Instructions for Use

Cemented Stem

Legends of the symbols used on packaging

REF	Number in the catalogue	LOT	Batch code
STERILE R	Sterile Product – Sterilized by Gamma Radiation		Manufacturing date
	Valid until		Consult the instructions for use
	Fragile, handling with care		Keep away from the sun
	Keep dry		Single use product
	Do not re-sterilize		Limit of Temperature (40°C)
	Do not use if the packaging is damaged		

Characteristics and Technical Specifications of the Product:

Technical Name: Implant

Commercial Name: Cemented Stem

Commercial Model:

- Femoral Prosthesis Type Charnley Modular;
- Femoral Prosthesis Máxima;
- Femoral Prosthesis MD4 without Coating;
- Femoral Prosthesis Type Muller Modular;
- SPOAC System Femoral Stem;
- Femoral Prosthesis SPOAC NG;
- Modular Prosthesis Type Thompson;

Accessories:

- Distal Centralizer - PMMA;
- Distal Centralizer Femoral Prosthesis Conical– UHMWPE;
- Distal Centralizer Femoral Prosthesis Máxima – PMMA;
- Distal Centralizer SPOAC – PMMA;
- Distal Centralizer SPOAC NG;
- Femoral Mesh;
- Cement Restrictor;
- Cement Restrictor – PMMA;

Raw Material:

- Stainless Steel Alloy (18Cr-14Ni-2.5Mo) – Femoral Prosthesis Type Charnley Modular / Femoral Prosthesis Máxima / Femoral Prosthesis MD4 without Coating / Femoral Prosthesis Type Muller Modular / SPOAC System Femoral Stem / Femoral Prosthesis SPOAC NG / Modular Prosthesis Type Thompson / Accessory: Femoral Mesh;
- Chromium Cobalt Alloy (Co-28Cr-6Mo) – Femoral Prosthesis Máxima / Femoral Prosthesis SPOAC NG;
- Ultra High Molecular Weight Polyethylene (UHMWPE) – Accessories: Distal Centralizer Femoral Prosthesis Conical – UHMWPE / Distal Centralizer SPOAC NG / Cement Restrictor;
- Polymethylmethacrylate (PMMA) – Accessories: Distal Centralizer PMMA / Distal Centralizer Femoral Prosthesis Máxima – PMMA / Distal Centralizer SPOAC – PMMA / Distal Centralizer SPOAC NG / Cement Restrictor – PMMA;
- Polyetheretherketone (PEEK) – Distal Centralizer SPOAC NG;

Sterile Product

Sterilization Method: Gamma Radiation (Dose 25 kGy):

Validity: 05 years (from sterilization date);

Description

The product consists of an implantable device invasive surgically of long term use, intended to hip joint replacement procedures.

The hip joint replacement procedure is performed in circumstances in that this joint is compromised in skeletally mature individuals, due to pathologies such as non inflammatory degenerative disease articular (osteoarthrosis), avascular necrosis of femoral head, acetabular protrusion, traumatic arthritis, epiphyseal proximal slip of femur, ankylosis of origin non infectious and arthrodesis of hip.

Cemented Stem is formed by cone and body, produced in various lengths. The cone can receive heads with different diameters and lengths of neck. The Necks: are presented with angulations of 130º, 135º and 140º in relation to the longitudinal prosthetic axis, therefore, ranging the dimensions of the offset.

The commercial models that compose the Cemented Stem family presents a polished surface and a conical system type Morse, in that the distal migration of component generates radial forces of compression, which stabilize the implant and reduce the tension efforts for the cement-bone interface ensuring higher longevity to prosthetic reconstruction. It also allows the modularity of the femoral head and keeps the tolerances within of fairly narrow limits, which minimizes the effects of friction and corrosion by friction.

It follows illustrative images of the commercial models that compose the Cemented Stem family:

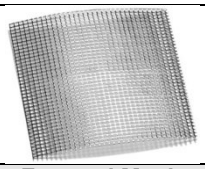
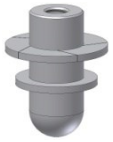
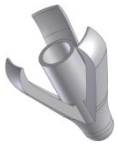
			
Femoral Prosthesis Type Charnley Modular Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	**Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Cobalt Chrome Alloy (Co-28Cr-6Mo)	**Femoral Prosthesis without Coating** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	**Femoral Prosthesis Type Muller Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
			
SPOAC System Femoral Stem Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	**Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Cobalt Chrome Alloy (Co-28Cr-6Mo)	**Modular Prosthesis Type Thompson** Liga de Aço Inox (18Cr-14Ni-2.5Mo)	

The Femoral Mesh, Cement Restrictor and Distal Centralizer are accessories of the commercial models Cemented Stem.

The Femoral Mesh is accessory of all commercial models and is intended to procedures that needs of reinforcement of the intramedullary channel.

The Distal Centralizer is intended for fixation of stem tip to centralize the prosthesis during its cementation.

Finally, the Cement Restrictor is inserted into the femoral channel acting as a cap at time of the stem cementation, preventing the cement spread through this channel. The Distal Centralizer.

