Instructions Use

Sliding Screw

Symbols used in packaging

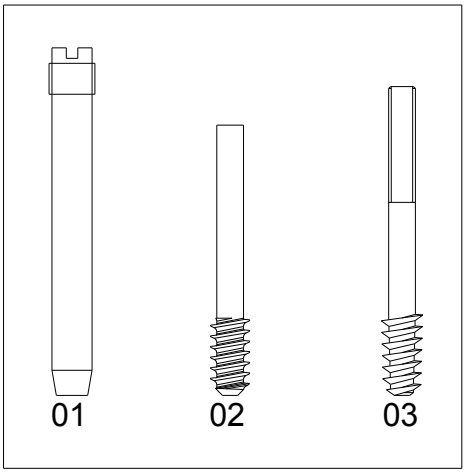
REF	Product Code		Avoid direct exposition at sunlight
LOT	Lot Code		Keep protected of humidity
	Consult instructions for use		Take care - Fragile
Material SS	Steel Stainless (ASTM F 138)		Do not use if the package is damaged
DD/MM/YYYY	Manufacturing date		
NON STERILE	Non Sterile		Single use product

Description:

Sliding Screw: The sliding screws in Steel Stainless ASTM F138, are implantable devices used together with the Tube Plate or Locked Nail. These devices are disposable and shall not be reused.

The instructions here presented are valid for all sliding screws, with its models and measure. See the available models below:

Sliding Screw	Richards Sliding Screw
	
Zimmer Sliding Screw	**HBF Sliding Screw**
	



Composition:

The Sliding Screws are made in Steel Stainless according to the specification ASTM F138: Standard Specification for Wrought 18 Chromium -14 Nickel - 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).

Purpose:

The DHS/DCS Sliding Screws Richards and Zimmer types were developed for being used together with the respective tube plates (DHS/DCS, Richards and Zimmer), in the femur neck transcervical fixation and in the femur distal third condyles region. The use of long or short thread depends on proximal fragment (femoral head) to be submitted to interfragmentary compression or in the corrective osteotomies fixation.

The HBF Sliding Screws were developed to be used together with the locked nail for Femur fixation.

Presentation Forms:

The Sliding Screws are available in the following measures:

Table – Sliding Screws

Code	Description
04.24.28.22050	DHS/DCS Thread Sliding Screw 22 x 50 mm
04.24.28.22055	DHS/DCS Thread Sliding Screw 22 x 55 mm
04.24.28.22060	DHS/DCS Thread Sliding Screw 22 x 60 mm
04.24.28.22065	DHS/DCS Thread Sliding Screw 22 x 65 mm
04.24.28.22070	DHS/DCS Thread Sliding Screw 22 x 70 mm
04.24.28.22075	DHS/DCS Thread Sliding Screw 22 x 75 mm
04.24.28.22080	DHS/DCS Thread Sliding Screw 22 x 80 mm
04.24.28.22085	DHS/DCS Thread Sliding Screw 22 x 85 mm
04.24.28.22090	DHS/DCS Thread Sliding Screw 22 x 90 mm
04.24.28.22095	DHS/DCS Thread Sliding Screw 22 x 95 mm
04.24.28.22100	DHS/DCS Thread Sliding Screw 22 x 100 mm
04.24.28.22105	DHS/DCS Thread Sliding Screw 22 x 105 mm
04.24.28.22110	DHS/DCS Thread Sliding Screw 22 x 110 mm
04.24.28.22115	DHS/DCS Thread Sliding Screw 22 x 115 mm
04.24.28.22120	DHS/DCS Thread Sliding Screw 22 x 120 mm
04.24.28.22125	DHS/DCS Thread Sliding Screw 22 x 125 mm
04.24.28.22130	DHS/DCS Thread Sliding Screw 22 x 130 mm
04.24.28.28050	DHS/DCS Thread Sliding Screw 28 x 50 mm
04.24.28.28055	DHS/DCS Thread Sliding Screw 28 x 55 mm
04.24.28.28060	DHS/DCS Thread Sliding Screw 28 x 60 mm
04.24.28.28065	DHS/DCS Thread Sliding Screw 28 x 65 mm
04.24.28.28070	DHS/DCS Thread Sliding Screw 28 x 70 mm
04.24.28.28075	DHS/DCS Thread Sliding Screw 28 x 75 mm
04.24.28.28080	DHS/DCS Thread Sliding Screw 28 x 80 mm
04.24.28.28085	DHS/DCS Thread Sliding Screw 28 x 85 mm
04.24.28.28090	DHS/DCS Thread Sliding Screw 28 x 90 mm
04.24.28.28095	DHS/DCS Thread Sliding Screw 28 x 95 mm
04.24.28.28100	DHS/DCS Thread Sliding Screw 28 x 100 mm
04.24.28.28105	DHS/DCS Thread Sliding Screw 28 x 105 mm
04.24.28.28110	DHS/DCS Thread Sliding Screw 28 x 110 mm
04.24.28.28115	DHS/DCS Thread Sliding Screw 28 x 115 mm
04.24.28.28120	DHS/DCS Thread Sliding Screw 28 x 120 mm
04.24.28.28125	DHS/DCS Thread Sliding Screw 28 x 125 mm
04.24.28.28130	DHS/DCS Thread Sliding Screw 28 x 130 mm
04.24.29.18050	Richards Type Thread Sliding Screw 18 x 50 mm
04.24.29.18055	Richards Type Thread Sliding Screw 18 x 55 mm
04.24.29.18060	Richards Type Thread Sliding Screw 18 x 60 mm

