Instruction of Use

CONNECTORS AND HOOKS

Legend of the symbols used in the packages

REF	Product Code		Avoid direct exposition to sunlight
LOT	Batch Number		Protect from humidity
	Read use instructions		Caution ! Fragile !
Material Ti/Al/V	Ti/Al/Va (ASTM F136) Alloy		Do not use if package is violated
DD/MM/YYY	Date of Manufacturing		Due Date
NON STERILE	Non sterile		One time use Product

DESCRIPTION:
Connectors and hooks are implant mechanisms made of Titanium alloy.
The design of the pieces has been projected to perfectly adapt to the anatomy of the patient's column. They have a blocking mechanism that facilitates the insertion of the stem, and a better fixation. The hooks have an internal fixation mechanism, only.

COMPOSITION:
The connectors and hooks are made of Titanium alloy, to attend to the requirements of the specification rule ASTM F136- Specification for machine-made Titanium Alloy-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) R56401 for use in surgical implantation.

INDICATION:
It is indicated to vertebral column deformities (congenital, idiopathy, neuromuscular), scoliosis, tumors, fractures.

FORMS OF PRESENTATION:
The Connectors and Hooks are available in the following models and dimensions:

Connectors:

Table - Connectors

Nº	CÓDIGO	DESCRIÇÃO
01	04.09.01.00000	Gancho CrossLink
02	04.09.01.00001	Gancho CrossLink II Ti – Para Barra Tranversal
03	04.09.02.45016	Gancho Distrator Laminar Gescol Ti 4,5 x 16 mm
04	04.09.02.50014	Gancho Distrator Laminar Gescol Ti 5,0 x 14,0 mm.
05	04.09.02.75014	Gancho Distrator Laminar Gescol Ti 7,5 x 14,0 mm

Hooks:

Table - Hooks

Nº	CÓDIGO	DESCRIÇÃO
01	04.09.01.00000	CrossLink Hook
02	04.09.01.00001	CrossLink II Ti* Hook, for Transversal Bar

03	04.09.02.45016	Gescol Laminar Distrator Hook Ti 4,5 x 16 mm
04	04.09.02.50014	Gescol Laminar Distrator Hook Ti 5,0 x 14,0 mm
05	04.09.02.75014	Gescol Laminar Distrator Hook Ti 7,5 x 14,0 mm
06	04.09.05.45009	Right Gescol Laminar Distrator Hook Ti 4,5 x 9,0 mm
	04.09.05.50014	Right Gescol Laminar Distrator Hook Ti 5,0 x 14,0 mm
07	04.09.06.45009	Left Gescol Laminar Distrator Hook Ti 4,5 x 9,0 mm
	04.09.06.50014	Left Gescol Laminar Distrator Hook Ti 5,0 x 14,0 mm
08	04.09.03.50014	Long Gescol Laminar Distrator Hook Ti Longo 5,0x14 mm
09	04.09.04.12016	Gescol Pedicular Distrator Hook 12,0 x 16 mm
	04.09.04.80016	Gescol Pedicular Distrator Hook Ti 8,0 x 16 mm
10	04.09.09.75014	Laminar Hook 7,5 x 14 mm – Pedicol Advanced
	04.09.09.90014	Laminar Hook 9 x 14 mm – Pedicol Advanced
11	04.09.10.12016	Pedicol Advanced Hook Ø 12 x 16 mm
	04.09.10.80016	Pedicol Advanced hook Ø 8 x 16 mm
12	04.09.13.45016	Gescol Plus Laminar Distrator Hook Ti 4,5 x 16 mm
	04.09.13.50014	Gescol Plus Laminar Distrator Hook Ti 5,0 x 16 mm
	04.09.13.75014	Gescol Plus Laminar Distrator Hook Ti 7,5 x 14 mm
13	04.09.17.45009	Left Gescol Plus Laminar Distrator Hook Ti 4,5x9,0mm
	04.09.17.50014	Left Gescol Plus Laminar Distrator Hook Ti 5,0x14,0mm
14	04.09.14.50014	Long Gescol Plus Laminar Distrator Hook Ti 5,0x14 mm
15	04.09.16.45009	Right Gescol Plus Laminar Distrator Hook Ti 4,5x9,0mm
	04.09.16.50014	Right Gescol Plus Laminar Distrator Hook Ti 5,0x14,0 mm
16	04.09.15.12016	Gescol Plus Pedicular Distrator Hook Ti 12,0x16,0mm
	04.09.15.80016	Gescol Plus Pedicular Distrator Hook Ti 8,0 x 16 mm

To implant the Connectors and Hooks, it is necessary to use specific instrumental, to be acquired separately of the implanting products.
Contact your MDT representative to obtain additional information regarding the instrumental.

