Instructions for Use

Non-Cannulated Screw

Keys used on packaging and labeling

	Reference number (filled with product code)		Lot Number
	Manufacturing Date		Read instructions for use
	Single-use product		Do not use if package is violated
	Non sterile		Keep protected from sunlight
	Fragile, handle with care		Keep dry

Product features and technical specifications

Technical Name: Implantable Screws

Trade Name: Non-Cannulated Screw

Commercial Models:

- Cortical Screw Thread 1.25 mm Ø 3,5 mm;
- Cortical Screw Thread 1.75 mm Ø 3,5 mm;
- Cortical Screw Thread 1.75 mm Ø 4,5 mm;
- Cortical Screw Ø 5,0 mm;
- Cortical Screw Ø 6,2 mm;
- Cancellous Screw Partial Thread Ø 4,0 mm;
- Cancellous Screw Full Thread Ø 4,0 mm;
- Cancellous Screw Partial Thread 16 mm Ø 6.5 mm
- Cancellous Screw Partial Thread 32 mm Ø 6.5 mm;
- Cancellous Screw Full Thread Ø 6,5 mm;
- Malleolar Screw Ø 4,5 mm;

Accessories

- Washer for Screw Ø 3,5 mm;
- Washer for Screw Ø 4,5 mm;
- Washer for Screw Ø 6.5 mm.

Raw Material: Stainless steel alloy (18Cr-14Ni-2.5Mo) ASTM F-138

Validity: Undefined

Non-Sterile Product

Sterilization method: Sterilization by moist heat (autoclave)

Description

The commercial models that make up the Non-Cannulated Screw family consist of implantable, surgically invasive components of long-term use, indicated for upper and lower limbs osteosynthesis surgical procedures, with or without associated plates.

The commercial models that make up the Non-Cannulated Screw family are manufactured from 18Cr-14Ni-2.5Mo stainless steel alloy. They present hexagonal wrench connection, spherical head; asymmetric thread; no self-tapping nor self-drilling geometry and shall be implanted by using specific instruments, taps and drills for preparation of the insertion hole.

Cortical screws applies to the cortical bone, at diaphysis regions, with bi-cortical fixation.

Cancellous screws are intended to be applied on cancellous bone of metaphysis or epiphysis. Due to the porous characteristic of cancellous bone, its threads are longer than those of cortical screws are, in order to confer compressive action, during fixation to medullar bone, greater degree of bone-metal contact greater and pullout resistance.

Below follows illustrative images of commercial models that make up the Non-Cannulated Screw family:

				
Cortical Screw Thread 1.25 mm Ø 3,5 mm	**Cortical Screw Thread 1.75 mm Ø 3,5 mm**	**Cortical Screw Thread 1.75 mm 4,5 mm**	**Cortical Screw Ø 5,0 mm**	**Cortical Screw Ø 6.2**

				
Cancellous Screw Partial Thread Ø 4.0 mm	**Cancellous Screw Full Thread Ø 4,0 mm**	**Cancellous Screw Partial Thread 16 mm 6.5 mm**	**Cancellous Screw Thread 32 mm Ø 6,5 mm**	**Cancellous Screw Full Thread Ø 6,5 mm**


Malleolar Screw Ø 4.5 mm

The washer for screw is the accessory for commercial models that make up the Non-Cannulated Screw family. They are made from 18Cr-14Ni-2.5Mo stainless steel alloy and are available in diameters of 3.5, 4.5, and 6.5 mm. Their purpose is to be used in combination with screws for reduction and stabilization of fractures when these are implanted directly into the bone without the association of plates. Below follows illustrative images of the accessories:

		
Washer for Screw Ø 3,5 mm	**Washer for Screw Ø 4,5 mm**	**Washer for Screw Ø 6,5 mm**

Composition

The materials selected for manufacturing the product present properties required to achieve its intended purpose. This selection took into account factors like biocompatibility and required physical, chemical, and mechanical properties for the product.

The commercial models that make up the Non-Cannulated Screw family are manufactured from 18Cr-14Ni-2.5Mo stainless steel alloy, material whose properties make it ideal for the manufacture of implantable medical devices.