04.24.29.18065	Richards Type Thread Sliding Screw 18 x 65 mm
04.24.29.18070	Richards Type Thread Sliding Screw 18 x 70 mm
04.24.29.18075	Richards Type Thread Sliding Screw 18 x 75 mm
04.24.29.18080	Richards Type Thread Sliding Screw 18 x 80 mm
04.24.29.18085	Richards Type Thread Sliding Screw 18 x 85 mm
04.24.29.18090	Richards Type Thread Sliding Screw 18 x 90 mm
04.24.29.18095	Richards Type Thread Sliding Screw 18 x 95 mm
04.24.29.18100	Richards Type Thread Sliding Screw 18 x 100 mm
04.24.29.18105	Richards Type Thread Sliding Screw 18 x 105 mm
04.24.29.18110	Richards Type Thread Sliding Screw 18 x 110 mm
04.24.29.18115	Richards Type Thread Sliding Screw 18 x 15 mm
04.24.29.18120	Richards Type Thread Sliding Screw 18 x 120 mm
04.24.29.18125	Richards Type Thread Sliding Screw 18 x 125 mm
04.24.29.18130	Richards Type Thread Sliding Screw 18 x 130 mm
04.24.29.28050	Richards Type Thread Sliding Screw 28 x 50 mm
04.24.29.28055	Richards Type Thread Sliding Screw 28 x 55 mm
04.24.29.28060	Richards Type Thread Sliding Screw 28 x 60 mm
04.24.29.28065	Richards Type Thread Sliding Screw 28 x 65 mm
04.24.29.28070	Richards Type Thread Sliding Screw 28 x 70 mm
04.24.29.28075	Richards Type Thread Sliding Screw 28 x 75 mm
04.24.29.28080	Richards Type Thread Sliding Screw 28 x 80 mm
04.24.29.28085	Richards Type Thread Sliding Screw 28 x 85 mm
04.24.29.28090	Richards Type Thread Sliding Screw 28 x 90 mm
04.24.29.28095	Richards Type Thread Sliding Screw 28 x 95 mm
04.24.29.28100	Richards Type Thread Sliding Screw 28 x 100 mm
04.24.29.28105	Richards Type Thread Sliding Screw 28 x 105 mm
04.24.29.28110	Richards Type Thread Sliding Screw 28 x 110 mm
04.24.29.28115	Richards Type Thread Sliding Screw 28 x 15 mm
04.24.29.28120	Richards Type Thread Sliding Screw 28 x 120 mm
04.24.29.28125	Richards Type Thread Sliding Screw 28 x 125 mm
04.24.29.28130	Richards Type Thread Sliding Screw 28 x 130 mm
04.24.30.20050	Zimmer Type Thread Sliding Screw 20 x 50 mm
04.24.30.20055	Zimmer Type Thread Sliding Screw 20 x 55 mm
04.24.30.20060	Zimmer Type Thread Sliding Screw 20 x 60 mm
04.24.30.20065	Zimmer Type Thread Sliding Screw 20 x 65 mm
04.24.30.20070	Zimmer Type Thread Sliding Screw 20 x 70 mm
04.24.30.20075	Zimmer Type Thread Sliding Screw 20 x 75 mm
04.24.30.20080	Zimmer Type Thread Sliding Screw 20 x 80 mm
04.24.30.20085	Zimmer Type Thread Sliding Screw 20 x 85 mm
04.24.30.20090	Zimmer Type Thread Sliding Screw 20 x 90 mm
04.24.30.20095	Zimmer Type Thread Sliding Screw 20 x 95 mm
04.24.30.20100	Zimmer Type Thread Sliding Screw 20 x 100 mm
04.24.30.20105	Zimmer Type Thread Sliding Screw 20 x 105 mm
04.24.30.20110	Zimmer Type Thread Sliding Screw 20 x 110 mm
04.24.30.20115	Zimmer Type Thread Sliding Screw 20 x 115 mm
04.24.30.20120	Zimmer Type Thread Sliding Screw 20 x 120 mm
04.24.30.20125	Zimmer Type Thread Sliding Screw 20 x 125 mm
04.24.30.20130	Zimmer Type Thread Sliding Screw 20 x 130 mm
04.24.30.28055	Zimmer Type Thread Sliding Screw 28 x 55 mm
04.24.30.28060	Zimmer Type Thread Sliding Screw 28 x 60 mm

