Instructions for Use

Uncemented Stem – Hydroxyapatite

Subtitles of the symbols used on the packaging

REF	Catalogue Number	LOT	Batch Code
STERILE R	Sterile Product - Sterilized by Gamma Radiation	CE XXXX	Product certified in accordance with Directive 93/42/EEC). When applicable.
	Date of Manufacture		Valid until
	Consult instructions for use		Single-Use Product
	Do not use if package is damaged		Do not re-sterilize
	Keep out of the sun		Fragile, handle with care.
	Keep Dry		Temperature Limit (40°C);

Features and technical specifications of the product

Technical Name: Modular Stem for hip Arthroplasty

Trade Name: Uncemented Stem – Hydroxyapatite

Trade Models:

- PHENOM HA Ti Primary Femoral Prosthesis;
- PHENOM HA Ti Revision Femoral Prosthesis;
- PHENOM Taper HA Ti Primary Femoral Prosthesis;

Raw Materials:

Prosthesis (substrate): Titanium Alloy (Ti-6Al-4V) – ASTM F136;

Duplo Coating: Pure Titanium (Ti) – ASTM F1580/ Hydroxyapatite ($Ca_5(OH)(PO_4)_3$) – ISO 13779-2;

Sterile Product

Sterilization Method: Gamma Radiation (dosage of 25 kGy)

Validity: 05 years (after sterilization date)

Description

The Uncemented Stem – Hydroxyapatite 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 PHENOM HA Ti Femoral Prosthesis, and PHENOM Taper HA Ti Femoral Prosthesis are intended to the replacement of natural articulation in hip arthroplasty total or partial procedures or of hip revision.

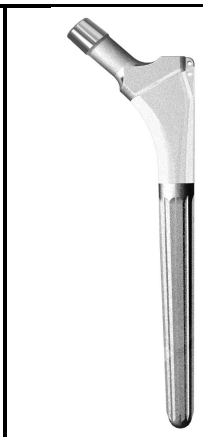
Made from Titanium alloy (Ti-A-4V), the femoral prosthesis consist of a cone (Morse type conical system 12/14), which enables femoral head modularity and the longitudinal body. They are coated with pure titanium (Ti) double coating and hydroxyapatite ceramic ($Ca_5(OH)(PO_4)_3$) applied by plasma spray sprinkling. Fixation to the femur intramedullary canal is uncemented through (press-fit) impaction.

The **PHENOM HA Ti Femoral Prosthesis** is indicated to primary and revision procedures, has conical size that provides greater axial stability and better stress mechanical transmission to bone. In its primary version, the prosthesis has ¾ of the longitudinal body coated with double (Ti+ HA) coating, which

stimulates which stimulates osseous growth and potentiates the fixation of the prosthesis in the intramedullary canal. The neck of the Stem is presented with angulation of 135º in relation to the longitudinal prosthetic axis and variable 'off-set' ranging between 35.0 mm and 42.5 mm. It is available for the market with diameters from 10 mm to 18 mm and lengths from 137mm to185 mm. The prosthesis in its version for revision has the proximal portion of the longitudinal body coated with double coating (Ti + HA). At the distal portion, the prosthesis is corrugated for increased rotational stability and has fins that stimulate bone growth and enhance the fixation in the intramedullary canal. The neck of the stem is available with angle of 135 º and 130 º in relation to the longitudinal prosthetic axis and *off-sets* "of 37.5 mm and 42.5 mm, respectively. It is available for commercialization in diameters from 12.5 mm to 20.0 mm and lengths ranging from 180 mm to 260 mm.

The **PHENOM Taper HA TI Femoral** Prosthesis is indicated for primary procedures, it has cuneiform size with triple wedge in the anteroposterior, medium-lateral and proximal-distal plans, which provide its greater axial stability and better stress mechanical transmission to bone. The prosthesis has a proximal piece of longitudinal body lined with duple coating (Ti+HA). The neck of stem has angulations of 135º and 130º in relation at prosthetic longitudinal axis and four off-sets variations: 34 mm (section of 06 at 09 mm) and 43 (section of 10 at 18 mm); 40 (section of 06 at 13 mm) and 46 mm (section of 14 at 18 mm), respectively. It is available for commercialization with trapezoidal section ranging of 06 at 18 mm and length ranging of 121 mm at 163 mm.

Next, illustrative images of trade models which form the family of the Uncemented Stem – Hydroxyapatite:

<table>
<tr><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Primary</td><td>Revision</td><td>Primary</td></tr>
<tr><td colspan="2">Femoral Prosthesis PHENOM HA Ti</td><td>PHENOM Taper HA Ti Femoral Prosthesis</td></tr>
</table>

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 the Uncemented Stem – Hydroxyapatite is made of Titanium Alloy (Ti-6Al-4V) ASTM F-136, coated with Pure Titanium (Ti) double coating and Hydroxyapatite Ceramic ($Ca_5(OH)(PO_4)_3$).

The manufacturing material and the coating materials are 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*.

On the other hand, the Pure Titanium (Ti) double coating and the Hydroxyapatite Ceramic ($Ca_5(OH)$ $(PO_4)_3$) that cover the body of the longitudinal femoral stems meet the requirements specified by ASTM F1580 - *'Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants' and ISO 13779-2 - 'Implants for surgery - Hydroxyapatite - Part 2: Coatings of hydroxyapatite*', respectively.

The choice of these materials for the manufacture of commercial models and accessories that make up the family of the Uncemented Stem – Hydroxyapatite 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 Purpose

The product is intended to the uncemented proximal fixation by impaction (press-fit) in the intramedullary canal of the femur in primary and revision partial or total arthroplasty procedures.