The 18Cr-14Ni-2.5Mo stainless steel alloy employed to manufacture the product meets the requirements specified by ASTM F-138 - Standard Specification for Wrought 18 Chromium-14 Nickel-Molybdenum 2.5 Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).

Characterized as a material with suitable physical, chemical, and mechanical properties for this purpose, it possesses proven biocompatibility by vast clinical history widely described in the literature.

Indication and Purpose

The Non-Cannulated Screw is indicated for fracture reduction, stabilization and fixation by interfragmentary compression of the upper and lower limbs in surgical procedures of osteosynthesis in combination with plates or washers.

The product herein described was designed for use under the circumstances described above, so that any other uses are considered contraindicated or without scientific basis.

Contraindications

The contraindications for using the device are listed below, being up to the attending surgeon to indicate the procedures after a thorough study of the case:

- Patients with general or specific active infections that can lead to complications with the fixation;
- Patients with impaired general health status and / or immunosuppressed, that are unable to undergo a surgical procedure ;
- Patients who are sensitive to foreign bodies. In these specific cases, tests shall be performed;
- Patients with advanced osteoporosis and / or other bone affections that may compromise the stability of fixation;
- Patients who makes use of narcotics, alcohol or tobacco.

Presentation Form

The commercial models that make up the Non-Cannulated Screw family are packed in polypropylene double plastic bag.

The secondary plastic bag contains a leaflet with instructions for use, which states the indication of non-sterile product, as well as the instructions for handling and using the product.

On the packaging, a label containing the information required to identify the product is attached.

The Non-Cannulated Screw is presented in the following commercial models, and each of these models and their accessories (integral parts) are available for sale in the following dimensions:

List of commercial models that make up the non-cannulated screw family

Illustrative Image	Code	Commercial Model	Sizes (Diameter x Length)	Material	Qty per Packaging
	04.24.07.35XXX	Cortical Screw Thread 1.25 mm Ø 3.5 mm	**Ø 3.5 mm -** 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 100 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	06
	04.24.08.35XXX	Cortical Screw Thread 1.75 mm Ø 3.5 mm	**Ø 3.5 mm -** 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 100 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	06
	04.24.08.45XXX	Cortical Screw Thread 1.75 mm Ø 4.5 mm	**4,5 mm -** 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 mm.	Stainless steel alloy (18Cr-14Ni-2.5Mo)	05
	04.24.39.50XXX	Cortical Screw Ø 5.0 mm	**Ø 5.0 mm -** 14, 16, 18, 20, 22, 24, 25, 26, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.24.10.62XXX	Cortical Screw Ø 6.2 mm	**Ø 6.2 -** 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.24.11.40XXX	Spongy Screw Partial Thread Ø 4.0mm	**4.0 mm Ø -** 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 100 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02
	04.24.12.40XXX	Spongy Screw Full Thread	**4.0 mm Ø -** 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 100 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02
	04.24.13.65XXX	Cancellous Screw Partial Thread 16 mm 6.5 mm	**Ø 6.5 mm -** 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02
	04.24.14.65XXX	Cancellous Screw Partial Thread 32 mm Ø 6.5 mm	**Ø 6.5 mm -** 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.24.12.65XXX	Cancellous Screw Full Thread Ø 6.5 mm	**Ø 6.5 mm -** 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02
	04.24.17.450XX	Malleolar Screw Ø 4.5 mm	**4,5 mm -** 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02

Accessories (integral part)

Illustrative Image	Code	Commercial Model	Sizes (diameter / length)	Material	Qty per Packaging
	04.02.02.00035	Washer for screw Ø 3.5 mm	- Ø 3,7 mm - Thickness: 1.0 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02
	04.02.02.00045	Washer for screw Ø 4.5 mm	- Ø 4.7 mm - Thickness: 1.6 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	02
	04.02.03.00065	Washer for screw Ø 6,5 mm	- Ø 6.5 mm - Thickness: 1.6 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01

Ancillary Components

The ancillary implants for the Non-Cannulated Screw are:

- Straight plates;
- Special plates;
- Tube plates;
- Angled plates;

Ancillary implants are manufactured from 18Cr-14Ni-2.5Mo stainless steel alloy that meets the requirements specified by ASTM F-138 - Standard Specification for Wrought 18 Chromium-14 Nickel-Molybdenum 2.5 Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).