							
Femoral Mesh	**Cement Restrictors**		**Distal Centralizers**				

Composition

The selected materials for composition of product present the properties required to achieve the desired performance. This selection considered factors such as biocompatibility and mechanical, chemical, physical properties required for the product.

The commercial models that compose the Cemented Stem and the Femoral Mesh accessory are manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) that meets the specified requirements by the standards 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 ASTM F-139 – Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673).

The commercial models Femoral Prosthesis Máxima and Femoral Prosthesis SPOAC NG can also be manufactured from chromium cobalt casting alloy (Co-28Cr-6Mo) that meets the specified requirements by the standard ASTM F-75 - Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

In turn, the Distal Centralizer Femoral Prosthesis Conical– UHMWPE, Distal Centralizer SPOAC NG – UHMWPE and Cement Restrictor are manufactured from polymer Ultra-High-Molecular-Weight Polyethylene that meets the specified requirements by the standard ASTM F-648 – Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.

The Distal Centralizer PMMA, Distal Centralizer Femoral Prosthesis Máxima – PMMA, Distal Centralizer SPOAC – PMMA, Distal Centralizer SPOAC NG – PMMA and Cement Restrictor – PMMA are manufactured from polymer Polymethylmethacrylate (PMMA) that meets the specified requirements by the standard NBR ISO 5833 – Implantes para Cirurgia – Cimentos de Resina Acrílica (Surgery Implants – Cements of Acrylic Resin).

Finally, the Distal Centralizer SPOAC NG – PEEK is manufactured from polymer Polyetheretherketone (PEEK) that meets specified requirements by the standard ASTM F-2026 – Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.

The above materials were selected for the manufacture of commercial models of the Cemented Stem and related accessories, due to its properties, which makes them ideal materials for the production of implantable medical devices.

Characterized as a material with mechanical, chemical, physical properties favorable for this purpose, presents biocompatibility proven by a vast clinical historic widely described in the worldwide literature.

Indication and Purpose

The hip joint replacement procedure is performed in circumstances in skeletally mature individuals have this joint is damaged, due to pathologies such as non inflammatory degenerative disease articular (osteoarthrosis), avascular necrosis of femoral head, acetabular protrusion, traumatic arthritis, epiphyseal proximal slip of femur, ankylosis of origin non infectious and arthrodesis of hip.

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

The product described here was developed for use in the circumstances described above, so that any other use is considered contraindicated or no scientific substrate that supports its use.

Contra indication

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

- Patients with active general infection or specifics that can lead the complications;
- Patients with general state impaired and/or immune compromised unable to be submitted to a surgical procedure;
- Patients with sensibility to foreign bodies, in this cases, tests must be performed;
- Patients with osteoporosis and/or others bone affections that may compromise the outcome of the arthroplasty;
- Patients with rapidly destructive bone disease or osteonecrosis post-irradiation;
- Patients with progressive neurological diseases;
- Patients with circulatory diseases location and with insufficiency arterial or venous;
- Patients that use narcotic substances, alcohol or smoke;
- Patients with absence of bone support that enable a proper fixation of the implant;
- Patients with absence or paresis of the muscles that control the hip.

Forms of Presentation

The commercial models that compose the Cemented Stem family are packed unitarily in system of primary package, acting as a sterilization barrier.

The product is supplied in the sterile condition and the method of sterilization by gamma radiation (dose 25 kGy) is adopted. This procedure is performed by qualified third company.

After the product is sterilized, properly packaged and labeled in its primary packaging, it is packed in a cardboard carton (secondary packaging), which follows with a leaflet with instructions for use and five-way of traceability label.

On the primary packaging and on the cardboard carton is pasted a label containing needed information for identification of the product.

Forms of Presentation

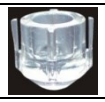
The Cemented Stem is presented in the following commercial models, being that each one of these commercial models and its accessories (integral parts) are available for marketing in the following dimensions:

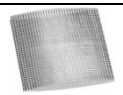
List of commercial models an its respective accessories that compose the Cemented Stem

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packed Quantity
	04.30.41.XXXXX	Femoral Prosthesis Type Charnley Modular Cone 10/11 Primary;	Narrow: 35 and 40; Standard: 35 and 40; With Flange; Extra Reinforced; Necks:: 10 and 20 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.20.XXXXX	Femoral Prosthesis Type Charnley Modular Cone 12/13 Primary;	Narrow: 35 and 40; Standard: 35 and 40; With Flange; Extra Reinforced; Necks:: 10 and 20 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.21.XXXXX	Femoral Prosthesis Type Charnley Modular Cone 12/13 Revision;	Narrow: 35 and 40; Standard: 35 and 40; With Flange: 200 mm; With Flange: +60, +90 mm Extra Reinforced; Necks:: 10 and 20 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.22.XXXXX	Femoral Prosthesis Type Charnley Modular Cone 12/14 Primary;	Narrow: 35 and 40; Standard: 35 and 40; With Flange; Extra Reinforced; Necks:: 10 and 20 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.23.XXXXX	Femoral Prosthesis Type Charnley Modular Cone 12/14 Revision;	Narrow: 35 and 40; Standard: 35 and 40; With Flange; Extra Reinforced; Necks:: 10 and 20 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.01.37XXX	Femoral Prosthesis Máxima 37,5 mm Cone 12/13 Primary;	Offset: 37,5 mm; Cone: 12/13; Nºs: 01, 02, 03;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.03.44XXX	Femoral Prosthesis Máxima 44,0 mm Cone 12/13 Primary;	Offset: 44,0 mm; Cone: 12/13; Nºs: 01, 02, 03, 04;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01

