














Instructions of use

System for Hip Arthroplasty - MD Forte

Legends of the symbols used on packaging

	Product Code		Batch Number
	Sterile product – Sterilized by Gamma Radiation		Date of Manufacturing
	Expired date		See instructions for use
	Single use product		Do not re-sterilize
	Do not use if package is damaged		Avoid direct exposition to sunlight
	Caution - Fragile		Temperature limit (40°C)
	Protect from Humidity		

Characteristics and Technical Specifications of the Product:

Technical Name: System for Hip Arthroplasty

Trade Name: System for Hip Arthroplasty - MD Forte

Components of the System:

- MD Acetabular Cup Ti (Ø Outer – 46 to 70 mm/ Ø Inner – 35 to 52 mm);
- Acetabular Screw Ti (Ø 6.5 mm – length from 15 to 55 mm);
- Acetabular Insert MD Delta (Ø Outer – 35 to 52 mm/ Ø Inner – 28 to 40 mm);
- Interchangeable Femoral Head Forte Ceramic (Ø Outer – 28 to 40 mm – Cones variando from – 3.5 mm to + 8.0 mm);

Raw Material:

- MD Acetabular Cup Ti – Titanium Alloy (Ti-6Al-4V);
- Acetabular Screw Ti – Titanium Alloy (Ti-6Al-4V);
- Acetabular Insert MD Delta – Ceramic (Al₂O₃);
- Interchangeable Femoral Head Forte Ceramic – Ceramic (Al₂O₃)

Sterile Product

Sterilization Method: Gamma Radiation (Dose 25 kGy);

Validity: 03 years

Description

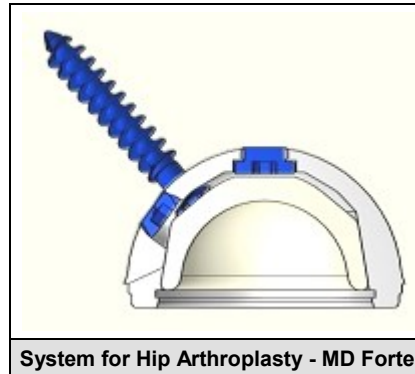
The System for Hip Arthroplasty - MD Forte consists of a set of implants surgically invasive of long-term use, composed of the following components:

- MD Acetabular Cup Ti
- Acetabular Screw Ti
- Acetabular Insert MD Delta
- Interchangeable Femoral Head Forte Ceramic

The components described above, connected together, and are intended to replace the hip joint in total arthroplasty procedures.

The System for Hip Arthroplasty - MD Forte intended to skeletally mature individuals to total hip replacement in patients with damage to this joint, resulting from natural wear of the acetabulum or noninflammatory degenerative joint (osteoarthritis), avascular necrosis femoral head, acetabular protrusion, osteoarthritis secondary to trauma, proximal femoral epiphysiolysis, sequelae of fractures of the pelvis, ankylosis or surgical arthrodesis of the hip.

Formed by MD Acetabular Cup Ti coated (with titanium powder sprinkling by *plasma spray*) and Acetabular Insert MD Delta (Ceramic) the system is fixed to the acetabular cavity of the patient by impaction (*press fit*) and posterior fixation screwed (Acetabular Screw). The acetabular and femoral portions are interconnected by an Interchangeable Femoral Head Forte Ceramic that fit the femoral stem (cone morse connection), it fits into the acetabular insert, enabling the articulated movement between the two segments. The following image illustrates the System for Hip Arthroplasty - MD Forte:



Composition

The selected materials present the properties required to achieve the desired performance for the System for Hip Arthroplasty - MD Forte. This selection considered factors such as biocompatibility and other properties required for the product.

The titanium alloy (Ti-6Al-4V) - used for the manufacture of components MD Acetabular Cup Ti and Acetabular Screw Ti - ceramic and alumina - used for the manufacture of components Acetabular Insert MD Delta and Interchangeable Femoral Head Forte Ceramic - have the properties that make them ideal materials for the production of implantable medical devices. Its main properties are biocompatibility, mechanical strength and wear resistance.

