











Instructions for Use

Pedicol Plus Posterior Spine System

Legends of the symbols used on packaging

	Product Code		Keep protected of humidity
	Manufacturing Date		Batch Number
	Single Use Product		Read the Use Instructions
	Non Sterile		Do not use if the packaging is violated
	Take Care - Fragile		Avoid exposure to direct sunlight

Specifications and technical characteristics of the product

Technical Name: Column Posterior System for fixing on blade, pedicle, apophysis or massive articular

Commercial Name: Pedicol Plus Posterior Spine System

System Components:

- Pedicol Plus Monoaxial Screw;
- Pedicol Plus Monoaxial Spondylo Screw;
- Pedicol Plus Polyaxial Screw;
- Pedicol Plus Polyaxial Spondylo Screw;
- Gescol Plus Distractor Hook (Laminar/ Pedicular);
- Pedicol/ Gescol Plus Compression Screw;
- Longitudinal Rod for Pedicular Screw – Internal Hexagonal;
- GFE Cone Morse Cross Link Hook for Bar Ø 5.5 mm;

Raw Material: Titanium Alloy (Ti-6Al-4V)

Non Sterile Product

Sterilization Method: Sterilization by humid heat (autoclave)

Validity: Indeterminate

Description

The components that compose the Pedicol Plus Posterior Spine System consist of surgical invasive implants of long term use for fixation and stabilization of the vertebral column.

The product was designed to fixation and stabilization of the thoracic segments, thoraco lumbar, lumbar and lumbosacral with bars and screws by posterior access in surgical procedures for arthrodesis of the vertebral column.

The objective of the Pedicol Plus Posterior Spine System is to treat instabilities and/or deformities, constituting an internal fixation system mono and multi segmental that ensure immediate stability of instrumented segments. Its components were designed to adapt itself to anatomy of the patient's column.

This internal fixation system of the vertebral column uses the vertebral pedicle as anchorage point. The screw base is fixed along the pedicle (following the column physiological curve) so that the bar can be implanted in straight line, propitiating the mechanical support of the loads and movements in which are submitted the vertebral column.

Following, the description of the components that compose the Pedicol Plus Posterior Spine System:

The **Screws** are manufactured from titanium alloy (Ti-6Al-4V). Versions are presented in: monoaxial, spondylo monoaxial, polyaxial, and spondylo polyaxial with cylindrical shape and asymmetric, shallow thread (type HA). The dimensions vary from diameter 4,8 to 8,5 mm and length from 25 to 55 mm.

The **Hooks** are manufactured from titanium alloy (Ti-6Al-4V). The drawing of parts was designed to adapt itself to anatomy of the patient column. They have upper locking device which facilitates the fitting of the rods and a better grip.

The **compression screw** is made from titanium alloy (Ti-6Al-4V), has hexagonal shape, whose purpose is fixing and blocking the bolt head and/or hooks to the longitudinal bar, thus constituting the stabilization system.

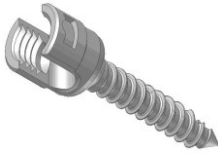
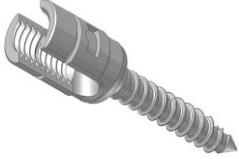





The **Longitudinal Bars**, fabricated from titanium alloy (Ti-6Al-4V) are cylindrical shaped, to provide a coupling with the screw or hooks. Its cylindrical shape allows – during the implantation of the components – the surgeon to slide the bar over the screws and/or hooks, to obtaining the alignment necessary before the instrumented segment stabilization.




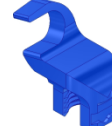


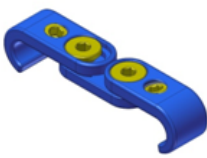
The bars can be curved (molded) when necessary to take the most appropriate and desired spinal contour. It is possible to achieve such a contour more successfully, making a series of small incremental adjustments in the bar, ensuring the same stress distribution curves of the adjustments. Thus, at the end of the procedure, the strength of polyaxial system should be comparable to the monoaxial system.

The plain bars have in their ends an internal hexagonal, whose function is the coupling to the instruments for insertion, allowing maneuver *in situ*. The plain bars are available for commercialization in the diameter 5,5 mm and lengths varying between 50 and 500 mm

The **Cross Link Cone Morse Hook**, manufactured from titanium alloy (Ti-6Al-4V), has two claws attached to a plain bar with lengths ranging from 35 to 58 mm. They are intended to fixing between the longitudinal bars of the column, in order to connect them and promote additional stability to the system.