The correct selection of models and sizes of the Non-Cannulated Screw, as well as their ancillaries to be implanted is the surgeon's responsibility, who is also responsible for the surgical technique to be used, and must be familiar with the material, the application method, and the surgical procedure to be performed.

The success of the procedure is linked to the correct selection, positioning, and fixation of the devices, which is the responsibility of the surgeon who assesses the patient and decides which implants must be employed. It is also linked to strict compliance with recommended post-operative care by the attending surgeon.

Below follows the indication for ancillary components and their correct combination with commercial models that make up the Non-Cannulated Screw family:

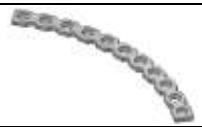
Ancillaries	Commercial Models
Straight plate - 1/3 Tubular	Cortical screw thread 1.25 mm Ø 3.5 mm Cortical screw thread 1.75 mm Ø 3.5 mm Cancellous screw partial thread Ø 4,0 mm Cancellous screw full thread Ø 4,0 mm
Straight Plate Self-Compression Short	
Straight Plate Self-Compression Narrow	
Malleable Straight Plate	
Bridge Straight Plate Self-Compression Narrow	
"T" Special Plate for Small Fragments	Cortical screw thread 1.25 mm Ø 3.5 mm Cortical screw thread 1.75 mm Ø 3.5 mm Cancellous screw thread Partial Ø 4.0 mm Cancellous screw thread Total Ø 4.0 mm
"T" Special Plate Oblique Right for Small Fragments	
"T" Special Plate Oblique Left for Small Fragments	
Straight Plate Self-Compression Wide	Cortical screw thread 1.75 mm Ø 4,5 mm

Straight Plate Semi Tubular	Cancellous screw thread 16 mm Ø 6.5 mm Cancellous screw thread 32 mm Ø 6.5 mm Cancellous screw full thread Ø 6,5 mm
Bridge Straight Plate Self-Compression Wide	
"L" Special Plate - Left	
"L" Special Plate - Right	
Special Arched Plate for Pelvic Reconstruction	Cortical screw thread 1.25 mm Ø 3.5 mm Cortical screw thread 1.75 mm Ø 3.5 mm Cancellous screw partial thread Ø 4.0 mm Cancellous screw full thread Ø 4.0 mm Cortical screw thread 1.75 mm Ø 4,5 mm Cancellous screw thread 16 mm Ø 6.5 mm Cancellous screw thread 32 mm Ø 6.5 mm Cancellous screw full thread Ø 6,5 mm
Special Straight Plate for Pelvic Reconstruction	
Special Plate for Straight Acetabulum Fracture	
Angled Tube Plate Type DCS 95º A / C	Cortical screw thread 1.75 mm 4,5 mm Cancellous screw thread 16 mm Ø 6.5 mm Cancellous screw thread 32 mm Ø 6.5 mm Cancellous screw full thread Ø 6,5 mm
Angled Tube Plate Type DHS 135º A / C	
Angled Tube Plate Type DHS 150º A / C	
Angled Plate A / C 95º	Cortical screw thread 1.75 mm Ø 4,5 mm Cancellous screw - thread 32 mm Ø 6.5 mm
Angled Plate A / C 130º	

Ancillary components listed above are not subjects of this registration process and must therefore be purchased separately and always from the same manufacturer or from another one, duly appointed by the former.

