific or general active infections that may to complications;
- Patients with general impaired state and/or immune compromised, unable to be submitted to a surgical procedure;
- Patients with sensibility to foreign bodies, in these cases, tests should be performed;
- Patients with osteoporosis and/or bone affections that may compromise the arthroplasty results;
- Patients carriers of bone disease destructive quickly or osteonecrosis post-irradiation;
- Patients carriers of progressive neurologic diseases;
- Patients carriers of local circulatory diseases and with arterial or venous insufficiencies;
- Patients who use narcotic substance, alcohol or smoke;

- Patients less bone support that permit a implant adequate fixation;
- Patients with absence or partial paralysis of the muscles that control the hip.

Form of Presentation

The commercial models that compose the family of the Bipolar Cup are unitarily packed in primary package system which acts as a barrier of sterilization.

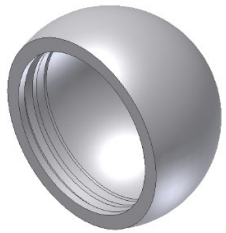
The product is supplied in a sterile condition, being that the adopted sterilization method is by Gamma Radiation (25kGy dose), performed procedure by qualified outsourced company dully.

After of the product sterilization, is packaged in its labeled primary package dully and packed in a cardboard box (secondary package), which follow with a note with instructions for use and five traceability labels.

Above the primary package and over the cardboard box is glued a label with necessary informations for product identification.

The Bipolar Cup is presented in the following commercial models, being which each one of commercial models are available for marketing in the following dimensions:

List of commercial models that compose the family of the Bipolar Cup

Illustrative Image	Code	Description	Dimensions	Material de Fabricação	Qtde Embalada
	04.01.01.220XX	Bipolar Cup with Lock	**Ø 22 mm** – 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52 54 mm	Polyethylene (UHMWPE) Steel Stainless Alloy (18Cr-14Ni-2,5Mo)	01
	04.01.01.260XX		**Ø 26 mm** – 40, 42, 44, 46, 48, 50, 52 mm	Polyethylene (UHMWPE) Steel Stainless Alloy (18Cr-14Ni-2,5Mo)	01
	04.01.01.280XX		**Ø 28 mm** – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60 mm	Polyethylene (UHMWPE) Steel Stainless Alloy (18Cr-14Ni-2,5Mo)	01
	04.01.01.320XX		**Ø 28 mm** – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60 mm	Polyethylene (UHMWPE) Steel Stainless Alloy (18Cr-14Ni-2,5Mo)	01

Ancillary Components

The ancillary implants of the register objects are:

- Interchangeable Femoral Head (short, middle, long and extra-long Neck);
- Interchangeable Femoral Head (Necks of -04 to +09);
- Cemented Femoral Head: Máxima and SPOAC NG;
- No Cemented MD-6 Femoral Prosthesis;
- Endoprosthesis IOT Modular.

The cemented femoral prosthesis and the interchangeable femoral head are made from steel stainless Alloy (18Cr-14Ni-2.5Mo) that meet specified requirements by standard ASTM F-138 138 – Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants.

The components of the Endoprosthesis Modular IOT and No Cemented Femoral Prosthesis are made from titanium Alloy (Ti-6Al-4V) that meet specified requirements by standard ASTM F-136 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

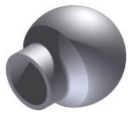
The correct selection of models, measures and commercial models combinations that compose the family of the Bipolar Cup, as well as of their ancillary that will be implanted are responsibility of the surgeon who is responsible for the technique adopted. The surgeon should be familiar with the material, method of application and surgical procedure to be adopted too.

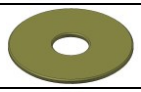
The success of the procedure is linked to the correct selection, combination, positioning and fixation of the devices, which is the responsibility of the surgeon that assesses the patient and decides which the implants to be used. It is also bound to strict compliance with postoperative care recommended by the responsible surgeon.