04.24.30.28065	Zimmer Type Thread Sliding Screw 28 x 65 mm
04.24.30.28070	Zimmer Type Thread Sliding Screw 28 x 70 mm
04.24.30.28075	Zimmer Type Thread Sliding Screw 28 x 75 mm
04.24.30.28080	Zimmer Type Thread Sliding Screw 28 x 80 mm
04.24.30.28085	Zimmer Type Thread Sliding Screw 28 x 85 mm
04.24.30.28090	Zimmer Type Thread Sliding Screw 28 x 90 mm
04.24.30.28095	Zimmer Type Thread Sliding Screw 28 x 95mm
04.24.27.12080	HBF - Femoral / Proximal Sliding Screw - 80mm
04.24.27.12085	HBF - Femoral / Proximal Sliding Screw - 85 mm
04.24.27.12090	HBF - Femoral / Proximal Sliding Screw - 90 mm
04.24.27.12095	HBF - Femoral / Proximal Sliding Screw - 95 mm
04.24.27.12100	HBF - Femoral / Proximal Sliding Screw - 100 mm
04.24.27.12105	HBF - Femoral / Proximal Sliding Screw - 105 mm
04.24.27.12110	HBF - Femoral / Proximal Sliding Screw - 110 mm
04.24.27.12115	HBF - Femoral / Proximal Sliding Screw - 115 mm
04.24.27.12120	HBF - Femoral / Proximal Sliding Screw - 120 mm
04.24.65.10070	HBF – Sliding Screw - 2 Ø 10,2 x 70 mm
04.24.59.21070	Godoy Moreira Sliding Screw 21 x 70 mm
04.24.59.21080	Godoy Moreira Sliding Screw 21 x 80 mm
04.24.59.21090	Godoy Moreira Sliding Screw 21 x 90 mm
04.24.59.21100	Godoy Moreira Sliding Screw 21 x 100 mm
04.24.59.21110	Godoy Moreira Sliding Screw 21 x 110 mm
04.24.59.21120	Godoy Moreira Sliding Screw 21 x 120 mm

Table – Sliding Protectors

Code	Description
04.41.01.10050	HBF – Sliding Protector - 2 Ø 10,5 x 50 mm
04.41.01.10055	HBF – Sliding Protector - 2 Ø 10,5 x 55 mm
04.41.01.10060	HBF – Sliding Protector - 2 Ø 10,5 x 60 mm
04.41.01.10065	HBF – Sliding Protector - 2 Ø 10,5 x 65 mm
04.41.01.10070	HBF – Sliding Protector - 2 Ø 10,5 x 70 mm
04.41.01.10075	HBF – Sliding Protector - 2 Ø 10,5 x 75 mm
04.41.01.10080	HBF – Sliding Protector - 2 Ø 10,5 x 80 mm
04.41.01.10085	HBF – Sliding Protector - Ø 10,5 x 85 mm
04.41.01.10090	HBF – Sliding Protector - 2 Ø 10,5 x 90 mm
04.41.01.10095	HBF – Sliding Protector - 2 Ø 10,5 x 95 mm
04.41.01.10100	HBF – Sliding Protector - 2 Ø 10,5 x 100 mm

Important:

To implant the Sliding Screws needs to use the specific instrumental that should be acquired separately of the screws.