List of ancillary components to screw not cannulated family

Illustrative Image	Code	Description of Ancillary Component	Sizes	Material	Qty Packed
	4:28:01.XXXXX	Straight Plate 1/3 Tubular	10x1,5 mm - 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, and 14 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:28:02.XXXXX	Straight Plate A / C Small	10x03 mm - 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, and 16 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:28:03.XXXXX	Straight Plate Self-Compression Narrow	12x04 mm - 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, and 18 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01

	4:28:04.XXXXX	Straight Plate Self-Compression Wide	16x05 mm - 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, and 22 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:28:07.XXXXX	Malleable Straight Plate	Length: 71-199 mm 04, 05, 06, 07, 08, 09, 10, 11, and 12 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:28:08.XXXXX	Straight Plate Semi Tubular	1.5 x 14 mm - 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, and 14 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:28:09.XXXXX	Bridge Straight Plate Self-Compression Short	05 holes - 200 mm; 250 mm; 10 holes - 140; 160; 250; 280; 300; 320 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:28:10.XXXXX	Bridge Straight Plate Self-Compression Wide	08, 10, 12, 14 holes;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:26:03.XXXXX	"L" Special Plate - Left	Length: 58.5 mm to 236 mm 02-13 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:26:04.XXXXX	"L" Special Plate - Right	Length: 58.5 mm to 236 mm 02-13 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:26:07.XXXXX	"T" Special Plate for Small Fragments	Length: 40.2 to 148.2 mm 03 and 04 holes x 03 to 12 holes in the stem	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:26:13.XXXXX	"T" Special Plate Oblique Right for Small Fragments	Length: 71-280 mm 02-15 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:26:14.XXXXX	"T" Special plate Oblique Left for Small Fragments	Length: 71-280 mm 02-15 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.26.19.00XXX	Straight Special Plate for Pelvic Reconstruction	Length: 58.2-238.2 mm 03-20 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.26.18.00XXX	Special Arched Plate for Pelvic Reconstruction	Length: 35.1 to 201.6 mm 03-20 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01

	04.26.19.20XXX	Special Plate for Acetabulum Fracture	Length: 34.2 to 238.2 mm 03-20 Holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:27:14.XXXXX	Angled Tube Plate Type DCS 95º A / C	Tube Length: 28 mm; Tube diameter: 12.7mm; Plate length: 110-334 mm; Qty of holes: 02-16;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.27.15.000XX	Angled Tube Plate Type DHS - 135º	Tube Length: 39 mm; Tube diameter: 12.7mm; Plate length: 79-303 mm Qty of Holes: 02-16 holes	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	04.27.20.000XX	Angled Tube Plate Type DHS - 150º	Tube Length: 39 mm Tube diameter: 12.7 mm Plate length: 79-303 mm Qty of holes 04, 05, 06, 08, 10, 12;	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:27:01.XXXXX	Angled Plate A / C 95º	04, 05, 06, 07, 08, 09, 10, 11, 12, 14, 16, 18, 20 holes Blade length: 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, and 100 mm Plate length: 75-331 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01
	4:27:02.XXXXX	Angled Plate A / C 130º	04, 05, 06, 07, 08, 09, 10, 12, 14, 16 and 18 holes Blade length: 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 and 100 mm Plate length: 78-302 mm	Stainless steel alloy (18Cr-14Ni-2.5Mo)	01

Support Materials

Support materials are instruments solely designated for implantation of components that make up the Non-Cannulated Screw family.

These instruments are manufactured from materials that are specified by ASTM F899 - Standard Specification for Stainless Steel for Surgical Instruments, which provide them with high strength and durability.

The instruments below are not subjects for this registration process and must therefore be purchased separately and always from the same manufacturer or from another one, duly appointed by the former.

See listing below for instruments made available by MDT to be used in surgeries for implantation of Non-Cannulated Screw:

- 0T.04 - Instrumental - Large Fragments
- 0T.05 - Instrumental - Small Fragments - Thread 1.75 mm
- 0T.12 - Instrumental - Small Fragments - Thread 1.25 mm
- 0T.07 - Instrumental for Angled Plate
- 0T.08 - Instrumental DHS - DCS

The instruments are supplied decontaminated but not sterilized. Surgical instruments are subject to wear during normal use and can be damaged or broken.

Inadequate sterilization of surgical instruments can cause infection. The instruments must be used only for their intended purposes and shall be inspected regularly to check for possible wear or damage.