	04.30.04.44XXX	Femoral Prosthesis Máxima 44,0 mm Cone 12/13 Revision;	Offset: 44,0 mm; Cone: 12/13; Nºs: 01, 03 Lengths: 250 and 300 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.02.37XXX	Femoral Prosthesis Máxima 37,5 mm Cone 12/14 Primary;	Offset: 37,5 mm; Cone: 12/14 Nºs: 01, 02, 03;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.86.41XXX	Femoral Prosthesis Máxima 41,0 mm Cone 12/14 Primary;	Offset: 41,0 mm; Cone: 12/14 Nºs: 01, 02, 03 and 04; Length: 149 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.05.44XXX	Femoral Prosthesis Máxima 44,0 mm Cone 12/14 Primary;	Offset: 44,0 mm; Cone: 12/14; Nºs: 01, 02, 03 and 04;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.87.41XXX	Femoral Prosthesis Máxima 41,0 mm Cone 12/14 Revision;	Offset: 41,0 mm; Cone: 12/14 Nºs: 01, 02 and 03; Lengths: 200 and 230 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.06.44XXX	Femoral Prosthesis Máxima 44,0 mm Cone 12/14 Revision;	Offset: 44,0 mm; Cone: 12/14; Nºs: 01, 02, 03, 04; Lengths: 230 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.45.37XXX	Femoral Prosthesis Máxima Primary 37,5 mm Cone 12/14 Primary – CrCo	Offset: 37,5 mm Cone: 12/14 Nºs: 00, 01, 02, 03	Cobalt Chrome Alloy (Co-28Cr-6Mo)	01
	04.30.88.41XXX	Femoral Prosthesis Máxima 41,0 mm Primary – Cr Co;	Offset: 41,0 mm Cone: 12/14 Nºs: 01, 02, 03 and 04 Length: 149 mm	Cobalt Chrome Alloy (Co-28Cr-6Mo)	01
	04.30.46.44XXX	Femoral Prosthesis Máxima Primary 44,0 mm Cone 12/14 Primary – CrCo	Offset: 44,0 mm Cone: 12/14 Nºs: 01, 02, 03 and 04	Cobalt Chrome Alloy (Co-28Cr-6Mo)	01
	04.30.89.41XXX	Femoral Prosthesis Máxima 41,0 mm Revision – CrCo;	Offset: 41,0 mm Cone: 12/14 Nºs: 01, 02 and 03 Lengths: 200 and 230 mm	Cobalt Chrome Alloy (Co-28Cr-6Mo)	01
	04.30.47.44XXX	Femoral Prosthesis Máxima Primary 44,0 mm Cone 12/14 Primary – CrCo	Offset: 44,0 mm Cone: 12/14 Nºs: 01 02 and 03 Lengths: 200 and 230 mm	Cobalt Chrome Alloy (Co-28Cr-6Mo)	01

	04.30.13.XXXXX	Femoral Prosthesis MD4 without Coating Cone 10/11 Primary;	Cone: 10/11; Diameters: 09, 10, 11, 12, 13, 14, 15, 16, 17 mm; Lengths: 117, 122, 127,132,137, 142, 147, 152, 157 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.14.XXXXX	Femoral Prosthesis MD4 without Coating Cone 10/11 Revision;	Cone: 10/11; Diameters: 10, 11, 12, 13, 14, 15, 16 and 17 mm Lengths: 170, 180, 190, 200, 210, 260, 220, 230, 240 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.15.XXXXX	Femoral Prosthesis MD4 without Coating Cone 12/14 Primary;	Cone: 12/14; Diameter: 09, 10, 11, 12, 13, 14, 15, 16 and 17 mm; Lengths: 117, 122, 127, 132, 137, 142, 147, 152, 157 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.16.XXXXX	Femoral Prosthesis MD4 without Coating Cone 12/14 Revision;	Cone: 12/14; Diameter: 10, 11, 12, 13, 14, 15, 16 and 17 mm Lengths: 170, 180, 190, 200, 210, 260, 220, 230, 240 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.42.00XXX	Femoral Prosthesis Type Muller Modular Cone 10/11 Primary;	Cone: 10/11 Sizes: 05.5, 07.5, 10.0, 12.5, 15.0, 17.5, 20.0 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.28.00XXX	Femoral Prosthesis Type Muller Modular Cone 12/13 Primary;	Cone: 12/13; Sizes: 05.5, 07.5, 10.0, 12.5, 15.0, 17.5, 20.0 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.29.00XXX	Femoral Prosthesis Type Muller Modular Cone 12/13 Revision;	Cone: 12/13; Sizes: 05.5, 07.5, 10.0, 12.5, 15.0, 17.5, 20.0 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.30.00XXX	Femoral Prosthesis Type Muller Modular Cone 12/14 Primary;	Cone: 12/14; Sizes: 05.5, 07.5, 10.0, 12.5, 15.0, 17.5, 20.0 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.31.00XXX	Femoral Prosthesis Type Muller Modular Cone 12/14 Revision;	Cone: 12/14; Sizes: 05.5, 07.5, 10.0, 12.5, 15.0, 17.5, 20.0 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.17.XXXXX	SPOAC System Femoral Stem Cone 10/11;	Cone: 10/11; Diameters: 05, 06, 07, 08, 09, 10 mm Lengths: 130, 135, 140, 145, 150, 155 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01