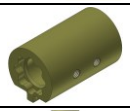
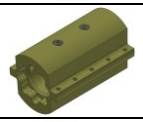
The follow, indication of the ancillary components and its correct combination with the commercial models that compose the family of the Bipolar Cup:

Bipolar Cup – Commercial Models	Ancillary – Cephalic Components	Ancillary – Femoral Components
Bipolar Cup Steel Stainless Alloy (18Cr-14Ni-2.5Mo) / Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(short, middle, long and extra-long Neck)** Steel Stainless Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks of -04 to +09)** Steel Stainless Alloy (18Cr-14Ni-2.5Mo)	**Máxima Femoral Prosthesis** Steel Stainless Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Steel Stainless Alloy (18Cr-14Ni-2.5Mo)
Bipolar Cup Steel Stainless Alloy (18Cr-14Ni-2.5Mo) / Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(short, middle, long and extra-long Neck)** Steel Stainless Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks of -04 to +09)** Steel Stainless Alloy (18Cr-14Ni-2.5Mo)	**MD-6 Femoral Prosthesis** Titanium Alloy (Ti-6Al-4V)
Bipolar Cup Steel Stainless Alloy (18Cr-14Ni-2.5Mo) / Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(short, middle, long and extra-long Neck)** Steel Stainless Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks of -04 to +09)** Steel Stainless Alloy (18Cr-14Ni-2.5Mo)	**Endoprosthesis IOT Modular** Titanium Alloy (Ti-6Al-4V)

List of ancillary of the commercial models that compose the family of the Bipolar Cup

Illustrative Image	Code	Commercial Model	Dimensions	Raw Material	Packaged Quantity
Cephalic Components					
	04.04.03.XXXXX	Interchangeable Femoral Head Cone 12/14	Diameter: 22, 26, 28 e 32 mm; Necks: Short, Middle, Long and Extra-long;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
	04.04.07.XXXXX	Interchangeable Femoral Head Cone 12/14 (Necks ranging of -04 to +09)	Diameter: 22 mm – Necks -02, Standard, +03; Diameter: 26 mm – Necks -04, -02, Standard, +03, +06, +09; Diameter: 28 mm – Necks -04, -02, Standard, +03, +06, +09;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
Femoral Components					
No Cemented Femoral Prosthesis					
	04.30.51.XXXXX	No Cemented MD-6 Femoral Prosthesis Cone 12/14 mm Off-set 43 mm 130º	**Ø 14 e 15 mm –** 100, 150, 180, 230 mm; **Ø 16, 17, 18, 19 e 20 mm** – 100, 150, 180, 230, 280 mm; **Ø 21, 22, 23, 24 e 25 mm** – 150, 180, 230, 280 mm.	Titanium Alloy (Ti-6Al-4V)	01
	04.30.52.XXXXX	No Cemented MD-6 Femoral Prosthesis Cone 12/14 mm Off-set 37 mm 135º	**Ø 14 e 15 mm –** 100, 150, 180, 230 mm; **Ø 16, 17, 18, 19 e 20 mm** – 100, 150, 180, 230, 280 mm; **Ø 21, 22, 23, 24 e 25 mm** – 150, 180, 230, 280 mm;	Titanium Alloy (Ti-6Al-4V)	01
Cemented Femoral Prosthesis					
	04.30.01.37XXX	Máxima Femoral Prosthesis 37,5 mm Cone 12/13 Primary;	Offset: 37,5 mm; Cone: 12/13; Nºs: 01, 02, 03;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
	04.30.03.44XXX	Máxima Femoral Prosthesis 44,0 mm Cone 12/13 Primary;	Offset: 44,0 mm; Cone: 12/13; Nºs: 01, 02, 03, 04;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
	04.30.04.44XXX	Máxima Femoral Prosthesis 44,0 mm Cone 12/13 Revision;	Offset: 44,0 mm; Cone: 12/13; Nºs: 01, 03 Lengths: 250 e 300 mm;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
	04.30.02.37XXX	Máxima Femoral Prosthesis 37,5 mm Cone 12/14 Primary;	Offset: 37,5 mm; Cone: 12/14 Nºs: 01, 02, 03;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
	04.30.05.44XXX	Máxima Femoral Prosthesis 44,0 mm Cone 12/14 Primary;	Offset: 44,0 mm; Cone: 12/14; Nºs: 01, 02, 03 e 04;	Steel Stainless (18Cr-14Ni-2.5Mo)	01