The trade models that make up the family of the Uncemented Stem – Hydroxyapatite 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 inflammatory or no degenerative joint diseases:

- Osteoarthritis;
- Rheumatoid arthritis;
- Avascular necrosis of the femoral head;
- Acetabular protrusion;
- Proximal femoral epiphysiolysis;

Additionally, can be use in the no-union treatment and neck femoral fractures and your sequels:

- Femur proximal fractures (femoral neck and trochanteric) with head involvement, that are uncontrollable using others techniques;
- Pelvis fractures sequelae;
- Osteoarthritis secunary to trauma.

Also is indicated to use in revision procedures in others treatments or devices that have failure and in functional deformities corrections.

The products described herein were 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 Uncemented Stem – Hydroxyapatite are unitarily packed in primary packaging blister type system, sealed with surgical grade paper (Tyvek® 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.

The Family of the Uncemented Stem - Hydroxyapatite is available in the following trade models, and each of these trade models are available for marketing in the following dimensions:

List of the trade models which make up family of the Uncemented Stem - Hydroxyapatite

Trade Models					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Packed Quantity**
	04.30.70.10137	PHENOM HA Ti Femoral Primary Prosthesis Ø 10x137 mm;	**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 **Cervico-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V) ASTM F-136 + Double Coating of Pure Titanium (Ti)/ Hydroxyapatite Ceramic ($Ca_5(OH)(PO_4)_3$) ASTM F-1580/ ISO 13779-2	01
	04.30.70.11143	PHENOM HA Ti Femoral Primary Prosthesis Ø 11x143 mm;			
	04.30.70.12149	PHENOM HA Ti Femoral Primary Prosthesis Ø 12x149 mm;			
	04.30.70.13155	PHENOM HA Ti Femoral Primary Prosthesis Ø 13x155 mm;			
	04.30.70.14161	PHENOM HA Ti Femoral Primary Prosthesis Ø 14x161 mm;			
	04.30.70.15167	PHENOM HA Ti Femoral Primary Prosthesis Ø 15x167 mm;			
	04.30.70.16173	PHENOM HA Ti Femoral Primary Prosthesis Ø 16x173 mm;			
	04.30.70.17179	PHENOM HA Ti Femoral Primary Prosthesis Ø 17x179 mm;			
	04.30.70.18185	PHENOM HA Ti Femoral Primary Prosthesis Ø 18x185 mm;			
	04.30.81.12518	PHENOM HA Ti Femoral Revision Prosthesis Ø 12,5x180 mm Off-set 37,5 mm;	**Diameter:** 12,5; 13,0; 14,0; 15,0; 16,0; 17,0 mm; **Length:** 180, 220, 260 mm; **Cone:** 12/14 mm; **Off-set:** 37,5 mm; **Cervico-diaphyseal angle:** 135º;	Titanium Alloy (Ti-6Al-4V) ASTM F-136 + Double Coating of Pure Titanium (Ti)/ Hydroxyapatite Ceramic ($Ca_5(OH)(PO_4)_3$) ASTM F-1580/ ISO 13779-2	01
	04.30.81.12522	PHENOM HA Ti Femoral Revision Prosthesis Ø 12,5x220 mm Off-set 37,5 mm;			
	04.30.81.12526	PHENOM HA Ti Femoral Revision Prosthesis Ø 12,5x260 mm Off-set 37,5 mm;			
	04.30.81.13018	PHENOM HA Ti Femoral Revision Prosthesis Ø 13,0x180 mm Off-set 37,5 mm;			
	04.30.81.13022	PHENOM HA Ti Femoral Revision Prosthesis Ø 13,0x220 mm Off-set 37,5 mm;			
	04.30.81.14018	PHENOM HA Ti Femoral Revision Prosthesis Ø 14,0x180 mm Off-set 37,5 mm;			
	04.30.81.14022	PHENOM HA Ti Femoral Revision Prosthesis Ø 14,0x220 mm Off-set 37,5 mm;			
	04.30.81.15018	PHENOM HA Ti Femoral Revision Prosthesis Ø 15,0x180 mm Off-set 37,5 mm;			
	04.30.81.15022	PHENOM HA Ti Femoral Revision Prosthesis Ø 15,0x220 mm Off-set 37,5 mm;			
	04.30.81.15026	PHENOM HA Ti Femoral Revision Prosthesis Ø 15,0x260 mm Off-set 37,5 mm;			
	04.30.81.16018	PHENOM HA Ti Femoral Revision Prosthesis Ø 16,0x180 mm Off-set 37,5 mm;			
	04.30.81.16022	PHENOM HA Ti Femoral Revision Prosthesis Ø 16,0x220 mm Off-set 37,5 mm;			
	04.30.81.16026	PHENOM HA Ti Femoral Revision Prosthesis Ø 16,0x260 mm Off-set 37,5 mm;			
	04.30.81.17018	PHENOM HA Ti Femoral Revision Prosthesis Ø 17,0x180 mm Off-set 37,5 mm;			
	04.30.81.17022	PHENOM HA Ti Femoral Revision Prosthesis Ø 17,0x220 mm Off-set 37,5 mm;			
	04.30.81.17026	PHENOM HA Ti Femoral Revision Prosthesis Ø 17,0x260 mm Off-set 37,5 mm;			
	04.30.82.16018	PHENOM HA Ti Femoral Revision Prosthesis Ø 16,0x180 mm Off-set 42,5 mm;	**Diameter:** 16,0; 17,0; 18,0; 19,0; 20,0 mm; **Length:** 180, 220, 260 mm; **Cone:** 12/14 mm; **Off-set:** 42,5 mm; **Cervico-diaphyseal angle:** 130º;	Titanium Alloy (Ti-6Al-4V) ASTM F-136 + Double Coating of Pure Titanium (Ti)/ Hydroxyapatite	01
	04.30.82.16022	PHENOM HA Ti Femoral Revision Prosthesis Ø 16,0x220 mm Off-set 42,5 mm;			
	04.30.82.16026	PHENOM HA Ti Femoral Revision Prosthesis Ø 16,0x260 mm Off-set 42,5 mm;			
	04.30.82.17018	PHENOM HA Ti Femoral Revision Prosthesis Ø 17,0x180 mm Off-set 42,5 mm;			
	04.30.82.17022	PHENOM HA Ti Femoral Revision Prosthesis Ø 17,0x220 mm Off-set 42,5 mm;			
	04.30.82.17026	PHENOM HA Ti Femoral Revision Prosthesis Ø 17,0x260 mm Off-set 42,5 mm;			

