Instruction for Use

Intersomatic Cage

Legends of symbols used in the packaging

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

Product technical specifications and Characteristics

Technical Name: Device of disc replacement intersomatic space

Commercial Name: Intersomatic Cage

Commercial Models:

- Fusion Cylinder (oval holes);
- Cage Cylinder;
- Fusion Cylinder (round holes);
- Cervical S Cylinder;
- Fusion Cage;
- Intersomatic Cage Self-locking Internal Flap Fusimax;
- Intersomatic Cage Self-locking External Flap Fusimax;
- Cervical Intersomatic Cage;
- Lumbar Intersomatic Cage;
- Intersomatic Cage Self-tapping;
- Rectangular Intersomatic Cage Fusimax;
- Posterior Intervertebral Spacer;
- Anterior Intersomatic Cage Fusimax;
- Lateral Intersomatic Cage Fusimax;
- Transforaminal Intervertebral Spacer;

Accessories:

- Screw for Reinforcement Ring;
- Ring of Reinforcement for Fusion Cylinder;
- Cylinder for Anterior Intersomatic Cage Fusimax;
- Screw for Anterior Intersomatic Cage Fusimax;

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

Product Non Sterile

Sterilization Method: Sterilization by moist heat (autoclave)

Validity: Indeterminate

Description

The commercial models that compose the Intersomatic Cage family consist of implantable devices applicable to the thoracic and cervical segments, surgically invasive of use in long-term for procedures of stabilization of the vertebral column.

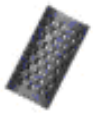
The product is a capsule with side walls leaked or not, built from titanium alloy (Ti-6Al-4V), it is presented in specific shapes according to its purpose and indication.

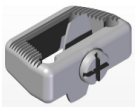
Its purpose is to complete and maintain the intersomatic space after performing of procedures of the vertebral column discectomy.

The principle of functioning of the implants is the maintenance of intersomatic space and support compression loads that are submitted to cervical and lumbar segments of the vertebral column until occurs the fusion bone (arthrodesis) between the bone graft contained in its interior and the vertebral segment instrumented.

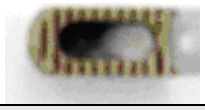
The product is biocompatible and adapts to the column bone geometry. It supports mechanical strength in the required proportion because presents elastic module and interfaces with the bone, properly for transmission of loads.

The Intersomatic Cage family is presented in the following commercial models:

			
Fusion Cylinder (oval holes)	**Cage Cylinder**	**Cervical S Cylinder**	**Fusion Cylinder (round holes)**

			
Fusion Cage	**Intersomatic Cage Self-locking Internal Flap Fusimax**	**Intersomatic Cage Self-locking External Flap Fusimax**	**Cervical Intersomatic Cage**

				
Lumbar Intersomatic Cage	**Intersomatic Cage Self-tapping**	**Paralell**	**Angled**	**Striped**
		Rectangular Intersomatic Cage Fusimax		

			
Posterior Intervertebral Spacer	**Anterior Intersomatic Cage Fusimax**	**Lateral Intersomatic Cage Fusimax**	**Transforaminal Intervertebral Spacer**

The accessories of commercial models are: Fusion Cylinder, Ring of Reinforcement and its screw, Rectangular Intersomatic Cage Fusimax, Cylinder for Anterior Intersomatic Cage Fusimax and its screw, whose purpose is to reinforce the product to support the loads.

			
Ring of Reinforcement for Fusion Cylinder	**Screw for Reinforcement Ring**	**Cylinder for Anterior Intersomatic Cage Fusimax**	**Screw for Anterior Intersomatic Cage Fusimax**

Composition

The selected materials for composition of the product present the properties required to achieve the intended performance for the commercial models that compose the Intersomatic Cage family. This selection considered factors as biocompatibility and mechanical, chemical and physical properties, required for the product.

The commercial models that compose the Intersomatic Cage family are manufactured from titanium alloy (Ti-6Al-4V) due to its properties that it makes an ideal material for producing of implantable medical devices. Its main properties are biocompatibility and mechanical strength.

The titanium alloy (Ti-6Al-4V) used for manufacture of the commercial models that compose the Intersomatic Cage family meets the specified requirements by the standard ASTM F-136 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy 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 the standard ASTM F-136, presents biocompatibility proven by a vast historic widely described in the worldwide literature.

