Instructions for Use

Hip Total System

Keys of symbols used on the packaging

REF	Reference number (filled with product code)	LOT	Lot Code
STERILE R	Sterile Product - Sterilized by Gamma Radiation		Manufacturing Date
	Expiry Date		See instructions for use
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Single-use product
	Do not re-sterilize	40°C	Upper temperature limit (40° C)
	Do not use if package is damaged		

Product features and technical specifications

Technical Name: Implantable Material

Trade Name: Hip Total System

System Components:

- Acetabulum MD5 - Porous Coated 18 points;
- Acetabular Insert 09 points;
- Acetabular Screw MD5;
- Interchangeable Femoral Head - CrCo;
- Maxima Femoral Prosthesis - CrCo;

Accessories:

- Femoral Prosthesis' Conical Distal Centralizer;
- Cement Restrictor PE;
- Acetabular Mesh;
- Acetabular Mesh;
- Acetabular Reinforcement;
- Femoral Mesh;

Raw Material:

- Acetabulum MD5 - Porous Coated 18 points, Interchangeable Femoral Head CrCo and Máxima Femoral Prosthesis CrCo - Co-28 Cr-6 Mo Cobalt Chrome Molybdenum Alloy;
- Acetabular Screw MD5 and Accessories: Acetabular Mesh and Femoral Mesh - 18-Cr 14-Ni 2.5-Mo stainless steel alloy;
- Acetabular Insert 09 points and Accessories: Cement Restrictor Conical Femoral Prosthesis and Distal Centralizer – Ultra High Molecular Weight Polyethylene (UHMWPE);

Validity: 05 years (from date of sterilization)

Sterile Product

Sterilization method: Gamma Radiation

Description

The product consists of a set of surgically invasive implantable devices for long-term use, intended for hip joint replacement procedures.

The Hip Total System is composed by the Acetabulum MD5 - Porous Coated 18 points, the Acetabular Screw MD5, the Acetabular Insert 09 points, the Interchangeable Femoral Head CrCo and Maxima Femoral Prosthesis CrCo. Its accessories are the Acetabular Mesh, the Femoral Mesh, the Cement Restrictor PE and the Femoral Prosthesis' Conical Distal Centralizer, each one with its own specificity, intending to replace the hip joint in primary arthroplasty and revision procedures.

The Hip Total System is intended for use in skeletally mature patients, in the reconstruction of the femoral portion in total arthroplasties of the hip, presenting damage from non-inflammatory degenerative joint disease (osteoarthritis), avascular necrosis of the femoral head, acetabular protrusion, osteoarthritis secondary to trauma, proximal femoral epiphysiolysis, pelvis fracture sequelae, ankylosis or surgical hip arthrodesis.

The product comprises a hybrid system formed by Maxima Femoral Prosthesis CrCo, which has to be fixed to the adjacent bone by means of acrylic bone cement for orthopedic use (Polymethylmethacrylate or PMMA), provided separately, and the Acetabulum MD5 - Porous Coated 18 Points, which must be fixed to the patient's acetabular cavity by impaction *(press fit).* The acetabular and femoral portions are interconnected by a metallic spherical head that, when fitted to the femoral component by a cone morse system, accommodates it in the acetabular component, promoting articular movement between the two parts.

Below, there is an illustrative image of each component making up the Hip Total System:

				
Acetabulum MD5 - Porous Coated 18 Points	**Acetabular Screw MD5**	**Acetabular Insert 09 Points**	**Interchangeable Femoral Head CrCo**	**Maxima Femoral Prosthesis CrCo**

Optionally, the surgeon may also employ the following accessories. Acetabular Mesh and Femoral Mesh (for procedures requiring reinforcements) Cement Restrictor PE (inserted into the patient's femoral channel, it works as a buffer when cementing the stem in order to prevent the cement from spreading around the channel) and the Femoral Prosthesis' Conical Distal Centralizer (fixed to the stem end, it intends to center the prosthesis during its cementing).