	04.30.82.18018	PHENOM HA Ti Femoral Revision Prosthesis Ø 18,0x180 mm Off-set 42,5 mm;		Ceramic ($Ca_5(OH)(PO_4)_3$) ASTM F-1580/ ISO 13779-2	
	04.30.82.18022	PHENOM HA Ti Femoral Revision Prosthesis Ø 18,0x220 mm Off-set 42,5 mm;			
	04.30.82.18026	PHENOM HA Ti Femoral Revision Prosthesis Ø 18,0x260 mm Off-set 42,5 mm;			
	04.30.82.19018	PHENOM HA Ti Femoral Revision Prosthesis Ø 19,0x180 mm Off-set 42,5 mm;			
	04.30.82.19022	PHENOM HA Ti Femoral Revision Prosthesis Ø 19,0x220 mm Off-set 42,5 mm;			
	04.30.82.19026	PHENOM HA Ti Femoral Revision Prosthesis Ø 19,0x260 mm Off-set 42,5 mm;			
	04.30.82.20018	PHENOM HA Ti Femoral Revision Prosthesis Ø 20,0x180 mm Off-set 42,5 mm;			
	04.30.95.10006	PHENOM Taper HA Ti Femoral Prosthesis Primary 06 mm Off-set 34 mm - 135°	**Size:** 06, 07, 08, 09, 10, 11, 12, 13 mm **Length:** 121, 124, 127, 130, 133, 136, 139, 142 mm **Cone:** 12/14 mm; **Off-set:** 40 mm; **Cervico-diaphyseal angle:** 130º;	Titanium Alloy (Ti-6Al-4V) ASTM F-136 + Double Coating of Pure Titanium (Ti)/ Hydroxyapatite Ceramic ($Ca_5(OH)(PO_4)_3$) ASTM F-1580/ ISO 13779-2	01
	04.30.95.10007	PHENOM Taper HA Ti Femoral Prosthesis Primary 07 mm Off-set 34 mm - 135°			
	04.30.95.10008	PHENOM Taper HA Ti Femoral Prosthesis Primary 08 mm Off-set 34 mm - 135°			
	04.30.95.10009	PHENOM Taper HA Ti Femoral Prosthesis Primary 09 mm Off-set 34 mm - 135°			
	04.30.95.10010	PHENOM Taper HA Ti Femoral Prosthesis Primary 10 mm Off-set 43 mm - 135°			
	04.30.95.10011	PHENOM Taper HA Ti Femoral Prosthesis Primary 11 mm Off-set 43 mm - 135°			
	04.30.95.10012	PHENOM Taper HA Ti Femoral Prosthesis Primary 12 mm Off-set 43 mm - 135°			
	04.30.95.10013	PHENOM Taper HA Ti Femoral Prosthesis Primary 13 mm Off-set 43 mm - 135°			
	04.30.95.10014	PHENOM Taper HA Ti Femoral Prosthesis Primary 14 mm Off-set 43 mm - 135°			
	04.30.95.10016	PHENOM Taper HA Ti Femoral Prosthesis Primary 16 mm Off-set 43 mm - 135°			
	04.30.95.10018	PHENOM Taper HA Ti Femoral Prosthesis Primary 18 mm Off-set 43 mm - 135°			
	04.30.95.00006	PHENOM Taper HA Ti Femoral Prosthesis Primary 06 mm Off-set 40 mm - 130°			
	04.30.95.00007	PHENOM Taper HA Ti Femoral Prosthesis Primary 07 mm Off-set 40 mm - 130°			
	04.30.95.00008	PHENOM Taper HA Ti Femoral Prosthesis Primary 08 mm Off-set 40 mm - 130°			
	04.30.95.00009	PHENOM Taper HA Ti Femoral Prosthesis Primary 09 mm Off-set 40 mm - 130°			
	04.30.95.00010	PHENOM Taper HA Ti Femoral Prosthesis Primary 10 mm Off-set 40 mm - 130°			
	04.30.95.00011	PHENOM Taper HA Ti Femoral Prosthesis Primary 11 mm Off-set 40 mm - 130°			
	04.30.95.00012	PHENOM Taper HA Ti Femoral Prosthesis Primary 12 mm Off-set 40 mm - 130°			
	04.30.95.00013	PHENOM Taper HA Ti Femoral Prosthesis Primary 13 mm Off-set 40 mm - 130°			
	04.30.95.00014	PHENOM Taper HA Ti Femoral Prosthesis Primary 14 mm Off-set 46 mm - 130°	**Size:** 14, 16, 18 mm **Length:** 150, 156, 162 mm **Cone:** 12/14 mm **Off-set:** 46 mm **Cervico-diaphyseal angle:** 130º		
	04.30.95.00016	PHENOM Taper HA Ti Femoral Prosthesis Primary 16 mm Off-set 46 mm - 130°			
	04.30.95.00018	PHENOM Taper HA Ti Femoral Prosthesis Primary 18 mm Off-set 46 mm - 130°			