For more information about the instrumental, consult your representative.

Warnings and Precautions

To use the product, the responsible medical team must take into account the following warnings and precautions:

- Non-cannulated screw shall only be used after a detailed analysis of the surgical procedure to be adopted and after reading the product instructions for use;
- The product must be used by specialized surgical teams, with specific knowledge and capability about osteosynthesis techniques in upper and lower limbs, being the responsibility of the surgeon the choice and mastery over the technique to be applied;
- Improper selection and choice of implants to be used, as well as mistakes in indication, handling and application technique can cause excessive tensions and tractions on the implant, possibly leading to failure by fatigue, fracture or implant looseness;
- The clinical results and the durability of the implants are extremely dependent on an accurate surgical technique ;
- Risks of implant failure are higher in patients who practice strenuous activities or sports;
- The product shall not be used if an adequate bone support does not exist to ensure implant stability ;
- The patient must submit to periodic medical follow-up to check the conditions of the implant, the bone and adjacent tissues;
- The use of antibiotics is advisable in cases where there is local or systemic predisposition or actual occurrence of infections;
- The implant shall not be used with components from other manufacturers or with dissimilar intended purpose. The combination of implants from different manufacturers or with dissimilar intended purpose can result in incongruence between components;
- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations ;
- The opening of the package for surgical use must be done by nurses qualified for this procedure ;
- Do not use the product if packaging is violated;
- Handle with care;
- Single-use Product - Do not reuse it;
- Never reuse an implant. Although they may seem undamaged, previous mechanical stresses applied to them may originate imperfections that would shorten its lifespan in case of re-implantation;

- Non-sterile Product - It must be sterilized before use and handled correctly to avoid contamination;
- Inadequate sterilization of the product may cause infection;
- REPROCESSING PROHIBITED;
- Manufacturing date, expiry date, and lot number: see label.

Adverse effects

Every surgical procedure presents risks and the possibility of complications, the infections, bleedings, drug allergic reactions and anesthetic risks being some common ones, among others. The following complications and adverse effects can also be associated with the implantation of the product:

- Absent or delayed osseointegration that results in rupture of the implant;
- Loosening, disassembling, displacement, torsion or breakage of the implant;
- Deformation or fracture of the implant;
- Pain, discomfort or abnormal sensations due to the product
- Reactions to foreign body ;
- Bone necrosis or adjacent soft tissue necrosis ;

The decision on removing the implant due to the above adverse effects is the surgeon's responsibility.

Instructions for Use

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

- Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- The product shall be handled with due care in appropriate locations (materials central and operating rooms);
- The product shall only be used by specialized surgical teams, with knowledge and specific training in arthroplasty techniques, being the responsibility of the surgeon the choice and mastery over the technique to be applied;
- In cases of component loosening, a revision surgery must be performed;
- The product lifespan is characterized by the time required for the completion of osseointegration, limited to a maximum of one (1) year. After this period, in case of absence or problems with bone consolidation, it poses risk of product failure due to excessive mechanical demand.

Guidelines to Patient and / or Legal Representative

The team in charge must instruct the patient or his legal representative on:

- Adequate care and restrictions during the postoperative period. The capacity and willingness of the patient to follow these guidelines are one of the most important aspects in a surgical procedure involving the vertebral spine;
- The fact that the risks are greater when the product is used in patients with predisposition to disobey medical guidelines, care and postoperative restrictions, such as children, elderly, mentally ill and/or chemically addicted people;
- 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 physical effort, early load and other situations;
- All postoperative restrictions, especially those related to sports and occupational activities;
- The need for periodic medical follow-up, to check the conditions of the implant, bone, and adjacent tissues;
- The fact that not performing revision surgery after 01 (one) year, in cases where there was no osseointegration, may lead the implant to mechanical failure;
- The need for revision surgery, in case of loosening of components;

- The fact that implants can interfere with imaging test results. Thus, implant bearers shall report this fact when performing such tests ;
- The information listed in this item "Guidelines for Patient and / or Legal Representative" and in item "Adverse Effects".