	04.30.18.XXXXX	SPOAC System Femoral Stem Cone 12/14;	Cone: 10/14; Diameters: 05, 06, 07, 08, 09, 10 mm Lengths: 130, 135, 140, 145, 150, 155 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.50.XXXXX	Femoral Prosthesis SPOAC NG Cone 12/14 Primary;	Offset: 33,0; 36,8; 40,0; 43,0 e 47,0 mm; Angle: 130º, 135º, 140º; Sizes: 01, 02, 03, 04, 05;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.30.26.XXXXX	Femoral Prosthesis SPOAC NG Cone 12/14 Primary - CrCo	Offset: 33,0; 36,8; 40,0; 43,0 and 47,0 mm 135º and 140º Sizes: Nº 01,02, 03, 04, 05	Cobalt Chrome Alloy (Co-28Cr-6Mo)	01
	04.30.37.XXXXX	Modular Prosthesis Type Thompson;	Cone: 12/13 and 12/14;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
Accessories					
	04.06.01.000XX	Distal Centralizer PMMA	Diameters: 10, 11, 12, 13, 14, 15, 16 mm	Polymethylmethacrylate (PMMA)	01
	04.06.02.00000	Distal Centralizer Femoral Prosthesis Conical	One size fits all	Polymethylmethacrylate (PMMA)	01
	04.06.02.00001	Distal Centralizer Femoral Prosthesis Conical– PMMA	One size fits all	Polymethylmethacrylate (PMMA)	01
	04.06.03.XXXXX	Distal Centralizer SPOAC – PMMA	05x10, 05x11, 06x11, 06x13, 07x13, 07x15, 08x13, 08x15, 09x15, 10x15	Polymethylmethacrylate (PMMA)	01

	04.06.04.000XX	Distal Centralizer SPOAC NG	One size fits all	Polyethylene (UHMWPE) Polymethylmethacrylate (PMMA) Polyetheretherketone (PEEK)	01
	04.31.03.015XX	Femoral Mesh	150x130, 150x150, 150x180 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.32.01.000XX	Cement Restrictor	Diameters: 15, 18, 21, 24 mm	Polyethylene (UHMWPE)	01
	04.32.02.000XX	Restrictor Cement – PMMA	Diameters: 09, 11, 13, 15 mm	Polymethylmethacrylate (PMMA)	01

Ancillary Components

Following, are listed the ancillary components compatible to the commercial models that compose the Cemented Stem:

- Bipolar Cup;
- Cemented Cups;
- Non Cemented Cups;
- Acetabular Inserts;
- Interchangeable Femoral Heads;
- Bone Cement;

The Bipolar Cup is manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) that meets the specified requirements by the standard ASTM F-138 – Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants, and from polymer Polyethylene (UHMWPE) that meets the specified requirements by the standard ASTM F-648 – Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, through the machining process.

The cemented cups, models Charnley, Máxima, Muller, SPOAC and SPOAC NG, are manufactured from polymer Polyethylene (UHMWPE) that meets the specified requirements by the standard 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 the spacers that are in the external portion of the product, are manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) and polymer Polymethylmethacrylate (PMMA) that meets the specified requirements by the standards ASTM F-138 – Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants and ABNT NBR ISO 5833 – Implants for surgery – Cements of acrylic resin, respectively.

The non cemented cups, models MD4 and MD, are manufacture from titanium alloy (Ti-6Al-4V) that meets the specified requirements by the standard ASTM F-136 – 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 forging and/or machining manufacturing process. The coating of titanium powder (for plasma spray) that cover the cups meets the specified requirements by the standard ASTM F-1580 – Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.

The 09 Points acetabular insert is manufactured from polymer Polyethylene (UHMWPE) that meets the specified requirements by the standard 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 Ceramic interchangeable femoral head, models Forte and Delta, are manufactured from alumina ceramic of high purity (Al_2O_3) that meets the specified requirements by the standard ISO 6474 – Implants for surgery – Ceramic materials based on high purity alumina, through the sintering process, supplied by the third company (CeramTec) duly qualified.

The interchangeable femoral head of stainless steel, is manufactured from stainless steel alloy (18Cr-14Ni-2.5Mo) and stainless steel alloy (21Cr-10Ni-3Mn-2.5Mo) that meets the specified requirements by the standard ASTM F-138 – 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 interchangeable femoral head CrCo is manufactured from cobalt chrome alloy (Co-28Cr-6Mo) that meets the specified requirements by the standard ASTM F-75- Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075), through the microfusion process.