Ancillary Components

Here are the ancillary components compatible with trade models that make up the family of the Uncemented Stem - Hydroxyapatite:

- Bipolar Cup;
- Cemented acetabulum;
- Uncemented acetabulum;
- Acetabular inserts;
- Interchangeable Femoral Heads;

The ancillary components listed above are not object of this registration process, therefore they must be purchased separately but always from the same manufacturer or those suggested by them.

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.

The Cemented Acetabular Cup, models Maxima, 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 Acetabular Cup models MD4 - *Plasma Spray* and MD Ti (with and without holes), 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 implants when produced from this material are obtained through the manufacturing process of forging and / or machining. The coating of titanium powder (applied by spray plasma spray) covering the acetabulum 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 Acetabular Insert 09 Points and PHENOM Poly Acetabular Insert 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.

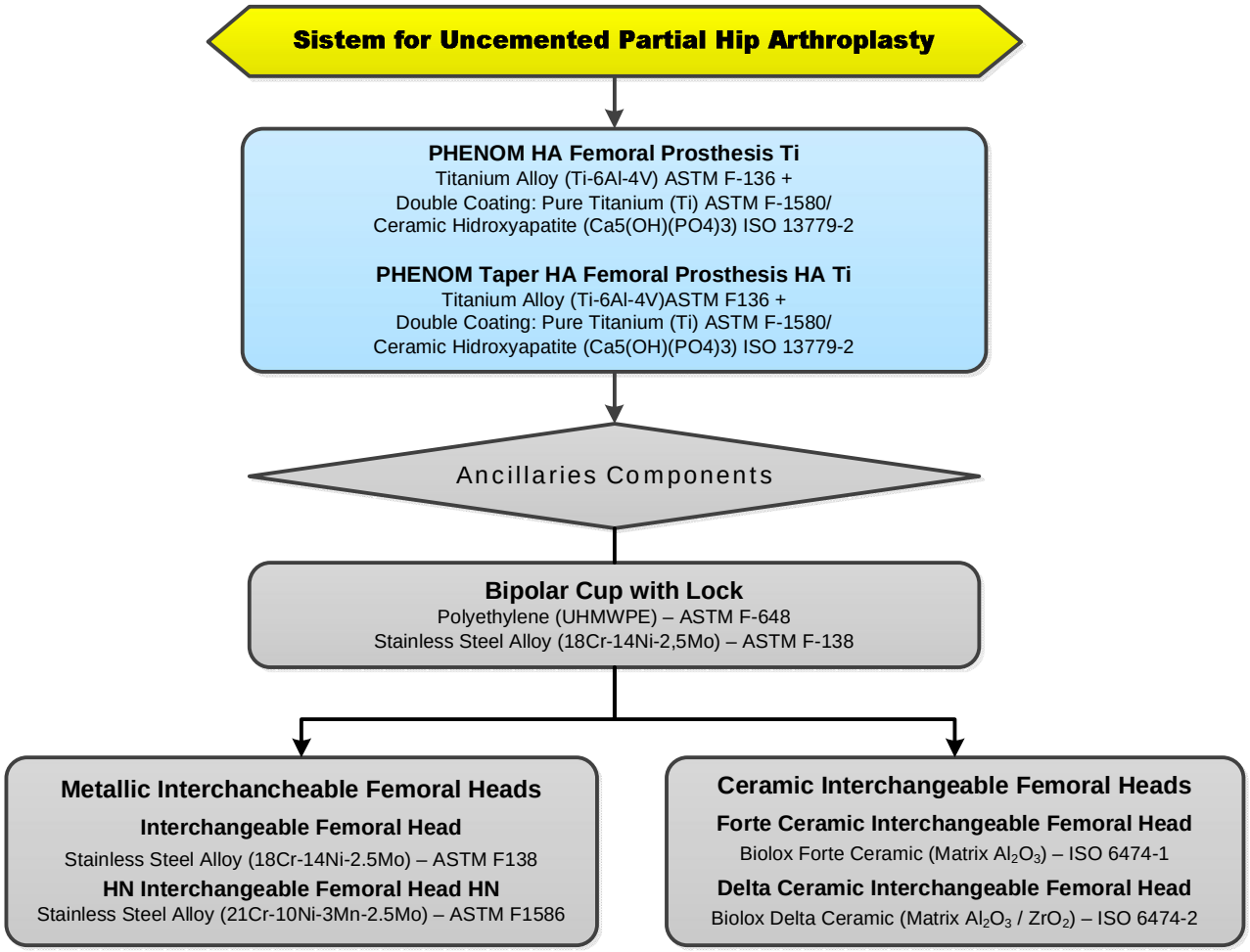
The Ceramic Components MD Delta Acetabular Insert and the Ceramic Interchangeable Femoral Heads are made from high purity alumina ceramic (Al_2O_3), which meets the requirements specified by ISO 6474 - *Implants for surgery - Ceramic materials based on high purity alumina, through the sintering process,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