Indication and Purpose

It is used to correct the congenital or degenerative diseases in the vertebral column, for arthrodesis and maintenance of the intervertebral space. Intersomatic cages are indicated for cases of disc hernia, deformities, tumors, fractures, disc replacement and restoration of the intervertebral space.

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

Below are the relative contra indications for the product use, leaving to the surgeon in charge the surgical procedure indication, after a detailed study of the case:

- Patients with general active infections or specific and can lead to complications with the fixation;
- Patients with impaired general status and/or immunocompromised, unable to be submitted to a surgical procedure;
- Patients with sensibility to foreign bodies, being that in suspected cases, tests must be performed;
- Patients with advanced osteoporosis and/or other bone affections that may compromise the fixation stability;
- Patients who use narcotic substances, alcohol or smoke;

Forms of Presentation

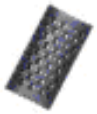
The commercial models that compose the Intersomatic Cage family are available for marketing unitarily packaged in double plastic packaging of polypropylene, in the non sterile condition.

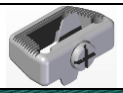
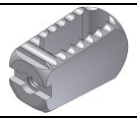
Inside of the second packaging follow a leaflet with the use instructions that presents its condition of non sterile product, as well as instructions for handling and use of the product.

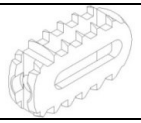
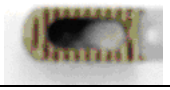
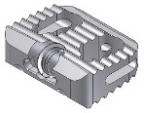
Over the packaging is pasted a label containing the necessary information for the product identification.

Intersomatic Cage family is presented in the following commercial models, being that each one of these models is available to marketing in the following dimensions.

List of commercial models and accessories that compose the Intersomatic Cage family

Illustrative Image	Code	Commercial Model	Dimensions	Manufacturing Material	Quantity Packed
	04.36.03.XXXXX	Fusion Cylinder (oval holes)	Ø 12 mm – 15, 17, 20, 22, 25, 30, 35, 40, 45, 50 mm; Ø 16 mm – 15, 17, 20, 22, 25, 30, 35, 40, 45, 50, 55, 60 mm; Ø 20 mm – 20, 25, 30, 35, 40, 45, 50, 55, 60 mm; Ø 28 mm – 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.03.XXXXX	Cage Cylinder	Ø 12 mm – 82 mm; Ø 15 mm – 82 mm; Ø 20 mm – 82 mm; Ø 25 mm – 82 mm; Ø 30 mm – 82 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.04.XXXXX	Fusion Cylinder (round holes);	Ø 09 mm – 04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20, 25, 30 mm; Ø 10 mm – 04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20, 25, 30 mm; Ø 11 mm – 04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20, 25, 30 mm; Ø 12 mm – 04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20, 25, 30 mm; Ø 13 mm – 04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20, 25, 30 mm; Ø 14 mm – 04, 05, 06, 07, 08, 09, 10, 12, 14, 16, 18, 20, 25, 30 mm; Ø 15 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm; Ø 18 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm; Ø 20 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm; Ø 23 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm; Ø 25 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm; Ø 28 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm; Ø 30 mm – 14, 16, 18, 20, 22, 24, 26, 30, 32, 34, 36, 38, 40, 45, 50, 55, 60, 65, 70, 75, 80, 82 mm;	Titanium Alloy (Ti-6Al-4V)	01

