














Instructions for Use

Non Cemented Stem without Coating

Legend of Symbols Use on Packages

	Number in the Catalogue;		Batch Number;
	Sterile Product – Sterilized by Gamma Radiation;		Expiration Date;
	Manufacturing Date;		Single Use Product;
	Consult the Use Instructions;		Do not re-sterilized;
	Do not use if the packaging is damaged;		Fragile, handling with care;
	Keep away from the sun;		Temperature Limit (40°C);
	Keep dry;		

Specifications and technical characteristics of the product

Technical Name: Modular Stem for Hip Arthroplasty

Commercial Name: Non Cemented Stem without Coating

Commercial Models:

- MD-6 Non Cemented Femoral Prosthesis with Proximal Fixation;
- MD-6 Non Cemented Femoral Prosthesis with Distal Fixation;

Matéria Prima: Titanium Alloy (Ti-6Al-4V)

Sterile Product

Sterilization Method: Gamma Radiation (25 kGy doses)

Validity: 05 years (after sterilization date)

Description

Non Cemented Stem without Coating family consists of surgically invasive implants of long term use, in procedures of hip joint replacement.

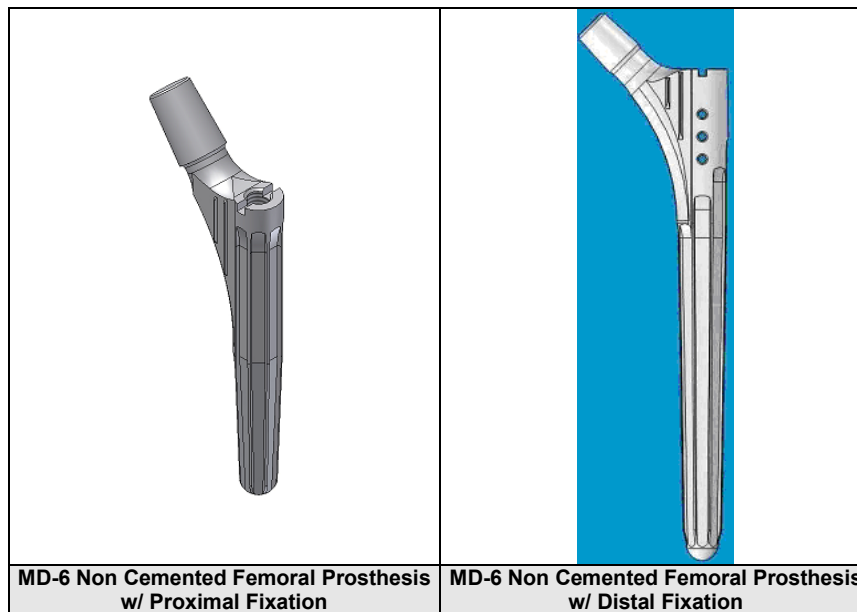
It is composed by the commercial models MD-6 Non Cemented Femoral Prosthesis with Proximal Fixation and MD-6 Non Cemented Femoral Prosthesis with Distal Fixation, each one with its specific indication, for natural joint replacement of hip in arthroplasty procedures.

Femoral prosthesis consists of a device provided with cone (12/14) and longitudinal body. They are available for consumption in several measures, present variation in the diameter and length. The cone is interchangeable with single size (12/14) and can be connected to diverse sizes of heads. The necks present itself with angulations of 130°, 135° and 140° in relation to the longitudinal prosthetic axis that offer variation in dimensions of offset.

It has a rough surface (non cemented) and is provided with conical system type Morse, in which distal migration of the component generate radial compressive forces that stabilize the implant and decrease the efforts of tension for the interface bone-implant ensuring higher longevity to prosthetic reconstruction. The cones type Morse allow the modularity of the femoral head maintaining the tolerances inside of limits very narrow, in which minimize the effects of friction and corrosion for friction.

It is manufactured from titanium alloy (Ti-6Al-4V), the family of Non Cemented Stem without Coating is provides of longitudinal grooved body and axis with cone (12/14). It is available for commercialization in different sizes of diameter and length. The stem body has a rough coating obtained by blasting that allow higher adherence of the stem to the bone of patient. The femur is fixed by press-fit, in other words, it is not necessary cementation. The axis can be connected to the heads with several diameters and lengths.