Below, there are illustrative images of each accessory of the Hip Total System:

			
Acetabular screen	**Femoral Mesh**	**Cement Restrictor PE**	**Femoral Prosthesis' Conical Distal Centralizer**

Composition

The components that make up the Hip Total System are manufactured from materials of proven biocompatibility, in accordance with requirements specified in standards. Below, the composition of each of the components and its respective specifications:

The components Acetabulum MD5 - Porous Coated 18 points, Interchangeable Femoral Head CrCo and Maxima Femoral Prosthesis CrCo are manufactured from Co-28 Cr-6 Mo cast alloy of cobalt chromium molybdenum, according to requirements specified by ASTM F75 - Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075). The microspheres coating type Porous Coated of the Acetabulum MD5 - Porous Coated 18 points is also composed of Co-28 Cr-6 Mo cobalt chromium molybdenum alloy, according to requirements specified by ASTM F1377 - Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075).

The components Acetabular Insert 09 Points and the accessories Cement Restrictor PE and Femoral Prosthesis' Conical Distal Centralizer are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) polymer, according to requirements specified by standard NBR ISO 5834-2 - Implants for surgery - Ultra-high molecular weight polyethylene - Part 2: Molded products.

This material, extensively studied in the literature, presents satisfactory results in long-term follow-ups.

The component Acetabular Screw MD5 is manufactured from 18-Cr 14-Ni 2.5-Mo stainless steel alloy, according to requirements specified by ASTM F138 standard - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants. Meanwhile, accessories Acetabular Mesh and Femoral Mesh are manufactured from 18-Cr 14-Ni 2.5-Mo stainless steel alloy, according to requirements specified by ASTM F139 - Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants.

The choice for this alloy is due to its well-characterized mechanical and metallurgical properties, as well as its results in service - widely described in literature worldwide - that confirm its biocompatibility and mechanical strength, suitable for the intended purpose.

Indication and purpose

The components that make up the Hip Total System are indicated to replace the hip joint in a surgical procedure called total hip arthroplasty. This procedure is performed in circumstances in which the joint, in skeletally mature individuals, is compromised because of conditions such as non-inflammatory degenerative joint disease (osteoarthritis), avascular necrosis in the femoral head, acetabular protrusion, traumatic arthritis, slipped proximal femoral epiphysis, ankylosis of non-infectious origin, hip arthrodesis.

The application of the product must consider the defect, pathology, bone characteristics, and muscle loads and forces (tension and traction) acting on the segment to be treated.

The product herein described was developed for use in the circumstances described above, so that all other uses are considered contraindicated or without scientific basis.

Contraindication

The contraindications for using the device are listed below, being up to the attending surgeon to indicate the procedures after a thorough study of the case:

- Patients with general or specific active infections that can lead to complications;
- Patients with impaired general health status and / or immunocompromised unable to undergo a surgical procedure;
- Patients with sensitivity to foreign bodies, and in such cases tests shall be performed;
- Patients with osteoporosis and / or other bone disorders that may compromise the result of the arthroplasty;
- Patients suffering from rapidly destructive bone diseases or post-irradiation osteonecrosis;
- Patients with progressive neurological diseases;
- Patients with local circulatory diseases and arterial or venous insufficiencies;
- Patients who make use of narcotics, alcohol or tobacco;
- Patients without adequate bone support to allow for adequate fixation of the implant;
- Patients whose hip muscles are absent or paralyzed.

Presentation Form

The components that make up the Hip Total System are unitarily packaged in Blister or Tyvek type primary packaging, which serve as sterilization barrier.

The components are supplied sterile and the adopted sterilization method is gamma radiation, procedure that is performed by a duly qualified third-party company.

Once sterilized, already labeled and primarily packaged components are also unitarily packed in a cardboard carton (secondary packaging), which contains a leaflet with instructions for use and five copies of traceability label.

Over primary packaging (Blister or Tyvek) and secondary packaging (cardboard carton) a label is glued, containing necessary information for product identification.

