Use Instructions

Non Cemented Stem in Titanium

Legend of symbology adopted in the product labeling

REF	Product Code in the Catalog	LOT	Batch Number
STERILE R	Sterile Product – Sterilized by Gamma Radiation	CE XXXX	Product certified in accordance with Directive 93/42/EEC. If applicable
	Manufacturing Date		Expiration date
	Read Use Instructions		Single Use Product
	Do not use if package is dammaged or violated		DO NOT Re-sterilize
	Avoid direct exposition to sunlight		Fragile – Handle with care
	Keep Dry		Temperature Limit (40°C)

Features and technical specifications of the product

Technical Name: Implantable Material

Trade Name: Non Cemented Stem in Titanium

Trade Models:

- Femoral Prosthesis MD4 – Porous Coated;
- Femoral Prosthesis MD4 – Plasma Spray;
- Femoral Prosthesis EZ-Fit PS Ti;
- Femoral Prosthesis PHENOM PS Ti;

Raw Materials:

- **Prosthetics (substrate) –** Titanium Alloy (Ti-6Al-4V)
- **Coating:** Titanium (Porous Coated or Plasma Spray);

Sterile Product

Sterilization Method: Gamma Radiation (dosage of 25 kGy)

Expiration: 05 years (after sterilization date)

Description:

The Non Cemented Stem in Titanium Family is formed by implantable devices, surgically invasive. They are for long term utilization and are used in surgical procedures for articular replacement of the hip.

It is formed by the trade model Femoral Prosthesis MD4 (with Porous Coated titanium coating or or Plasma Spray sprinkling); Femoral Prosthesis EZ-Fit PS Ti and Femoral Prosthesis PHENOM PS Ti, each one with its specific indication, and is intended to the replacement of natural articulation in hip arthroplasty total or partial procedures.

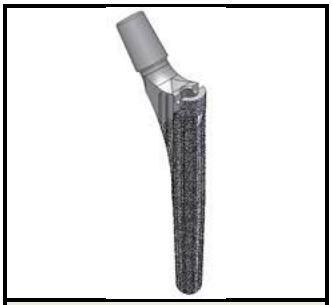
Made from Titanium alloy (Ti-A-4V), the femoral prosthesis consist of a cone (Morse type conical system 12/14), which enables femoral head modularity and the longitudinal body with titanium coating. Fixation to the femur intramedullary canal is uncemented through (press-fit) impaction, in which the component distal migration generates radical compression strength which stabilizes the implant and reduces tension strengths to the implant-bone interface, guaranteeing greater prosthetic reconstruction longevity.

The family of Non Cemented Stem in Titanium is intended to skeletally mature patients for reconstruction of femoral portion in partial or total hip arthroplasty in patients who have damage to this joint due to degenerative joint disease non inflammatory (osteoarthritis), avascular necrosis of the head femoral, acetabular protrusion, osteoarthritis secondary to trauma, proximal femoral epiphysiolysis, sequelae of fractures of the pelvis, ankylosis or surgical arthrodesis of the hip.

The **Femoral Prosthesis MD4** has two options of rough coating, Titanium microspheres called **Porous Coated** or titanium powder sprinkled by **Plasma Spray**, which facilitates the adhesion of the prosthesis to the bone. Stems with ¾ of the longitudinal surface coated are indicated for primary procedures, and stems with the entire longitudinal extension are for reviews. Commercially available in various lengths and diameters, the prosthesis has a 135 º angle relative to its longitudinal prosthetic axis.

Primary	Review	Primary	Review
Femoral Prosthesis MD4 – Porous Coated		Femoral Prosthesis MD4 – Plasma Spray	

The **Femoral Prosthesis EZ-Fit PS Ti** outer surface is titanium coated by plasma spray aspersion and is indicated for primary procedures with proximal fixation. It has a conical shape that provides greater axial stability and better transmission of the mechanical efforts to the bone. The prosthesis is corrugated for increased rotational stability and has fins around the longitudinal body that stimulates bone growth in these areas, enhancing the fixation of the prosthesis in the intramedullary canal. The neck of the stem is presented with angles of 130 °, 135 ° and 140 ° in relation to the longitudinal prosthetic axis and five off-set variants of 33, 37, 40, 43 and 47 mm which, together with the possibilities of variation of femoral heads, provide the surgeon with a wide range of possibilities for mounting the implant as needed by the patient. Available for commercialization with diameters ranging from 14 to 20 mm, it is 100 mm long.