Non Cemented Stem without Coating family presents the advantage of modularity of the cone, allowing to the surgeon possibilities of assembling of implant according to his necessity, using a variety of diameter of heads, lengths of neck and sizes of stem. Non Cemented Stem without Coating family is indicated for primary and revision surgeries, according to its length. Illustrative image of Non Cemented Stem without Coating family, is as follows:



Composition

Non Cemented Stems without Coating family is manufactured from titanium alloy (Ti-6Al-4V) that meets specified requirements by standard ASTM F136 – Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) R56401 for application in Surgical Implants (Standard Specification for Wrought Titanium-6Aluminum -4Vanadium ELI -Extra Low Interstitial- Alloy for Surgical Implant Applications).

Indication and Purpose

Non Cemented Stem without Coating family is indicated for use in patients skeletally mature as part of the reconstruction of the femoral portion in total hip arthroplasty in patients that present damages in this articulation, resulting from degenerative non-inflammatory articular disease (osteoarthritis), avascular necrosis of the femoral head, acetabular protrusion, secondary osteoarthritis to traumatism, femoral proximal epiphysiolysis and sequels of fracture of the pelvis, ankylosis or surgical arthrodesis of hip.

The purpose of Non Cemented Stem without Coating family is the proximal/distal fixation in hip joint replacement procedures, both for primary cases as in revision cases.

The products here described were developed for use in the circumstances mentioned above, so that any other use is considered contraindicated or without scientific substratum to support such use.

Contraindication

Following, are listed the related contra indications for the device use, leaving to the surgeon in charge the procedure indication, after a detailed study of the case:

- Existence of general active infections or specific that can lead to complications;
- Patients with impaired general state and/or immune compromised, unable to be submitted to a surgical procedure;
- Sensibility to foreign bodies. In suspect cases, tests in the patients must be performed;

- Patients with osteoporosis and/or bone affections that may compromise the arthroplasty result;
- Patients with rapidly destructive bone disease or osteonecrosis post-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.

Forms of Presentation

Commercial models that compose the Non Cemented Stem without Coating family are unitarily packaged in primary double blister packing that works as a barrier to sterilization.

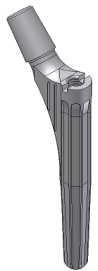
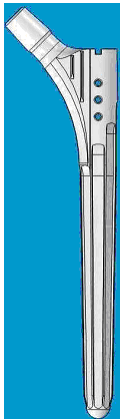
Non Cemented Stem without Coating family is supplied in the sterile product condition. The sterilization method adopted is gamma radiation (25 kGy doses), procedure performed by third company suitably qualified.

After sterilization of the components packaged in its primary packaging suitably labeled, they are packaged in a cardboard box (secondary packaging), in which follows with a leaflet with use instructions and five copies of traceability label.

On the primary packaging and its cardboard box is pasted a label, containing the necessary information for the product identification.

Non Cemented Stem without Coating family is presented in the following commercial models, being that each one of these models is available for marketing in the following dimensions:

List of Commercial models that compose the Non Cemented Stem without Coating family

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packaged Quantity
	04.30.56.XX100	MD-6 Ti Non Cemented Femoral Prosthesis Cone 12/14 – 100 mm Offset 33mm – 140°;	Diameters – 14, 15, 16, 17, 18, 19, 20 mm;	Titanium alloy (Ti-6Al-4V)	01
	04.30.52.XX100	MD-6 Ti Non Cemented Femoral Prosthesis Cone 12/14 – 100 mm Offset 37 mm - 135°;	Diameters – 14, 15, 16, 17, 18, 19, 20 mm;	Titanium alloy (Ti-6Al-4V)	01
	04.30.57.XX100	MD-6 Ti Non Cemented Femoral Prosthesis Cone 12/14 – 100 mm Offset 40 mm - 135°;	Diameters – 14, 15, 16, 17, 18, 19, 20 mm;	Titanium alloy (Ti-6Al-4V)	01
	04.30.51.XX100	MD-6 Ti Non Cemented Femoral Prosthesis Cone 12/14 – 100 mm Offset 43 mm - 130°;	Diameters – 14, 15, 16, 17, 18, 19, 20 mm;	Titanium alloy (Ti-6Al-4V)	01
	04.30.58.XX100	MD-6 Ti Non Cemented Femoral Prosthesis Cone 12/14 – 100 mm Offset 47 mm - 130°;	Diameters – 14, 15, 16, 17, 18, 19, 20 mm;	Titanium alloy (Ti-6Al-4V)	01
	04.30.52.XXXXX	MD-6 Ti Non Cemented Femoral Prosthesis with Distal Fixation Cone 12/14;	Diameter 14 mm – 150, 180, 230; Diameter 15 mm – 150, 180, 230; Diameter 16 mm – 150, 180, 230, 280 mm; Diameter 17 mm – 150, 180, 230, 280 mm; Diameter 18 mm – 150, 180, 230, 280 mm; Diameter 19 mm – 150, 180, 230, 280 mm; Diameter 20 mm – 150, 180, 230, 280 mm; Diameter 21 mm – 150, 180, 230, 280 mm; Diameter 22 mm – 230, 280 mm;	Titanium alloy (Ti-6Al-4V)	01