The titanium alloy (Ti-6Al-4V) used for the manufacture of components MD Acetabular Cup Ti and Acetabular Screw Ti meets the requirements specified by ASTM F-136 - Standard Specification for Wrought Titanium-6Aluminum 4Vanadium-ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

The coating of titanium powder applied to the MD Acetabular Cup Ti sprinkling by *plasma spray* meets the requirements specified by ASTM F-1580 - Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.

Characterized as an alloy with favorable mechanical and metallurgical properties for this purpose, the titanium alloy (Ti-6Al-4V) specified by ASTM F-136 used for the composition and the coating of MD Acetabular Cup Ti, presents biocompatibility proven by a long history widely described in world literature.

In turn, the ceramic alumina, used to manufacture the components Acetabular Insert MD Delta and Interchangeable Femoral Head Forte Ceramic, meets the requirements specified by ISO 6474 - Implants for surgery - Ceramic materials based on high purity alumina.

The behavior of alumina ceramics are: compressive strength, fatigue resistance and high resistance to wear by achieving excellent surface finish, it is possible to obtain a surface roughness $<0.02 \mu\text{m}$.

The alumina ceramic is biocompatible and bio-inert, as evidenced by a multitude of independent studies around the world. Since 1970, the material has been used in hip arthroplasty procedures. Components to the based of alumina ceramics were implanted in more than 1 million patients and based on biological and mechanical evaluations based on that history, the material was approved as an implant material by various public bodies and national health authorities around the world, for example, Japan, USA and France.

Indication and Purpose

The System for Hip Arthroplasty - MD Forte is indicated for use in skeletally mature patients for total hip replacement in patients with damage to this joint, resulting from natural wear of the acetabulum or noninflammatory degenerative joint (osteoarthritis), necrosis avascular femoral head, acetabular protrusion, osteoarthritis secondary to trauma, proximal femoral epiphysiolysis, sequelae of fractures of the pelvis, ankylosis or surgical arthrodesis of the hip.

Note: The product described here was developed for use under the circumstances described above, so that any other uses are considered as contraindication or without scientific substrate that support its use.

Contra Indication

Below are listed the contraindication on use the product, where the surgeon is responsible, after a rigorous study, the indication of the procedures:

- Patients with active general infection or specifics that can lead the complications;
- Patients with general state impaired and/or immuno compromised unable to be submitted to a surgical procedure;
- Patients with sensitivity to a foreign bodies, in this case, tests should be realized;
- Patients with osteoporosis and/or others bone disorders that may compromise the outcome of the arthroplasty;
- Patients with rapidly destructive bone disease or osteonecrosis after irradiation;
- Patients with progressive neurological diseases;
- Patients with circulatory diseases location and with insufficiency arterial or venous;
- Patients that use narcotic substances, alcohol or smoke;
- Patients with absence of bone support, enabling a proper setting of the implant;
- Patients with absence or paresis of the muscles controlling the hip.

Presentation form

The components that comprise the System for Hip Arthroplasty - MD Forte are packed unitarily in primary double blister packing PET sealed with surgical grade paper Tyvek type and/or double cover of PET/PE and Tyvek which works as a barrier to sterilization.



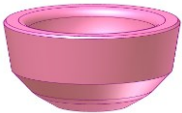
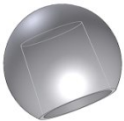
The components that comprise the System for Hip Arthroplasty - MD Forte is supplied in sterile condition, and the sterilization method used is sterilization by gamma irradiation (dose 25 kGy).

After sterile the components packed in properly labeled packaging are its primary are packaged in their cardboard carton (secondary packaging), which follows with a leaflet with instructions for use and five-way traceability label.

The primary package and the carton is pasted a label containing the information needed to identify the product.