Nº	**CÓDIGO**	**DESCRIÇÃO**
01	02.55.01.00001	Small reducer for pedicle
02	02.55.01.00002	Large reducer fo pedicle
03	02.55.02.00000	Transversal reducer
04	02.27.05.00001	GESCOL Hook positioner
05	02.07.02.00001	Gescol Manual Moulding for Pedicol Bar

The instrumentals are to be acquired separately, but always from the same manufacturer of the implant. The instrumentals are supplied uncontaminated, but not sterilized.
The surgical instruments are subject to wastage during its normal use and can break.
The surgical instruments are to be used for their proposed purposes only.
All instruments should be inspected regularly to verify possible wastage and damage.
The surgical instruments are to be acquired separately, always from the same manufacturer of the implant.
The instrumentals are supplied uncontaminated, but not sterilized. They bring the following information engraved:

- Product code
- Batch number
- Company logotype

COUNTER INDICATION:
Like any medical treatment, in general, all surgical technique even when well applied, may present problems, complications and situations where the final objective of the treatment is not partially or totally obtained, being its contraindication relevant, depending on each case and subject to the criterion and evaluation of the doctor, involving the anatomy, local biology and the precaution taken during planning and preparation before surgery, the performance and application of a perfect technique intra-operative and the socio-economical and cultural profile, in the sense that the patient will co-operate and respect the recommendations to be followed after the surgery.
However, there are rules to be followed to avoid such problems.
Some of the most frequent indications concerning to implant, although relevant (left to doctor´s discretion), are the following:

- Poor quality of cutaneous covering and soft tissues could take to the exhibition of synthesis material by skin necrosis, facilitating the installation and maintenance of infectious processes.
- The Connector and the Hook should not be used in case there is no good osseous support to assure the implant stability. In these circumstances, supplementary methods of bone grafting are to be used, be it (AUTOLOGO) or homologous, or yet, with the help of a reinforcement screen.
- Osseous necrosis induced by irradiation in consequence of radiotherapy due to cancer treatment is contraindication, once the lack of osseous support can lead to premature loosening of the implant. In this case, other techniques and implantation systems should be used.
- Local circulatory diseases, being it arterial or veined, which predispose the appearance of dehiscence and skin necrosis, appearance or maintenance of infections to thrombus embolism phenomenon.
- Systemic diseases, that due to reduction of local or general defenses or of circulatory condition may predispose to complications like dehiscence and infection.
- Neurological diseases that can bring alteration in bone resistance, or neuromuscular activity, that can overcharge the implant.
- Bone diseases rapidly destructive (example: Charcot Arthropathy, osseous tumors, etc).
- Osteonecrosis, especially post-irradiation ones, may originate infection and dehiscence problems.

- The known presence of any peculiar condition of the patient that can bring bio-incompatibility with the metallic alloy used in manufacturing of the implants.

This System is also contraindicated to the following patients:

- Young and dynamic
- Sports activities performers
- Above 102 kilos
- Presenting infectious pathology, previous or present
- Presenting aspects of dementia or neurological alterations of the inferior members
- Peculiar conditions of the patient: senility, alcoholism and infections. These conditions should be carefully investigated by the doctor, who should alert the patient regarding to the risks that such particularities can bring.

The Complications can demand additional surgery and they can include:

- Non unification or its delay, pseudo-arthrosis
- Loosening, torsion or breakage of the components
- Fracture of the vertebral process
- Neurological damage or loss of the neurological function
- Infection
- Dysfunction of the Bladder and/or Intestine
- Paralysis

The use on the above mentioned situations can cause wastage or precocious loosening of the screw, due to excess of mechanical claiming, infection and prosthetic wrench.