The Hip Total System consists of the following components and these components are available for sale in the following dimensions:

Acetabulum MD5 - Porous Coated				
Illustrative image	**Code**	**Description**	**Material**	**Qty Packed**
	04.01.22.22044	Acetabulum MD5 - Porous Coated Ø 22x44 mm 18 points w / insert;	**Co-28 Cr-6 Mo Cobalt Chrome Molybdenum Alloy**	**01**
	04.01.22.22046	Acetabulum MD5 - Porous Coated Ø 22x46 mm 18 points w / insert;		
	04.01.22.22048	Acetabulum MD5 - Porous Coated Ø 22x48 mm 18 points w / insert;		
	04.01.22.22050	Acetabulum MD5 - Porous Coated Ø 22x50 mm 18 points w / insert;		
	04.01.22.22052	Acetabulum MD5 - Porous Coated Ø 22x52 mm 18 points w / insert;		
	04.01.22.22054	Acetabulum MD5 - Porous Coated Ø 22x54 mm 18 points w / insert;		
	04.01.22.22056	Acetabulum MD5 - Porous Coated Ø 22x56 mm 18 points w / insert;		
	04.01.22.22058	Acetabulum MD5 - Porous Coated Ø 22x58 mm 18 points w / insert;		
	04.01.22.22060	Acetabulum MD5 - Porous Coated Ø 22x60 mm 18 points w / insert;		
	04.01.22.22062	Acetabulum MD5 - Porous Coated Ø 22x62 mm 18 points w / insert;		
	04.01.22.22064	Acetabulum MD5 - Porous Coated Ø 22x64 mm 18 points w / insert;		
	04.01.22.26048	Acetabulum MD5 - Porous Coated Ø 26x48 mm 18 points w / insert;		
	04.01.22.26050	Acetabulum MD5 - Porous Coated Ø 26x50 mm 18 points w / insert;		
	04.01.22.26052	Acetabulum MD5 - Porous Coated Ø 26x52 mm 18 points w / insert;		
	04.01.22.26054	Acetabulum MD5 - Porous Coated Ø 26x54 mm 18 points w / insert;		
	04.01.22.26056	Acetabulum MD5 - Porous Coated Ø 26x56 mm 18 points w / insert;		
	04.01.22.26058	Acetabulum MD5 - Porous Coated Ø 26x58 mm 18 points w / insert;		
	04.01.22.26060	Acetabulum MD5 - Porous Coated Ø 26x60 mm 18 points w / insert;		
	04.01.22.26062	Acetabulum MD5 - Porous Coated Ø 26x62 mm 18 points w / insert;		
	04.01.22.26064	Acetabulum MD5 - Porous Coated Ø 26x64 mm 18 points w / insert;		
	04.01.22.28050	Acetabulum MD5 - Porous Coated Ø 28x50 mm 18 points w / insert;		
	04.01.22.28052	Acetabulum MD5 - Porous Coated Ø 28x52 mm 18 points w / insert;		
	04.01.22.28054	Acetabulum MD5 - Porous Coated Ø 28x54 mm 18 points w / insert;		
	04.01.22.28056	Acetabulum MD5 - Porous Coated Ø 28x56 mm 18 points w / insert;		
	04.01.22.28058	Acetabulum MD5 - Porous Coated Ø 28x58 mm 18 points w / insert;		
	04.01.22.28060	Acetabulum MD5 - Porous Coated Ø 28x60 mm 18 points w / insert;		
	04.01.22.28062	Acetabulum MD5 - Porous Coated Ø 28x62 mm 18 points w / insert;		
	04.01.22.32054	Acetabulum MD5 - Porous Coated Ø 32x54 mm 18 points w / insert;		
	04.01.22.32056	Acetabulum MD5 - Porous Coated Ø 32x56 mm 18 points w / insert;		
	04.01.22.32058	Acetabulum MD5 - Porous Coated Ø 32x58 mm 18 points w / insert;		
	04.01.22.32060	Acetabulum MD5 - Porous Coated Ø 32x60 mm 18 points w / insert;		
	04.01.22.32062	Acetabulum MD5 - Porous Coated Ø 32x62 mm 18 points w / insert;		
	04.01.22.32064	Acetabulum MD5 - Porous Coated Ø 32x64 mm 18 points w / insert;		