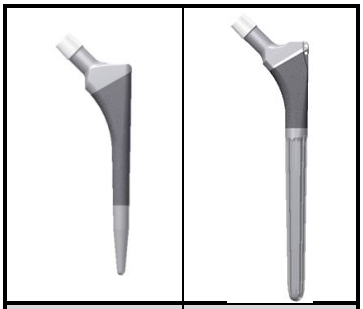


Femoral Prosthesis EZ-Fit PS Ti

The **Femoral Prosthesis PHENOM PS Ti** outer surface is titanium coated by plasma spray aspersion and is indicated for primary and review procedures. The version for primary procedures has a conical shape that provides greater axial stability and better transmission of the mechanical efforts to the bone. ¾ of its longitudinal body is titanium coated which stimulates bone growth and enhances the prosthesis fixation to the intramedullary canal. The neck of the stem is presented with angle of 135° in relation to the prosthetic longitudinal axis and off-set variants from 35.0 mm to 42.5 mm. Available for commercialization with diameters ranging from 10 to 18 mm, and lengths ranging from 137 mm to 185 mm.

The version for review procedures has its longitudinal body proximal portion titanium coated. The prosthesis is corrugated in its distal portion for greater rotational stability and it has fins which stimulate bone growth and enhances fixation to the intramedullary canal. The neck of the stem is presented with

angles of 135° and 130° in relation to the longitudinal prosthetic axis and off-set from 37.5 mm and 42.5 mm respectively. Available for commercialization with diameters ranging from 12,5 to 20 mm, and lengths ranging from 180 mm to 260 mm.



Primary	Review
Femoral Prosthesis PHENOM PS Ti	

Composition

The materials selected for manufacturing meet the physico-chemical and mechanical properties required to achieve the desired performance for the product. The selection considered factors such as the effects of manufacturing, handling, sterilization, storage, and possible reactions of stuff with human tissues and body fluids.

The Family of Non Cemented Stem in Titanium is made of Titanium Alloy (Ti-6Al-4V). The manufacturing material is compatible with biological tissues, cells and body tissues which they come in contact with in implantable state, evidenced by historical usage in similar applications which are available in the scientific and clinical literature all over world. This confirmation also applies to the possible products of wear and degradation of the materials at acceptable levels throughout its use.

The material used to manufacture the product and its respective combinations to the articulating and touch surfaces are related respectively in Annexes A, B and C of ABNT NBR ISO 21534 - Implants for non-active surgery - Implants for replacing joints - Specific Requirements, which establishes the relationship of standards for materials regarded acceptable through proven use by scientific and clinical literature for implant manufacturing.

The titanium alloy (Ti-6Al-4V) used to manufacture the product meets the requirements specified by ASTM F-136 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.

The titanium coating applied on the trade models Femoral Prosthesis MD4 (Porous Coated and Plasma Spray),Femoral Prosthesis EX-Fit PSTi, Femoral Prosthesis PHENOM PS Ti, meet the requirements specified by ASTM F1580 - Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.

The choice of these materials for the manufacture of the trade models which made up the Family of the Non Cemented Stem in Titanium was based on similarity criteria (results widely described in literature) and their biocompatibility features and physico-chemical and mechanical properties proven by these materials specification standards.

Indication and Finality

The trade models that make up the Family of the Non Cemented Stem in Titanium are indicated to be used in skeletally mature patients, as part of the femoral portion reconstruction in hip partial and total arthroplasty in patients who have damage in this joint due to non-inflammatory degenerative joint disease (osteoarthritis), avascular necrosis of the femoral head, acetabular protrusion, osteoarthritis secondary to trauma, proximal femoral epiphysiolysis, and pelvis fractures sequelae, ankylosis or surgical arthrodesis of the hip.

The product is intended to the non-cemented fixation by impaction (press-fit) in hip partial or total arthroplasty procedures, in both, primary or review cases.

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

Contraindication

Below are the relative contraindications for the use of the device. The surgeon in charge must firstly have a thorough study of the case before indicating the procedures:

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

Form of Presentation

The trade models that make up the family of the Non Cemented Stem in Titanium are unitarily packed in primary packaging blister type system, sealed with surgical grade paper (Tyvec® type) or in surgical wrapping system Tyvec® type, which act as a shield for the sterilization.

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

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

On the primary packaging as well as on the carton a label containing the necessary information for identification of the product is glued.

Forms of Presentation

The Family of the Non Cemented Stem in Titanium is presented in the following trade models, and each of them is available for use in the folowwing dimensions:

List of the trade models which make up the Family of the Non Cemented Stem in Titanium