ADVERSE EFFECTS:

In addition to the fact that obvious risks can occur in the presence of orthopedic implants, like failure, loosening and breakage, the following tissue adverse answer risks and possible complications should be presented and discussed with the patient:

- Although there is not a connection scientifically proved reference the use of orthopedic implants with the characteristics of the materials used in the Connectors and the Hooks *MDT and the occurrence of Cancer, any risks and uncertainties reference long terms effects of joint substitution, should be discussed with the patient previously to the surgery. The patient should also be informed that any circumstances that should bring tissue chronic injury, may be cancerous. Cancerous tissue found next to implantations may be related to factors not linked directly to the implant itself, such as: primary lung tumor metastasis, breast, digestive system and other, or also due to implantation of cancerous cellules which may occur during surgical procedures or diagnostics like biopsy, and from progression of the Paget's disease.
- Implantation of material not familiar to organic tissues can result in inflammatory reactions, which can occur, for example, in the presence of debris arose from implant (like metallic debris or polyethylene), which can cause histiocytic answer, granuloma of strange body type, which can cause osseous destruction, associated or not to the loosening of the implant.
- Sensibility or atopy to metal can be found after implantation of orthopedical devices, like what occurs with Nickel, Cobalt and Chromo, which are present in stainless steel

alloys of orthopedic use. Therefore, Titanium and its alloys used in orthopedic implants, are by far, less anti-hygienic and are recommended to be used also in patients with prior historical allergy or sensibility to metals.

PRECAUTIONS:

- The Surgeon should not begin the clinical use of the Connectors and Hooks before reading carefully its use instructions. Additionally, he should use the Connectors and Hooks in special environment (ambulatory or surgical room). The medical team should verify the integrity of the screws and instrumentals before its use and also at the end of the sterilization process.
- It is advisable the use of preventive antibiotic therapy in patients carriers of joint substitutions that are submitted to proceedings that can cause transitory bacteremia (odontological procedure, endoscopy, groin vessel catheterism and other minor surgical proceedings).
- The Connectors and Hooks were conceived to be implanted through instrumental use, specially developed for this purpose. Any improvisation with different instrumental or inaccurate surgical technique may jeopardize the fixation quality and/or the implantation positioning.
- ONE TIME USE PRODUCT – DO NOT RE-USE
- The Connectors and Hooks are not supplied sterilized.
- They should be washed and sterilized before used and correctly manipulated to avoid contamination.
- Discard and DO NOT USE open or damaged devices. Use only devices properly packed in shut and not damaged packages.

THE PATIENT SHOULD BE ADVISED OF:

- The patient should be informed of all the restrictions after surgery, mainly the ones related to sports and occupational activities.
- The patient should be carefully oriented in regards to the cautions to be taken after surgery. The capacity and the determination of the patient to strictly follow the instructions are one of the most important aspects of an orthopedic surgical procedure.
- Children, old aged people, patient with mental problems, and chemical addicts may represent a bigger risk to failure of the device, once these patients tent to ignore instructions and restrictions.
- The patient should be instructed, subject the doctors´ discretion, to use external supports, aid to wander and orthopedic devices, projected to immobilize the broken area and to limit the weight.
- The patient should be informed that the product does not substitute as well as does not have the same performance of the bone and, therefore, can break, lose its shape or release due to excess of activity, precocious loading, etc.
- The patient should be oriented to inform being a carrier of an implant in case of being submitted to Magnetic Resonance examination.
- It is necessary a medical periodical evaluation to be observed possible alterations in the implant and in the adjacent bone. Without such evaluation it will not be possible to detect loosening of components or the appearance of Osteolise.

- The information listed in the topics: Indication, Counter-Indication, Warning and Cautions.

WARNING:

- The package opening should be done by the nursing personnel, who is qualified for this procedure.
- Do not use the product if its term is due or its package is violated. The adequate handling of this material is responsibility of the qualified personnel.
- Product of hospitalar use only. * Discard after removing. We recommend to cut or file the pieces to avoid its reuse; however to discard the product, the local legislation should be observed.
- Inadequate sterilization of the surgical instrumental can cause prosthetic infection.
- Never reuse an implant. Even though it does not present any external damage, its previous manipulation can reduce its durability
- Product not sterilized. * Wash and sterilize the product before its use and manipulate same properly to avoid contamination.
- Every material removed, damaged or inadequate for use, should be sent to the manufacturer to be destroyed.
- Manipulate the product with care.
- The patient should visit the doctor periodically to check the conditions of the implant and adjacent bone.
- The resistance limit of the implant, which vary according to its type, should be respected, otherwise there will be risk of weakness and possible breakage of material.
- Take the product off its package for sterilization. The package is inappropriate for the sterilization procedure.
- Components of different manufacturers should not be used.
- Manufacturing date, due date and batch number: see the label

INSTRUCTIONS OF USE:

The surgery techniques vary according to the surgeon, who will choose the surgery method, type and dimension of the products to be used, as well as the criterion for evaluation of the surgery results.

