Instructions for Use

Chromium (Cr) Cobalt (Co) Cemented Base Component

Legends of Symbols used in the Packaging

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

Product technical specifications and Characteristics

Technical Name: Implant

Commercial Name: Chromium (Cr) Cobalt (Co) Cemented Base Component

Business Models:

- Tibial Base Modular III Primary – CrCo;
- Tibial Base Modular III Revision – CrCo;

Accessories

- Extensor Pin Modular III Straight;
- Extensor Pin Modular III Angled;
- Tibial Wedge Modular III Partial Angled;
- Tibial Wedge Modular III Partial Parallel;
- Tibial Wedge Modular III Total Angled;
- Tibial Wedge Modular III 1/3 Angled;

Raw Material:

- Chromium Cobalt Alloy (Co-28Cr-6Mo)

Sterile Product

Sterilization Method: Gamma Radiation (Dose 25 kGy)

Validity: 05 years (from sterilization)

Description

The CrCo Cemented Base Component consists of surgically implantable devices of long term use, which composes the modular prosthesis, intended for knee joint replacement in procedures of conventional arthroplasty primary or revision.

The implant together with other components is intended to replace the articular surface of distal femur, proximal tibia and patellar surface, during surgical procedure of total knee joint replacement, is performed in circumstances where this joint in - skeletally mature individuals – is found damaged as a

result of pathologies such as degenerative joint disease non-inflammatory (osteoarthrosis), traumatic arthritis, ankylosis of non-infectious origin and arthrodesis of the knee.

The CrCo Cemented Base Component is manufactured from Chromium Cobalt Casting Alloy (Co-28Cr-6Mo) is a piece with two distinct regions: a base of settlement where the plateau component is fitted (integrant part of the knee prosthesis) and one fixation stem, which is cemented in the region intramedullary of tibia, providing rotational stability anterior, posterior and lateral medial. The fixation stem of revision base has fitting for coupling of extender pin, by junction cone Morse.

It is presented in versions for primary and revision procedures with four different sizes: small, medium, large and extra-large, as follow:

	
Tibial Base Modular III Primary – CrCo	**Tibial Base Modular III Revision – CrCo**

The accessories of the CrCo Cemented Base Component are extensor pin and tibial wedges. These parts are used optionally for cases where the surgeon does not find a good bone bed for prosthesis fixation. They are manufactured from Chromium Cobalt Casting Alloy (Co-28Cr-6Mo). The accessories are more commonly used in revision surgery cases, in other words, when is necessary the change of a primary base by a revision base. It follows illustrative images of accessories:

		
Extensor Pin Modular III Straight	**Extensor Pin Modular III Angled**	**Tibial Wedge Modular III Partial Angled**
		
Tibial Wedge Modular III Partial Parallel	**Tibial Wedge Modular III Total Angled**	**Tibial Wedge Modular III 1/3 Angled**

Composition

The selected material for composition presents the required properties to achieve the desired performance for the product (See description of performance desired in the item 1.6 of this report). This selection considered factors as biocompatibility and mechanical, chemical, physical properties required for the product.

The CrCo Cemented Base Component and its accessories are produced from Chromium Cobalt Casting Alloy (Co-28Cr-6Mo).

The chromium cobalt casting alloy (Co-28Cr-6Mo) used for manufacturing of product meets specified requirements by standard ASTM F-75 - Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

The manufacturing material meets the specifications required for implantable medical devices manufacturing. His choice was based on criteria of similarity (results widely described in literature) and by their biocompatibility characteristics and mechanic strength.

Indication and Purpose

The CrCo Cemented Base Component together with components is intended to replace the articular surface of proximal tibia, during surgical procedure of total knee joint replacement, is performed in circumstances where this joint in - skeletally mature individuals – is found damaged as a result of pathologies such as degenerative joint disease non-inflammatory (osteoarthrosis), traumatic arthritis, ankylosis of non-infectious origin and arthrodesis of the knee.

The CrCo Cemented Base Component should be fixed to the adjacent bone, in any circumstances, by means of acrylic cement of orthopedic use (Polymethylmethacrylate – PMMA).

The product described here was development for use in the circumstances aforementioned, as well as, any other using is considered contraindicated or without scientific substrate.

