Instructions for Use

SAFE Posterior Spine System

Legends of the symbols used on packaging

	Product Code		Batch Number
	Manufacturing Date		Read the Use Instructions
	Single Use Product		Do not use if the packaging is violated
	Non Sterile		Avoid exposure to direct sunlight
	Take Care - Fragile		Mark CE according to Directive 93/42/CEE – MDD. When applicable.
	Keep protected of humidity		

Specifications and technical characteristics of the product

Technical Name: Implantable Material

Commercial Name: SAFE Posterior Spine System

System Components:

- SAFE Monoaxial Screw;
- SAFE Monoaxial Spondylo Screw;
- SAFE Polyaxial Screw;
- SAFE Polyaxial Spondylo Screw;
- SAFE Iliac Screw;
- SAFE Hooks (Laminar/Pedicular);
- SAFE Connectors;
- SAFE Compression Screw;
- Longitudinal Bar for Pedicular Screw – External Hexagon;
- Connection Bar for Bridge Hook;
- CrossLink Hook II Ti;

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 SAFE Posterior Spine System consist of surgical invasive implants of long term use to 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 SAFE Posterior Spine System is 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 components description that compose the SAFE Posterior Spine System:

The **Screws** are manufactured from titanium alloy (Ti-6Al-4V). Are presented in the versions: monoaxial, spondylo monoaxial, polyaxial, and spondylo polyaxial and iliac with cylindrical shape and shallow thread. The dimensions vary of 4,8 to 8,1 mm of diameters and 25 to 55 mm of lengths.

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.

The **Connectors for Bar Extension** are made from titanium alloy (Ti-6Al-4V), in the right and left versions, intended to connections between bars when is needed review' surgery for adjacent segments arthrodesis to the already instrumented.

The **Sacroiliac Connectors** are made from titanium alloy (Ti-6Al-4V), in the right and left versions, intended to connection of iliac screw to longitudinal bars.

The **Compression Screw** is fabricated from titanium alloy (Ti-6Al-4V), has hexagonal shape, whose purpose is the fixation and blockade of screw head and/or hooks to longitudinal bar, thus constituting the stabilization system.

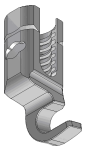
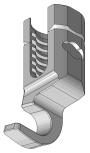
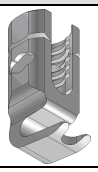
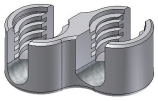
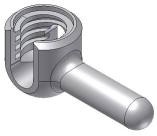
The **Longitudinal Bars**, fabricated from titanium alloy (Ti-6Al-4V), have a cylindrical shape, to provide a coupling with the screw or hooks. Its cylindrical shape allows that the surgeon slides the bar over the screws and/or hooks to obtaining of need alignment before the instrumented segment stabilization.

When necessary, the bars can be curved (moulded), to take the most appropriate form of desired spinal contour. Making a series of gradual adjustments small in the bar is possible to have success with such contours, ensuring the same distribution of tensions to curvatures of the adjustments. So, to the procedure end, the polyaxial system resistance should be compared with of monoaxial system.

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

The **Connection Bar**, manufactured from titanium alloy (Ti-6Al-4V) has a shape square with lengths varying between 40 and 100 mm. Its function is the connection between plain bars complementing the system assembly. The use of Connection Bar aims to provide system rotational stability.

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

<table>
<tr><td colspan="2">  </td><td>  </td><td>  </td><td>  </td><td>  </td></tr>
<tr><td colspan="2">SAFE Monoaxial Screw</td><td>SAFE Monoaxial Spondylo Screw</td><td>SAFE Polyaxial Screw</td><td>SAFE Polyaxial Spondylo Screw</td><td>SAFE Iliac Screw</td></tr>
<tr><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Laminar Right</td><td>Laminar Left</td><td>Pedicular</td><td colspan="2">Connector of Extension for Right/Left Bar</td><td colspan="2">Sacroiliac Connector Right / Left</td></tr>
<tr><td colspan="3">SAFE Hooks</td><td colspan="4">SAFE Connectors</td></tr>
</table>

			
SAFE Compression Screw	**Longitudinal Bar for Pedicular Screw – External Hexagon**	**Connection Bar for Bridge Hook**	**CrossLink Hook II Ti**

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 SAFE 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 SAFE Posterior Spine System has as purpose 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 SAFE 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

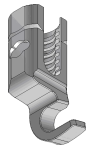
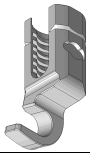
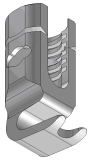
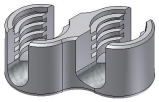
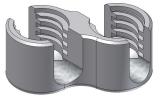
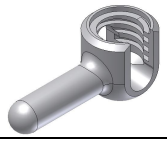
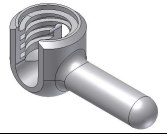
The components that compose the **SAFE Posterior Spine System** are available for marketing unitarily packed in the non sterile product condition in polypropylene plastic packaging double.