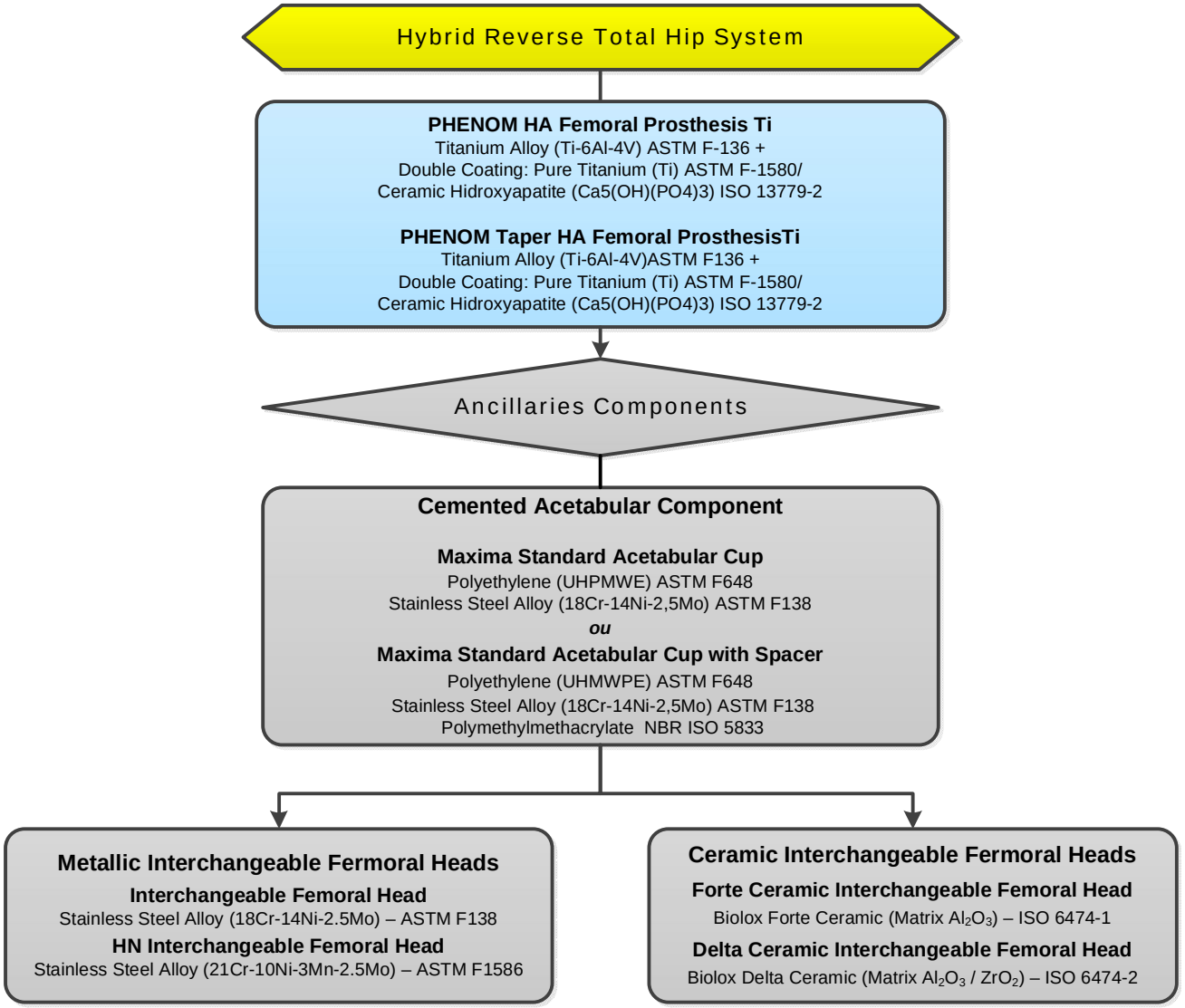
The metallic interchangeable femoral heads are manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) and stainless steel alloy (21cr-10Ni-2.5Mo-3mn), which meets the requirements specified by ASTM F138 - *Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar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