	04.30.06.44XXX	Máxima Femoral Prosthesis 44,0 mm Cone 12/14 Revision;	Offset: 44,0 mm; Cone: 12/14; Nºs: 01, 02, 03, 04; Lengths: 230 mm;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
	04.30.50.XXXXX	Femoral Prosthesis SPOAC NG	Offset: 33,0; 36,8; 40,0; 43,0 e 47,0 mm; Angle: 130º, 135º, 140º; Sizes: 01, 02, 03, 04, 05;	Steel Stainless (18Cr-14Ni-2.5Mo)	01
Endoprosthesis IOT Modular					
	04.07.23.000XX	Tibial Plateau	54, 57, 59, 62, 64, 67, 69, 72 mm	Polyethylene UHMWPE	01
	04.07.36.000XX	Ring of Support for Endoprosthesis	Ø2x40 mm; Ø2x46 mm; Ø2x52 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.07.40.XXXXX	Endoprosthesis IOT Modular Nail	Cone 12/14 Ø8 – 45, 70, 95 mm Ø9 – 45, 70, 95 mm Ø10 – 45, 70, 95 mm Ø11 – 95, 130, 160 mm Ø12 – 95, 130, 160, 180, 200, 250 mm Ø14 – 95, 130, 160, 180, 200, 250 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.07.42.12095	Endoprosthesis Modular IOT Right/Left Ti	Cone 12/14 – 123,2 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.07.43.0000X	Endoprosthesis Modular IOT Base Tibial	Cone 12/14 – 100 mm	Titanium Alloy (Ti-6Al-4V)	01

	04.07.44.000XX	Endoprosthesis Modular IOT Component Intermediary	Cone 12/14 - 25, 50, 100 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.07.46.00000	Endoprosthesis Modular IOT Component Trochanteric	Cone 12/14 – Size only	Titanium Alloy (Ti-6Al-4V)	01
	04.07.47.00045	Endoprosthesis Modular IOT Component Diafisario Internal	Cone 12/14 – 45 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.07.48.00025	Endoprosthesis Modular IOT Component Diafisario External	Cone 12/14 – 25 mm	Titanium Alloy (Ti-6Al-4V)	01
	07.07.49.00048	Endoprosthesis Modular IOT Component Angular Right/Left	Cone 12/14 – 48 mm	Titanium Alloy (Ti-6Al-4V)	01
	07.07.50.0000X	Endoprosthesis Modular IOT Articulated Knee	Cone 12/14 – 103 e 113 mm	Titanium Alloy (Ti-6Al-4V) Polyethylene UHMWPE	01
	07.07.51.000XX	Endoprosthesis Modular IOT Component Tibial Proximal	Cone 12/14 - 54, 59, 64, 69 mm	Titanium Alloy (Ti-6Al-4V) Polyethylene UHMWPE	01
	07.07.52.1XXXX	Endoprosthesis Modular IOT Nail Fem. With Anti-Curvato	Cone 12/14 - 11x130 mm; 12x130 mm; 13x130 mm; 14x130 mm	Titanium Alloy (Ti-6Al-4V)	01

Support Materials

The support materials are instrumentals designed only for implantation of the Bipolar Cup and their above ancillary respectives.

These instrumentals are made in steel stainless that meet specified requirements by standard ASTM F-899 – Standard Specification for Stainless Steel for Surgical Instruments, which provides high resistance and durability.

The instrumentals below are not object this registry process and must therefore be purchased separately and always from the same manufacturer of the implant or indicated by them.

Below is a list of available instrumentals by manufacturer or by them indicated to implantation of the Bipolar Cup and their respectives ancillary:

- 0Q-07 – Instrumental Bipolar

The instrumentals are provided decontaminated, but not sterilized. Inadequate sterilization of surgical instruments can cause infection.

The surgical instrumentals are subject to wear and tear during the normal use, and it can therefore break. The instruments should be used only for its purpose and should be inspected regularly to check for possible wear and damage.