The Tube Plates used together with the Sliding Screws should be acquired separately of the screws.

The instrumental to implantation of the Sliding Screws is registered by Anvisa under nºs. 10231160137/ 10231160138/ 10231160139/ 10231160144.

The Tube Plates are registered by Anvisa under nº. 10417940029.

Consult your representative MDT for more information about the instrumental and tube plates.

The instrumental to implantation of Sliding Screws is consists of the following items:

Table – Instrumentals

Code	Description
02.15.03.00001	DHS Combined Reamer
02.15.03.00003	DCS Combined Reamer
02.01.01.35235	Hexagonal Key 3,5 mm
02.25.06.00000	Introducer of Sliding Screw
02.68.01.00000	Extensor Guide DHS-DCS Sliding Screw
02.03.04.12220	Tap to DHS/DCS Sliding Screw
02.14.05.00001	Impactor for Tube Plate
02.11.12.00002	Long Centralizer Handle
02.11.12.00001	Short Centralizer Handle
02.11.13.00000	Cable “T” for Angled Guide
07.08.07.25230	Steinmann Type Wire Ø2,5 x 230mm
02.05.00.24070	Depth Gauge 70 mm
02.31.01.16185	Scale Measuring 160 mm Canulated
02.10.01.32150	Plain Helicoid Drill Ø 3,2 x 150 mm
02.10.01.45150	Plain Helicoid Drill Ø 4,5 x 150 mm
02.03.01.45175	Ø 4,5 x 1,75 Cortical Tap
02.03.02.65275	Cancellous Tap Ø 6.5 x 2,75
02.02.04.32031	Double Guide with Removes Tip Ø 3,2 mm
02.02.02.45047	Simple Serrated Guide for Drill Ø4,5mm
02.02.01.32037	Simple Guide to Drill 3.2 mm
02.02.19.00095	95º Angled Guide – DCS
02.02.19.00135	135º Angled Guide – DCS

The instrumentals must be acquired separately and always of the same implant manufacturer. The instrumentals are supplied decontaminated, but not sterilized.

The surgical instruments are subject to wear and tear during the normal use and it can be break. The surgical instruments must be used only for its purpose. All instruments should be inspected regularly to check possible wear and damage.

The surgical instruments must be acquired separately and always of the same implant manufacturer.

The instrumentals are supplied decontaminated, but not sterilized. Receiving engraving of:

- Product Code;
- Number of batch;
- Company logo.

Contra indications

To what medical treatment of general manner may concern, all surgical technique, even when properly applied can present problems, complications and situations in which the final objective is not totally or partially achieved, and being their contra-indications always dependent upon the assistant-surgeon evaluation of the case and criteria, starting from the anatomy, local biology and systemic, the care of planning and preoperative prepare, the execution and application of perfect technique at intra operative and even the socioeconomic and cultural profile and so that there is respect and the patient cooperation the after surgery recommendations and follow-up. However, there are rules to be followed to avoid problems.

Below, are listed some contra indications although concerning (medical criteria), most often related to the implant:

- The ideal application of plates and screws, is done in the situation where they are subjected preferable to tensile forces (tension band), this requires that the fracture is comminuted, is anatomically reconstructed, although this is not always possible. The option for use as “plate in

bridge" or "plate in wave" in comminuted and unstable fractures is perfectly possible since that there is aware that the implant will be required beyond its normal capacity and if the fracture not consolidate in a term average of 3 to 4 months, can lead to osteosynthesis failure with breaks and loosening of material;