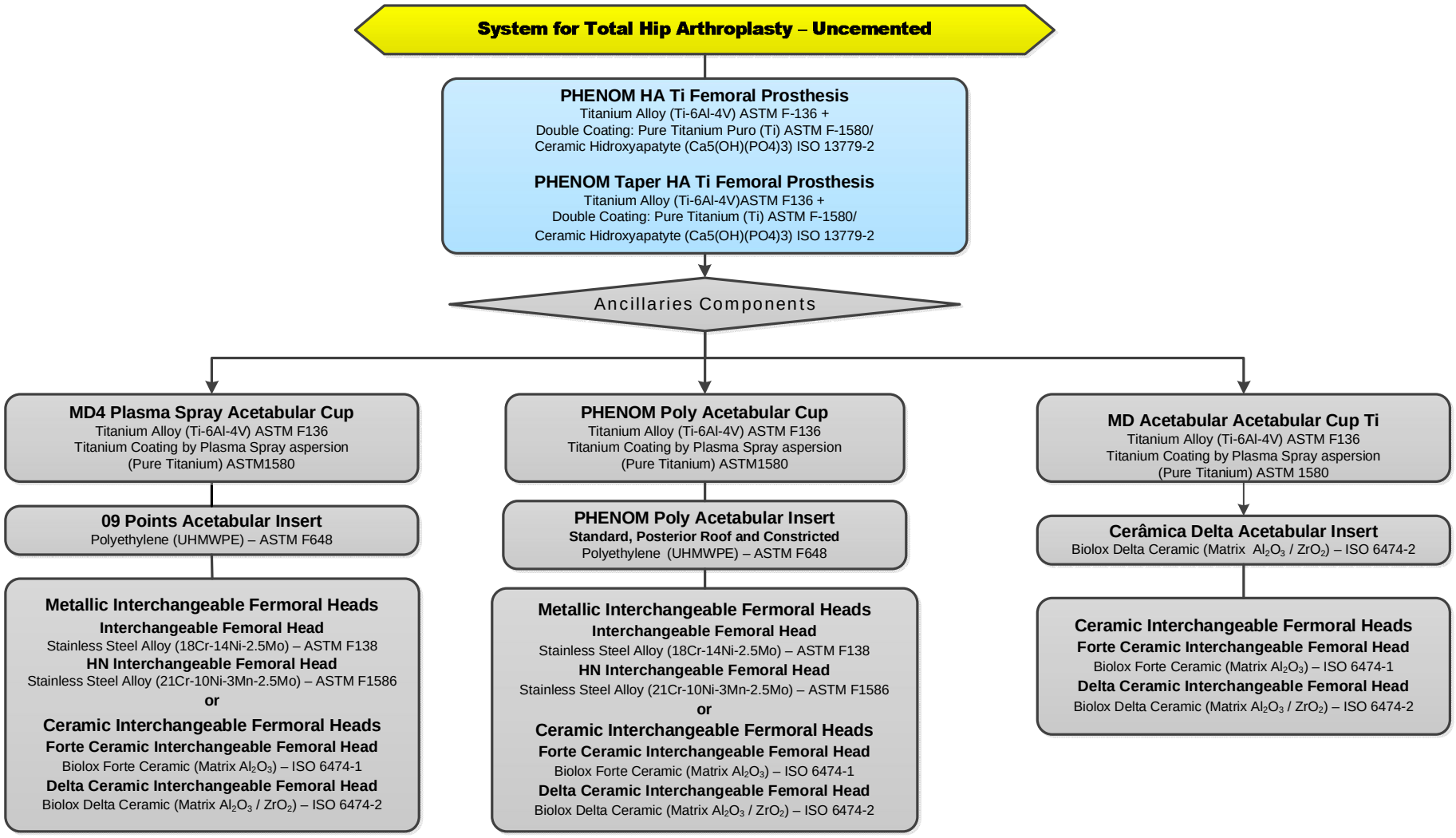
The surgeon in charge is responsible for the correct selection of models, sizes and combinations of the trade models that make up the family of the Uncemented Stem - Hydroxyapatite as well as their ancillary to be implanted. He is also in charge of choosing the adopted technique and must be familiar 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.

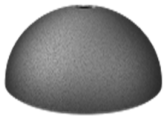
Next, indication of the ancillary components and their right combination with the trade models which make up the family of the Uncemented Stem - Hydroxyapatite for the following mounting options:

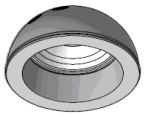
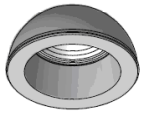
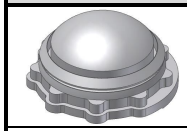
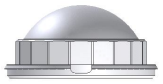
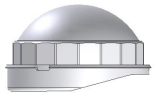
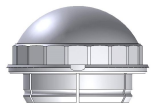


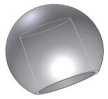
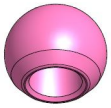

Hybrid Reverse Total Hip System
PHENOM HA Femoral Prosthesis Ti
Titanium Alloy (Ti-6Al-4V) ASTM F-136 +
Double Coating: Pure Titanium (Ti) ASTM F-1580/
Ceramic Hidroxyapatite (Ca5(OH)(PO4)3) ISO 13779-2
PHENOM Taper HA Femoral ProsthesisTi
Titanium Alloy (Ti-6Al-4V)ASTM F136 +
Double Coating: Pure Titanium (Ti) ASTM F-1580/
Ceramic Hidroxyapatite (Ca5(OH)(PO4)3) ISO 13779-2
Ancillaries Components
Cemented Acetabular Component
Maxima Standard Acetabular Cup
Polyethylene (UHPMWE) ASTM F648
Stainless Steel Alloy (18Cr-14Ni-2,5Mo) ASTM F138
ou
Maxima Standard Acetabular Cup with Spacer
Polyethylene (UHMWPE) ASTM F648
Stainless Steel Alloy (18Cr-14Ni-2,5Mo) ASTM F138
Polymethylmethacrylate NBR ISO 5833
Metallic Interchangeable Fermoral Heads
Interchangeable Femoral Head
Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F138
HN Interchangeable Femoral Head
Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo) – ASTM F1586
Ceramic Interchangeable Fermoral Heads
Forte Ceramic Interchangeable Femoral Head
Biolox Forte Ceramic (Matrix Al2O3) – ISO 6474-1
Delta Ceramic Interchangeable Femoral Head
Biolox Delta Ceramic (Matrix Al2O3 / ZrO2) – ISO 6474-2