The bone cement is manufactured from polymer Polymethylmethacrylate (PMMA) that meets the specified requirements by the standard ABNT NBR ISO 5833 – Implants for surgery – Cements of acrylic resin.

The surgeon is responsible by the correct selection of models, measures and combination of the commercial models that compose the Cemented Stem family and by adopted technique, as well as their ancillary that will be implanted. He must be familiar with the material, method of application and surgical procedure to be adopted.

The success of the procedure is linked to correct selection, combining, positioning and fixation of the devices, which is under the doctor's responsibility, which evaluates the patient and decides which implants to use. It is also bound to strict accomplishment with the postoperative cares recommended by the doctor in charge.

It follows, indications of ancillary components and their correct combination with the commercial models that compose the Cemented Stem family, for the following assembly possibilities:

Ancillary – Acetabular Components	Ancillary – Cephalic Components	Commercial models – Cemented Stem
----------	**Monopolar Head** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	**Femoral Prosthesis Type Charnley Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis MD4 without Coating** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis Type Muller Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **SPOAC System Femoral Stem** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Modular Prosthesis Type Thompson** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Bipolar Cup Stainless Steel Alloy (18Cr-14Ni-2.5Mo) / Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks from – 04 to +09)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo)	**Femoral Prosthesis Type Charnley Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis MD4 without Coating** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis Type Muller Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **SPOAC System Femoral Stem** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Modular Prosthesis Type Thompson** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

Bipolar Cup Stainless Steel Alloy (18Cr-14Ni-2.5Mo) / Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks from – 02 to +09)** Cobalt Chrome Alloy (Co-28Cr-6Mo)	**Femoral Prosthesis Máxima** Cobalt Chrome Alloy (Co-28Cr-6Mo) **Femoral Prosthesis SPOAC NG** Cobalt Chrome Alloy (Co-28Cr-6Mo)
Bipolar Cup Stainless Steel Alloy (18Cr-14Ni-2.5Mo) / Polyethylene (UHMWPE)	**Forte Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3) Or **Delta** **Delta Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3)	**Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Cup Type Charnley Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks from – 04 to +09)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo)	**Femoral Prosthesis Type Charnley Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Máxima Cup Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks from – 04 to +09)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo) Or **Forte Ceramic Interchangeable Femoral Head**	**Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

	Alumina Ceramic (Al_2O_3) Or **Delta Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3)	
Máxima Cup Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks from – 02 to +09)** Cobalt Chrome Alloy (Co-28Cr-6Mo)	**Femoral Prosthesis Máxima** Cobalt Chrome Alloy (Co-28Cr-6Mo)
Cup Type Muller Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks from – 04 to +09)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo)	**Femoral Prosthesis Type Muller Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
SPOAC Cup Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks from – 04 to +09)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo)	**SPOAC System Femoral Stem** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
SPOAC NG Cup Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head**	**Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

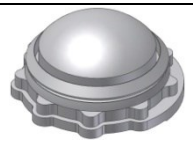
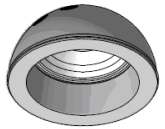
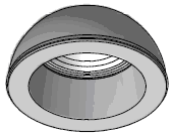
	(Necks from – 04 to +09) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo) Or **Forte Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3) Or **Delta Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3)	
SPOAC NG Cup Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks from – 02 to +09)** Cobalt Chrome Alloy (Co-28Cr-6Mo)	**Femoral Prosthesis SPOAC NG** Cobalt Chrome Alloy (Co-28Cr-6Mo)
Cup MD4 Plasma Spray Titanium Alloy (Ti-6Al-4V) **+** **Acetabular Insert 09 Points** Polyethylene (UHMWPE)	**Interchangeable Femoral Head** **(Necks: Short, Medium, Long and Extra-Long)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head** **(Necks from – 04 to +09)** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Or **Interchangeable Femoral Head HN** **(Necks from – 04 to +09)** Stainless Steel Alloy (21Cr-10Ni-3Mn-2.5Mo)	**Femoral Prosthesis Type Charnley Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis MD4 without Coating** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis Type Muller Modular** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **SPOAC System Femoral Stem** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Modular Prosthesis Type Thompson** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)
Cup MD4 Plasma Spray Titanium Alloy (Ti-6Al-4V)	**Interchangeable Femoral Head** **(Necks from – 02 to +09)**	**Femoral Prosthesis Máxima** Cobalt Chrome Alloy (Co-28Cr-6Mo)

+ **Acetabular Insert 09 Points** Polyethylene (UHMWPE)	Cobalt Chrome Alloy (Co-28Cr-6Mo)	**Femoral Prosthesis SPOAC NG** Cobalt Chrome Alloy (Co-28Cr-6Mo)
Cup MD4 Plasma Spray Titanium Alloy (Ti-6Al-4V) **+** **Acetabular Insert 09 Points** Polyethylene (UHMWPE)	**Forte Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3) Or **Delta Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3)	**Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Stainless Steel Allo'y (18Cr-14Ni-2.5Mo)
Cup MD Acetabular Ti Titanium Alloy (Ti-6Al-4V) **+** **Acetabular Insert MD Poli** **(Standard, Constrict, with Rim)** Polyethylene (UHMWPE)	**Forte Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3) Or **Delta Ceramic Interchangeable Femoral Head** Alumina Ceramic (Al_2O_3)	**Femoral Prosthesis Máxima** Stainless Steel Alloy (18Cr-14Ni-2.5Mo) **Femoral Prosthesis SPOAC NG** Stainless Steel Alloy (18Cr-14Ni-2.5Mo)

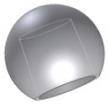
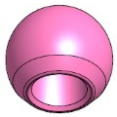
The ancillary components listed are not objects of this registration process and must, therefore, be acquired separately and always from the same manufacturer or appointed by him.