Acetabular Insert - 09 points				
Illustrative image	**Code**	**Description**	**Material**	**Qty Packed**
	04.13.02.22044	Acetabular Insert 09 points Ø 22x44 mm;	Ulta High Molecular Weight Polyethylene (UHMWPE)	01
	04.13.02.22046	Acetabular Insert 09 points Ø 22x46 mm;		
	04.13.02.22048	Acetabular Insert 09 points Ø 22x48 mm;		
	04.13.02.22050	Acetabular Insert 09 points Ø 22x50 mm;		
	04.13.02.22052	Acetabular Insert 09 points Ø 22x52 mm;		
	04.13.02.22054	Acetabular Insert 09 points Ø 22x54 mm;		
	04.13.02.22056	Acetabular Insert 09 points Ø 22x56 mm;		
	04.13.02.22058	Acetabular Insert 09 points Ø 22x58 mm;		
	04.13.02.22060	Acetabular Insert 09 points Ø 22x60 mm;		
	04.13.02.22062	Acetabular Insert 09 points Ø 22x62 mm;		
	04.13.02.22064	Acetabular Insert 09 points Ø 22x64 mm;		
	04.13.02.26048	Acetabular Insert 09 points Ø 26x48 mm;		
	04.13.02.26050	Acetabular Insert 09 points Ø 26x50 mm;		
	04.13.02.26052	Acetabular Insert 09 points Ø 26x52 mm;		
	04.13.02.26054	Acetabular Insert 09 points Ø 26x54 mm;		
	04.13.02.26056	Acetabular Insert 09 points Ø 26x56 mm;		
	04.13.02.26058	Acetabular Insert 09 points Ø 26x58 mm;		
	04.13.02.26060	Acetabular Insert 09 points Ø 26x60 mm;		
	04.13.02.26062	Acetabular Insert 09 points Ø 26x62 mm;		
	04.13.02.26064	Acetabular Insert 09 points Ø 26x64 mm;		
	04.13.02.28050	Acetabular Insert 09 points Ø 28x50 mm;		
	04.13.02.28052	Acetabular Insert 09 points Ø 28x52 mm;		
	04.13.02.28054	Acetabular Insert 09 points Ø 28x54 mm;		
	04.13.02.28056	Acetabular Insert 09 points Ø 28x56 mm;		
	04.13.02.28058	Acetabular Insert 09 points Ø 28x58 mm;		
	04.13.02.28060	Acetabular Insert 09 points Ø 28x60 mm;		
	04.13.02.28062	Acetabular Insert 09 points Ø 28x62 mm;		
	04.13.02.28064	Acetabular Insert 09 points Ø 28x64 mm;		
	04.13.02.32054	Acetabular Insert 09 points Ø 32x54 mm;		
	04.13.02.32056	Acetabular Insert 09 points Ø 32x56 mm;		
	04.13.02.32058	Acetabular Insert 09 points Ø 32x58 mm;		
	04.13.02.32060	Acetabular Insert 09 points Ø 32x60 mm;		
	04.13.02.32062	Acetabular Insert 09 points Ø 32x62 mm;		
	04.13.02.32064	Acetabular Insert 09 points Ø 32x64 mm		

Acetabular Screw MD5				
Illustrative image	**Code**	**Description**	**Manufacturing Equipment**	**Qty Packed**
	04.24.00.65015	Acetabular screw MD5 - 15 mm;	18-Cr 14-Ni 2.5-Mo stainless steel alloy	01
	04.24.00.65020	Acetabular screw MD5 - 20 mm;		
	04.24.00.65025	Acetabular screw MD5 - 25 mm;		
	04.24.00.65030	Acetabular screw MD5 - 30 mm;		
	04.24.00.65035	Acetabular screw MD5 - 35 mm;		
	04.24.00.65040	Acetabular screw MD5 - 40 mm;		