Illustrative Image	Code	Description	Dimensions	Made of	Qtty Packed
	04.30.09.XXXXX	Femoral Prosthesis MD4 w/ Porous Coated Cone 10/11 – Primary	**Diameter:** 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; **Length:** 117, 122, 127, 132, 137, 142, 147, 152, 157 mm; **Cone:** 10/11 mm; **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V)/ Titanium microsphere coating (Porous Coated)	01
	04.30.11.XXXXX	Femoral Prosthesis MD4 w/ Porous Coated Cone 12/14 – Primary	**Diameter:** 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; **Length:** 107, 112, 117, 122, 127, 132, 137, 142, 147, 152, 157, 160, 180, 200 mm; **Cone:** 12/14 mm; **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V)/ Titanium microsphere coating (Porous Coated)	01
	04.30.10.XXXXX	Femoral Prosthesis MD4 w/ Porous Coated Cone 10/11 – Review	**Diameter:** 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; **Length:** 117, 170, 180, 190, 200, 210, 220, 230, 240 mm **Cone:** 10/11 mm; **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V)/ Titanium microsphere coating (Porous Coated)	01
	04.30.12.XXXXX	Femoral Prosthesis MD4 w/ Porous Coated Cone 12/14 – Review	**Diameter:** 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; **Length:** 170, 180, 190, 200, 210, 220, 240, 260, 300 mm; **Cone:** 12/14 mm; **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V)/ Titanium microsphere coating (Porous Coated)	01
	04.30.48.XXXXX	Femoral Prosthesis MD4 Ti w/ Plasma Spray Cone 12/14 – Primary	**Diameter:** 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; **Length:** 107, 112, 117, 122, 127, 132, 137, 142, 147, 152, 157, 160, 180, 200 mm; **Cone:** 12/14 mm; **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V) Titanium coating by Plasma Spray Aspersion	01
	04.30.49.XXXXX	Femoral Prosthesis MD4 Ti w/ Plasma Spray Cone 12/14 – Review	**Diameter:** 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; **Length:** 170, 180, 190, 200, 210, 220, 230, 240, 260 mm; **Cone:** 12/14 mm; **Cervical-diaphyseal angle:** 135º;	Ttianium Alloy (Ti-6Al-4V) Titanium coating by Plasma Spray Aspersion	01

	04.30.66.XXXXX 04.30.65.XXXXX 04.30.67.XXXXX 04.30.64.XXXXX 04.30.68.XXXXX	Femoral Prosthesis EZ-Fit PS Ti	**Diameter:** 14, 15, 16, 17, 18, 19 and 20 mm; **Length:** 100 mm; **Cone:** 12/14 mm; **Off-set:** 33, 37, 40, 43, 47 mm; **Cervical-diaphyseal angle:** 140º, 135º, 130º;	Titanium Alloy (Ti-6Al-4V) Titanium Coating by Plasma Spray Aspersion	01
	04.30.69.XXXXX	Femoral Prosthesis PHENOM PS Ti Primary	**Diameter:** 10, 11, 12, 13, 14, 15, 16, 17, 18 mm; **Length:** 137, 143, 149, 155, 161, 167, 173, 179, 185 mm; **Cone:** 12/14 mm; **Off-set:** 35,0 à 42,5 mm **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V) Titanium Coating by Plasma Spray Aspersion	01
	04.30.86.XXXXX	Femoral Prosthesis PHENOM PS Ti Review Off-set 37,5mm	**Diameter:** 12.5, 14, 15.5, 17, 18.5, 20 mm; **Length:** 180, 220, 260 mm; **Cone:** 12/14 mm; **Off-set:** 37.5 mm; **Cervical-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V) Titanium Coating by Plasma Spray Aspersion	01
	04.30.87.XXXXX	Femoral Prosthesis PHENOM PS Ti Review Off-set 42,5mm	**Diameter:** 15.5, 17, 18.5, 20 mm; **Length:** 180, 220, 260 mm; **Cone:** 12/14 mm; **Off-set:** 42.5 mm; **Cervical-diaphyseal angle:** 130º;	Titanium Alloy (Ti-6Al-4V) Titanium Coating by Plasma Spray Aspersion	01

Ancillary Components

Here are the ancillary components compatible with trade models that make up the family of the Non Cemented Stem in Titanium:

- Bipolar Cup;
- Cemented Acetabula;
- Uncemented Acetabula;
- Acetabular inserts;
- Interchangeable Femoral Head (metallic and ceramic);

The **Bipolar Cup** is made of stainless steel alloy (18Cr-14Ni-2.5Mo), which meets the requirements specified in ASTM F138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants; from the polymer Polyethylene Ultra High Molecular Weight Polyethylene (UHMWPE) that meets the requirements specified in ASTM F-648 - Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, through the machining process, followed by machining (dome) and machining (insert and lock).

The Cemented Acetabula, models **Máxima** and **SPOAC NG**, are made from the polymer Polyethylene Ultra High Molecular Weight Polyethylene (UHMWPE), which meets the requirements specified in ASTM F-648 - Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, through the machining process. The ring and spacers contained in the outer portion of the product are manufactured from stainless steel alloy (18Cr-14Ni-2 5MO) and polymer polymethylmethacrylate (PMMA) that meet the requirements of ASTM F-138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for surgical Implants (UNS S31673) and ISO 5833 - Implants for surgery - acrylic resin cements, respectively.

