Instructions for Use

Anterolateral System for Thoracolumbar Spine

Legends of the symbols used on packaging

	Product Code		Batch Code
	Manufacturing Date		Consult the Use Instructions
	Single Use Product		Do not use if the packaging is damaged
	Non Sterile		Keep out of the sun
	Fragile, handling with care	CE XXXX	Conformity Mark Directive 93/42/CEE - When applicable
	Keep dry		

Specifications and technical characteristics of the product

Technical Name: Spine Anterior System for intersomatic fixation

Commercial Name: Anterolateral System for Thoracolumbar Spine

System Components:

- Ti Thoracic Plate;
- Ti Lumbar Plate;
- Thoracic Screw;
- Lumbar Screw;
- Accessory: Hex nut for thoracolumbar screw;

Raw Material: Titanium Alloy (Ti-6Al-4V) – ASTM F-136

Non Sterile Product

Sterilization Method: Sterilization by humid heat (autoclave)

Validity: Indeterminate

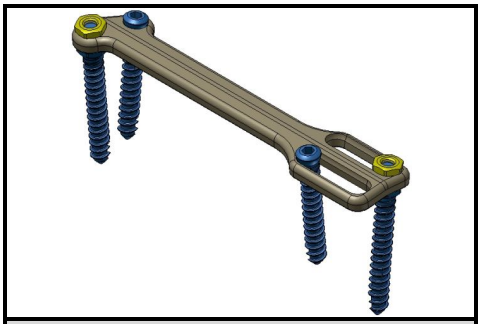
Description

The Anterolateral System for Thoracolumbar Spine is formed by surgical invasive implants of long term use for the anterolateral fixation of the thoracic, thoracolumbar and lumbar segments of the vertebral column.

The operating principle of the Anterolateral System for Thoracic-Lumbar Spine is to act as an internal fixator, maintaining or restoring the stability of the column, in order to prevent or correct deformities of varying etiologies. At the same time, the implant associated with bone graft insertion, propitiates bone fusion by arthrodesis of the instrumented segments.

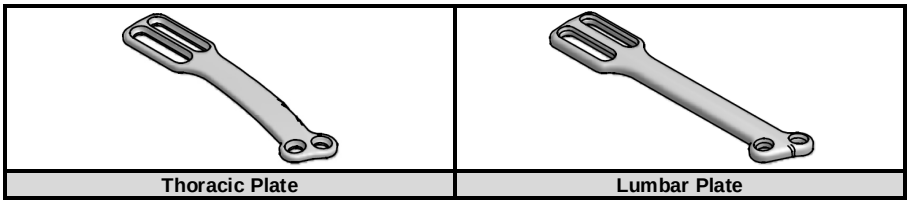
The product is a rigid segmental anterolateral fixation system in which the longitudinal component is a dimensioned plate for the application to the lateral face of the thoracic and lumbar segments or thoracolumbar transition, complemented by screws and nut for bone fixation. The system was designed to support loads of axial compression, flexion-extension, and rotation of the vertebral bodies. This way, it performs the immobilization of the segments and also the transmission or relieving mechanical stress on the components of the spine acting as a bridge (tension band).

The product is characterized for supporting mechanical stress at the required extent, presenting tensile modulus and interfaces with the bone, suitable for transmission of forces on the thoracic and lumbar spine and thoracolumbar transition for it is biocompatible and adapt to the bone geometry of the vertebral column.