Interchangeable Femoral Head - CrCo				
Illustrative image	**Code**	**Description**	**Material**	**Qty Packed**
	04.04.08.22001	Conical Interchangeable Femoral Head12/14 Ø22mm Neck - 2mm CrCo;	Co-28 Cr-6 Mo Cobalt Chrome Molybdenum Alloy	01
	04.04.08.22002	Conical Interchangeable Femoral Head12/14 Ø22mm Neck Standard CrCo;		
	04.04.08.22003	Conical Interchangeable Femoral Head12/14 Ø22mm Neck + 3mm CrCo;		
	04.04.08.26001	Conical Interchangeable Femoral Head12/14 Ø26mm Neck -2 mm CrCo;		
	04.04.08.26002	Conical Interchangeable Femoral Head12/14 Ø26mm Neck Standard CrCo;		
	04.04.08.26003	Conical Interchangeable Femoral Head12/14 Ø26mm Neck + 3mm CrCo;		
	04.04.08.26004	Conical Interchangeable Femoral Head12/14 Ø26mm Neck - 4mm CrCo;		
	04.04.08.26006	Conical Interchangeable Femoral Head12/14 Ø26mm Neck + 6mm CrCo;		
	04.04.08.26009	Conical Interchangeable Femoral Head12/14 Ø26mm Neck + 9mm CrCo;		
	04.04.08.28001	Conical Interchangeable Femoral Head12/14 Ø28mm Neck -2 mm CrCo;		
	04.04.08.28002	Conical Interchangeable Femoral Head12/14 Ø28mm Neck Standard CrCo;		
	04.04.08.28003	Conical Interchangeable Femoral Head12/14 Ø28mm Neck + 3mm CrCo;		
	04.04.08.28004	Conical Interchangeable Femoral Head12/14 Ø28mm Neck -4mm CrCo;		
	04.04.08.28006	Conical Interchangeable Femoral Head12/14 Ø28mm Neck + 6mm CrCo;		
	04.04.08.28009	Conical Interchangeable Femoral Head12/14 Ø28mm Neck + 9mm CrCo.		

Máxima Femoral Prosthesis				
Illustrative image	**Code**	**Description**	**Material**	**Qty Packed**
	04.30.45.37001	Máxima Femoral Prosthesis 37.5 mm Cone 12/14 Primary 1 - CrCo;	Co-28 Cr-6 Mo Cobalt Chrome Molybdenum Alloy	01
	04.30.45.37002	Máxima Femoral Prosthesis 37.5 mm Cone 12/14 Primary 2 - CrCo;		
	04.30.45.37003	Máxima Femoral Prosthesis 37.5 mm Cone 12/14 Primary 3 - CrCo;		
	04.30.46.44001	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Primary 1 - CrCo;		
	04.30.46.44002	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Primary 2 - CrCo;		
	04.30.46.44003	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Primary 3 - CrCo;		
	04.30.46.44004	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Primary 4 - CrCo;		
	04.30.47.44001	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Revision 1 - CrCo;		
	04.30.47.44002	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Revision 2 - CrCo;		
	04.30.47.44003	Máxima Femoral Prosthesis 44.0 mm Cone 12/14 Revision 3 - CrCo;		