Inside of second packaging follow five traceability labels and a note with the use instructions, in which presents this condition of non sterile product, as well as the instructions for handling and product use. Over the packaging is glued a label containing the necessary information for the product identification.

The SAFE Posterior Spine System is comprised by the following components, being that each one of these components is available for marketing in the following dimensions:

List of Components that compose the SAFE Posterior Spine System:

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packaged Quantity
	04.24.90.XXXXX	SAFE Monoaxial Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.3 mm – 30, 35, 40, 45, 50, 55 mm; Ø 8.1 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.88.XXXXX	SAFE Monoaxial Spondylo Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.3 mm – 30, 35, 40, 45, 50, 55 mm; Ø 8.1 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.91.XXXXX	SAFE Polyaxial Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.3 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.7 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.89.XXXXX	SAFE Polyaxial Spondylo Screw;	Ø 4.8 mm – 25, 30, 35, 40 mm; Ø 5.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 6.5 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.3 mm – 30, 35, 40, 45, 50, 55 mm; Ø 7.7 mm – 30, 35, 40, 45, 50, 55 mm;	Titanium Alloy (Ti-6Al-4V)	01

	04.43.01.730XX	SAFE Iliac Screw;	Ø 7.3 mm – 30, 35, 40, 45 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.31.XXXXX	SAFE Laminar Hook Right;	6,2x05 mm; 8,5x05 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.32.XXXXX	SAFE Laminar Hook Left;	6,2x05 mm; 8,5x05 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.33.XXXXX	SAFE Pedicular Hook;	5,5x08 mm; 7,0x08 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.20.04.00001	SAFE Right Extension Connector for Bar Ø 5.5 mm;	Single;	Titanium Alloy (Ti-6Al-4V)	01
	04.20.04.00002	SAFE Left Extension Connector for Bar Ø 5.5 mm;	Single;	Titanium Alloy (Ti-6Al-4V)	01
	04.20.07.000XX	SAFE Right Sacroiliac Connector;	20 mm; 25 mm; 30 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.20.08.000XX	SAFE Left Sacroiliac Connector;	20 mm; 25 mm; 30 mm;	Titanium Alloy (Ti-6Al-4V)	01

	04.24.09.00010	SAFE Compression Screw;	Single;	Titanium Alloy (Ti-6Al-4V)	01
	04.03.09.55XXX	Longitudinal Bar for Pedicular Screw – External Hexagon	Ø 5.5 mm – 050, 060,0 70, 080,0 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 250, 300, 350, 400, 450, 500, 550, 600 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.03.01.00XXX	Connection Bar for Bridge Hook;	40, 50, 60, 70, 80, 100 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.09.01.00001	Cross Link Hook II Ti	Single;	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 SAFE 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 him 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 SAFE Posterior Spine System:

- 0C.32 – Instrumental – SAFE System

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 SAFE 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;
- The 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;
- The product should not be used with components from other manufacturers or purpose. The combination of implant of manufacturers or different purpose can result in incongruence between the components;

- The care of these materials are the responsibility of qualified personnel, which should follow the standards and/or other local regulations applied;
- 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;
- PROHIBITED REPROCESS;
- 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 the 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 applies;
- 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 represents a risk of implant failure by excessive mechanical stress;
- May be necessary the review' surgery, in the above cited case or if is observed the loosening of components;

- For the application of the components that compose the SAFE Posterior Spine System is necessary the use of specific instrumental, indicated in topic: “Support Materials”. They should be not used with other instruments than those indicated by the manufacturer, due to possibility of dimensional incompatibility and/or functional;

Guidance to the patient and/or the Legal Representative

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

- The adequate 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 guidelines medical, 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;
- 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, the medical criteria exclusively 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 in a superior term the 01 (one) year, in cases in which not occurred bone fusion (pseudoarthrosis) 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 carrying out 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 the 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 SAFE 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 SAFE 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	134º à 137º	10 minutes

The sterilization process must meet the theoretical probability of the presence of vitals microorganisms to a maximum of $1x10^{6}$ (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 (materials central) of the health service.

Cleaning

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

When components use, 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' equipments 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.

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 contain the product data as: code, description and lot number, among other information as the number of the product registration at ANVISA.

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.

Other information

Manufactured and distributed by:

MDT – Indústria Comércio Importação e Exportação de Implantes Ltda.

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

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

Technical Responsible: Miguel Lopes Monte Junior – 0601150192

CE 0297 (according to Directive 93/42/EEC)

Review: 00

Issue: March 28th 2011

Registration ANVISA #: 10417940075

MDT

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 CAP (Customer Service Department) manufacturer, as following:

Customer Service Department – CAP:

Telephone: +55 19 2111.6500

FAX: +55 19 2111.6500

http://www.mdt.com.br/contato

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

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