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packaged Quantity
			Diameter 23 mm – 230, 280 mm; Diameter 24 mm – 230, 280 mm; Diameter 25 mm – 230, 280 mm;		

Ancillary Components

The ancillaries' implants to the commercial models that compose the Non Cemented Stem without Coating family are:

- Cemented Cup;
- Non Cemented Cup;
- Acetabular Insert;
- Femoral Interchangeable Head;

Cemented cups - Máxima and NG Spoac are manufactured from polymer Ultra High Molecular Weight Polyethylene (UHMWPE) that meets the specified requirements by standard ASTM F-648 - Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, through machining process.

Non cemented cup – MD5 Porous Coated, is manufactured from manufactured of molten alloy of cobalt chrome molybdenum (Co-28Cr-6Mo) that meets the specified requirements by standard ASTM F-75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075). Implants produced from this material are obtained by microfusion process followed by machining. The microspheres coating (porous coated) of cobalt chromium molybdenum (Co-28Cr-06Mo), which covers MD5 cup meets the specified requirements by standard ASTM F-1377 - Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075).

Non cemented cups – MD4 Plasma Spray and Acetabular MD Ti, are manufactured from titanium alloy (Ti-6Al-4V) that meets the specified requirements by standard ASTM F-136 – Standard Specification for Wrought Titanium-6Aluminum -4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. Implants produced from this material are obtained through forging and/or machining process. Titanium powder coating (plasma spraying) that covers cups meets the specified requirements by standard ASTM F-1580 – Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.

Acetabular Inserts – 09 Points and MD Poli (Standard/ with Posterior Rim/ Constrict) are manufactured from polymer Ultra High Molecular Weight Polyethylene (UHMWPE) that meets the specified requirements by standard ASTM F-648 – Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, through machining process.

Ceramic components – Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) and MD Delta Acetabular Insert are manufactured from high purity alumina ceramic (Al₂O₃) that meets the specified requirements by standard ISO 6474 – Implants for surgery – Ceramic materials based on high purity alumina, through sintering process. They are supplied by third company (CeramTec) suitably qualified.

Interchangeable Femoral Head Cone 12/14 (Necks Short, Medium, Long, Extra-Long/ Necks varying of -04 mm to +09 mm) is manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) that meets the specified requirements by standard ASTM F138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants, through machining process.

The correct selection of models, measures and combinations of commercial models that compose the Non Cemented Stem without Coating family, as well as, its ancillaries to be deployed is the responsibility of the surgeon who is also responsible for the surgical technique used; he must be familiar with the material, the method of application and surgical procedure to be performed.

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

Following, the indication of ancillary components and its correct combination with the commercial models that compose the Non Cemented Stem without Coating:

Ancillary – Cup	Ancillary – Interchangeable Femoral Head	Commercial Models – Non Cemented Stem without Coating
<p style="text-align: center;">Máxima STD Cup Polyethylene (UHMWPE) – ASTM F-648</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">Máxima STD Cup w/ Spacer Polyethylene (UHMWPE) – ASTM F-648</p>	<p style="text-align: center;">Interchangeable Femoral Head (Necks Short, Medium, Long, Extra-Long) Titanium Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">Interchangeable Femoral Head (Necks -04 to +09 mm) Titanium Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) Alumina Ceramic (Al₂O₃) – ISO 6474</p>	<p style="text-align: center;">MD-6 Non Cemented Femoral Prosthesis with Proximal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">MD-6 Non Cemented Femoral Prosthesis with Distal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p>
<p style="text-align: center;">SPOAC NG Cemented Cup Polyethylene (UHMWPE) – ASTM F-648</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">SPOAC NG w/ PMMA Cemented Cup Polyethylene (UHMWPE) – ASTM F-648</p>	<p style="text-align: center;">Interchangeable Femoral Head (Necks Short, Medium, Long, Extra-Long) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">Interchangeable Femoral Head (Necks -04 to +09 mm) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) Alumina Ceramic (Al₂O₃) – ISO 6474</p>	<p style="text-align: center;">MD-6 Non Cemented Femoral Prosthesis with Proximal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">MD-6 Non Cemented Femoral Prosthesis with Distal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p>
<p style="text-align: center;">MD4 – Plasma Spray Cup Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">+</p> <p style="text-align: center;">09 Points Acetabular Insert Polyethylene (UHMWPE) – ASTM F-648</p>	<p style="text-align: center;">Interchangeable Femoral Head (Necks Short, Medium, Long, Extra-Long) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">Interchangeable Femoral Head (Necks -04 to +09 mm) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p>	<p style="text-align: center;">MD-6 Non Cemented Femoral Prosthesis with Proximal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">Or</p> <p style="text-align: center;">MD-6 Non Cemented Femoral Prosthesis with Distal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p>

	<p style="text-align: center;">Or</p> <p style="text-align: center;">Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) Alumina Ceramic (Al₂O₃) – ISO 6474</p>	
<p style="text-align: center;">MD5 – Porous Coated Cup Cobalt Chrome Molybdenum (Co-28Cr-6Mo) – ASTM F-75</p> <p style="text-align: center;">+</p> <p style="text-align: center;">09 Points Acetabular Insert Polyethylene (UHMWPE) – ASTM F-648</p>	<p>Interchangeable Femoral Head (Necks Short, Medium, Long, Extra-Long) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p>Interchangeable Femoral Head (Necks -04 to +09 mm) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p>Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) Alumina Ceramic (Al₂O₃) – ISO 6474</p>	<p>MD-6 Non Cemented Femoral Prosthesis with Proximal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">Or</p> <p>MD-6 Non Cemented Femoral Prosthesis with Distal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p>
<p style="text-align: center;">MD Ti Acetabular Cup Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">+</p> <p style="text-align: center;">MD Poli Acetabular Insert (Standard or Posterior Rim or Constrict) Polyethylene (UHMWPE)</p>	<p>Interchangeable Femoral Head (Necks Short, Medium, Long, Extra-Long) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p>Interchangeable Femoral Head (Necks -04 to +09 mm) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p>Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) Alumina Ceramic (Al₂O₃) – ISO 6474</p>	<p>MD-6 Non Cemented Prosthesis with Proximal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">Or</p> <p>MD-6 Non Cemented Prosthesis with Distal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p>
<p style="text-align: center;">MD Ti Acetabular Cup Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">+</p> <p style="text-align: center;">MD Delta Acetabular Insert Alumina Ceramic (Al₂O₃) – ISO 6474</p>	<p>Interchangeable Femoral Head (Necks Short, Medium, Long, Extra-Long) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p>Interchangeable Femoral Head (Necks -04 to +09 mm) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F-138</p> <p style="text-align: center;">Or</p> <p>Interchangeable Femoral Head Forte Ceramic (Necks -04 to +08 mm) Alumina Ceramic (Al₂O₃) – ISO 6474</p>	<p>MD-6 Non Cemented Prosthesis with Proximal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p> <p style="text-align: center;">Or</p> <p>MD-6 Non Cemented Prosthesis with Distal Fixation Titanium Alloy (Ti-6Al-4V) – ASTM F-136</p>

List of ancillary components to the commercial models that compose the Non Cemented Stem without Coating family