System for Total Hip Arthroplasty – Uncemented
PHENOM HA Ti Femoral Prosthesis
Titanium Alloy (Ti-6Al-4V) ASTM F-136 +
Double Coating: Pure Titanium Puro (Ti) ASTM F-1580/
Ceramic Hidroxyapatyte (Ca5(OH)(PO4)3) ISO 13779-2
PHENOM Taper HA Ti Femoral Prosthesis
Titanium Alloy (Ti-6Al-4V)ASTM F136 +
Double Coating: Pure Titanium (Ti) ASTM F-1580/
Ceramic Hidroxyapatyte (Ca5(OH)(PO4)3) ISO 13779-2
Ancillaries Components
MD4 Plasma Spray Acetabular Cup
Titanium Alloy (Ti-6Al-4V) ASTM F136
Titanium Coating by Plasma Spray aspersion
(Pure Titanium) ASTM1580
09 Points Acetabular Insert
Polyethylene (UHMWPE) – ASTM F648
Metallic Interchangeable Fermoral Heads
Interchangeable Femoral Head
Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F138
HN Interchangeable Femoral Head
Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo) – ASTM F1586
or
Ceramic Interchangeable Fermoral Heads
Forte Ceramic Interchangeable Femoral Head
Biolox Forte Ceramic (Matrix Al2O3) – ISO 6474-1
Delta Ceramic Interchangeable Femoral Head
Biolox Delta Ceramic (Matrix Al2O3 / ZrO2) – ISO 6474-2
PHENOM Poly Acetabular Cup
Titanium Alloy (Ti-6Al-4V) ASTM F136
Titanium Coating by Plasma Spray aspersion
(Pure Titanium) ASTM1580
PHENOM Poly Acetabular Insert
Standard, Posterior Roof and Constricted
Polyethylene (UHMWPE) – ASTM F648
Metallic Interchangeable Fermoral Heads
Interchangeable Femoral Head
Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – ASTM F138
HN Interchangeable Femoral Head
Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo) – ASTM F1586
or
Ceramic Interchangeable Fermoral Heads
Forte Ceramic Interchangeable Femoral Head
Biolox Forte Ceramic (Matrix Al2O3) – ISO 6474-1
Delta Ceramic Interchangeable Femoral Head
Biolox Delta Ceramic (Matrix Al2O3 / ZrO2) – ISO 6474-2
MD Acetabular Acetabular Cup Ti
Titanium Alloy (Ti-6Al-4V) ASTM F136
Titanium Coating by Plasma Spray aspersion
(Pure Titanium) ASTM 1580
Cerâmica Delta Acetabular Insert
Biolox Delta Ceramic (Matrix Al2O3 / ZrO2) – ISO 6474-2
Ceramic Interchangeable Fermoral Heads
Forte Ceramic Interchangeable Femoral Head
Biolox Forte Ceramic (Matrix Al2O3) – ISO 6474-1
Delta Ceramic Interchangeable Femoral Head
Biolox Delta Ceramic (Matrix Al2O3 / ZrO2) – ISO 6474-2

List of ancillary components compatible with the trade models that make up the family of Uncemented Stem - Hydroxyapatite

Bipolar Cup					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Packed Quantity**
	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 mm; **Ø 32 mm** – 42, 44, 46, 48, 50, 52, 54, 56, 58, 60 mm	Polyethylene (UHMWPE) ASTM F-648 Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F138	01
Cemented Acetabulum					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Packed Quantity**
	04.01.02.XXXXX	Maxima Acetabulum	**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) ASTM F-648 Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F138	01
	04.01.23.XXXXX	Maxima Acetabulum – PMMA	**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) ASTM F-648 Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F138 Polymethylmethacrylate (PMMA) – NBR ISO 5833	01
Uncemented Acetabulum					
	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) ASTM F136 Titanium Coating (Ti-6Al-4V) ASTM F1580	01
	04.01.34.00XXX	PHENOM Poly PS Acetabular Cup	**Diameters:** 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F136 Titanium Coating (Ti-6Al-4V) ASTM F1580	01
	04.01.34.01XXX	PHENOM Poly PS Acetabular Cup Without Holes	**Diameters:** 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F136 Titanium Coating (Ti-6Al-4V) ASTM F1580	01

	04.01.46.010XX	PHENOM Poly PS Acetabular Cup Multi Holes	**Diameters:** 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60,62, 64, 66, 68, 70 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F136 Titanium Coating (Ti-6Al-4V) ASTM F1580	01
	04.01.26. XXXXX	Acetabular MD Ti Cup (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) ASTM F136	01
	04.01.27. XXXXX	Acetabular MD Ti Cup (without 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) ASTM F136	01
	04.13.08.XXXXX	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;	Alumina Delta Ceramic (Al_2O_3) – ISO 6474	01
Acetabular Inserts					
	04.13.02.XXXXX	Acetabular Insert 09 Points	**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) ASTM F-648	01
	04.13.13.XXXXX	PHENOM Poly Acetabular Insert	**Diameters:** **Ø 22 mm:** 22x40/42, 22x44, 22x46/48, 22x50/52 22x54/56,22x58/60, 22x62/64, 22x66/68/70 mm; **Ø 28 mm:** 28x44, 28x46/48, 28x50/52, 28x54/56, 28x58/60 28x62/64, 28x66/68/70 mm; **Ø 32 mm:** 32x46/48, 32x50/52, 32x54/56, 32x58/60, 32x62/64, 32x66/68/70 mm;	Polyethylene (UHMWPE) - ASTM F-648	01
	04.13.14.XXXXX	PHENOM Poly Acetabular Insert Posterior Roof	**Diameters:** **Ø 22 mm:** 22x40/42, 22x44, 22x46/48, 22x50/52, 22x54/56, 22x58/60, 22x62/64, 22x66/68/70 mm; **Ø 28 mm:** 28x44, 28x46/48, 28x50/52, 28x54/56, 28x58/60, 28x62/64, 28x66/68/70 mm; **Ø 32 mm:** 32x46/48, 32x50/52, 32x54/56, 32x58/60, 32x62/64, 32x66/68/70 mm;	Polyethylene (UHMWPE) - ASTM F-648	01
	04.13.15.XXXXX	Inserto Acetabular PHENOM Poly Constrito	**Diameters:** **Ø 28 mm:** 28x46/48, 28x50/52, 28x54/56, 28x58/60, 28x62/64 28x66/68/70 mm; **Ø 32 mm:** 32x50/52, 32x54/56, 32x58/60, 32x62/64, 32x66/68/70 mm;	Polyethylene (UHMWPE) ASTM F-648	01

