Instructions for Use

Anterior System for Cervical Column – C-Lock

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
	Caution – Fragile		Mark CE according to Directive 93/42/CEE – MDD. When applicable
	Keep Protect of Humidity		

Specifications and technical characteristics of the product

Technical Name: Anterior System of Column for Intersomatic Fixation

Commercial Name: Anterior System for Cervical Column – C-Lock

Composed by:

- Anodized Anterior Cervical Plate;
- Screw for Cervical Plate 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 Anterior System for Cervical Column – C-Lock consist of surgically invasive implants of long term use to fixation and stabilization of the vertebral column.

The product was designed to fixation and stabilization of the cervical segment with plates and screws by anterior access in surgical procedures for arthrodesis of the vertebral column.

The Anterior System for Cervical Column – C-Lock is intended for treatment of pathologies of the cervical segment of vertebral column of origin degenerative, traumatic, congenital, neoplastic, infectious or otherwise, which the fixation is indicated.

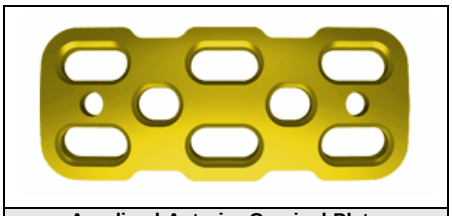
The functioning principle of implant is keep the relations between the spinal components, acting as a internal fixative and keeping the column stability, in order to prevent or correct deformities of varied etiologies.

The product constitute a segmental fixation system, where the longitudinal component is a dimensioned plate for application at anterior face of the cervical column or transition cervical-dorsal, with screws for bone fixation, intended to support loads of axial compression , flexor-extensor and rotation of the vertebral bodies.

The system is characterized by mechanical efforts support in the required proportion, presenting elasticity modulus and interface with the bone, proper to transmission of forces in the cervical column, beyond to be biocompatible and to adapt to bone geometry of the vertebral column. Thus, the implant performs the immobilization of the segments and transmission too, or relief of mechanical loads on the components of the vertebral column, acting as a bridge while promoting bone fusion for arthrodesis of instrumented segments, when associated with placement of bone grafting.

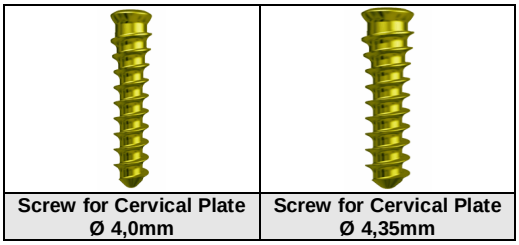
The **Anodized Anterior Cervical Plate** is manufactured from titanium alloy (Ti-6Al-4V), has low profile with thickness of 02 mm that facilitate its molding (when applicable). The device has longitudinal angulation accompanying the anatomical profile of the column and curvature accompanying the vertebral "circular" format. The holes to insertion of the screws are oblongs allowing its fixation and adaptation to several sizes of vertebrae.

To meet the clinical needs most varied and biotypes of patients, the plate is available for marketing with variations of length (24 to 107 mm) and quantity of holes (04 to 11 holes).



Anodized Anterior Cervical Plate

The **Screw for Cervical Plate Ti**, is manufactured from titanium alloy (Ti-6Al-4V), has asymmetrical thread profile and deep (type HB), with a cut in the tip which provides a characteristic self-tapping. The screw head has hexagonal crack with fitting type spherical (bottom part). The component is commercially available in diameters 4.0 and 4.35 mm, the latter for emergency cases, with lengths ranging from 10 to 22 mm for monocortical fixation.



Screw for Cervical Plate Ø 4,0mm	Screw for Cervical Plate Ø 4,35mm

Composition

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

The components that compose the Anterior System for Cervical Column – C-Lock 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 system components 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 a material with mechanical, chemical, physical properties favorable for this aim, presents biocompatibility proven by a vast clinical historic widely described in the worldwide literature.

Indication and Purpose

The Anterior System for Cervical Column – C-Lock is intended for treatment of pathologies of origin degenerative, traumatic, congenital, neoplastic or infectious of the cervical segment of the vertebral column.

The product was designed to fixation and stabilization of the cervical segment through of plates and screws by anterior access in surgical procedures for bone fusion of the vertebral column.

This type of procedure of spinal fixation can be indicated in clinical conditions very varied, as strategies of treatment adopted by the surgeon, however, the pathologies most commonly treated are:

- Cervical disc hernia;
- Cervical spondylosis;
- Trauma with fracture of vertebral body;
- Neplasm compromising the vertebral body;
- Anterior compression of marrow;
- Traumatic cervical luxation;
- Cervical instability of any etiology;
- Spinal infection with kyphotic deformity;
- Congenital deformities or acquired.

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:

- Existence of 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;
- Sensibility to foreign bodies. In suspect cases, tests in the patients should be performed;
- Patients with advanced osteoporosis and/or bone affections that may compromise the fixation stability;
- Patients who use narcotic substances, alcohol or smoke;

Forms of Presentation

The components that compose the Anterior System for Cervical Column – C-Lock are available for marketing unitarily packed in the non sterile product condition in double plastic packaging of polypropylene.

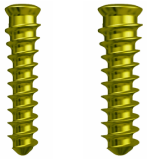
The components that compose the Anterior System for Cervical Column – C-Lock are available for marketing in the non sterile product condition.

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.

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

The Anterior System for Cervical Column – C-Lock 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 Anterior System for Cervical Column – C-Lock

Illustrative Image	Code	Description	Dimensions	Manufacturing Material	Packaged Quantity
	04.26.41.00XXX	Anodized Anterior Cervical Plate	Length: 024, 026, 028, 030, 032, 034, 036, 038, 040, 042, 044, 046, 048, 050, 054, 058, 062, 066, 068, 070, 076, 082, 088, 094, 100 e 107 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.24.34.XXXXX	Screw for Cervical Plate Ti	Diameter: 4,0 mm Length: 10, 12, 14, 16, 18, 20 mm; Diameter: 4,35 mm Length: 10, 12, 14, 16, 18, 20, 22 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 Anterior System for Cervical Column – C-Lock 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 below of instrumentals available by manufacturer or by them indicated to implantation of the Anterior System for Cervical Column C-Lock:

- 0C.29 – Instrumental – Anterior System for Cervical Column – C-Lock.

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 Anterior System for Cervical Column – C-Lock, the responsible team must consider the following warning and precautions:

- The Anterior System for Cervical Column – C-Lock 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 cervical 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 and tractions on the implant, leading to failure by fatigue, fracture and until their release;
- 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, against to the medical restriction;
- The screw implantation in improper positions can cause vascular damage, nerves or injuries in organs;
- 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 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 implant 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;
- Non Sterile Product – must be sterilized before use and handled properly to avoid contamination;
- Improper sterilization of implants can cause infection;
- PROHIBITED REPROCESS;
- 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;
- To application of Anterior System for Cervical Column – C-Lock is necessary the use of specific instrumental , indicated in the topic "Support Material", and due to possibility of functional and/or dimensional incompatibility should not be used with instruments other than those indicated by the manufacturer.

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 the Anterior System for Cervical Column – C-Lock 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 product 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 implanted product traceability. 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 implanted product. 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/CEE - MDD)

Review: 00

Issue: July 04th 2011

Registration ANVISA #: 10417940079

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.