Cemented Cups					
Illustrative Images	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Quantity Packaged**
	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;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Polyethylene (UHMWPE)	01
	04.01.09.XXXXX	Cup Type Charnley Standard	**Ø 22 mm –** 40, 43, 46, 48, 50, 52, 54, 56 mm; **Ø 28 mm –** 43, 46 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.16.XXXXX	Cup Type Charnley Standard with Spacer	**Ø 22 mm –** 40, 43, 46, 48 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Polymethylmethacrylate (PMMA)	01
	04.01.07.XXXXX	Cup Type Charnley w/ Flange	**Ø 22 mm –** 40, 43, 46, 48, 50, 52, 54 mm; **Ø 28 mm –** 40, 43, 48 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.14.XXXXX	Cup Type Charnley w/ Flange with spacer	**Ø 22 mm –** 40, 43, 44, 46, 48 mm; **Ø 28 mm –** 50, 52, 54, 56, 58, 60, 62 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Polymethylmethacrylate (PMMA)	01
	04.01.08.XXXXX	Cup Type Charnley with Posterior Rim	**Ø 22 mm –** 40, 43, 44, 46, 48, 50, 52, 54, 56 mm; **Ø 28 mm –** 40, 43, 48 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.15.XXXXX	Cup Type Charnley with Posterior Rim with Spacer	**Ø 22 mm –** 40, 43, 46, 48 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Polymethylmethacrylate (PMMA)	01

	04.01.02.XXXXX	Standard Maxima Cup	**Ø 26 mm –** 44, 46, 48, 50, 52, 54, 56, 58, 60 mm; **Ø 28 mm –** 44, 46, 48, 50, 52, 54, 56, 58, 60 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.23.XXXXX	Standard Maxima Cup with 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
	04.01.11.XXXXX	Cup Type Muller Standard	**Ø 26 mm –** 44, 46, 48, 50, 52, 54, 56, 58 mm; **Ø 28 mm –** 44, 46, 48, 50, 52, 54, 56, 58, 60 mm; **Ø 32 mm –** 48, 50, 54 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.18.XXXXX	Cup Type Muller Standard with Spacer	**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
	04.01.10.XXXXX	Cup Type Muller with Posterior Rim	**Ø 28 mm –** 44, 46, 48, 50, 52, 54, 56, 58, 60 mm; **Ø 32 mm –** 50 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.17.XXXXX	Cup Type Muller with Posterior Rim with Spacer	**Ø 28 mm –** 44, 46, 48, 50, 52, 54, 56, 58, 60, 62 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Polymethylmethacrylate (PMMA)	01
	04.01.21.XXXXX	Cup Type Muller with Lock	**Ø 22 mm –** 44, 46, 50, 52, 54, 56, 60 mm; **Ø 28 mm –** 44, 46, 48, 50, 52, 54 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.01.12.2XXXX	Standard SPOAC Cup	**Ø 22 mm –** 42, 44,46 mm; **Ø 28 mm –** 48, 50, 52 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01

	04.01.13.2XXXX	Standard SPOAC Cup with Spacer	**Ø 22 mm –** 42, 44,46 mm; **Ø 28 mm –** 42, 44, 46, 48, 50, 52 mm; **Ø 32 mm –** 48, 50, 52, 54, 56, 58, 60, 62 mm;	Polyethylene (UHMWPE) Stainless Steel Alloy (18Cr-14Ni-2.5Mo) Polymethylmethacrylate (PMMA)	01
	04.01.24.XXXXX	SPOAC NG 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 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 Cups					
Illustrative Images	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Quantity Packaged**
	04.01.04.XXXXX	MD4 Cup – Plasma Spray	**Diameter –** 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70 mm;	Titanium Alloy (Ti-6Al-4V) Titanium Coating (Ti-6Al-4V)	01
	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)	01
	07.01.26. XXXXX	MD Acetabular 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) Titanium Coating (Ti-6Al-4V)	01
	07.01.27. XXXXX	MD Acetabular 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) Titanium Coating (Ti-6Al-4V)	01