Contra indication

The relative contra indications for use of the device are listed below, leaving to the surgeon in charge the surgical procedure indication, after a detailed study of the case:

- Patients with general active infections or specific that can lead to complications;
- Patients with impaired general state and/or immune compromised, unable to be submitted to a surgical procedure;
- Patients with sensibility to foreign bodies, and in these cases, tests should be performed;
- Patients with osteoporosis and/or bone affections that may compromise the result of arthroplasty;
- Patients with bone diseases quickly destructives or osteonecrosis post-irradiation;
- Patients with progressive neurological diseases;
- Patients with local circulatory diseases and arterial or venous insufficiencies;
- Patients who use narcotic substances, alcohol or smoke;
- Patients with absence of bone support that allow a proper fixation of the implant;
- Patients with absence or paresis of the muscles controlling the knee.

Forms of Presentation

The business models that compose the CrCo Cemented Base Component family and its respective accessories are packaged unitarily in system of primary packaging type Blister or surgical packaging type Tyvec, that act as a barrier of sterilization.

The business models that compose the CrCo Cemented Base Component family and its respective accessories are supplied in sterile condition, and the sterilization method used is the sterilization by gamma radiation (dose 25 kGy), procedure performed by qualified third company.

After the components are sterile and packed in its properly labeled primary packaging, are packed in a cardboard carton (secondary packaging), which follows with a leaflet with instructions for use and five-copies of the traceability label.

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

The CrCo Cemented Base Component is presented in the following business models, being that each one of these business models is available for marketing in the following dimensions:

List of business models that compose the CrCo Cemented Base Component family

Illustrative Images	Code	Description	Dimensions	Manufacturing Material	Packaged Quantity
	04.14.06.000XX	Tibial Base Modular III Primary - CrCo	Small, Medium, Large and Extra-Large;	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.14.07.000XX	Tibial Base Modular III Revision - CrCo	Small, Medium, Large and Extra-Large;	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
Accessories					
	04.25.02.XXXXX	Extensor Pin Straight Modular III	Diameters: 11, 12, 13, 14, 15, 16 mm; Lengths: 70, 100 mm;	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.25.03.XXXXX	Extensor Pin Angled Modular III	Diameters: 11, 12, 13, 14, 15, 16 mm; Lengths: 70, 100 mm;	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.05.06.160XX	Tibial Wedge Modular III Partial Angled	Small, Medium, Large and Extra-Large;	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.05.06.260XX	Tibial Wedge Modular III Partial Angled	Small, Medium, Large and Extra-Large;		
	04.05.07.050XX	Tibial Wedge Modular III Partial Parallel 05 mm	Small, Medium, Large and Extra-Large;	Chromium Cobalt Alloy (Co-28Cr-6Mo).	01
	04.05.07.100XX	Tibial Wedge Modular III Partial Parallel 10 mm	Small, Medium, Large and Extra-Large;		
	04.05.08.070XX	Tibial Wedge Modular III Total Angled 07º	Small, Medium, Large and Extra-Large;	Chromium Cobalt Alloy (Co-28Cr-6Mo).	01
	04.05.09.220XX	Tibial Wedge Modular III 1/3 Angled 22º	Small, Medium, Large and Extra-Large;	Chromium Cobalt Alloy (Co-28Cr-6Mo).	01

Ancillary Components

The ancillary implants to the business models that compose the CrCo Cemented Base Component are:

- Femoral Component;
- Patellar Component;
- Plateau Component;

The Femoral Component is manufactured from chromium cobalt casting alloy (Co-28Cr-6Mo), which meets specified requirements by standard ASTM F-75 - Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

The Patellar Component and Plateau Component are manufactured from Polyethylene Ultra-High-Molecular-Weight (UHMWPE) that meets specified requirements by standard ASTM F-648 – Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.

The surgeon is responsible by the correct selection of models, measures and combination of the business models that compose the CrCo Cemented Base Component family and by adopted technique, as well as their ancillary that will be implanted. He should 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.

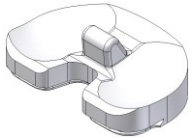
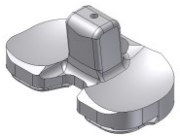
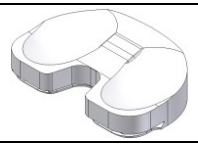
The CrCo Cemented Base Component should be fixed to the adjacent bone by means of acrylic cement of orthopedic use, which should be acquired separately, since it did not is object of this register.