The uncemented acetabulum model **MD5**, is manufactured from cobalt chromium molybdenum cast alloy (Co-28Cr-6Mo) that meets the requirements specified in ASTM F-75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075). The coated microspheres (porous coated) cobalt chromium molybdenum (Co-28Cr-06Mo) covering the acetabulum MD5 meets the requirements specified by ASTM F-1377 - Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075). The implants when produced from this material are obtained through the micro-fusion manufacturing process followed by machining.

The uncemented Acetabula models MD4 and MD are manufactured from titanium alloy (Ti-6Al-4V) that meets the requirements specified by ASTM F136 - 'Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications'. The titanium coating (by plasma spray aspersion) which overlays the acetabula meets the requirements specified by ASTM F1580 - 'Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants'. The implants when produced from this material are obtained through the manufacturing process of forging and / or machining.

The **Acetabular Insert 9-point** is made from the polymer Polyethylene Ultra High Molecular Weight Polyethylene (UHMWPE), which meets the requirements specified in ASTM F-648 - Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical implants through the machining process.

The Ceramic Components: **MD Delta Acetabular Insert** and the **Ceramic Interchangeable Femoral Heads (Forte and Delta)** are made from high purity alumina ceramic (Al_2O_3), which meets the requirements specified by ISO 6474 - Implants for surgery - Ceramic materials based on high purity alumina, through the sintering process, provided by (CeramTec), a certified outsource partner.

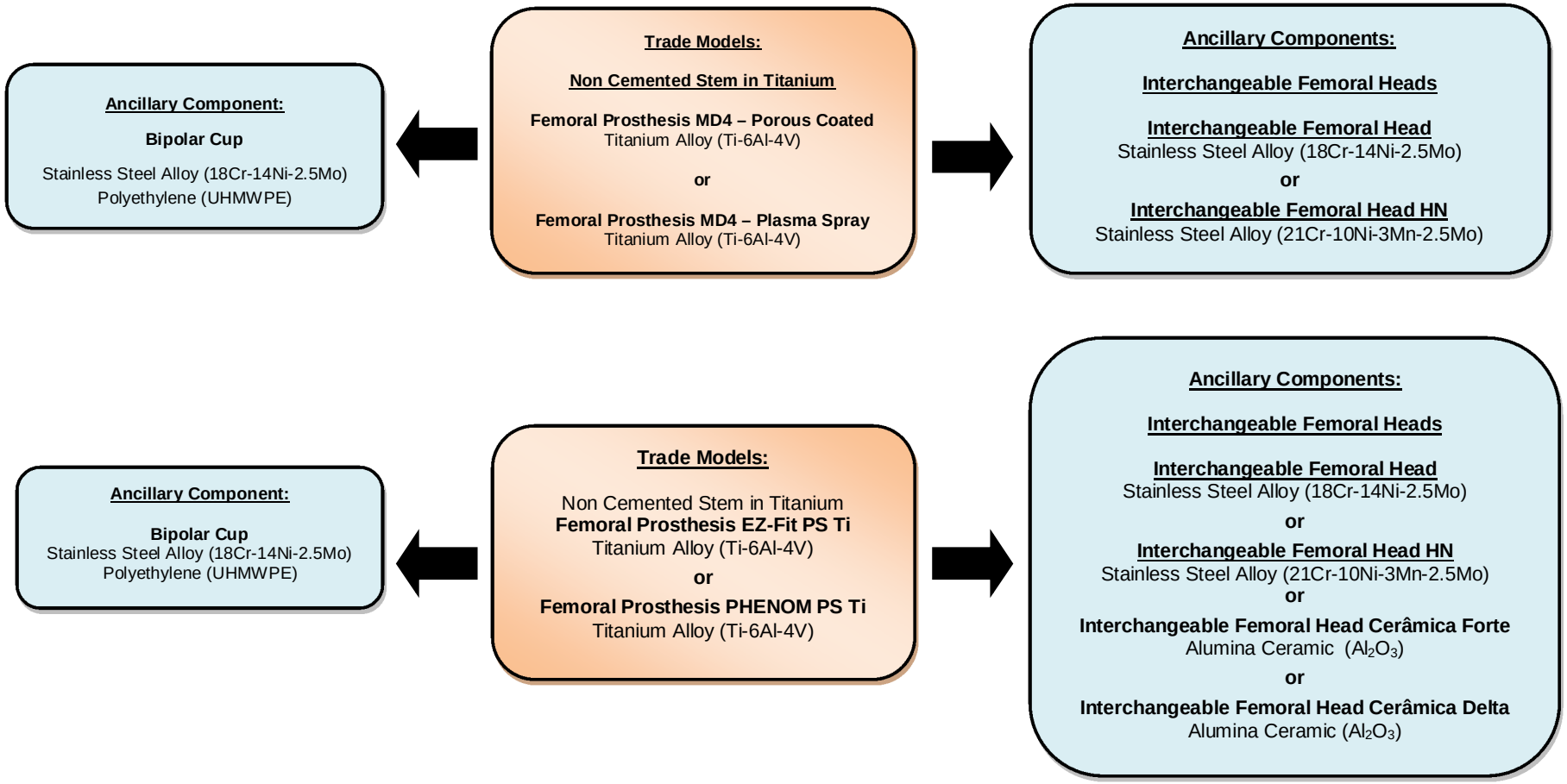
The **metallic interchangeable femoral heads** are manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) and stainless steel alloy with high levels of nitrogen (21cr-10Ni-2.5Mo-3mn), which meets the requirements specified by ASTM F138 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants and ASTM F-1586 - Standard Specification for Wrought Nitrogen Strengthened 21Chromiun - 10Nickel - 3Manganese - 2.5Molybdenum Stainless Steel Alloy Bar for Surgical Implants, respectively, through the machining process.