Anterolateral System for Thoracolumbar Spine

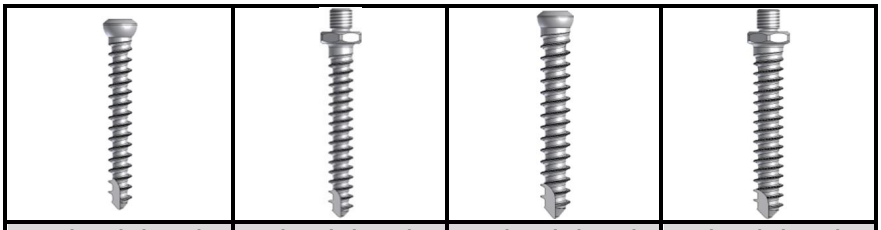
The components Thoracic Plate and Lumbar Plate are made of titanium alloy (Ti-6Al-4V), thickness of 3.18 mm and 4.75 mm, respectively. Both have an angle of 10º to follow the anatomic profile of the column and increase resistance to screw pullout. The holes for insertion of the screw, at one end of the plate, are round for coupling the screw head and at the other end the hole is oblong type with the possibility of screw adjustment, providing a better positioning of the plate. In order to meet several clinical needs and patient's biotypes, the thoracic plate is available for commercialization in lengths ranging from 40 mm to 110 mm and the lumbar plate is available for commercialization in lengths ranging from 50 mm to 130 mm.



Thoracic Plate	Lumbar Plate

The components Thoracic Screw and Lumbar Screw are made of titanium alloy (Ti-6Al-4V) have parallel thread with asymmetric profile and shallow type, with a cut at the tip, which provides a self-drilling feature. The unthreaded head screws have internal hex slit for coupling the screwdriver (male) of 3.5 mm, while the threaded head screws have external hex feature for coupling the screwdriver (female) of 9.0 mm.

The screws are available for sale in Ø 5.5 mm and lengths ranging from 25 mm to 45 mm in the thoracic version and Ø 6.5 mm and lengths ranging from 35 mm to 55 mm in the lumbar version.



Unthreaded Head	Threaded Head	Unthreaded Head	Threaded Head
Thoracic Screw		Lumbar Screw	

The Hex Nut for Thoracolumbar Screw complements the system with ancillary function and is manufactured from titanium alloy (Ti-6Al-4V). It has hexagonal design, whose purpose is the fixation and blocking of the thoracic and lumbar threaded head screws to the thoracic and/or lumbar plates, thus forming the stabilization system.

Hex Nut for Thoracic Lumbar Screw

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 form Anterolateral System for Thoracolumbar Spine are made of titanium alloy (Ti-6Al-4V) due to its properties that make it an ideal material to the production of implantable medical devices. Its main properties are the biocompatibility, mechanical resistance and corrosion 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).

The manufacturing material is compatible with biological tissues, cells and bodily tissues which they come in contact with in implantable state, proven by a vast similar use historic available in worldwide scientific and clinical literature.

Indication and Purpose

The Anterolateral System for Thoracolumbar Spine is used in fixation procedures and spinal fusion through left anterolateral approach of the thoracic and lumbar segments and thoracolumbar transition. The product is indicated for the treatment of spinal diseases of degenerative, traumatic, congenital, neoplastic, infectious, rheumatic origins or others for which the fixation is indicated.

The product design was projected for fixation exclusively on the left anterolateral portion of the thoracic and / or lumbar spine including the thoracolumbar transition. The system can be associated, under medical criteria, with bone graft placement, with or without osteo-conductive material in the intervertebral space, with or without intersomatic devices.

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

Contraindication

Next, the related contra indications for the product use are listed, 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;
- The system should not be used on the right anterolateral face of the thoracic lumbar spine and/or thoracolumbar transition;

Forms of Presentation

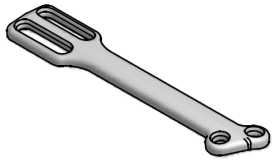
The components that compose the Anterolateral System for Thoracolumbar Spine are available for the market unitarily packed in polypropylene plastic double packaging

The components that compose the System are available for commercialization in the non-sterile product condition. Inside the second packaging are five copies of the traceability label and a leaflet with the use instructions, which presents this condition of non-sterile product, as well as the instructions for handling and product use.

Over the packaging a label containing the necessary information for the product identification is pasted.