It follows, indications of ancillary components and their correct combination with the business models that compose CrCo Cemented Base Component family:

Ancillary Femoral Component	Ancillary Plateau Component	Business Models Cemented Base Component - CrCo	Ancillary Patellar Component
Femoral Component Modular III Chromium Cobalt Alloy (Co-28Cr-6Mo)	**Tibial Plateau Modular III** Polyethylene (UHMWPE)	**Tibial Base Modular III Primary – CrCo** Chromium Cobalt Alloy (Co-28Cr-6Mo	**Patellar Component Biconvex** Polyethylene (UHMWPE) **Or** **Patella of Triple Fixation** Polyethylene (UHMWPE)
Femoral Component Modular III Revision Chromium Cobalt Alloy (Co-28Cr-6Mo)	**Tibial Plateau Modular III Revision** Polyethylene (UHMWPE)	**Tibial Base Modular III Revision – CrCo** Chromium Cobalt Alloy (Co-28Cr-6Mo	**Patellar Component Biconvex** Polyethylene (UHMWPE) **Or** **Patella of Triple Fixation** Polyethylene (UHMWPE)
Femoral Component Modular III P/L Chromium Cobalt Alloy (Co-28Cr-6Mo)	**Tibial Plateau Modular III P/L** Polyethylene (UHMWPE)	**Tibial Base Modular III Primary – CrCo** Chromium Cobalt Alloy (Co-28Cr-6Mo	**Patellar Component Biconvex** Polyethylene (UHMWPE) **Or** **Patella of Triple Fixation** Polyethylene (UHMWPE)

The ancillary components related to follow are not objects of this registration process and should therefore be purchased separately and always from the same manufacturer or indicated by the manufacturer.

List of ancillary components to the business models that compose the CrCo Cemented Base Component family

Illustrative Images	Codes	Description of Ancillary Components	Dimensions	Manufacturing Material	Packaging Quantity
	04.15.04.000XX	Femoral Component Modular III Right	Small, Medium, Large and Extra-Large	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.15.05.000XX	Femoral Component Modular III Left	Small, Medium, Large and Extra-Large	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.15.08.000XX	Femoral Component Modular III Revision Right	Small, Medium, Large and Extra-Large	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.15.09.000XX	Femoral Component Modular III Left	Small, Medium, Large and Extra-Large	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.15.06.000XX	Femoral Component Modular III P/L Right	Small, Medium, Large and Extra-Large	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
	04.15.07.000XX	Femoral Component Modular III P/L Left	Small, Medium, Large and Extra-Large	Chromium Cobalt Alloy (Co-28Cr-6Mo)	01
Illustrative Images	**Codes**	**Description of Ancillary Components**	**Dimensions**	**Manufacturing Material**	**Packaging Quantity**
	04.17.02.01XXX	Tibial Plateau Modular III Small	08, 09, 10, 12, 15, 18, 21, 25 mm	Polyethylene (UHMWPE)	01
	04.17.02.02XXX	Tibial Plateau Modular III Medium	08, 09, 10, 12, 15, 18, 21, 25 mm		
	04.17.02.03XXX	Tibial Plateau Modular III Large	08, 09, 10, 12, 15, 18, 21, 25 mm		
	04.17.02.04XXX	Platô Tibial Modular III Extra-Grande	08, 09, 10, 12, 15, 18, 21, 25 mm		
	04.17.06.010XX	Tibial Plateau Modular III Revision for Base S and Femur S or M	10, 12, 15, 18, 21, 25 mm	Polyethylene (UHMWPE)	01
	04.17.06.020XX	Tibial Plateau Modular III Revision for Base M and Femur S or M	10, 12, 15, 18, 21, 25 mm		
	04.17.07.020XX	Tibial Plateau Modular III Revision for Base M and Femur L	10, 12, 15, 18, 21, 25 mm		
	07.17.07.030XX	Tibial Plateau Modular III Revision for Base L and Femur M	10, 12, 15, 18, 21, 25 mm		
	04.17.06.030XX	Tibial Plateau Modular III Revision for Base L and Femur L or XL	10, 12, 15, 18, 21, 25 mm		
	04.17.06.040XX	Tibial Plateau Modular III Revision for Base XL and Femur L or XL	10, 12, 15, 18, 21, 25 mm		
	04.17.04.01XXX	Tibial Plateau Modular III – P/L Small	08, 10, 12, 15, mm	Polyethylene (UHMWPE)	01
	04.17.04.02XXX	Tibial Plateau Modular III – P/L Medium	08, 10, 12, 15, mm		
	04.17.04.03XXX	Tibial Plateau Modular III – P/L Large	08, 10, 12, 15 mm		
	04.17.04.04XXX	Tibial Plateau Modular III – P/L Extra-Large	08, 10, 12, 15 mm		