Interchangeable Femoral Heads					
Illustrative Image	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Packed Quantity**
	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, -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) ASTM F138	01
	04.04.11.XXXXX	HN Interchangeable Femoral Head	**Ø 22 mm:** -2, Std, +3 mm; **Ø 26 mm:** -4, -2, Std, +3, +6, + 9 mm; **Ø 28 mm:** -4, -2, Std, +3, +3.5, +6, +9 mm; **Ø 32 mm:** -4, -2, Std, +3, +4, +6, +7, +9 mm;	Stainless Steel Alloy High Nitrogen (21Cr-10Ni-3Mn-2.5Mo) ASTM F1586	01
	04.04.09.XXXXX	Ceramic Forte Interchangeable Femoral Head Neck 12/14	**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	Ceramic Forte Ceramic (Al_2O_3) – ISO 6474-1	01
	04.04.10.XXXXX	Ceramic Delta Interchangeable Femoral Head Neck 12/14	**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;	Biolox Delta Ceramic (Al_2O_3/ ZrO_2) ISO 6474-2	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 – Unique Acetabular (National Shavings);
- Instrument – Unique Acetabular (Imported Shavings);
- Instrument – Unique Next Acetabular;
- Instrument – PHENOM PrimaryUncemented;
- Instrument – PHENOM Revision Uncemented;
- Instrument – PHENOM Taper Primary Uncemented

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;
- The conical connection allows that the head has a reliable insertion and resistant to torsion, generating a uniform force transmission between the components head and femoral stem. Soon, the head must have a perfect coupling on the femoral stem cone;
- Thus, only must be use components with conical identical measurers, how specified by manufacturer in the topic “Form of Presentation” in the instructions of use and product labeling;
- 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.

Specifics instructions of use: use of prosthesis in association with ceramic head

Before initiating the insertion of ceramic component, the cone of prosthesis must be free waste as tissue fragments or bone particles.

The following are described the procedures for implantation of component Delta/ Forte Ceramic Interchangeable Femoral Head:

- The stem cone protection only must be removed in the moment of coupling with the head;
- Before the coupling of head in the femoral stem, wash well the stem cone and dry it carefully;
- Examine mindfully the femoral stem cone and the head internal cone and make sure if they are waste free as tissue fragments and bone particles or of cement;
- The head must be manually coupling at the femoral stem cone by a slight rotation and an axial pressure that keeps immobile in the cone;
- Put the impactor with polymeric tip (provided in the instrument indicated by manufacturer) in the head and apply a slight hammer blow in the axial way for the head final fixation over the stem cone. With the blow the superficial structure of the metallic stem cone deforms plastically proving a great pressure distribution and a resistant fixation at torsion.
- Never blow the ceramic head with the metallic hammer. Only use the polymeric hammer specially developed by manufacturer for the component implantation.

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 No Coating Uncemented Stem Family 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 surgeon in charge and his team must use the traceability labels provided in five copies inside the product package, pasting them in the patient records for maintenance of the implanted product traceability. Beside this, one of this labeling must be provide to patient for the information about implanted product in your chirurgic procedure.

The information necessary for the product traceability in the labels are:

- Manufacturer Identification ;
- Component Code;
- Component Batch Number;
- Description of the Component (in three languages: – Portuguese, English and Spanish);
- Quantity;
- ANVISA Registration Number;
- Technical Name;
- Product Trade Name;
- Other components which integrate the system ;

Traceability information is required for notifying the Sanitary Surveillance Agency ANVISA, either by the health service or by the patient him/herself, when serious adverse events occur, so that it helps to drive appropriate investigations.

Storage and Transport

For the storage it is recommended dry and airy place, without exposure to light incidence, humidity or contaminants 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 S.A.

Address: Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP

CEP: 13.505-600

Phone/Fax: (19) 2111-6500

CNPJ: 01.025.974/0001-92

Technician Responsible: Miguel Lopes Monte Junior – CREA: 0601150192

CE 0297 (According to 93/42/EEC Directive). If applicable.

ANVISA Registration nº.: 10417940092

Review: 02

Issue: December 12th, 2016

ALERT
INSTRUCTIONS FOR USE

In compliance to the Normative Instruction IN n° 04 from 2015, which establishes the regulation to provide instructions for use of Medical Devises in a non-printed manner, we provide on this warning the procedures that must be followed in order to obtain the electronic version of the IFU from the manufacture's website.

The INSTRUCTIONS FOR USE provide clear and detailed information on the features of the product regarding the precautions and warnings, instructions for safe use, mandatory use by a trained surgeon physician, as well as the sizes available for sale in order to avoid erroneous handling. The restrictions for combinations of models from other brands or manufacturers are also indicated in the INSTRUCTIONS FOR USE of the product.

The document containing the INSTRUCTIONS FOR USE for the proper use and handling of the product is available at the website: **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.