Following, illustrative images of components that compose the Pedicol Plus Posterior Spine System:

			
Pedicol Plus Monoaxial Screw	Pedicol Plus Monoaxial Spondylo Screw	Pedicol Plus Polyaxial Screw	Pedicol Plus Polyaxial Spondylo Screw
			
Gescol Plus Lamina Distractor Hook	Gescol Plus Lamina Distractor Hook Long	Gescol Plus Pedicular Distractor Hook	

			
Gescol Plus Right Lamina Distractor Hook		Gescol Plus Left Lamina Distractor Hook	
			
Pedicol/Gescol Plus Compression Screw	Longitudinal Bar for Pedicular Screw – Internal Hexagonal	GFE Cone Morse Cross Link Hook for Bar Ø 5.5 mm	

Composition

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

The components that compose the Pedicol Plus Posterior Spine System are manufactured from titanium alloy (Ti-6Al-4V) due to its properties that it makes an ideal material to producing of implantable medical devices. Its main properties are the biocompatibility, mechanical resistance and wear resistance.

The titanium alloy (Ti-6Al-4V) used to manufacturing of the product meets specified requirements by standard ASTM F-136 - Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) for Surgical Implant Applications (UNS R56401).

Characterized as an alloy with mechanical and metallurgic properties favorable for this aim, the titanium alloy (Ti-6Al-4V) specified by standard ASTM F-136 presents biocompatibility proven by a vast historic widely described in the worldwide literature.

Indication and Purpose

The purpose of the Pedicol Plus Posterior Spine System is the fixation and stabilization of the thoracic segments, thoraco lumbar, lumbar and lumbosacral by posterior access in surgical procedures of the vertebral column. It is indicated for:

- Coronal axis deformities (scoliosis) or sagittal (kyphosis or lordosis);
- Degenerative Instabilities – Review of surgeries, stenosis, spondylolisthesis, intervertebral disc degeneration, pseudoarthrosis;
- Tumors – Surgical treatments for stabilization;
- Fractures and dislocations.

The use of the Pedicol Plus Posterior Spine System, by posterior access may also be associated with the use of intervertebral spacers, depending on the pathology to be treated.

The product described here was developed for use in the above circumstances; and any other using is considered contra indicated or without scientific substrate.

Contra Indication

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

- Patients with general active infections or specific that can lead to complications with the fixation;
- Patients with impaired general state and/or immune compromised, unable to be submitted to a surgical procedure;
- Patients with sensibility to foreign bodies, being that in these cases, tests should be performed;
- Patients with osteoporosis and/or bone affections that may compromise the fixation stability;
- Patients who use narcotic substance, alcohol or smoke;

Forms of Presentation

The components that compose the Pedicol Plus Posterior Spine System are available for commercialization, unitarily packed in the non-sterile product condition in double polypropylene plastic packaging.

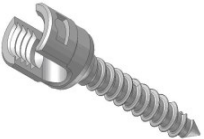
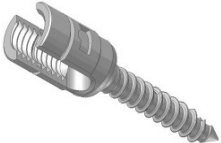

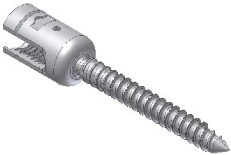



The components that compose the Pedicol Plus Posterior Spine System are available for commercialization in non-sterile product condition.

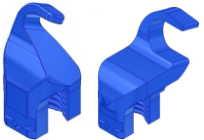
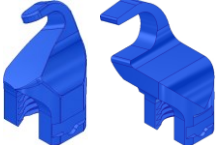


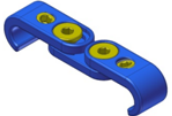
Inside of second packaging are five copies of traceability labels and a note with the use instructions, which presents this condition of non-sterile product, as well as the instructions for handling and using the product.

On the packaging is glued a label containing the necessary information for the product identification.

The Pedicol Plus Posterior Spine System is presented by the following components, and each one is available for marketing in the following dimensions:

List of Components that compose the Pedicol Plus Posterior Spine System:

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packaged Quantity
	04.24.60.XXXXX	Pedicol Plus Monoaxial Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 25, 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 8.5 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.63.XXXXX	Pedicol Plus Monoaxial Spondylo Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 25, 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 8.5 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.61.XXXXX	Pedicol Plus Polyaxial Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 25, 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.5 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.64.XXXXX	Pedicol Plus Polyaxial Spondylo Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 25, 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.5 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.13.XXXXX	Gescol Plus Laminar Distractor Hook Ti	4,5x16 mm; 5,0x14 mm; 7,5x14 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.14.XXXXX	Gescol Plus Laminar Distractor Hook Ti Long	5,0x14 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.15.XXXXX	Gescol Plus Pedicular Distractor Hook Ti	8,0x16 mm;	Titanium Alloy (Ti-6Al-4V)	01