Illustrative Images	Codes	Description of Ancillary Components	Dimensions	Manufacturing Material	Packaging Quantity
	04.16.01.000XX	Patellar Component Biconvex Modular III	Diameters – 26, 28, 30, 32, 34, 36, 38 mm;	Polyethylene (UHMWPE)	01
	04.16.03.XXXXX	Patella of Triple Fixation	Diameters – 26, 28, 30, 32, 34, 36, 38 mm;	Polyethylene (UHMWPE)	01

Support Material

The support materials are the instrumentals designed solely for CrCo Cemented Base Component implantation and their respective ancillaries aforementioned.

These instrumentals are made in stainless steel that provides high strength and durability, according to specified requirements by standard ASTM F-899 – Standard Specification for Stainless Steel for Surgical Instruments.

The instrumentals below are not object of this registration process and must, therefore, be purchased separately and always from the same manufacturer of the implant or indicated by him.

See list of instrumentals below, available by manufacturer or by him indicated to implantation of the CrCo Cemented Base Component and their respective ancillaries:

- 0J.03 – Instrumental –Knee Modular III;
- 0J.05 – Instrumental –Knee Modular III P/L;
- 0J.07 – Instrumental –Knee Modular III Revision;

The instrumentals are provided decontaminated, but not sterilized. Improper sterilization of surgical instruments can cause infection.

The surgical instrumentals are subject to wear and tear during the normal use, and it can therefore break. The instruments should be used only for its purpose and should be inspected regularly to check possible wear and damage.

For more information about the instrumental, consult the representative.

Warning and Precautions

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

- The product must be only used after a detailed analysis of the surgical procedure to be adopted and reading of this use instruction;
- The product must be only used by specialized surgical team, with specific knowledge and training on the techniques of arthroplasty, and the surgeon in charge by the choice and domain of technique to be applied;
- The selection and inappropriate choice of the implants to be used, as well as the mistakes in the indication, handling and application technique can cause excessive tensions and tractions on the implant, leading to failure by fatigue, fracture and to release them;
- The clinical results and the durability of the implants are extremely dependents on an accurate surgical technique;
- Implantation under inadequate bone bed can cause premature loosening and progressive loss of bone stock;
- The product should be used together with acrylic bone cement;
- The use in patients with predisposing to disobey the medical guidelines and postoperative restrictions, as children, elderly, individuals with neurological disorders or dependent in narcotic substances, represent a greater risk for failure of the implant;
- The risks of failure of the implant are greater in patients engaged in efforts activities or practice sports activities, during the postoperative period, contrary to medical restriction;
- The postoperative complications represent a greater risk when the product is used in patients with functional expectations beyond those that can be promoted by articular replacement, patients with morbid obesity and patients with small bones;
- The CrCo Cemented Base Component and their respective ancillary should be not used if they do not get a bone support appropriate to ensure the stability of the implant;
- The patient must make a periodic medical monitoring to check the conditions of the implant, of the bone and adjacent tissues;

- The medical criterion, can be use 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 should not be used with components from other manufacturers or purpose. The combination of implants of manufacturers or different purpose can result in incongruence between the components;
- Should be observed strictly the identification of the product and not allow the combination with components of other manufacturer or purpose;
- The care with this material are responsibility of qualified personnel, which should follow the standards and/or other applicable 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 should not be used;
- The opening of the packaging for surgical use should only be performed by qualified personnel for this procedure;
- Do not use the product if its validity is expired or its packaging is violated.
- Handle with care;
- Single use product – Do not reuse;
- The implants must NEVER be reused. Although they may seem undamaged, tensions previous that they have been submitted can cause imperfections that would reduce the lifetime of the product in a re-implantation;
- Improper sterilization of implants can cause infection;
- PROHIBITED REPROCESS;
- Sterile Product – Do not re-sterilize;
- Manufacturing date, validity term and batch number: see label.