The surgeon in charge is responsible for the correct selection of models, sizes and combinations of the trade models that make up the family of the Non Cemented Stem in Titanium as well as their ancillary to be implanted. He is also in charge of choosing the adopted technique and must be familiar with the material, the application method and the surgical procedure adopted.

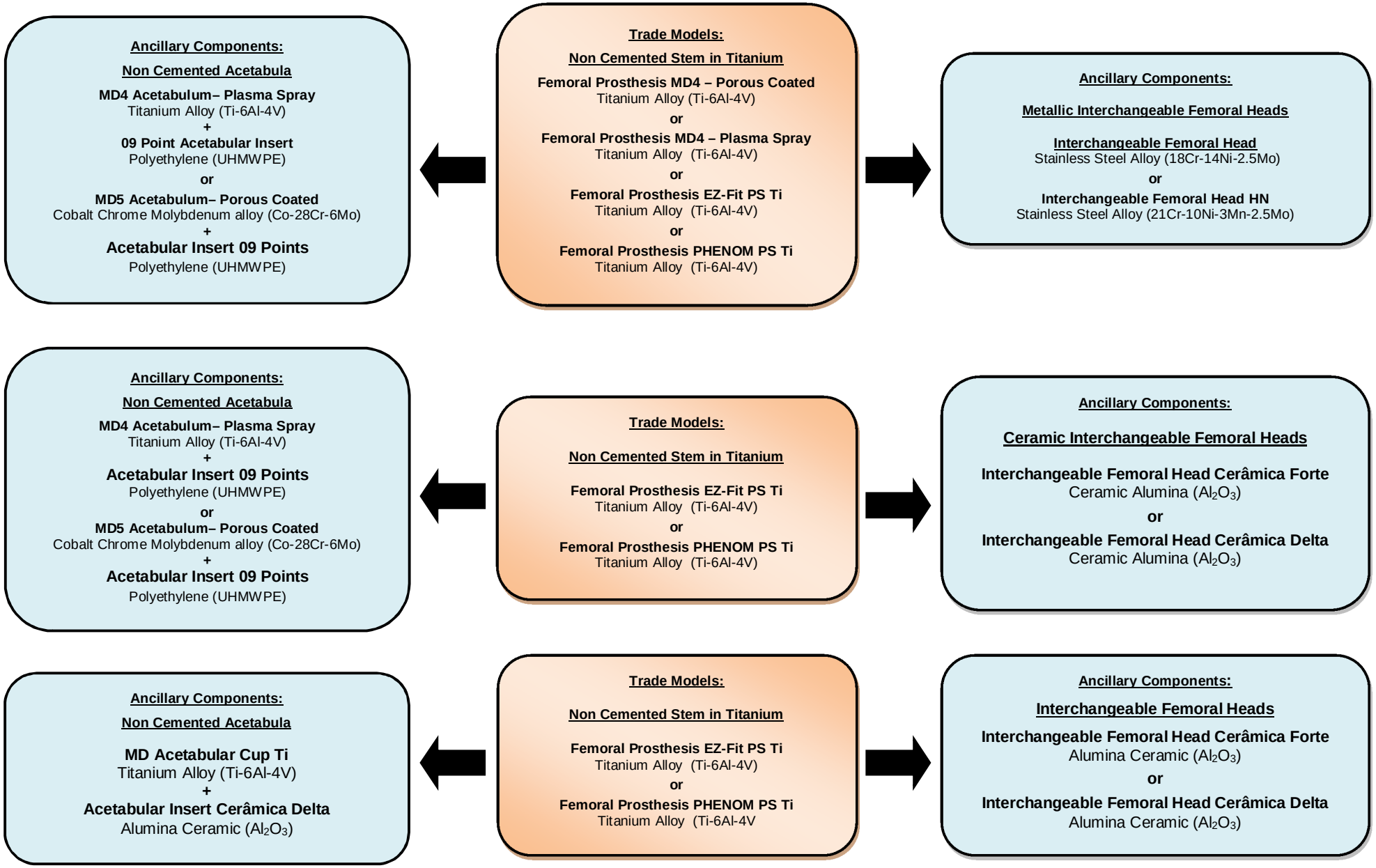
The procedure success depends upon the surgeon in charge and the correct selection, combination, positioning and fixation of the devices, after evaluating the patient and deciding which implant has to be used. It is also linked to the strict compliance with postoperative care recommended by the surgeon.