The System for Hip Arthroplasty - MD Forte comprises the following components MD Acetabular Cup Ti, Acetabular Screw Ti, Acetabular Insert MD Delta and Interchangeable Femoral Head Forte Ceramic being that each of these components are available for market individually on the following dimensions:

System for Hip Arthroplasty - MD Forte

Image	Code	Description	Dimensions (Ø Outer x Ø Inner)	Manufacturing Material	Qty packaged
	04.01.26.XXXXX	MD Acetabular Cup Ti	46x35, 48x35, 50x37, 52x37, 54x39 56x41, 58x44, 60x44, 62x48, 64x48, 66x52, 68x52, 70x52 mm;	Titanium Alloy (Ti-6Al-4V)	01
Image	Code	Description	Dimensions (Ø Outer x Ø Inner)	Manufacturing Material	Qty packaged
	04.24.01.XXXXX	Acetabular Screw Ti	Ø 6.5 mm – 15, 20, 25, 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
Image	Code	Description	Dimensions (Ø Outer x Ø Inner)	Manufacturing Material	Qty packaged
	04.13.08.XXXXX	Acetabular Insert MD Delta	35x28, 37x28, 39x28, 41x32, 44x32, 44x36, 48x32, 48x36, 48x40, 52x32, 52x36, 52x40	Ceramic (Al ₂ O ₃)	01
Image	Code	Description	Dimensions (Ø Outer x Ø Inner)	Manufacturing Material	Qty packaged
	04.04.09.XXXXX	Interchangeable Femoral Head Cone 12/14 Forte Ceramic	Ø 28 mm: -3,5, Standard, +3,5 mm; Ø 32 mm: -4,0, Standard, +4,0, +7,0 mm; Ø 36 mm: -4,0, Standard, +4,0, +8,0 mm; Ø 40 mm: -4,0, Standard, +4,0, +8,0 mm;	Ceramic (Al ₂ O ₃)	01

The correct selection of models and sizes of components to be deployed is the responsibility of the surgeon who is also responsible for the surgical technique used, this should be familiar with the material, the method of application and surgical procedure to be performed.

The success of the procedure is on the correct selection, placement and fixation devices, which is the responsibility of the surgeon who assesses the patient and decides on the implants to be used. It is also bound to strict compliance with postoperative care recommended by the surgeon in charge.

Ancillary Components

The ancillaries' components to the product object of the registration are:

- Femoral prosthesis SPOAC NG;
- Femoral prosthesis MD6;

The femoral prostheses SPOAC NC and MD6 are manufactured from titanium alloy (Ti-6Al-4V) which meets the requirements specified by ASTM F-136 - Standard Specification for Wrought Titanium-6Aluminum 4Vanadium-ELI (Extra Low Interstitial) Alloy Surgical Implant for Applications (UNS R56401).


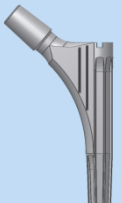
The femoral prosthesis SPOAC NG is manufactured from stainless steel alloy ((18Cr-14Ni-2.5Mo) that meets the requirements specified by ASTM F-138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).

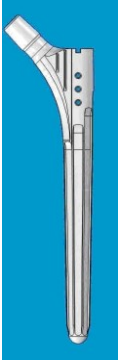
The correct selection of models and measures of system components, as well as their ancillary to be deployed is the responsibility of the surgeon who is also responsible for the technique adopted, this should be familiar with the material, method of application and the surgical procedure to be adopted.

The success of the procedure is on the correct selection, placement and fixation devices, which is the responsibility of the surgeon who evaluates the patient and to decide which implant to use. It is also bound to strict compliance with postoperative care recommended by the surgeon in charge.

The following ancillary are not objects of this registration process and should therefore be purchased separately and always from the same manufacturer or indicated by the manufacturer.