	04.09.16.XXXXX	Gescol Plus Right Laminar Distractor Hook Ti	4.5x13 mm; 5,0x13 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.17.XXXXX	Gescol Plus Left Laminar Distractor Hook Ti	4.5x13 mm; 5,0x13 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.09.00008	Pedicol/ Gescol Plus Compression Screw	Single	Titanium Alloy (Ti-6Al-4V)	01
	04.03.06.XXXXX	Longitudinal Bar for Pedicular Screw – Internal Hexagonal	Ø 5.5 mm – 050, 060, 070, 080, 090, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 250, 300, 350, 400, 450, 500 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.09.29.550XX	GFE Cone Morse Cross Link Hook for Bar Ø 5.5mm	Length: From 35,0 to 37,5 mm; From 37,0 to 40,0 mm; From 39,5 to 46,5 mm; From 46,0 to 58,0 mm	Titanium Alloy (Ti-6Al-4V)	01

The correct selection of models and measures of the system components that will be implanted is responsibility of the surgeon in charge for the technique adopted. The surgeon 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, positioning and fixation of the devices, which are the responsibility of the surgeon that assesses the patient and decides which the implants to be used. It is also bound to strict compliance with postoperative care recommended by the surgeon in charge.

Support Material

The supporting materials are instrumentals designed solely for components that compose the Pedicol Plus Posterior Spine System implantation.

These instrumentals are made in stainless steel that meets the specified requirements by standard ASTM F-899 – Standard Specification for Stainless Steel for Surgical Instruments, which gives them high resistance and durability.

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

See list of instrumentals below available by manufacturer or by them indicated to implantation of the Pedicol Plus Posterior Spine System:

- Instrumental – Pedicol Plus;
- Instrumental – Gescol Plus;

The instrumentals are provided decontaminated, but not sterilized. Inadequate 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 for possible wear and damage.

For more information about the instrumental, consult the representative.

Warning and Precautions

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

- The Pedicol Plus Posterior Spine System must be only used after a detailed analysis of the surgical procedure to be adopted and complete reading of this use instruction;
- The product must be only used by specialized surgical team, with specific knowledge and capacity on the vertebral column stabilization techniques, being the responsibility of the surgeon the choice and dominion of the technique to be applied;
- The selection and inadequate choice of the implants to be used, as well as the mistakes in the indication, handling and surgical technique can cause excessive tensions 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;
- The product using must always be associated with bone grafting;
- The surgical procedure for Intersomatic bone fusion presents risks of vascular injuries, visceral, neural, pseudoarthrosis, among others;
- 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 risk of failure of the implant are greater in patients engaged in efforts activities or practice sports activities, during the postoperative period, contrary to the medical restriction;
- The postoperative complications represent a greater risk when the product is used in patients with morbid obesity;
- The product should not be used if it do not have an adequate bone support to ensure the implant stability;
- The screw implantation in improper positions can cause vascular damage, nerves or injuries in organs;
- The patient must make a periodic medical monitoring to check the conditions of the implant, of the bone and adjacent tissues;
- Under medical criteria, 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;
- Under medical criteria, longitudinal bars might be molded, when needed, in order to take the most properly spinal contour. However such molding should avoid movement repetition on determined point, for such repetition can lead to fatigue and consequent fracture of the material.

- The longitudinal bars should be molded ONLY ONCE, through small gradual adjustments, ensuring the distribution of stresses on the bar;
- After being molded once, the bars CANNOT be remolded.
- The product should not be used with components made by other manufacturers or distinct aim.
- The combination of implants from different manufacturers or purposes may result in a mismatch between system components as well as incompatibility between the materials for manufacturing the components, resulting in a risk of galvanic corrosion;
- Qualified personnel should be in charge of looking after this material, which should follow the standards and/or further local regulations applicable;
- Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary the operator 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 the 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;
- REPROCESS PROHIBITED;
- Non Sterile Product – must be sterilized before use and handled properly to avoid contamination;
- Improper sterilization of implants can cause infection;
- Manufacturing date and batch number: see label.

Adverse Effects

Every surgical procedure presents risks and possibility of complications, being that any 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:

- Risks of vascular injury, visceral and neural;
- Absence or delay of bone fusion (pseudoarthrosis) resulting in implant breaking;
- Loosening, dismemberment, displacement, twisting or break of the implant;
- Deformation or fracture of the implant;
- Fracture of vertebrae parts;
- Pains, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Bone necrosis or adjacent soft tissues;
- Break of the device that can make its removal difficult or impractical.