	04.36.04.XXXXX	Cervical S Cylinder	Ø 10 mm – 80,5 mm; Ø 12 mm – 80,5 mm; Ø 14 mm – 80,5 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.15.XXXXX	Fusion Cage	05.0x11x13, 05.5x11x13, 06.0x11x13, 06.5x11x13, 07.0x11x13, 08.0x11x13, 10.0x13x15 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.20.XXXXX	Intersomatic Cage Self-locking Internal Flap Fusimax - Ti	05x09x14, 05x12x14, 05x14x14 mm, 06x09x14, 06x12x14, 06x14x14 mm, 07x09x14, 07x12x14, 07x14x14 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.31.XXXXX	Intersomatic Cage Self-locking External Flap Fusimax – Ti	05x09x14, 05x12x14, 05x14x14 mm, 06x09x14, 06x12x14, 06x14x14 mm, 07x09x14, 07x12x14, 07x14x14 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.14.XXXXX	Cervical Intersomatic Cage	Ø 07 mm – 12, 14 mm; Ø 08 mm – 12, 14 mm; Ø 09 mm – 12, 14 mm; Ø 10 mm – 12, 14 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.13.XXXXX	Lumbar Intersomatic Cage	Ø 10 mm – 20, 25, 30 mm Ø 12 mm – 20, 25, 30 mm Ø 14 mm – 20, 25, 30 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.36.18.XXXXX	Self-tapping Cage Fusimax	Ø 08 mm – 25, 30 mm Ø 10 mm – 25, 30 mm Ø 12 mm – 25, 30 mm Ø 14 mm – 25, 30 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.36.16.XXXXX	Rectangular Intersomatic Cage Fusimax	10x08, 10x09, 10x10, 10x11, 10x12, 10x13 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.16.XXXXX	Rectangular Intersomatic Cage Fusimax – Special	10x07x20, 10x08x20, 10x09x20, 10x10x20, 10x11x20, 10x12x20, 10x13x20 mm; 10x08x40, 10x10x40, 10x12x40, 10x14x40 mm; 10x08x45, 10x10x45, 10x12x45, 10x14x45 mm; 10x08x50, 10x10x50, 10x12x50, 10x14x50 mm; 10x08x55, 10x10x55, 10x12x55, 10x14x55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.19.XXXXX	Rectangular Intersomatic Cage Fusimax – Special	20x08x40, 20x10x40, 20x12x40, 20x14x40 mm; 20x08x45, 20x10x45, 20x12x45, 20x14x45 mm; 20x08x50, 20x10x50, 20x12x50, 20x14x50 mm; 20x08x55, 20x10x55, 20x12x55, 20x14x55 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.17.XXXXX	Rectangular Intersomatic Cage Fusimax Angled 5º	10x8.5, 10x9.5, 10x10.5, 10x11.5, 10x12.5, 10x13.5 mm	Titanium Alloy (Ti-6Al-4V)	01
		Rectangular Intersomatic Cage Fusimax Angled 5º -	10x8.5x20, 10x9.5x20, 10x10.5x20, 10x11.5x20, 10x12.5x20, 10x13.5x20 mm		

		Special			
	04.36.08.XXXXX	Rectangular Lumbar Intersomatic Cage Fusimax – Striped	06x08, 07x09, 08x10, 09x11, 10x12, 11x13, 12x14 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.36.05.XXXXX	Posterior Intervertebral Spacer – Titanium	6.5, 08, 8.7, 10, 10.8, 12, 12.2, 14 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.36.12.XXXXX		08x20, 10x20 mm;		
	04.36.21.XXXXX	Anterior Intersomatic Cage Fusimax Ti Parallel	08x20, 08x25, 08x30 mm; 10x20, 10x25, 10x30 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.22.XXXXX	Anterior Intersomatic Cage Fusimax Ti 05º	10x20, 10x25, 10x30 mm; 12x20, 12x25, 12x30 mm;		
	04.36.11.XXXXX	Anterior Intersomatic Cage Fusimax Ti 10 °	12x20, 12x25, 12x30 mm; 14x20, 14x25, 14x30 mm;		
	04.36.12.XXXXX	Anterior Intersomatic Cage Fusimax Ti 15 °	14x20, 14x25, 14x30 mm; 16x20, 16x25, 16x30 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.81.XXXXX	Anterior Intersomátic Cage Fusimax Ti 30º	17x20, 17x25, 17x30 mm; 18x20, 18x25, 18x30 mm;	Titanium Alloy (Ti-6Al-4V)	01
		Anterior Intersomátic Cage Fusimax Ti 40º	20x22, 20x25, 20x30 mm; 24x25, 24x30 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.09.XXXXX	Lateral Intersomatic Cage Fusimax Ti 05 °	10x45, 12x45, 14x45 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.10.XXXXX	Lateral Intersomatic Cage Fusimax Ti Ti 10 °	10x45, 12x45, 14x45 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.36.10.XXXXX	Transforaminal Intervertebral Spacer	08, 10, 12 mm	Titanium Alloy (Ti-6Al-4V)	01
Illustrative Image	**Code**	**Commercial Model**	**Dimensions**	**Manufacturing Material**	**Quantity Packed**
	04.40.03.XXXXX	Ring of Reinforcement for Fusion Cylinder	Diameter – 09, 10, 11, 12, 13, 14, 15, 18, 20, 23, 25, 28, 30 mm	Titanium Alloy (Ti-6Al-4V)	01
	04.24.25.00000	Screw for Reinforcement Ring	Single	Titanium Alloy (Ti-6Al-4V)	01
	04.24.25.00001	Screw for Reinforcement Ring – Cross Drive	Single	Titanium Alloy (Ti-6Al-4V)	01
	04.36.76.XXXXX	Cylinder for Anterior Intersomatic Cage Fusimax	M08 – 21, 27, 33 mm; M09 – 21, 27, 33 mm; M10 – 21, 27, 33 mm;	Titanium Alloy (Ti-6Al-4V)	01
	04.43.05.450XX	Screw for Anterior Intersomatic Cage Fusimax	Ø 4.5 mm – 20, 25, 30, 35, 40, 45, 50 mm;	Titanium Alloy (Ti-6Al-4V)	01