List of Ancillaries components

Image	Code	Description	Dimensions	Manufacturing Material	Qty packaged
	04.30.50.XXXXX	SPOAC- NG Femoral Prosthesis - Cone 12/14 - Primary	33,0 mmx140° – n. 01, 02, 03, 04 e 05; 36,8 mmx135° - n. 01, 02, 03, 04 e 05; 40,0 mmx135° - n. 01, 02, 03, 04 e 05; 47,0 mmx130° - n. 01, 02, 03, 04 e 05;	Stainless steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.51.XX100	MD-6 Non Cemented Femoral Prosthesis Cone 12/14 - 100 mm off-set 43 mm – 130°	Diameter – 14, 15, 16, 17, 18, 19 mm	Titanium Alloy (Ti-6Al-4V)	01

	04.30.52.XX100	MD-6 Non Cemented Femoral Prosthesis Cone 12/14 - 100 mm off-set 37 mm – 135°	Diameter – 14, 15, 16, 17, 18, 19 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.30.52.XXXXX	MD-6 Non Cemented Femoral Prosthesis w/ Distal Fixation Cone 12/14.	14x180, 14x230, 15x150, 16x150, 16x180, 16x230, 16x280, 17x150, 17x180, 17x230, 17x280, 18x150, 18x180, 18x230, 18x280, 19x180, 19x230, 19x280, 20x150, 20x180, 20x230, 20x280, 21x150, 21x180, 21x230, 21x280, 22x230, 22x280, 23x230, 23x280, 24x230, 24x280, 25x230, 25x280;	Titanium Alloy (Ti-6Al-4V)	01

Support Material

The support materials are the instruments designed only for deployment of the System for Hip Arthroplasty - MD Forte.

These instruments are made of stainless steel with meets the requirements specified by ASTM F899 – Standard Specification for Stainless Steel for Surgical Instruments, which provides high strength and durability

The instruments below are not objects of this register and should therefore be purchased separately and always the same manufacturer of the implant or indicated by the manufacturer.

See below list for the instruments available from the manufacturer or indicated by the manufacturer for deployment of the System for Hip Arthroplasty - MD Forte:

- 0Q.25 – Instrumental Acetabular Unique Primária – National Raemer;
- 0Q.33 – Instrumental Acetabular Unique Primária – National Raemer;

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

Surgical instruments are subject to wear during normal use and it can thus be broken The instruments must be used only for the purposes for which they are intended, and should be inspected regularly for wear and possible damage.

For more information about the instrumental, see the representative.

Warning and Precautions

To use the product the team should consider the following warnings and precautions:

- The System for Hip Arthroplasty - MD Forte should be used only after a detailed analysis of the surgical procedure to be adopted and read this instruction of use;
- The product should only be used by specialized surgical teams with knowledge and specific training on the techniques of arthroplasty, and it is the responsibility of the surgeon the choice and mastery of technique to be applied;
- The selection and inappropriate choice of implants to be used, as well as mistakes at the indication, handling and application technique can cause excessive stress and tensions on the implant, causing the failure by fatigue, fracture and loosening up of the same;
- The clinical results and durability of the implants are highly dependent on surgical technique with accuracy;
- The deployment on an inadequate bone bed can cause premature loosening and progressive loss of bone stock. In these cases additional methods of bone grafting in conjunction with screens and reinforcements should be adopted;
- The product should not be used in conjunction with bone cement
- The use of the fixation screws is limited to fixation of the acetabulum;
- The inadequate setting of acetabulum can cause loosening and/or early wear and progressive loss of bone stock;
- The incorrect locking of the insert acetabular can lead to decoupling of the components (acetabular insert and cup).
- The used in patients with predisposing to disobey the medical guidelines and restrictions postoperative, such as children, elderly, individuals with neurological disorders or addict, represent a major risk for failure of the implant;
- The risk of implant failure are higher in patients who perform activities of work or practicing sports activities during the postoperative period, contrary to medical restrictions;
- The postoperative complications are a major risk when using the product in patients with functional expectations than those what can be promoted by joint replacement, patients with morbid obesity and patients with small frame;
- System for Hip Arthroplasty - MD Forte should not be used if they do not get a bone support adequate to ensure the stability of the implant;
- The patient must make a periodic medical monitoring (follow-up) to check the conditions of the implant, the bone and adjacent tissues;