	07.13.08.XXXXX	KMT 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;	Delta Ceramic Alumina (Al_2O_3)	01
Femoral Interchangeable Heads					
Illustrative Images	**Code**	**Description**	**Dimensions**	**Manufacturing Material**	**Quantity Packaged**
	04.04.04.XXXXX	Monopolar Head Cone 12/13	**Diameters:** 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.04.06.XXXXX	Monopolar Head Cone 12/14	**Diameters:** 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54 mm;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.04.01.XXXXX	Interchangeable Femoral Head Cone 10/11	**Ø 22 mm –** Short, Medium, Long, Extra-Long; **Ø 26 mm –** Short, Medium, Long, Extra-Long; **Ø 28 mm –** Short, Medium, Long, Extra-Long; **Ø 32 mm –** Short, Medium, Long, Extra-Long;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.04.02.XXXXX	Interchangeable Femoral Head Cone 12/13	**Ø 22 mm –** Short, Medium, Long, Extra-Long; **Ø 26 mm –** Short, Medium, Long, Extra-Long; **Ø 28 mm –** Short, Medium, Long, Extra-Long; **Ø 32 mm –** Short, Medium, Long, Extra-Long;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.04.03.XXXXX	Interchangeable Femoral Head Cone 12/14	**Ø 22 mm –** Short, Medium, Long, Extra-Long; **Ø 26 mm –** Short, Medium, Long, Extra-Long; **Ø 28 mm –** Short, Medium, Long, Extra-Long; **Ø 32 mm –** Short, Medium, Long, Extra-Long;	Stainless Steel Alloy (18Cr-14Ni-2.5Mo)	01
	04.04.07.XXXXX	Interchangeable Femoral Head Cone 12/14 (Necks varying from -04 to +09)	**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
	04.04.08.XXXXX	Interchangeable Femoral Head Cone 12/14 CrCo (Necks varying from -04 à +09)	**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;	Cobalt Chrome Molybdenum Alloy (Co-28Cr-6Mo)	01
	04.04.11.XXXXX	Interchangeable Femoral Head HN (Necks varying from -04 à +09)	**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 High Nitrogen (21Cr-10Ni-3Mn-2.5Mo)	01

	04.04.09.XXXXX	Interchangeable Femoral Head Cone 12/14 Forte Ceramic	**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	Forte Ceramic Alumina (Al_2O_3)	01
	04.04.10.XXXXX	Interchangeable Femoral Head Cone 12/14 Delta Ceramic	**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;	Delta Ceramic Alumina (Al_2O_3)	01

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

Support Material

The support materials are the instruments designed only for deployment of the Cemented Stem and their respective ancillary above.

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

The instruments below are not objects of this register and must, therefore, be purchased separately and always the same manufacturer of the implant or appointed by him.

See list below of instruments provided by the manufacturer or appointed by him for the implantation of Stem Cemented and their ancillary:

- Instrumental – Bipolar;
- Instrumental – Acetabular Unique (National Rasps);
- Instrumental – Acetabular Unique (Imported Rasps);
- Instrumental – Acetabular Unique Next
- Instrumental SPOAC;
- Instrumental – Muller;
- Instrumental – Charnley;
- Instrumental – Maxima Primary Standard;
- Instrumental – Maxima Revision
- Instrumental – SPOAC NG (Milling);
- Instrumental – SPOAC-NG (Compression);

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

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

For more information about the instrumental, see the representative.

Warning and Precautions

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

- Cemented Stem must be used only after a detailed analysis of the surgical procedure to be adopted and reading this instruction of use;
- The product must only be used by specialized surgical teams with knowledge and specific training on the techniques of arthroplasty, and it is the responsibility of the surgeon the choice and mastery of technique to be applied;
- The selection and inappropriate choice of implants to be used, as well as mistakes in the indication, handling and application technique can cause excessive tensions and tractions on the implant, causing the failure by fatigue, fracture and loosening;
- The clinical results and durability of the implants are highly dependent on an accurate surgical technique;
- The implantation on an inadequate bone bed can cause premature loosening and progressive loss of bone stock. In these cases additional methods of bone grafting together with screens and reinforcements must be adopted;
- The product must not be used together with bone cement;
- The use in patients with predisposing to disobey the medical guidelines and restrictions postoperative, such as children, elderly, individuals with neurological disorders or drug addicts, represent a greatest risk for failure of the implant;
- The risk of implant failure are higher in patients who perform activities of work or practicing sports activities during the postoperative period, contrary to medical restrictions;
- The postoperative complications are at greatest risk when the product is used in patients with functional expectations beyond those what can be promoted by joint replacement, patients with morbid obesity and patients with small bones structure;
- Cemented Stems must not be used if they do not get a bone support adequate to ensure the stability of the implant;
- The patient must make a periodic medical monitoring (follow-up) to check the conditions of the implant, the bone and adjacent tissues;

- As the medical criterion, can be used an antibioticterapy prophylactic pre and perioperative, and the antibioticterapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections;
- The implant must not be used with components from other manufacturers or purpose. The combination with implants of manufacturers or different purposes can result in incongruence between the components;
- It must be observed closely the identification of the product and are not allowed combinations with components from other manufacturers or purpose;
- The care of this material are the responsibility of qualified personnel, which must follow the standards and/or other local regulations;
- Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary the user perform an inspection of the product integrity, when the packaging is opened, and if any abnormality is observed the product must not be used;
- The opening of the packaging for surgical use must only be performed by qualified personnel for this procedure;
- Do not use the product if the validity is expired or packing is violated.
- Handle with care;
- Single use product - Do not reuse;
- Implants must NEVER be reused. Although they may look undamaged, pre-tensions to which they were subjected may cause imperfections that would reduce the lifetime of the product in a reimplantation;
- PROHIBITED REPROCESSING;
- Sterile product - Do not re-sterilize;
- Manufacturing date, validity term and batch number: See label;