The surgeon is responsible by the correct selection of models and measures of the Intersomatic Cages to be implanted, as well as by the technique applied. The surgeon must 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 is under the doctor's responsibility, which evaluates the patient and decides which implants must be used. It is also bound to strict accomplishment with the postoperative cares recommended by the doctor in charge.

Support Material

The support materials are the instrumentals designed only for deployment of the commercial models that compose the intersomatic Cage family aforementioned.

These instrumentals are made in stainless steel as the specified requirements by standard ASTM F-899 – Standard Specification for Stainless Steel for Surgical Instruments.

Instrumentals below are not object of this registration process and must therefore be acquired separately and always from the same manufacturer of the implant or appointed by them.

See below the instrumentals available by the manufacturer or other appointed by them for implantation of the commercial models that compose the Intersomatic Cage family:

- Instrumental – Fusion Cylinder CTL;
- Instrumental – Cervical Fusion System Fusimax/ Fusifix;
- Instrumental – Cervical Intersomatic Cage;
- Instrumental – Lumbar Intersomatic Cage;
- Instrumental – Self-tapping Cage Fusimax;
- Instrumental – Lumbar Fusion System Fusimax/ Fusifix;
- Instrumental – Anterior Intersomatic Cage Fusimax (Cage on Cage)
- Instrumental – Transforaminal Intersomatic Cage Fusimax;

Instrumentals are provided decontaminated, but not sterilized. Improper sterilization of surgical instrumental can cause infection.

The surgical instruments are subject to wear and tear during the normal use, and it can therefore break. The instrumentals must be used only for its purpose and must be inspected regularly to checking of possible wear and damages.

For more information about the instrumental, consult the representative.

Precautions and Warnings

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

- Intersomatic Cage must be used after a detailed analysis of the surgical procedure to be adopted and the reading of this instruction for use;
- The product must be used only by specialized surgical teams, with specific knowledge and training on spinal fusion, being the responsibility of the surgeon the choice and mastery of the technique to be applied;
- The bone fusion of the vertebral column is a surgical procedure of universal recognition, so the indications and knowledge of techniques are responsibility of surgeon, restricting to him these instructions and clarifications about details and particularities of the implants;
- The selection and inadequate choice of the implants to be used, as well as the mistakes in the indication, handling and technique of application can cause excessive tensions and tractions on the implant, leading to failure by fatigue, fracture;
- The use of the Intersomatic Cage must always be associated with bone grafting using;
- The clinical results and the durability of the implants are extremely dependents on an accurate surgical technique;
- The surgical procedure for intersomatic bone fusion presents risks of vascular lesions, visceral, neural, pseudoarthrosis, among others;
- The use in patients with predisposing to disobey the medical guidelines and postoperative restrictions such as children, elderly, individuals with neurological disorders or dependent in narcotic substances, represent a greater risk for failure of the implant;
- The risk for 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 complications postoperative represent a greater risk when the product is used in patients with obesity morbid;
- The Intersomatic Cage must not be used if it do not have an adequate bone support to ensure the implant stability;
- The patient must have periodic medical monitoring to check the conditions of the implant and the adjacent bone;

- The medical criterion, can be use an antibioticterapy prophylactic pre and perioperative, as well as antibioticterapy in cases where there is a local predisposition and/or systemic or where there is occurrence of infections;
- The implant must 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 this material are the responsibility of qualified personnel, which must follow the standards and/or other local regulations applicable;
- Fall and crushing on hard surfaces can cause damage to the product, thus, it is necessary the user to perform an inspection of the product integrity, when the packaging is opened, and if any abnormality is observed the product must not be used;
- The opening of the packaging for surgical use must only be performed by qualified personnel to perform 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 look undamaged, pre-tensions to which they were subjected may 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;
- Inadequate sterilization of the product can cause infection;
- Date of manufacture and batch number: See label.