- To the medical criteria, can be use an antibiotic therapy prophylactic pre and perioperative, and the antibiotic therapy 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 implant of manufacturers or different purposes can result in inconsistency between the components;
- MD Forte ceramic components can only be combined with other ceramic components MD (Forte or Delta) or polyethylene components from the same manufacturer. It is forbidden to mix with other ceramics or metals;
- It should be observed closely the identification of the product and are not allowed combinations of components from other manufacturers or purpose;
- The system of docking cone Morse between components, generate a transmission of uniform force, leading to a docking system reliable and resistant to twisting. Thus, components should only be used with conical identical measures as specified by the manufacturer on the topic "Presentation Form ";
- The care of this material are the responsibility of qualified personnel, which should follow the standards and/or other local regulations;
- The opening of the packaging for surgical use should only be performed by qualified personnel for this procedure;
- Do not use the product if it has expired date or pack raped;
- Handle with care;
- Product use only - Do not reuse;
- The implants should NEVER be reused. Although they may look undamaged, prior to the tensions that they have been submitted can cause imperfections that would reduce the lifetime of the product in a reimplantation;
- Sterile product - Do not re-sterilize;
- PROHIBITED REPROCESSING;
- Date of manufacture, expiry date and batch number: See label;

Adverse Effects

Every surgical procedure presents risks and potential complication, and some common risks are infection, bleeding, allergic reaction drug and anesthetic risks, among others, may still be associated with the deployment of the product, the following complications and adverse effects:

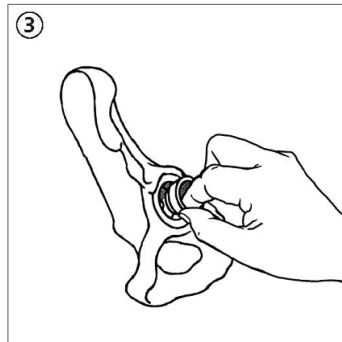
- Displacement, deformation, fracture of the implant or osteolysis;
- Loosening or displacement of the implant;
- Necrosis of bone or adjacent soft tissues.
- Reaction to foreign body;
- Inflammatory reactions, associated or not to displacement and/or loosening of the implant;
- Pain, discomfort or abnormal sensations due to the product;
- Displacement of the implant after deployment;
- Complications such as pelvic hematoma, vesical fistula, thrombosis of the external iliac artery, paralysis of the sciatic nerve, intra-pelvic fatal hemorrhage due to penetration of the pelvic trans-acetabular by the fixing screws.

Instructions for Use

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

- The care of this material is the responsibility of the personnel, which should follow the standards and/or other local regulations;
- The product should be handled with appropriate care in appropriate 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 arthroplasty, and the responsibility of the surgeon the choice and mastery of the technique to be applied;
- To avoid risks, the fixing screw should be implanted in the posterior portion of the acetabulum (superior and inferior quadrants);

- The medical criteria, must be adopted prior to insertion of cementless acetabulum, bone grafting methods (with or without the use of screens and reinforcements) for restoration of bone stock, in cases where they do not get a cavity with hemispherical acetabular viable bone bed;
- The medical criteria, after insertion of the acetabulum, if not get a good stability of the implant should be used fixing screws to obtain the necessary stability;



- The shelf-life established for the System for Hip Arthroplasty - MD Forte is 10 (ten) years, provided the devices are implanted by adopting a surgical technique and observing the details of the topics "Indication and Purpose", "Contraindication", "Warnings and Precautions" and "Instructions for Use";

may be needed, the performance of revision surgery after the period of life time, if observed the wear and/or release of components;

- For application of System for Hip Arthroplasty - MD Forte is required the use of specific instruments, as mentioned above and should not, due to possible incompatibility dimensional and/or functional, to be used with instruments other than those indicated by the manufacturer;

Specific operating instructions for use to assemble system

Before starting the insertion of ceramic components, the surface of the other prosthetic components must be free of waste as tissue fragments, particles of bone or cement.