The column fixation in any level is a surgical procedure of universal recognition, however, the bone fusion of one or more vertebral-motors segments can cause overload over the adjacent levels.

Use Instructions

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

- The care of this material is responsibility of the qualified personnel, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (materials central and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for vertebral column stabilization, being the surgeon in charge by the choice and dominion of the surgical technique to be performed;

- The torque to be applied on screw during the bone insertion depends on its characteristics and conditions. Only the surgeon in charge must decide which torque to be applied;
- The implant useful life is characterized by the required time to effectuation of bone fusion, limiting to the maximum term of 01 (one) year. After this period in case of absence or problems with the bone consolidation (pseudoarthrosis), these can represent a risk of implant failure by excessive mechanical stress;
- A review surgery may be necessary, in the above cited case or if is observed the loosening of components;
- For the application of the components that compose the Pedicol Plus Posterior Spine System is necessary the use of specific instrumental, indicated in topic: "Support Materials". They should not be used with other instruments than those indicated by the manufacturer, due to possibility of dimensional and/or 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 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 in the vertebral column;
- 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 nor does 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;
- The need to restrict the effort activities or sportive practice during the postoperative period, whose extension is defined by the surgeon in charge;
- The increase of the postoperative complications risk in patients' with morbid obesity;
- 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 review surgery in a superior period of 01 (one) year, in cases in which bone fusion (pseudoarthrosis) did not occur, can lead the mechanical failure of the implant ;
- The need of review surgery in cases of components loosening;
- The fact that implants can interfere with results of imaging examinations. Thus, implant users should report this fact when submitted to such examinations;
- 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 non-sterile condition and should be removed from its original packaging and packed in proper **recipient** for sterilization (provided by the manufacturer) before use.

The indicated sterilization method for sterilization of components that compose the Pedicol Plus Posterior Spine System is the sterilization by moist heat (autoclave);

The implants are provided decontaminated by manufacturer, but should be properly handled and sterilized, as instructions below, to avoid implant contamination and consequent infection to the patient;

Sterilization Parameter

The sterilization of the components of Pedicol Plus Posterior Spine System should be done as parameters described in the table below:

Method	Cycle	Temperature	Exposure Times
Moist Heat (autoclave)	Pre-Vacuum Sterilization (vacuum) Drying	134° à 137°	10 minutes

The sterilization process must meet the theoretical probability of the presence of viable microorganisms to a maximum of 1×10^6 (S.A.L. [Sterility Assurance Level] = 10^{-6}).

The equipment conditions (autoclave) used during the sterilization process (maintenance, calibration program, etc) as well as the guarantee of use of a proper sterilization process and the product sterility proof is responsibility of qualified personal (material center) of the health service.

Cleaning

The cleaning procedures described as follow are applied to the implants and their respective surgical instrumentals.

When using the components, these should be removed of its packaging and cleaned with alcohol for medical aims at 70% + distillate water 30%.

After cleaning the product must be rinsed with sterile distillate water and dried with cleaning cloth that does not release fibers.

If the cleaning process is made by thermo disinfectors' equipment with the help of descaling substances, the manufacturer guidelines should be adopted.

Contamination Risk

As this is an implantable product, in cases where there is need of components explantation, 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 applied.

Product Discard

The explanted components 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.

REPROCESS PROHIBITED.

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 of the labels for traceability supplied in the product packaging, pasting them into the patient's medical record to maintenance of the traceability of the product implanted. In addition, one of these labels should be supplied to the patient for that has information about the product implanted in his surgery.

The labels come for the following information necessary for the traceability of the product:

- Manufacturer Identification;
- Component Code;
- Component Batch Number;
- Component Description (in three languages – Portuguese, English and Spanish);
- Quantity;
- ANVISA Registration Number;
- Technical Name;
- Product Commercial Name;
- Further components that compose the System;

The traceability information are necessary to notifying by the health service and/or the patient to Sanitary Surveillance Agency - ANVISA and manufacturer, when there is occurrence of serious adverse events, for the conduct of appropriate investigations.

Storage and Transport

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

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

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

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

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

Further Information



Manufactured and distributed by:

MDT – Indústria Comércio Importação e Exportação de Implantes SA

Av. Brasil, nº. 2983 – Distrito Industrial – 13.505-600 - Rio Claro/SP – Brasil

Phone/Fax: (55-19) 2111-6500

CNPJ: 01.025.974/0001-92

Technical Responsible: Miguel Lopes Monte Júnior – CREA: 0601150192

ANVISA Registration #: 10417940083

Review: 00

Issue: April, 29th 2013

ALERT INSTRUCTIONS FOR USE

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

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

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

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

Customer Service Department:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

<http://www.mdt.com.br>

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

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



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