Next, indication of the ancillary components and their right combination with the trade models which make up the family of the Uncemented Stem - Hydroxyapatite for the following mounting possibilities:

System for Hip Partial Arthroplasty – Non Cemented



System for Hip Partial Arthroplasty – Non Cemented



System for Hip Total Arthroplasty – Hybrid

Ancillary Components:

Cemented Acetabula

Maxima Acetabulum
(with or without spacer)
Polyethylene (UHMWPE)
Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Polymethylmethacrylate (PMMA)

or

SPOAC NG Acetabulum
(with or without spacer)
Polyethylene (UHMWPE)
Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Polymethylmethacrylate (PMMA)

Trade Models:

Non Cemented Stem in Titanium

Femoral Prosthesis MD4 – Porous Coated
Titanium Alloy (Ti-6Al-4V)

or

Femoral Prosthesis MD4 – Plasma Spray
Titanium Alloy (Ti-6Al-4V)

Ancillary Components:

Interchangeable Femoral Heads

Interchangeable Femoral Head
Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

or

Interchangeable Femoral Head HN
Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo)

Ancillary Components:

Cemented Acetabula

Maxima Acetabulum
(with or without spacer)
Polyethylene (UHMWPE)
Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Polymethylmethacrylate (PMMA)

or

SPOAC NG Acetabulum
(with or without spacer)
Polyethylene (UHMWPE)
Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Polymethylmethacrylate (PMMA)

Trade Models:

Non Cemented Stem in Titanium

Femoral Prosthesis EZ-Fit PS Ti
Titanium Alloy (Ti-6Al-4V)

or

Femoral Prosthesis PHENOM PS Ti
Titanium Alloy (Ti-6Al-4V)

Ancillary Components:

Interchangeable Femoral Heads

Interchangeable Femoral Head
Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

or

Interchangeable Femoral Head HN
Stainless Steel alloy (21Cr-10Ni-3Mn-2.5Mo)

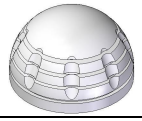
or

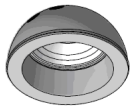
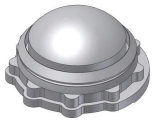
Interchangeable Femoral Head Cerâmica Forte
Alumina Ceramic (Al_2O_3)

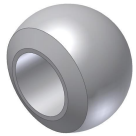
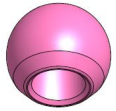
or

Interchangeable Femoral Head Cerâmica Delta
Alumina Ceramic (Al_2O_3)

List of Ancillary Components compatible with the trade models wchich make up the Family of the Non Cemented Stem in Titanium:

Bipolar Cup					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Made of**	**Qtty Packed**
	04.01.01.XXXXX	Bipolar Cup with lock	**Ø 22 mm** – 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54 mm; **Ø 26 mm** – 40, 42, 44, 46, 48, 50, 52, 54, 56 mm; **Ø 28 mm** – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60; **Ø 32 mm** – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2,5Mo)	01
Cemented Acetabula					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Made of**	**Qtty Packed**
	04.01.02.XXXXX	Máxima Acetabular Cup STD	**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;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2,5Mo)	01
	04.01.23.XXXXX	STD Máxima Acetabular 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;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2,5Mo)) Polymethylmethacrylate (PMMA)	01
	04.01.24.XXXXX	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** – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; **Ø 28 mm** – 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; **Ø 32 mm** – 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2,5Mo))	01
	04.01.25.XXXXX	SPOAC NG Cemented Cup w/ PMMA	**Ø 22 mm** – 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; **Ø 26 mm** – 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; **Ø 28 mm** – 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; **Ø 32 mm** – 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2,5Mo)) Polymethylmethacrylate (PMMA)	01