Below are the steps for deploying component Acetabular Insert MD Delta:

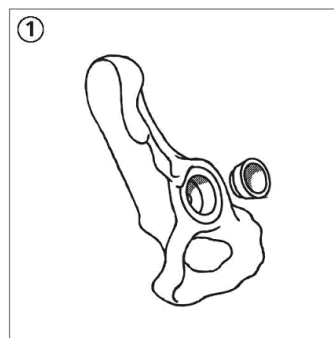


Figure 01: Once deployed the acetabulum in the pelvic cavity, verify its correct position and functioning (mobility) of the joint, using an implant of test. Make sure that the screws for fixation, when used, are properly adjusted.

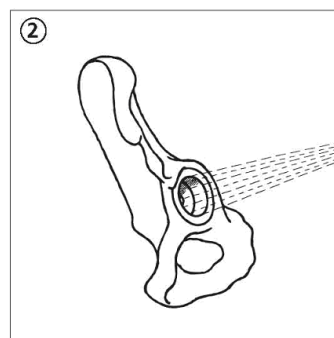


Figure 02: Remove the implant test, after checking, wash and dry the acetabulum. The surface should be free of bone waste or tissue.

Figure 03: The placement of the ceramic insert should be done by hand. Hold the ceramic insert with two fingers and insert the acetabulum. When the fingertips come in contact with the rim of the acetabulum, the insert will slide through its cavity.

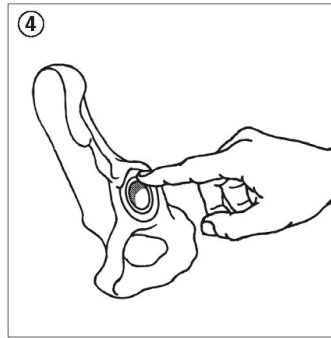


Figure 04: Control and, if necessary, correct the position of the insert touching the rim of the acetabulum. The metal rim of the acetabulum and ceramic of the insert should form a flat surface.

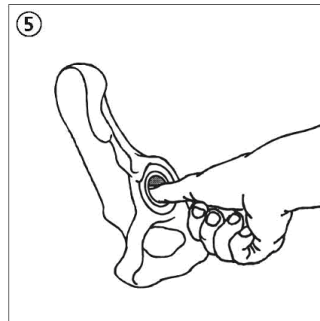


Figure 05: When the insert is positioned correctly, press it with your thumb over the acetabulum. To obtain the final fixing, the insert is placed in position with the aid of an impactor provided on specific instrumental indicated by the manufacturer (via a small axial hammer blow). The insert should never be placed with metallic hammer blows.

Below are the steps for deploying component Interchangeable Femoral Head Forte Ceramic:

- Protection of the cone stem should only be withdrawn when docking with the head;
- Prior to the docking with the head on the femoral stem, wash the cone stem dry carefully;
- Carefully examine the femoral cone stem and the inner cone of the head and make sure that these are free of waste as tissue fragments and particles of bone or cement;
- The head must be added manually on the femoral cone stem with a slight rotation and axial pressure that keeps static on the cone.
- Place the impactor with tip polymer (provided in the instrument specified by the manufacturer) on the head and apply a light hammer blow in the axial direction for a final fixing of the head on the cone stem. With the stroke the surface structure of the metallic cone stem deforms plastically providing optimal pressure distribution and a fixation resistant to twisting.

Guidance to the patient and/or the Legal Representative

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

- Appropriate care and restrictions during the postoperative period. The ability and willingness of patients 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 medical guidelines, care and post-operative restrictions, such as children, elderly, individuals with neurological disorders or adicties;
- The fact that the product does not replace and does not have the same performance of normal bone and therefore can break, strain or release is due to excessive work or activities of early load and other situations;

- All post-operative restrictions, particularly those related to occupational and sports activities;
- The postoperative complications are a risk when using the product in patients with functional expectations beyond what can be promoted by joint replacement, patients with morbid obesity and patients with small frame;
- The postoperative complications are a major risks when using the product in patients with functional expectations beyond what can be promoted by joint replacement, patients with morbid obesity and patients with small bone structure;
- The need to use, only the medical criteria, of external supports, aid to walk and orthopedic orthoses, designed to limit movement and/or load;
- The need for periodic medical monitoring to check the conditions of the implant, the bone and adjacent tissues;
- The fact that non-implementation of the revision surgery when the release of the components can result in progressive loss of bone stock;
- The fact that implants can interfere with test results of images examinations. Thus, patients with implants should report this fact when carrying out such examinations.
- Complications related to procedures for the hip arthroplasty, and the information listed in this topic "Guidelines for Patient and/or the Legal Representative" and in the "Adverse Effects".