Cemented Cups		
Code	Description	Available Sizes
04.01.02.XXXXXX	Máxima STD Cup	Ø 26 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60 mm; Ø 28 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60 mm;
04.01.23.XXXXXX	Máxima STD Cup w/ Spacer	Ø 26 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60 mm. Ø 28 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60 mm;
04.01.24.XXXXXX	SPOAC NG Cemented Cup	Ø 22 mm – 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; Ø 26 mm – 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; Ø 28 mm – 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; Ø 32 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;
04.01.25.XXXXXX	SPOAC NG w/ PMMA Cemented Cup	Ø 22 mm – 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; Ø 26 mm – 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; Ø 28 mm – 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; Ø 32 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;
Non Cemented Cups		
Code	Description	Available Sizes
04.01.04.XXXXXX	MD4 – Plasma Spray Cup	Ø 22 mm – 42, 44, 46, 48 mm; Ø 28 mm – 50, 52, 54, 56, 58, 60, 62, 66, 68, 70 mm;
04.01.22.XXXXXX	MD5 – Porous Coated Cup	Ø 22 mm – 44, 46, 48 mm; Ø 28 mm – 50, 52, 54, 56, 58, 60, 62 mm;
04.01.26. XXXXX	MD Acetabular Ti (with holes) Cup	Ø 46x35 mm; Ø 48x35 mm; Ø 50x37 mm; Ø 52x37 mm; Ø 54x39 mm; Ø 56x41 mm;
04.01.27. XXXXX	MD Acetabular Ti (without holes) Cup	Ø 58x44 mm; Ø 60x44 mm; Ø 62x48 mm; Ø 64x48 mm; Ø 66x52 mm; Ø 68x52 mm; Ø 70x52 mm;
Acetabular Inserts		
Code	Description	Available Sizes
04.13.02.XXXXXX	09 Points Acetabular Insert	Ø 22 mm – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm. Ø 26 mm – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm. Ø 28 mm – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm. Ø 32 mm – 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm.

04.13.05.XXXXXX	MD Poli – Standard Acetabular Insert	Ø 35 mm – 22 mm; Ø 37 mm – 22, 26 mm;
04.13.06.XXXXXX	MD Poli Acetabular Insert – w/ Posterior Rim	Ø 39 mm – 22, 26, 28 mm; Ø 41 mm – 22, 26, 28 mm;
04.13.07.XXXXXX	MD Poli Acetabular Insert – Constrict	Ø 44 mm – 22, 26, 28, 32 mm; Ø 48 mm – 22, 26, 28, 32 mm; Ø 52 mm – 22, 26, 28, 32 mm;
04.13.08.XXXXXX	MD Delta Acetabular Insert	Ø 35 mm – 28 mm; Ø 37 mm – 28 mm; Ø 39 mm – 32 mm; Ø 41 mm – 32 mm; Ø 44 mm – 32, 36 mm; Ø 48 mm – 32, 36, 40 mm; Ø 52 mm – 32, 36, 40 mm;
Femoral Heads		
Code	Description	Available Sizes
04.04.03.XXXXXX	Interchangeable Femoral Head Cone 12/14	Ø 22 mm: Short, Medium, Long and Extra-Long; Ø 26 mm: Short, Medium, Long and Extra-Long; Ø 28 mm: Short, Medium, Long and Extra-Long; Ø 32 mm: Short, Medium, Long and Extra-Long;
04.04.07.XXXXXX	Interchangeable Femoral Head Cone 12/14 mm	Ø 22 mm: -2, Standard, +3 mm; Ø 26 mm: -4, -2, Standard, +3, +6, +9 mm; Ø 28 mm: -4, -2, Standard, +3, +6, +9 mm;
04.04.09.XXXXXX	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;

The ancillary components related are not objects of this registration process and must, therefore, be acquired separately and always from the same manufacturer or appointed by him.

Support Material

The support materials are the instruments designed only for deployment of the Non Cemented Stem without Coating and its respective aforementioned ancillaries.

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 must therefore be purchased separately and always the same manufacturer of the implant or indicated by the manufacturer.

See list below of the instruments available from the manufacturer or indicated by the manufacturer for deployment of the Non Cemented Stem without Coating and its respective ancillaries:

- 0Q.28 – MD6 – Instrumental;
- 0Q.34 – MD6 – Basic Primary Femoral Instrumental;
- 0Q.36 – MD6 – Complementary Instrumental;

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 must be inspected regularly for wear and possible damage.

For more information about the instrumental, consult the representative.