The Anterolateral System for Thoracolumbar Spine consists of the following components, and each of these components are available for sale in the following dimensions:

List of the components of the Anterolateral System for Thoracolumbar Spine

Illustrative Image	Code	Description	Dimensions	Made of	Qtty Packed
	04.26.43.00040	Thoracic Plate Ti 040 mm;	**Length:** 40, 50, 60, 70, 80, 90, 100 and 110 mm; **Width:** 21 mm **Thickness:** 3,18 mm	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.26.43.00050	Thoracic Plate Ti 050 mm;			
	04.26.43.00060	Thoracic Plate Ti 060 mm;			
	04.26.43.00070	Thoracic Plate Ti 070 mm;			
	04.26.43.00080	Thoracic Plate Ti 080 mm;			
	04.26.43.00090	Thoracic Plate Ti 090 mm;			
	04.26.43.00100	Thoracic Plate Ti 100 mm;			
	04.26.43.00110	Thoracic Plate Ti 110 mm;			
	04.26.42.00050	Lumbar Plate Ti 050 mm;	**Length:** 50, 60, 70, 80, 90, 100, 110, 120 and 130 mm; **Width:** 25 mm **Thickness:** 4,75 mm	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.26.42.00060	Lumbar Plate Ti 060 mm;			
	04.26.42.00070	Lumbar Plate Ti 070 mm;			
	04.26.42.00080	Lumbar Plate Ti 080 mm;			
	04.26.42.00090	Lumbar Plate Ti 090 mm;			
	04.26.42.00100	Lumbar Plate Ti 100 mm;			
	04.26.42.00110	Lumbar Plate Ti 110 mm;			
	04.26.42.00120	Lumbar Plate Ti 120 mm;			
	04.26.42.00130	Lumbar Plate Ti 130 mm;			
	04.43.16.55025	Thoracic Screw Ø 5,5x25 mm;	**Diameter:** 5,5 mm: **Length:** 25, 30, 35, 40 and 45 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.43.16.55030	Thoracic Screw Ø 5,5x30 mm;			
	04.43.16.55035	Thoracic Screw Ø 5,5x35 mm;			
	04.43.16.55040	Thoracic Screw Ø 5,5x40 mm;			
	04.43.16.55045	Thoracic Screw Ø 5,5x45 mm;			
	04.43.15.55030	Thoracic Screw Ø 5,5x30 mm Head with Thread	**Diameter:** 5,5 mm: **Length:** 30, 35 and 40 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.43.15.55035	Thoracic Screw Ø 5,5x35 mm Head with Thread			
	04.43.15.55040	Thoracic Screw Ø 5,5x40 mm Head with Thread			

	04.43.14.65035	Lumbar Screw Ø 6,5x35 mm;	**Diameter:** 6,5 mm: **Length:** 35, 40, 45, 50 and 55 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.43.14.65040	Lumbar Screw Ø 6,5x40 mm;			
	04.43.14.65045	Lumbar Screw Ø 6,5x45 mm;			
	04.43.14.65050	Lumbar Screw Ø 6,5x50 mm;			
	04.43.14.65055	Lumbar Screw Ø 6,5x55 mm;			
	04.43.13.65040	Lumbar Screw Ø 6,5x40 mm Head with Thread;	**Diameter:** 6,5 mm: **Length:** 40, 45 and 50 mm;	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01
	04.43.13.65045	Lumbar Screw Ø 6,5x45 mm Head with Thread;			
	04.43.13.65050	Lumbar Screw Ø 6,5x50 mm Head with Thread;			
	04.22.06.00000	Hexagonal Nut for Thoracolumbar Screw	Single Size	Titanium Alloy (Ti-6Al-4V) ASTM F-136	01

The correct selection and combination of the components, dimensions and surgical technique for implanting the Anterolateral System for Thoracolumbar Spine is responsibility of the surgeon in charge, who 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 evaluates the patient and decides which implants to be used. It is also linked to strict compliance with postoperative care recommended by the surgeon in charge.