For more information on the instrumental, see the representative.

Warning and Precautions

For use of the product, the responsible team must consider the following warning and precautions:

- The Bipolar Cup must be only used after a detailed analysis of the surgical procedure to be adopted and complete reading of these instructions for use;
- The product must be used by specialized surgical team, with specific knowledge and capacity on the arthroplasty techniques, being the responsibility of the surgeon the choice and dominion of the technique to be applied;
- The selection and inadequate choice of the implants to be used, as well as the mistakes at the indication, handling and application technique can cause excessive tensions and tractions on the implant, leading to failure by fatigue, fracture and to release them;
- The clinical results and the durability of the implants are extremely dependents on a surgical precise technique;
- The implantation over inadequate bone bed can cause premature loosening and progressive loss of bone stock. In this cases supplemental methods of bone grafting in together with screens and reinforcements should be adopted;
- The product does not should be used together with bone cement;
- The inadequate fixation of bipolar cup can cause loosening and/or premature wear, as well as progressive loss of bone stock;
- The incorrect locking can cause the dissociation among the components that compose the bipolar cup (internal and external part);
- The use in patients with predisposing to disobey the medical guidelines and restrictions after surgery, as children, elderly, individuals with neurological disorders or dependent in narcotic substances, represent a greater risk for failure of the implant;
- The risk of failure of the implant are greater in patients engaged in efforts activities or practice sports activities, during the postoperative period, contrary to the medical restriction;
- The postoperative complications represent a greater risk when the product is used in patients with functional expectative beyond of what can be promoted by articular substitution, patients with morbid obesity and small frame;
- The Bipolar Cup and their respective ancillary should not be used if it do not have an adequate bone support to ensure the implant stability;
- The patient must make a periodic medical monitoring to check the conditions of the implant, of the bone and adjacent tissues;

- The medical criteria, can be use an antibioticterapy prophylactic pre and perioperative, and the antibioticterapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections;
- The implant should not be used with components from other manufacturers or purpose. The combination of implant of manufacturers or different purpose can result in incongruence among the components;
- It should be observed closely the identification of the product and are not allowed combinations of components from other manufacturers or purpose;
- The care of these materials are the responsibility of qualified personnel, which should follow the standards and/or other local regulations applied;
- Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary the user perform an inspection of the product integrity, when the packaging is opened, and if any abnormality is observed the product should not be used;
- The opening of the packaging for surgical use should only be performed by qualified personnel for this procedure;
- Do not use the product if the packaging is breached or with the validity expired;
- Handle with care;
- Product use only – Do not reuse;
- The implants must NEVER be reused. Although they may seem undamaged, tensions previous that they have been submitted can cause imperfections that would reduce the lifetime of the product in a re-implantation;
- PROHIBITED REPROCESS;
- Sterile Product – Do no Re-Sterilize;
- Manufacturing date, validity term and batch number: see label.

Adverse Effects

Every surgical procedure presents risks and possibility of complications, being that any common risks are infection, bleeding, drug allergic reaction and anesthetic risks, among others. The following complications and adverse effects can still be associated with the implantation of the product:

- Loosening, displacement, deformation, fracture of the implant or osteolysis;
- Post operative pain, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Bone necrosis or adjacent soft tissues;
- Break of the implant that can make its removal difficult or impractical.

Instruction of Use

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

- The care of this material is the responsibility of the qualified personnel, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (center of materials and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for non conventional arthroplasty, and the responsibility of the surgeon the choice and dominion of the technique to be applied;
- The Bipolar Cup shelf-life established is 10 (ten) years, since the devices are implanted and an adequate surgical technique is adopted, and the information on the topics “Indication and Purpose”, “Contraindication”, “Warnings and Precautions” and “Instructions for Use” are observed;
- May be necessary, the medical criteria the review surgery, after the period of life time if the wear and/or release of components are seen;
- Is advisable, previously to the insertion of the bipolar cup, the obtaining of a hemispherical acetabular cavity with viable bone bed, being that in any cases, method of bone grafting associated to use of screens and reinforcements should be adopted to establish the bone stock and ensure a good stability of the implant;

- For the application of Bipolar Cup and their ancillary components respective is necessary the use of specific instrumental indicated in topic: “Support Materials”. Should be not used with instruments other than those indicated by the manufacturer, due the possibility of dimensional incompatibility and/or functional;
- The correct combination of the Bipolar Cup and their ancillary components is indicated in topic: “Support Materials”. Should be not used with components other than those indicated by the manufacturer, due the possibility of dimensional and functional incompatibility.