Accessories					
Illustrative image	**Code**	**Description**	**Available Sizes**	**Material**	**Qty Packed**
	04.06.02.00000	Femoral Prosthesis' Conical Distal Centralizer	Single	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.32.01.00011	Cement Restrictor 11 mm - Fr;	11 mm	Ultra-High Molecular Weight Polyethylene (UHMWPE)	01
	04.32.01.00015	Cement Restrictor 15 mm - Fr;	15 mm		
	04.32.01.00018	Cement Restrictor 18 mm - Fr;	18 mm		
	04.32.01.00021	Cement Restrictor 21 mm - Fr;	21 mm		
	04.32.01.00024	Cement Restrictor 24 mm - Fr.	24 mm		
	04.31.01.00001	Small Acetabular Mesh;	Small	18-14 Cr-Ni-Mo 2.5 Stainless steel alloy	01
	04.31.01.00002	Medium Acetabular Mesh;	Medium		
	04.31.01.00003	Large Acetabular Mesh;	Large		
	04.31.02.00080	Acetabular Screen 80 mm;	80 mm	18-14 Cr-Ni-Mo 2.5 Stainless steel alloy	01
	04.31.02.00090	Acetabular Screen 90 mm;	90 mm		
	04.31.02.00100	Acetabular Screen 100 mm;	100 mm		
	04.31.04.00000	Small Metal Acetabular Reinforcement;	Small	18-14 Cr-Ni-Mo 2.5 Stainless steel alloy	01
	04.31.06.00000	Medium Metal Acetabular Reinforcement;	Medium		
	04.31.05.00000	Large Metal Acetabular Reinforcement;	Large		
	04.31.03.01513	Femoral Mesh 130 mm;	130 mm	18-14 Cr-Ni-Mo 2.5 Stainless steel alloy	01
	04.31.03.01515	Femoral Mesh 150 mm;	150 mm		
	04.31.03.01518	Femoral Mesh 180 mm.	180 mm		

The correct selection of models and sizes of the Hip Total System components is responsibility of the surgeon. The surgeon is also responsible for the technique used and should be familiar with the material, application method, and surgical procedure to be adopted.

The success of the procedure is linked to the correct selection, positioning and fixation of devices, which is the responsibility of the surgeon who assesses the patient and decides which implants to employ. It is also linked to strict compliance with the post-operative care recommended by the attending surgeon.

Support Material

Support materials are instruments solely designated for the implantation of the Hip Total System.

These instruments are manufactured from stainless steel, which meets the requirements specified by ASTM F899 - Standard Specification for Stainless Steel for Surgical Instruments, which provide high strength and durability.

The instruments below are not subjects for this registration process and must therefore be purchased separately and always from the same manufacturer or from another one, duly appointed by the former.

See listing below for instruments made available by the manufacturer for carrying out the hip arthroplasty procedures with Hip Total System.

- Instrument - Acetabular Unique;
- Instrument - Maxima Standard;

The instruments are supplied decontaminated but not sterilized. Surgical instruments are subject to wear during normal use and can therefore break.

The instruments shall be used only for their intended purposes and shall be inspected regularly for possible wear or damage.

For more information on the instruments, consult your representative.

Warnings and Precautions

For using the product the responsible medical team must take into account the following warnings and precautions:

- The Hip Total System should be used only after a detailed analysis of the surgical procedure to be adopted and reading these instructions for use;
- The product shall be used only by specialized surgical teams, with specific knowledge and capability about arthroplasty techniques, being the surgeon's responsibility the choice and mastery over the technique to be applied;
- Improper selection and choice of implants to be used, as well as mistakes in indication, handling and application technique can cause excessive tensions and tractions on the implant, possibly leading to failure by fatigue, fracture or implant looseness;
- Clinical results and durability of implants are extremely dependent on an accurate surgical technique;
- The implantation on inappropriate bone bed may cause premature loosening and progressive loss of bone stock. In these cases, additional bone grafting methods along with meshes and reinforcements shall be adopted;
- The acetabular component must not be used in conjunction with bone cement;
- The use of fixation screws is restricted to fixation of cementless acetabulum;
- Inadequate fixation of cementless acetabulum may cause looseness and / or premature wear and progressive loss of bone stock;
- Improper insertion of the fixation screw head into the cementless acetabulum hole can cause erosion by friction on the acetabular insert and consequent formation of debris;
- Incorrect locking of the acetabular insert can lead to dissociation between the components that make up the cementless acetabulum (cup and acetabular insert);
- The femoral component must be used only in conjunction with bone cement;
- The use in patients with predisposition to disobey medical guidelines and postoperative restrictions, such as children, the elderly, mentally ill and/or chemically addicted people, poses a higher risk of implant failure;
- Risks of implant failure are higher in patients who practice strenuous activities or sports during the postoperative period, contrary to medical restrictions;
- Postoperative complications pose a greater risk when using the product in patients with functional expectations beyond those that can be promoted by joint replacement, morbidly obese patients, and patients with small bone structure;
- The Hip Total System shall not be used if an adequate bone support does not exist to ensure implant stability;
- The patient must submit to periodic medical follow-up to check the conditions of the implant, the bone and adjacent tissues;
- At medical discretion, pre- and perioperative antibiotic prophylaxis, as well as antibiotic therapy, may be adopted in cases of local and / or systemic predisposition or occurrence of infections;