Adverse Effects

Every surgical procedure presents risks and possibility of complications, being that some common risks are infection, bleeding, drug allergic reaction and anesthetic risks, among others. It can still be associated with the implantation of the product, the following complications and adverse effects:

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

The column fixation at any level is a surgical procedure of universal recognition; meanwhile, the bone fusion of one or more motor vertebral segment can cause an overload on the adjacent levels.

Use Instructions

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

- The care of this material are the responsibility of qualified personnel, which must follow the standards and/or other local regulations applicable;
- The product must be handled with proper care in appropriate locations (center of materials and operating rooms);
- The product must only be used by specialized surgical teams, with specific knowledge and training on techniques and spinal fusion procedures, being the surgeon in charge by the choice and mastery of the surgical technique to be applied;
- The useful life of the implant is characterized by the time required to occurrence the bone fusion, limiting to a maximum of 01 (one) year. After this period, in the absence or problems

with bone healing (pseudoarthrosis), these conditions may represent a risk of implant failure by excessive mechanical stress;

- May be necessary to perform a review' surgery, in the case mentioned above or in cases where is observed release of components;
- For the application of the Intersomatic Cage is needed the use of specific instrumental indicated in the topic "Support Material" and due to possibility of functional and/or dimensional incompatibility must not be used with instruments other than those appointed by the manufacturer;

Guidance to the patient and/or the Legal Representative

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

- Appropriate care and restrictions during the postoperative period. The ability and willingness of patients 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 addicts;
- Must alert the patient and make him understand that the implant is used with purpose of fixation, while the bone grafting is not fully integrated and does not have the same performance of normal bone and therefore can break, deform or loosen due to excessive efforts or activities of early loading and other situations;
- The need to restrict the accomplishment of activities of efforts or sportive practices during the postoperative period, whose period is defined by the surgeon in charge;
- The increase of postoperative complications in patients with morbid obesity;
- The necessity of use, exclusively, the medical criterion 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) may lead to mechanical failure of the implant;
- The need of a 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 information listed in this topic "Guidance to the patient and/or the Legal Representative" and in the topic "Adverse Effects".

Sterilization

The commercial models that compose the Intersomatic Cage family are supplied in the non sterile condition and must 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 cages is the sterilization by moist heat (autoclave);

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

Sterilization Parameter

The sterilization of commercial models that compose the Intersomatic Cage family must 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 described cleaning procedures as follow are applied to the implants and their respective surgical instrumentals.

When to use the cages, these must be removed of its packaging and washed with alcohol for medical aims at 70% + distillate water 30%.

After cleaning, the products 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 the explantation of commercial models that compose the Intersomatic Cage 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 applicable.

Product Discard

The commercial models that compose the Intersomatic Cage family explanted 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 must 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, this 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;
- Number of product registration at ANVISA;

The surgeon in charge and his team must use the labels for traceability supplied in the product packaging, pasting them into the patient's medical record to maintenance of the traceability of the deployed product. In addition, one of these labels must be supplied to the patient to have information about the product implanted in his surgery.

The data of the products as: code, description, batch, registration number and other information are contained in the labels.

The traceability information is necessary for notification by the service of health and/or by the patient to the Sanitary surveillance Agency – ANVISA and to the manufacturer in cases of serious adverse events to conducting the 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 must be kept in its original packaging until the moment of its use, being that the surgical packaging opening and handling must 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 SA
Adress: Avenida Brasil, nº. 2983 – Distrito Industrial – Rio Claro/SP
Zip Code: 13.506-600
Phone/Fax: (55-19) 2111-6500
CNPJ: 01.025.974/0001-92
Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Registration ANVISA #:10417940059
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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.

MDT Implantes

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