Guidance to the patient and/or the Legal Representative

The responsible team must guide the patient or his legal representative on:

- The adequate 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 higher when using in patients with predisposition to disobey the guidelines medical, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or chemical dependents;
- The fact that the product does not substitute and does not have the same performance of normal bone and therefore can break, deform or loosen due to excessive effort or activities of early load and other situations;
- All postoperative restrictions, particularly those related to sports activities and occupational;
- The fact of the postoperative complications represents a higher risk when the product is used in patients with functional expectative beyond what can be promoted by articular substitution, patients with morbid obesity and patients with small frame;
- The necessity of use, the medical criteria exclusively of external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load;
- The necessity for periodic medical monitoring to check the conditions of the patient, the bone and the adjacent tissues;
- The fact that the non-performing of the surgery review when the components are loose can result in progressive loss of bone stock;
- The fact that implants can interfere with results of imaging examinations. Thus, implant users should report this fact when carrying out such examinations;
- Complications related to hip arthroplasty procedures, such as the information listed in this topic “Guidelines for Patient and/or the Legal Representative” and in the “Adverse Effects”.

Sterilization

The Bipolar cup is supplied in a sterile condition. The method adopted for sterilization is by Gamma Radiation (25 kGy).

The manufacturing of the Bipolar Cup is performed carefully in order to meet the intended purpose to the product. Thus, the surgical team and others involved must handle the device properly to minimize the infection risks.

Sterile Product – Do no Re-Sterilize.

Do not use if the package is damaged.

Risk of Contamination

It is an implantable product, in cases what there is the necessity of explant of the Cup Bipolar, there are risks of biologic contamination and transmission of viral diseases.

To minimize this risks, the explanted Bipolar Cup must be treated as contaminant potentially material, and must be adopted the standards and/or other local regulations applied;

Product Discard

The Bipolar Cup explanted or considered inadequate for use, must be discarded. It is recommended that prior to disposal, the product is mischaracterized, and to such the parts may be cut, twist or file.

The implants must be discarded in appropriate locations, to avoid contamination of the environment and other individuals. It is recommended the adoption of legal local regulations for disposal of the products potentially contaminants.

Product for single use – not reuse.

Traceability

To ensure the traceability of the implanted product, and comply with the requirements of the surveillance Agency, 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 implanted product traceability. The information necessary for traceability are the related 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;
- Register of the product at ANVISA;

The responsible surgeon and his team must use of the labels for traceability supplied in the product packaging, pasting them into the patient's medical record to maintenance of the traceability of the product implanted. In addition, one of the labels should be supplied to the patient for that has information about the product implanted in his surgery.

The labels contain the data of the product as: code, description, and lot number, among other information.

The traceability information are necessary to notify the department of health and/or the patient himself, the Sanitary Surveillance Agency - ANVISA and manufacturer, when there is occurrence of serious adverse events, for the conduct of appropriate investigations.

Storage and Transport

For storage, it is dry and airy place, with no incidence of exposure to light, moisture or contaminants.

As this is a sterile product, temperature and humidity of the storage locate should be monitored and maintained below 40º.

The implants can not be stored directly on the floor. Therefore, the use of shelves with at least 20 cm of height is recommended.

The product should be maintained in their original packaging until the moment of its use, being that the opening the package for surgical use and handling of the product should be performed by qualified personnel for this procedure;

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

For information about the date of manufacture, validity term and lot 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: 10417940055

Review: 01

Issue: March 12th, 2012.

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 SAC (Customer Service Department) manufacturer, as following:

Customer Service Department:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

http://www.mdt.com.br

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.