Sterilization

Commercial models that compose the Non-Cannulated Screw family are provided as non-sterile products and must be removed from its original package and placed in suitable containers for sterilization (supplied by manufacturer) before use.

The sterilization method suitable for sterilizing screws and their ancillary components is sterilization by moist heat (autoclave)

The implants are provided decontaminated by the manufacturer, but must be properly handled and sterilized, as per instructions below, in order to prevent implant contamination and subsequent infection to patient;

Sterilization Parameters

Sterilization of screws and their ancillary components must be performed according to the parameters described in the table below:

Method	Cycle	Temperature	Exposure Time
Moist heat (autoclave)	Pre-Vacuum Sterilization (Vacuum) Drying	134º to 137º	10 minutes

The sterilization process must meet the theoretical probability for presence of vital microorganisms to a maximum of 1 in 10^6 (SAL [Sterility Assurance Level] = 10^{-6}).

The condition of the equipment (autoclave) used during the sterilization process (calibration program, maintenance, etc.), as well as the assurance of using a suitable sterilization process and the proof of product sterility are responsibility of the qualified personnel (material centre) from health service.

Cleaning

Cleaning procedures described below apply to implants and their respective surgical instrumentals.

When using screws and their ancillaries, these shall be removed from their packages and cleaned with solution of 70% alcohol for medical purposes + 30% distilled water.

After cleaning, the products must be rinsed with sterile distilled water and dried with a lint-free cloth.

If the cleaning process is carried out in thermal disinfector equipment with the aid of descaling substances, the directions from the manufacturer must be adopted;

Contamination Risk

Since this is an implantable product, when there is need of explantation of components there are also risks of biologic contamination and viral disease transmission.

To minimize these risks, the explanted devices shall be treated as potentially contaminant materials and the applicable standards and/or other local regulations shall be adopted.

Product Disposal

The screws and their ancillary components that are explanted or considered unsuitable for use shall be disposed of. It is recommended that, prior to disposal, the product is mischaracterized and, for such, its parts can be cut, bent or filed.

The implants must be disposed in appropriate places, in order to avoid contamination of the environment and other subjects. The adoption of local legal regulations for disposal of potentially contaminating products is recommended.

Single-use product - Do not reuse it.

Traceability

To ensure traceability of the implanted product and comply with the health surveillance requirements, the surgeon or his team must register the information about the product in the patient's medical record. Furthermore, such information must be forwarded to the distributor of the product and to the patient, in order to complete the traceability cycle of the implanted product. The necessary information for traceability is relative to the product used, surgery and patient, such as below:

- Name of the patient who received the implant;
- Surgeon's name;
- Hospital name;
- Manufacturer's name;
- Supplier's Name;
- Date of surgery;
- Product code;
- Product lot number;
- Quantity used;
- Product registration at ANVISA;

The information necessary for traceability of the product, shown, are engraved on the implant or can be obtained from the label inside the packaging:

- Company logo;
- Manufacturing lot;
- Product code;

The traceability information is necessary for notification by the health service and/or the patients themselves to Sanitary Surveillance Agency - ANVISA and the manufacturer when there is occurrence of serious adverse events, for conducting appropriate investigations.

Storage and Transportation

For storage, a dry and airy place is recommended, without light incidence exposure, humidity or contaminating substances.

The implants cannot be stored directly on the floor. Thus, it is recommended to use shelves with a minimum height of 20 cm.

The product shall be kept in its original packaging until the moment of use and its opening and handling for surgical application shall be carried out by personnel that is trained for this procedure;

The product shall be properly transported, avoiding falls and friction that may damage the structure and surface of the part.

For information about the date of manufacture, expiry date, and lot 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: 13505-600
Phone/ Fax: (55-19) 2111-6500
CNPJ: 01.025.974/0001-92
Technician Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

ANVISA Registration Nº: 10417940052
Review: 02
Issue: December 12nd, 2014.

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 are indexed on the website by REGISTRATION/ CADASTRE ANVISA´s NUMBER and COMMERCIAL 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:
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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.

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