Non Cemented Acetabula					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Made of**	**Qtty Packed**
	04.01.04.XXXXX	MD4 Acetabular Cup – Plasma Spray	**Diameters:** 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 66, 68, 70 mm;	Titanium Alloy (Ti-6Al-4V)/ Titanium Coating by Plasma Spray Aspersion	01
	04.01.22.XXXXX	MD5 Cup – Porous Coated	**Diameters:** 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 66, 68, 70 mm;	Cobalt Alloy (Co-28-6Mo) / Cobalt Microspheres (Porous Coated)	??
	04.01.26. XXXXX	MD Acetabular Cup Ti (with holes)	**Diameters:** 46x35 mm; Ø 48x35 mm; 50x37 mm; 52x37 mm; 54x39 mm; 56x41 mm; 58x44 mm; 60x44 mm; 62x48 mm; 64x48 mm; 66x52 mm; 68x52 mm; 70x52 mm;	Titanium Alloy (Ti-6Al-4V)/ Titanium Coating by Plasma Spray Aspersion	01
	04.01.27. XXXXX	MD Acetabular Cup Ti (without holes)			
Acetabular Inserts					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Made of**	**Qtty Packed**
	04.13.02.XXXXX	09 Points Acetabular Insert	**Ø 22 mm** – 44, 46, 48 mm; **Ø 26 mm** – 48, 50, 52, 54, 56, 58, 60, 62 mm; **Ø 28 mm** – 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm; **Ø 32 mm** – 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;	Polyethylene (UHMWPE)	01

	04.13.08.XXXXX	Acetabular Insert Ceramic Delta	**Ø 28 mm –** A, B; **Ø 32 mm –** C, D, E, F; **Ø 36 mm –** E, F, G; **Ø 40 mm –** F, G;	Cerâmica Delta Alumina (Al_2O_3)	01
Interchangeable Femoral Heads					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Made of**	**Qtty Packed**
	04.04.07.XXXXX	Interchangeable Femoral Head	**Ø 22 mm:** -2, Std, +3 mm; **Ø 26 mm:** -4, -2, Std, +3, +6, + 9 mm; **Ø 28 mm:** -4, -3.5, -2, Std, +3, +3.5, +6, +9 mm; **Ø 32 mm:** -4, -2, Std, +3, +4, +6, +7, +9 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.04.10.XXXXX	Interchangeable Femoral Head HN	**Ø 22 mm:** -2, Std, +3 mm; **Ø 26 mm:** -4, -2, Std, +3, +6, + 9 mm; **Ø 28 mm:** -4, -3.5, -2, Std, +3, +3.5, +6, +9 mm; **Ø 32 mm:** -4, -2, Std, +3, +4, +6, +7, +9 mm;	Stainless Steel Alloy w/ high level of Nitrogen (21Cr-10Ni-3Mn-2.5Mo)	01
	04.04.09.XXXXX	Interchangeable Femoral Head Ceramic Forte	**Ø 28 mm:** -3,5, Std, +3,5 mm; **Ø 32 mm:** -4,0, Std, +4,0, +7,0 mm **Ø 36 mm:** -4,0, Std, +4,0, +8,0 mm **Ø 40 mm:** -4,0, Std, +4,0, +8,0 mm	Cerâmica Forte Alumina (Al_2O_3)	01
	04.04.10.XXXXX	Interchangeable Femoral Head Ceramic Delta	**Ø 28 mm:** -3,5, Std, +3,5 mm; **Ø 32 mm:** -4,0, Std, +4,0, +7,0 mm; **Ø 36 mm:** -4,0, Std, +4,0, +8,0 mm; **Ø 40 mm:** -4,0, Std, +4,0, +8,0 mm;	Cerâmica Delta Alumina (Al_2O_3)	01

The ancillary components listed above are not objects of this registration process and therefore must be purchased separately and always from the same manufacturer or any other designated by them

Supporting Materials

The supporting materials are the instruments designated solely for implanting the Uncemented Stem – Hydroxyapatite and its ancillaries mentioned above.

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

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

See below, list of instruments available from the manufacturer or their indication for implanting the family of the Uncemented Stem – Hydroxyapatite and its respective ancillaries:

- **Instrument – Bipolar**
- **Instrument – Acetabular Unique (National Shavings)**
- **Instrument – Acetabular Unique (Imported Shavings)**
- **Instrument – Acetabular Unique Next**
- **Instrument – MD4 Femoral**
- **Instrument – EZ-Fit/ Razor Fit – Proximal Fixation**
- **Instrument – PHENOM Primary - Non Cemented**

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

Surgical instruments are subject to wear and tear during their regular use. Therefore breaking may occur.

The instruments should only be used for the purpose they were designed to and should be inspected regularly for possible wear and damage.