Support Material

The supporting materials are instruments designed solely for implanting of the Anterolateral System for Thoracolumbar Spine.

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.

See below the list of the instruments available by the manufacturer or their indication for implanting the Anterolateral System for Thoracolumbar Spine:

- Instrument – Thoracolumbar Plate

The instruments 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 product 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, pseudarthrosis, among others;
- The product design was projected for fixation exclusively on the left anterolateral portion of the thoracic and/or lumbar spine including the thoracolumbar transition;
- The screw implantation in improper position can cause vascular damage, nerves or injuries in organs;
- 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 patient should undergo periodic medical monitoring to check the conditions of the implant, of the bone and adjacent tissues;

- A prophylactic pre and perioperative antibiotic therapy, can be used under medical criteria and the antibiotic therapy 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 made by other manufacturers or distinct aim. The combination of implants from different manufacturers or purposes may result in a incongruence between the components;
- Qualified personnel should be in charge of looking after this material, which should follow the standards and/or further local regulations applicable;
- Fall or 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;
- REPROCESS PROHIBITED;
- 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;
- Non Sterile Product – must be sterilized before use and handled properly to avoid contamination;
- Improper sterilization of products can cause infection;
- Manufacturing date and batch number: see label;

Adverse Effects

Every surgical procedure has risks and possible complications, and some common risks are infection, bleeding, drug allergic reactions and anesthetic risks, among others, and yet, the following complications and adverse effects can be associated with the implantation of the product:

- Risks of vascular injury, visceral and neural;
- Absence or delay of bone fusion (pseudarthrosis) 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 (pseudarthrosis), these can represents 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;
- Specific instruments are necessary for the application of the components that compose the product, indicated at the topic “Supporting Material”. They should not be used with other instruments than those indicated by the manufacturer, due to possibility of dimensional and/or functional incompatibly.

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 dependence;
- 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 (pseudarthrosis) 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 method for sterilization of the product is 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 product should be done according to the parameters described below:

Method	Cycle	*Temperature*	Exposure Times
Moist Heat (autoclave)	Pre-Vacuum Sterilization (vacuum) Drying	134º to 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 (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.

REPROCESSING 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 the traceability labels provided in five copies inside the product package. The labels are to be pasted onto the patient medical records for keeping the implanted product traceability. Besides that, one of those labels must have given the patient in order he or she can get information about the implanted product in his/her surgical procedure.

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;

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

Storage and Transport

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

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

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

CEP: 13.505-600

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

CNPJ: 01.025.974/0001-92

Technician Responsible: Miguel Lopes Monte Júnior – CREA: 0601150192

CE 0297 (according to Directive 93/42/EEC) if applicable.

ANVISA Registration nº.: 10417940088

Review: 00

Issue: Dec 16, 2013

ALERTA
INSTRUCCIÓN DE USO

Estas INSTRUCCIONES DE USO están disponibles en formato no impreso, disponibles en el la dirección electrónica del fabricante www.mdt.com.br.

Las INSTRUCCIONES DE USO están indexadas en el sitio web a través del NUMERO REGISTRO/ ANVISA y el respectivo NOMBRE COMERCIAL del producto, informados en el rótulo del producto adquirido.

Todas las INSTRUCCIONES DE USO disponibles en el sitio web tienen la identificación de la revisión y fecha de emisión del documento. Siendo que el usuario debe estar atento para la correcta versión (revisión y fecha de emisión) del documento en relación a la FECHA DE FABRICACIÓN informada en el rótulo del producto adquirido.

Caso sea de interés del usuario, las INSTRUCCIONES DE USO podrán ser suplidas en formato impreso, sin costo adicional. Siendo que la solicitación de las mismas deberá ser realizada junto al CAP (Canal de Atendimiento al Público) del fabricante, informado en secuencia:

Canal de Atendimiento al Público – CAP:

Teléfono:+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

Horario de atendimiento: 8hs a las 17hs, de lunes hasta viernes, excepto días festivos.