The sterilization of the Connectors and Hooks should be made according to the recommended instructions, as follows:

- Connectors and Hooks are to be manipulated exclusively in proper environment (ambulatory or surgical room) and the adequate manipulation care should be taken (use of sterilized gloves). Only qualified professionals should manipulate and implant the Connectors and Hooks.
- The Connectors and Hooks should be applied and adapted to the proper surgical techniques.
- The torque to be applied to the screw during insertion to the bone will depend on the condition and characteristic of the bone. The doctor will decide what torque to apply.
- The clinical results and durability of the implant will depend on the tridimensional alignment of the components, being, therefore, essential to apply a precise surgical technique.

- Use of distinct alloys in metallic joints can cause galvanic corrosion to the implantation.
- It is recommended to use the same methodology in the assembly of the system, so that its rigidity is not affected.
- Do not use Connectors and Hooks together with products of other brands, due to the fact that there can be incompatibility problems of materials.

CLEANING AND STERILIZATION:
Before starting the sterilization process, remove the implant and instrumental from their packages, and clean with 70% alcohol + 30% distilled water.
After cleaned, the products should be rinsed with sterilized distilled water and dried with a clean cloth that does not release fibres.

IMPORTANT:
Detergents that contain chlorine free from sodium dioxide should not be used.

STERILIZATION:
Before use in surgery, the instrumentals should be cleaned as described above and sterilized in the sterilizer. The sterilization does not substitute cleaning of the material.
Sterilizing by Autoclave is a safe process, however, if there is no control of the operational parameters the instrumental can be damaged:
Humidity + high temperature + Oxygen = corrosion = micro-fissure = crackle = breakage
The chosen sterilization process should attend to Rule EN556 that establishes that the theoretical probability of presence of vital microorganisms is equal to 1 over 10-6 (S.A.L. {Sterility Assurance Level]).
To clean and sterilize, the proper proceedings should be observed. Suggestion: Rule ASTM F1744: 1996.
The recommended cycle of sterilization is:

INSPECTION:
- Check the instrumentals to detect if they present damage or wastage in all handling stages.
- If any damage is detected, a representative of MDT Indústria e Comércio de Implantes Ortopédicos Ltda should be contacted for orientation.

CONTAMINATION RISK:
Taking into consideration that the Connector and the Hook make contact with tissue and fluids of the body, there is risk of biological contamination and transmission of infectious diseases such as Hepatitis and HIV, etc. Therefore, removed Connectors and Hooks should be treated as potentially contamination materials.

DISCARDING OF THE PRODUCT:
The product can be damaged if it falls or crushes over hard surfaces. The product integrity should be inspected when opening the package. Do not use the product if an irregularity is detected.

Method – Temperature Cicle – Time of Exposure
Pre-vacuum Steam [132º - 135º C - [270º - 275º F], minimum 10 minutes
After being removed from the patient, Connectors and Hooks should be discarded because they are not meant to be reused.
The implantations removed or defective due to accidents should be turned useless before being discarded. We recommend that the parts are cut, crooked or filed to avoid its reuse.
To discard removed Connectors and Hooks, follow the legal procedures for discarding of products potentially contaminants in force in the country where the material will be discarded.

TRACKING:
To assure tracking of implanted product and fulfill the Sanitary Authority requirements, we recommend that the surgeon responsible for the implant, report to the Distributor the following information reference the implanted product, patient and surgery made:
Name of the Surgeon
Date of Surgery
Name of the Patient
Product Code
Batch Number

The Connectors and Hooks bring the following information printed in the body:
Product Code
Batch Number
Name of the Company

STORAGE:
A dry and airy place is recommended for storage, far from direct sunlight.
Do not storage product directly on the ground (minimum high = 20 cm).
Product cannot be stored in high shelves, next to light fixture (for not to become exceedingly dry or have the label information faded).
Do not storage product in areas where contaminating substances are used, like insecticides, pesticides or cleaning material.

TRANSPORTATION:
The transportation should be carefully made, avoiding fall and friction of the product so that no damage is made. The integrity of the package has to be always observed.
The implant should be maintained in its original package up to the moment of its use, under the responsibility of the doctor/hospital team nominated for that purpose.

Date of manufacturing, due date and batch number: see product label
Do not use product if its date is due.

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: 13505-600
Phone/ Fax: (55-19) 2111-6500
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Technician Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

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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.