- The implant shall not be used with components from other manufacturers or with different intended purposes. The combination with implants from other manufacturers or with different intended purposes may result in incongruence between components;
- Product identification must be strictly checked and combinations with components from other manufacturers or purposes are not allowed;
- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- Falls or crushing on hard surfaces can cause damage to the product. Therefore, it is necessary that the operator performs an inspection of the product for its integrity when the package is opened, and if any abnormality is observed the product shall not be used;
- The opening of the package for surgical use must be done by nurses qualified for this procedure;
- Do not use the product if it is expired or the packaging is violated;
- Handle with care;
- Product for single use - Do not reuse;
- Never reuse an implant. Although they may seem undamaged, previous mechanical stresses applied to them may originate imperfections that would shorten its lifespan in case of re-implantation;
- Sterile product - Do not re-sterilize;
- REPROCESSING PROHIBITED;
- Manufacturing date, expiry date, and lot number: see label;

Adverse Effects

Every surgical procedure presents risks and the possibility of complications, the infections, bleedings, drug allergic reactions and anesthetic risks being some common ones, among others. The following complications and adverse effects can also be associated with the implantation of the product:

- Loosening, displacement, deformation, implant fracture or osteolysis;
- Postoperative pain, discomfort or abnormal sensations due to the product;
- Reactions to foreign body;
- Inflammatory reactions associated or not to implant loosening and / or displacement;
- Bone necrosis or adjacent soft tissue necrosis;
- Breakage of the implant that can make its removal difficult or impractical.
- Complications such as iliac hematoma, bladder fistula, thrombosis of the external iliac artery, sciatic nerve paralysis, fatal intra-pelvic hemorrhage as a result of transacetabular pelvic penetration by the fixation screws.

Instructions for Use

For correct use of the product, the following instructions must be followed:

- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- The product shall be handled with due care in appropriate locations (materials central and operating rooms);
- The product shall only be used by specialized surgical teams, with knowledge and specific training on arthroplasty techniques, being the responsibility of the surgeon the choice and mastery over the technique to be applied;
- To avoid risks associated with fixation of the cementless acetabulum, the fixation screw shall be implanted in the posterior portion of the acetabulum (upper and lower quadrants);
- Under medical discretion, bone grafting methods shall be adopted prior to insertion of the cementless acetabulum (with or without the use of meshes and reinforcements) to restore bone stock, in cases where a hemispherical acetabular cavity with viable bone bed cannot be obtained;
- Under medical discretion, if a good stability of the implant cannot be obtained after insertion of the cementless acetabulum, fixation screws must be used to obtain the required stability;
- The head, wrapped in surgical dressings, shall be coupled on the stem cone and impacted using a mallet. The frictional force that holds the head attached to the cone depends on the initial impaction;
- Under medical discretion, bone grafting methods shall be adopted (with or without the use of meshes and reinforcements) to restore the bone stock in cases where a medullar cavity with viable bone bed cannot be obtained;

- The established lifespan for the Hip Total System is 10 (ten) years, provided the devices are implanted using a proper surgical technique and taking into account the information on items "Indication and Purpose", "Contraindication", "Warnings and Precautions", and "Instructions for Use";
- Under medical discretion, revision surgery may be required after the lifespan period, in case of wear and / or looseness of components;
- For the application of Hip Total System it is necessary to use specific instrumentation, as indicated in item "Support Material", and, because of the possibility of dimensional and / or functional incompatibility, the product shall not be used with instruments other than those indicated by the manufacturer;
- The correct component combinations for the Hip Total System is indicated in item "Ancillary Components", and because of the possibility of dimensional and functional incompatibility, it shall not be used with components other than those indicated by the manufacturer.