Sterilization

The System for Hip Arthroplasty - MD Forte is supplied in sterile condition of product. The method of sterilization used for sterilization is Gamma radiation (sterilization dose 25 kGy).

The ceramic components sterilized by gamma radiation may present variation in their coloration, but it doesn't have any influence on the resistance or other properties of the materials.

The production of system components is made with high care so as to meet the performance desired for the product. Thus, the surgical team and all concerned should handle the devices adequately to minimize the risk of infection.

Sterile product – Do not re-sterilized.

Do not use the product if the packaging is violated.

Risk of Contamination

As this is an implantable product, where there is the need for explantation of the components, there are risks of biological contamination and transmission of viral diseases.

In order to minimize these risks, the explanted components should be treated as potentially contaminating material, one should adopt the standards and/or other local regulations.

Product Disposal

The explanted components or considered unsuitable for use should be discarded. It is recommended that prior to disposal, the product is adulterated, and to such the parts may be cut, twist or filing.

According to standard Law 6.360 from September 23rd 1976 and for RDC 156 from August 11th 2006, it constitutes a sanitary infraction reuse and reprocessing of single use products which, otherwise apply to the offender the penalty provided for in Article 10, item I and IV from Law # 6.437 from August 20th 1977.

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 – Do not reuse.

Traceability

To ensure traceability of the product implanted, and comply with requirements for health surveillance, the surgeon or his staff should record in the patient record information about the product. Furthermore, such information must also be passed on to the distributor of the product and the patient in order to complete the cycle of product traceability deployed. The information necessary for traceability are those relating to product use, surgery and patient, as follows:

- Name of patient who received the implant;

- Surgeon's name;
- Hospital's name
- Manufacturer's name;
- Supplier's name;
- Surgery date;
- Code of product;
- Batch number of the product;
- Quantities used
- Product registration ANVISA number,

The responsible surgeon and his team should make use of the labels for traceability provided in the product packaging, pasting them into the patient's medical record to maintain of the traceability of the product deployed. Moreover, such a label should be provided to the patient that has information about the product implanted in his surgery.

The labels are the data of the product as code, description, and lot of it, among other information.

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

On the label contains the following information necessary for traceability of the product:

- Identification of manufacturer;
- Code of the component;
- Batch number of the component;
- Description of the component (in three languages - Portuguese, English and Spanish);
- Quantity;
- Product registration ANVISA number,
- Technical name;
- Trade Product Name;
- Other integral components of the system;

The traceability information are required to notify the health service and/or by the patient to the Sanitary Surveillance Agency - ANVISA and the manufacturer, upon the occurrence of serious adverse events, for the conduct of due diligence.

Storage and Transport

For storage, it is recommend a cool dry place without exposure to sunlight, moisture or contaminants.

As it is a sterile product, moisture and temperature of the storage site should be monitored, and the temperature is kept below 40°C.

The implants can not be stored directly on the floor. Therefore, it is recommend the use of shelves with a minimum height of 20 cm.

The product should be kept in their original packaging until the moment of its use, while 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 falls and friction that may damage the structure and the part surface.

For information about the manufacturing date, expiration date and Lot #: See label.

Other information



Manufactured and distributed by:

MDT – Indústria Comércio Importação e Exportação de Implantes SA

Av. Brasil, nº. 2983 – Distrito Industrial

Rio Claro/SP – CEP 13505-600

Phone/ Fax: (55-19) 2111-6500

Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Registration ANVISA #: 10417940072

Review: 00

Issued: December, 20th 2010

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

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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.



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