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

Warning and Precautions

For the product use, the medical team in charge of the implant must consider the following warning and precautions:

- The product must only be used after a thorough analysis of the surgical procedure to be adopted and complete reading of these instructions for use;
- The product should only be handled by specialized surgical teams with specific knowledge and capacity building concerning arthroplasty techniques. The choice and dominance of the adopted technique to be applied are under the responsibility of the surgeon in charge;
- Inappropriate choice and selection of the implants to be used, as well as mistakes concerning the indication, handling and application technique might cause excessive stress and tractions on the implant leading to failure due to fatigue, fracture and even looseness;
- Clinical results and the durability of the implants are totally dependent upon a precise surgical technique;
- The implanting under improper bone bed can cause early looseness and progressive loss of bone stock. In such cases additional methods of bone grafting in conjunction with meshes and reinforcements should be adopted;
- The Product must not be used together with bone cement;
- A greater risk of the implant failure is its use in patients who are predisposed to disobey medical guidelines and postoperative restrictions, such as children, elderly, individuals with neurological changes, or addicted;
- Implant failure risks are greater in patients who practice physical exertion activities or those who practice sports during the postoperative period, contradicting the medical restrictions;
- The postoperative complications represent a greater risk in patients with functional expectations beyond the articular replacement load capacity; patients with morbid obesity and patients with small bone structure;
- The Product and its respective ancillaries should not be used whether there is not an appropriate osseous support that can guarantee the implant stability;

- The patient must be submitted to periodic medical monitoring to check the implant, the bone and the adjacent tissues conditions;
- The pre and perioperative prophylactic antibiotic therapy as well as antibiotic therapy - in cases there is a local and/or systemic predisposition or infections occur – are under medical criteria;
- The implant should not be used with components from other manufacturers or purpose. The combination of implants from different manufacturers or purposes can result incongruity among the components;
- The product identification must be strictly observed and are not permitted combinations with components from other manufacturers or purpose;
- Care of this material is of responsibility of skilled staff, who should follow the normalization and/or any applicable local regulations;
- Falls or crushing on hard surfaces might damage the product. So, it is necessary the handler to perform inspection of the product to check its integrity while it is unpacked and if there is any abnormality, the product SHOULD NOT be used;
- Only skilled staff for the surgical procedure may open the package;
- Do not use the product whether the validity period is expired or the package violated;
- Handle with care;
- Single use product – Do not reuse;
- The implants must NEVER be reused. Although they may seem undamaged, prior tensions they have been submitted may cause imperfections that would reduce the lifetime of the product in a re-implantation;
- REPROCESSING PROHIBITED;
- Sterile Product – Do Not Re-Sterilize;
- Manufacturing date and batch number: see label;

Adverse Effects

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

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

Use Instructions

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

- The care of this material is responsibility of the skilled staff, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (materials center and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for vertebral column stabilization, and the surgeon in charge is responsible for the choice and dominance of the surgical technique to be performed;
- Bone grafting methods (with or without the use of screens and ribs) should be adopted under medical criteria for restoration of bone stock in cases where they do not achieve a medullary cavity with viable bone bed;

- The washing and drying the cone of the Stem are required before the implantation of other ancillary components so as to ensure that there is no bone or tissue residuals in the joint between them;
- The useful life established for the product is 10 (ten) years, once the devices are implanted by adopting an appropriate surgical technique and observing the details of the topics "Indication and Purpose", "Contraindication", "Warnings and precautions and “Instructions for Use”;
- A revision surgery may be necessary in the case mentioned right above or if loosening of the components is observed;
- The correct matching of the product and its respective ancillary components is indicated in the “Ancillary Components”. Due to the possibility of dimensional and/or functional incompatibility it must not be used with any other components different from the ones indicated by the manufacturer.
- For applying the product and its respective ancillaries, specific instruments – indicated in the “Supporting Material” - are necessary. Due to the possibility of dimensional and/or functional incompatibility it MUST NOT be used with any other instruments different from the ones indicated by the manufacturer.

Guidance to the Patient and/or Legal Representative

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

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

Sterilization

The trade models which make up the Family of the Non Cemented Stem in Titanium are available in Sterile Product condition. It is adopted the Gamma Radiation (dosage of 25 kGy) Sterilization method.

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

Sterile Product – Do Not Re-sterilize.

Do Not use the product if the package is violated.

Contamination Risk

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

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

Product Discard

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

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

Single use product – do not reuse.

Traceability

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

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

The responsible surgeon and his team must make use of traceability labels provided in five (05) copies in the product packaging, gluing them in the patient record to maintain traceability of the implanted product. Furthermore, one of these labels should be provided to the patient so that s/he has information about the implanted product in their surgical procedure.

The labels show the product data such as code, description, lot, its ANVISA registration and other information.

The traceability information is needed for notification, the health service and / or the patients themselves the Health Surveillance Agency – ANVISA and the manufacturer, upon the occurrence of serious adverse events, to conduct the appropriate investigations.

Storage and Transport

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

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

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

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

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

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

Further Information

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

ANVISA Registration Nº: 10417940045
Review: 02
Issue: March, 31st 2014.

ALERT
INSTRUCTIONS FOR USE
(Texto Padrão Bulas)

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

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

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

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

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

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