Warning and Precautions

To use the product the team in charge must consider the following warnings and precautions:

- The product must be used only after a detailed analysis of the surgical procedure to be adopted and read this instruction of use;
- The product must 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 an accurate surgical technique;
- 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 must be adopted (except cephalic components);
- The use in patients with predisposing to disobey the medical guidelines and restrictions postoperative, such as children, elderly, individuals with neurological disorders or drug addicts, represent a greatest 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 at greatest risk when the product is used in patients with functional expectations beyond those what can be promoted by joint replacement, patients with morbid obesity and patients with small bones structure;
- No Cemented Stem without Coating and its respective ancillaries must not be used if they do not get a bone support adequate to ensure the stability of the implant;
- Femoral Prosthesis must not be used together with bone cements;
- The patient must make a periodic medical monitoring (follow-up) to check the conditions of the implant, the bone and adjacent tissues;
- As the medical criterion, can be used 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 must not be used with components from other manufacturers or purpose. The combination with implants of manufacturers or different purposes can result in incongruence between the components;
- It must be observed closely the identification of the product and are not allowed combinations with components from other manufacturers or purpose;

- The care of this material are the responsibility of qualified personnel, which must follow the standards and/or other local regulations applicable;
- 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 must not be used;
- The opening of the packaging for surgical use must only be performed by qualified personnel for this procedure;
- Do not use the product if it has expired date or packaging violated;
- Handle with care;
- Product use only - Do not reuse;
- The implants must NEVER be reused. Although they may look undamaged, prior to the tensions that they have been submitted can cause imperfections that must reduce the lifetime of the product in a reimplantation;
- PROHIBITED REPROCESSING;
- Single use product – Do not re-sterilized;
- Manufacturing date, 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;
- Post-operative pains, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Inflammatory reactions, associated or not to displacement and/or loosening of the implant;
- Necrosis of bone or adjacent soft tissues;
- Implant breakage can make their removal difficult or impractical;
- 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.

Use Instructions

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

- The care of this material is the responsibility of the personnel, which must follow the standards and/or other local regulations;
- The product must be handled with appropriate care in appropriate locations (center of materials and operating rooms);
- The product must 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;
- The established shelf-life of the Non Cemented Stem without Coating 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;
- To the medical criterion, 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 Non Cemented Stem without Coating is necessary the use of specific instruments, as mentioned in the topic "Support Material". Must 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 Non Cemented Stem without Coating and their ancillary components is indicated in topic "Support Materials". Must be not used with components other than those indicated by the manufacturer, due to the possibility of dimensional and functional incompatibility.

Guidance to the patient and/or the Legal Representative

The team responsible must 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 chemically dependent;
- 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 bones;
- 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 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 must 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

Non Cemented Stem without Coating is supplied sterile. The method of sterilization used is by Gamma Radiation (sterilization dose 25 kGy).

The production of Non Cemented Stem without Coating is made with high care so as to meet the performance desired for the product. Thus, the surgical team and all concerned must 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 need for explantation of the Non Cemented Stem without Coating, there are risks of biological contamination and transmission of viral diseases.

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

Product Discard

Non Cemented Stem without Coating 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 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 must use of the labels for traceability supplied (5 copies) 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 must be supplied to the patient for that has information about the product implanted in his surgery.

On the labels are described dates of product such as: code, description and batch number, among other information. Labels must be used as listed below:

- Label 1: in the patient's medical record (mandatory use);
- Label 2: in the medical report given to the patient;
- Label 3: in the tax document that generates collection document for the AIH, in cases of patients assisted by SUS (Single Health System) or invoice, in cases of patients assisted by supplementary health system;
- Label 4: available for the supplier control (historic register of distribution – RHD);
- Label 5: available for the surgeon in charge control;

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 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 must be monitored and maintained below 40°.

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

The product must be kept in their original packaging until the moment of its use, while opening the package for surgical use and handling of the product must be performed by qualified personnel for this procedure;

The product must 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

CNPJ: 01.025.974/0001-92

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Registration ANVISA #: 10417940068

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ALERT INSTRUCTIONS FOR USE

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

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

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

If it is interest to the user, the INSTRUCTIONS FOR USE may be provided in printed form, with no extra cost and the request of the same shall be held by the 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.



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