Adverse Effects

Every surgical procedure presents risks and possibility of complications, being that some common risks are infection, bleeding, drug allergic reaction and anesthetic risks, among others. The following complications and adverse effects can still be associated with the implantation of the product:

- 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 the loosening and/or release of the implant;
- Bone necrosis or adjacent soft tissues;
- Break of the implant which can make its removal difficult or impractical.

Use Instructions

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

- The care with this material is the responsibility of the qualified personnel, which should follow the standards and/or other local regulations applicable;
- The product should be handled with appropriate care in proper locations (materials central and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and specific training on techniques for arthroplasty, being the surgeon in charge by the choice and domain of the surgical technique to be applied;
- The useful life established for the CrCo Cemented Base Component is 10 (ten) years, since that the devices are implanted adopting a proper surgical technique and should be observed the information of the topics “Indication and Purpose”, “Contra indication”, “Warning and Precautions” and “Use Instructions”;

- The medical criterion may be necessary the revision surgery after the useful life period, if is observed wear and/or loosening of components;
- For application of the CrCo Cemented Base Component and their respective ancillary components is necessary the use of specific instrumental, indicated in topic: “Support Material”. They should be not used with other instruments than those indicated by the manufacturer, due to possibility of dimensional and/or functional incompatibility;
- The correct combination of the CrCo Cemented Base Component and their respective ancillary components is indicated in the topic “Ancillary Components”. Should not be used with components other than those indicated by manufacturer, due to possibility of dimensional and functional incompatibility;

Guidance to the patient and/or the Legal Representative

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

- The proper 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 higher when using in patients with predisposition to disobey the medical guidelines, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or chemical dependents;
- The fact that the product does not substitute and does not have the same performance of normal bone and therefore can break, deform or loosen due to excessive effort or activities of early load and other situations;
- All postoperative restrictions, especially the related to sportive activities and occupational;
- The fact that the postoperative complications represent a greater risk when the product is used in patients with functional expectations beyond those that can be promoted by articular replacement, patients with morbid obesity and patients with small bones;
- The necessity of use, exclusively, the medical criterion of external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load;
- The necessity for periodic medical monitoring to check the conditions of the implant, the bone and the adjacent tissues;
- The fact that the non-performing of the review surgery when the components release can results in progressive loss of bone stock;
- The fact that implants can interfere with results of imaging examinations. Thus, implant users should report this fact when carrying out such examinations;
- The complications related to the knee 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 product is supplied in the sterile product condition. The sterilization method is the sterilization by Gamma Radiation (dose 25kGy).

The production of CrCo Cemented Base Component is made with great care to meet the desired performance for the product. Thus, the surgical team and others involved should handle the devices properly to minimize the infection risk.

Sterile product – Do not re-sterilized.

Do not use the product if the packaging is violated.

Contamination Risk

As this is an implantable product, in cases where there is need the explantation of CrCo Cemented Base Component, there are risks of biologic contamination and viral disease transmission.

For minimize these risks, the explanted components should be treated as contaminant potentially material and should be adopted the standardization and/or other local regulations applicable.

Product Discard

The explanted CrCo Cemented Base Component or considered improper for use, should be discarded. It is recommended before discard that the product be mischaracterized, for this, the parts can be cut, bent or polished.

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 contaminants potentially 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. The necessary information for traceability is relatives to the product used, surgery and patient, as below:

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

The surgeon in charge and his team must use the labels for traceability supplied in the product packaging, pasting them into the patient's medical record to maintenance of the traceability of the implanted product. In addition, one of these labels should be supplied to the patient to have the information about the product implanted in his surgery.

The labels contain the product data such as: code, description, batch number and ANVISA registration, 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 light incidence, humidity or contaminants substances.

Because it is a sterile product, temperature and humidity of the storage site should 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 use, being that the surgical packaging opening and handling of the product 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, validity term and batch number: see label.

Other Information

Manufactured and distributed by:
MDT Indústria Comércio Importação e Exportação de Implantes SA.
Av. Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP
CEP 13.505-600
Phone/Fax: (55-19) 2111-6500
Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Review: 01
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Registration ANVISA #: 10417940061

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

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