Guidelines to Patient and / or Legal Representative

The attending surgical team shall instruct the patient and / or his legal representative on:

- Adequate care and restrictions during the postoperative period. The capacity and willingness of the patient to follow these guidelines are one of the most important aspects in a surgical procedure involving osteosynthesis;
- The fact that risks are greater in patients predisposed to not comply to medical guidelines, care, and postoperative restrictions, such as children, the elderly, subjects with neurological disorders or drug addicts;
- 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 physical effort, early load and other situations;
- All postoperative restrictions, especially those related to sports and occupational activities;
- Postoperative complications pose a greater risk to patients with functional expectations beyond what can be promoted by joint replacement, morbidly obese patients, and patients with small bone structure;
- The need to use, exclusively at medical discretion, external support, walking aid, and orthopedic devices designed to limit movements and / or loads;
- The need for periodic medical follow-up, to check the conditions of the implant, bone, and adjacent tissues;
- The fact that not performing revision surgery when components become loose can result in progressive loss of bone stock;
- The fact that implants can interfere with imaging test results. Thus, implant bearers shall report this fact when performing such tests.
- Complications related to hip arthroplasty procedures, as well as the information listed in this item "Guidelines to Patient and / or Legal Representative" and item "Adverse Effects".

Sterilization

The Hip Total System is supplied in sterile condition. The adopted sterilization method is gamma radiation.

The manufacturing of components is carefully carried out in order to meet the product's intended performance. Thus, the surgical team and others involved shall handle the devices properly so that infection risks are minimized.

Sterile product - Do not re-sterilize.

Do not use the product if packaging is violated.

Contamination Risk

Since this is an implantable product, when there is need of explantation of components there are also risks of biologic contamination and viral disease transmission.

To minimize these risks, the explanted devices shall be treated as potentially contaminant materials and the applicable standards and/or other local regulations shall be adopted.

Product Disposal

The devices that were explanted or regarded as inappropriate for use must be discarded. It is highly recommended that before discarded, the parts are cut, bent or sanded.

The implants shall be discarded in proper sites, to avoid environmental and other individuals' contamination. The adoption of local regulations for discarding potentially contaminant products is recommended.

Single-use product - Dot not reuse.

Traceability

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

- Name of the patient who received the implant;
- Surgeon's name;
- Hospital name;
- Manufacturer's name;
- Supplier's Name;
- Date of surgery;
- Product code;
- Product lot number;
- Quantity used;
- Product registration at ANVISA;

The attending surgeon and his team shall make use of the traceability labels provided in the product package, sticking them on the patient's medical record to maintain the traceability of the implanted product. Moreover, one of these labels shall be given to the patient so that he / she has information about the product implanted in the surgical procedure.

The labels bear the product data such as code, description and lot number, among other information.

Traceability information is necessary for notification by the health service and/or the patients themselves to Sanitary Surveillance Agency - ANVISA and the manufacturer when there is occurrence of serious adverse events, for conducting appropriate investigations.

Storage and Transport

For storage, a dry and airy place is recommended, without light incidence exposure, humidity or contaminating substances.

Since it is a sterile product, temperature and humidity at the storage site shall be monitored and kept below 40 ºC.

The implants cannot be stored directly on the floor. Thus, it is recommended to use shelves with a minimum height of 20 cm .

The product shall be kept in its original packaging until the moment of use and its opening and handling for surgical application shall be carried out by personnel that is trained for this procedure ;

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

For information about the date of manufacturing, expiry date, 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: 10417940023
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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 are indexed on the website by REGISTRATION/ CADASTRE ANVISA´s NUMBER and COMMERCIAL NAME of the product, informed at the label of the purchased product.

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.

MDTImplantes

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