Adverse Effects

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

- Loosening, displacement, deformation, fracture of the implant or osteolysis;
- Postoperative pains, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Inflammatory reactions, associated or not to loosening and/or release of the implant;
- Bone necrosis or adjacent soft tissues;
- Breaking of the implant that can make its removing difficult or impractical;

Instruction for Use

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

- The care with this material is the responsibility of the qualified personnel, which must follow the standards and/or other applicable local regulations;
- The product must be handled with appropriate care in proper locations (center of materials and operating rooms);
- The product must only be used by specialized surgical teams, with specific knowledge and training on techniques for arthroplasty, being the surgeon in charge by the choice and domain of the surgical technique to be applied;
- The Cemented Stem shelf-life established is 10 (ten) years, since the devices are implanted and an adequate surgical technique is adopted, and the information on the topics "Indication and Purpose", "Contra indication", "Warnings and Precautions" and "Instructions for Use" are observed;
- As the medical criterion, must be adopted methods of bone grafting (associated or not to use of screens and reinforcements), for restoration of bone stock in cases where there is not medullar cavity with viable bone bed;
- As the medical criterion, may be needed the performance of revision surgery after shelf life period, if observed wear and/or release of components;

- For application of the Cemented Stem and their respective ancillary components is necessary to use specific instrumental, indicated in topic: “Support Material”. They must be not used with other instruments than those appointed by the manufacturer, due to possibility of dimensional and/or functional incompatibility;
- The correct combination of the Cemented Stem with their respective ancillary components is indicated in the topic “Ancillary Components”. They must be not used with components other than those appointed by manufacturer, due to possibility of dimensional and functional incompatibility;

Guidance to the patient and/or the Legal Representative

The team responsible must guide the patient and/or his legal representative about:

- The appropriate care and restrictions during the postoperative period. The ability 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 greatest when used in patients with predisposing to disobey the medical guidelines and restrictions postoperative, such as children, elderly, individuals with neurological disorders or drug addicts;
- The fact that product does not replace and does not have the same performance of normal bone and, therefore, can break, deform or release due to efforts or excessive activities of early load and other situations;
- All post-operative restrictions, particularly those related to occupational and sports activities;
- The fact that postoperative complications represent a greater risk when the product is used in patients with functional expectations beyond those what can be promoted by joint replacement, patients with morbid obesity and patients with small bone structure;
- The need to use, exclusively the medical criterion: external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load;
- The need for periodic medical monitoring to check the conditions of the implant, bone and adjacent tissues;
- The fact that the non-performing of the revision surgery when the components release can results in progressive loss of bone stock;
- The fact that implants can interfere in the imaging exam results. Thus, implant users must report this fact when carrying out 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

Cemented Stem is supplied in the sterile production condition. The sterilization method used is by Gamma Radiation.

The Cemented Stem production is performed with great care in order to meet the performance intended for the product. Thus, the surgical team and all other concerned should handle the devices properly to minimize the risks of infection.

Sterile product – Do not re-sterilized.

Do not use the product if the packaging is violated.

Contamination Risk

This is an implantable product, in cases where the explantation of the Cemented Stem is need; there are risks of biological contamination and transmission of viral diseases.

To minimize these risks, Cemented Stem explanted must be treated as contaminating potentially material. All other applicable regulations must be adopted.

Product Disposal

The explanted Cemented Stem or considered improper for use, must be discarded. It is recommended before disposal that the product be mischaracterized, for this, the parts can be cut, bent or polished.

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

Single use product – do not reuse.

Traceability

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

- Name of patient who received the implant;
- Surgeon's name;
- Hospital's name
- Manufacturer's name;
- Supplier's name;
- Surgery date;
- Code of product;
- Batch number of the product;
- Quantities used
- Product registration at ANVISA;

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

The labels contain data of the product such as: code, description and batch number, among other information.

The traceability information is necessary for notification by the service of health and/or by the patient to the Sanitary surveillance Agency – ANVISA and to the manufacturer in cases of serious adverse events to conducting the appropriate investigations.

Storage and Transport

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

Because it is a sterile product, temperature and humidity of the storage site 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 must be kept in its original packaging until the moment of use, being that the surgical packaging opening and handling of the product must be done by trained personal for this procedure.

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

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

Other 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

Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Registration ANVISA #: 10417940039

Review: 06

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ALERT
INSTRUCTIONS FOR USE

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

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

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

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

Customer Service Department:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

http://www.mdt.com.br

Avenida Brasil, 2983 –Distrito Industrial CEP: 13505-600 | Rio Claro – São Paulo – Brasil

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

MDTImplantes

MDT®- INDÚSTRIA COMÉRCIO IMPORT. E EXPORT. DE IMPLANTES SA
Av. Brasil, 2983 - Dt. Industrial | 13505-600 - Rio Claro / SP - Brasil
Tel./Fax. +55 (19) 2111.6500 | www.mdt.com.br