- Poor quality of cutaneous coverage and soft tissues, in which can lead to exposure of the material synthesis by skin necrosis, facilitating installation and maintenance of infectious processes;
- Situations which require an excessive modeling of implant, beyond its normal resistance limit, for example: bone anatomy with difficult adaptation of plate to its surface, with repeated shunting of implant flexion;
- Certain allergies to steel stainless. In this case the doctor must apply exams and pertinent tests and evaluate the achievement surgical procedure;
- Local circulatory disease, arterial and venous insufficiencies that predisposing to the appearance of dehiscence and skin necrosis, to the appearance or maintenance of infections, problems and thromboembolic phenomena;
- Systemic diseases, which by diminution of local or general defenses or of circulatory conditions can predispose to complications as dehiscence and infections;
- Neurological disorders, that can bring change in bone strength, or neuro-muscular activity that can overload the implant;
- Bone diseases quickly destructive (for example: Charcot arthroplasty, bone tumors, etc.);
- Osteonecrosis, specially post-irradiation can bring infection troubles and dehiscence;
- The presence of the patient particulars conditions which can bring some bio-incompatibility with the metallic league used in the manufacturing implant.

This system is also contra indicated for patients:

- Young and active;
- That play sportive activities;
- With weight above 102 kilograms;
- With previous or actual infectious pathology;
- Particular conditions of the patient: senility, alcoholism and infections. These conditions should be carefully investigated by the surgeon, which should alert the patient about risks from these particularities;

The use in the above cases can cause wear or premature loosening of the Screw, by excessive mechanical stress, infection and prosthetic luxation.

Adverse Effects

In addition to the fact that obvious risks can happen at presence of orthopedic implants, as the failure, loosening and fracture, the following risks of adverse tissue answers and complications possible should be presented and discussed with the patient:

- Though no scientifically proven association between the use of orthopedic implants with the material features as the ones used in the nails and the occurrence of cancer, any risks and uncertainty about the long term articular substitution effects, should be discussed with the patient prior to the surgery. The patient should also be informed that any circumstances that may drive to chronic tissue damage can be oncogene. Cancerous tissues found in the implant vicinity may be related factors not linked directly to the implant such as: metastases from primary lung tumors, breast, digestive system and others, or yet due to the implantation of cancerous cells that may occur during operatory procedures or diagnoses such as biopsy or yet resulting from progression of the Paget illness;
- The implantation of foreign materials in organic tissues can elicit inflammatory responses that can happen, for example, at presence of debris from implants (such as metallic debris or polyethylene), which can cause response histiocytic type strange body granuloma of causing bone destruction, associated or not at implant loosening;
- Sensibility or atopic to metal can be found after the implantation of orthopedic devices, as for example, which happen with the nickel, cobalt and chrome that are presents in the steel

stainless league of orthopedic use. The titanium and its alloys of orthopedic use, are less antigenic accentually and have their use recommended in patients with historic of allergies or sensibility to metal;

Precautions

- The surgeon should not initiate the clinical use of the sliding screws before complete reading these instructions for use. Additionally, shall use the sliding screws together with the instrumentals, in specialized environments (ambulatory or operating rooms). The medical team should verify the screws and instrumentals integrity at the end of the sterilization process and before the use;
- It is recommended the use of prophylactic antibioticterapy in cases where there is local or systemic predisposition to infections occurrence;
- The sliding screw was designed to be implanted through the use of instrumental, specifically developed for this aims. Any improvisation with different instrumentals or inaccurate surgical technique may compromise the quality of fixation and/or implant positioning;
- The prophylaxis of thromboembolic complications occurrence is also recommended in lower limbs surgeries and patients who are predisposed to these phenomena, as risk factors already described in specific literature;
- SINGLE USE PRODUCT – DO NOT REUSE;
- The Sliding Screw is supplied sterile;
- Discard and DO NOT USE opened or damaged devices. Use only devices that are packaged in closed packages and undamaged;

The patient must be informed of:

- All the postoperative restrictions, particularly those related to sports and occupational activities;
- The patient should be adequately oriented about the post operative care. The capacity and willingness of the patient in follow the instructions is the most important aspect in an orthopedic surgical procedure;
- Children, elderly, patients with mental disturbs or chemical dependents, may represent a higher risk to the failure implant, because they can ignore the instructions and restrictions;
- Should instruct the patient, the medical criteria that use external supports, aid to ambulate and orthopedic appliances, designed to immobilize the fracture area and to limit the load;
- The fact that complications or failures in osteosynthesis are more likely to occur in:
  - Patients with functional expectative beyond what can be promoted by the surgery;
  - Patients with overweight, above 102 kilograms;
  - Patients with systemic or local diseases that cause bone disorders such as osteoporosis.
- When components loosen and osteolysis occurs and not is performed review surgery, can result in progressive loss of periprosthetic bone stock;
- Should alert the patient and make him understand that the product does not substitute and does not have the same performance of the normal bone and therefore can break, deform or loosen, due to excessive effort or activities of early load, etc;
- The patient should be oriented to inform that is implant user when submitted to Magnetic Resonance examinations;
- The need for periodic monitoring and medical evaluation to check the possible alterations of implant and adjacent bone. Only the accompanying can detect possible loosening of component or osteolysis occurrence;
- It is recommended to have radiographic and clinic monitoring during the postoperative, with the purpose of compare the initial postoperative condition and detect evidence to long term related with position change, loosening or fissure of components;
- The metallic materials, as well as the steel stainless, can interfere in the radiographies reading;
- The information listed in topics: Indications, Contra Indications, Warnings, and Precautions.

Warnings

- The opening of the package for surgical use should be performed by nursing team that is qualified for this procedure;
- Do not use the product if the packaging is breached or with the validity expired. The care with this material is responsibility of qualified team;
- Single use Hospital Medical Product - Discard after explantation. We recommend that the parts are cut, twist or file to its destruction, but to dispose of this product, observe, however, the local law;
- Inadequate sterilization of the surgical instrumental can cause prosthetic infection;
- Never reuse an implant, because even without external appearance of damage, previous tensions can reduce their lifetime;
- Non sterile Product – should be washed and sterilized before the use, correctly handle to avoid contamination;
- All explanted material, damaged or improper for use, should be sent to the manufacturer to be destroyed;
- Handling with care;
- The patient should have periodic medical monitoring to check the conditions of the implant and adjacent bone;
- Should be respected the limit of implant resistance, which varies by type, at risk of its weakening and possible fracture of the material;
- Should be unpacked to be sterilized, because this packaging is improper for this procedure;
- Do not use components of manufacturer others;
- Manufacturing date, validity term and batch number: see label.

Instructions for Use

The surgical techniques vary according to the surgeon choice, which is responsible by the method, type and dimension of products to be used, as well as, the evaluation criteria of the surgical results.

- Sterilize the screws according to the instructions recommended below;
- Handle exclusively the screws in specialized environments (ambulatory or operating rooms) with required care (handling only with sterile gloves). Only qualified professionals must handle and implant the screws;
- The Screws should be applied and adapted according to the requirement and adequate surgical techniques;
- The torque to be applied during the bone insertion depends of bone characteristics and conditions. The surgeon must decide which torque applies;
- The clinical results and the durability of the implants in the femur total arthroplasty are extremely dependents on an tridimensional align of the components, therefore being indispensable an accurate surgical technique;
- The use of different alloys in metallic junctions can cause galvanic corrosion of the implant;
- It's recommended to be used the same methodology for the system assembling so that it does not affect its rigidity.

Do not use the Sliding Screws together with products of other brands, because of having problems of materials incompatibility.

Cleaning and Sterilization

Before initiate the instrumentals and implants sterilization process, they must be removed of their package and cleaning with alcohol for medical ends at 70% + distilled water 30%.

After the cleaning, the products must be rinse with sterile distillate water and dried with cleaning cloth that does not release fibers.

Important

Detergents with free chlorine or sodium hydroxide should not be used.

Sterilization

Before the surgical use, the instrumentals must be cleaned as above described and sterilized by autoclave. The sterilization does not substitute the cleaning and never will be achieved with dirty material.

Autoclaving is a secure sterilization process, however, if there are not controls for the operational parameters, can cause damage at the instrumental:

Humidity + High temperature + Oxygen = Corrosion = Microfissure = Crack = Break

The selected sterilization process must meet, in any case, the standard EN556, which establishes the theoretical probability of presence of microorganism vital to a maximum of 1 $x10^6$ (S.A.L. [Sterility Assurance Level] = 10^{-6}).

For cleaning and sterilization, observe the appropriate procedures. As a suggestion, use the standard ASTM F1744:1996.

The recommended sterilization cycle is:

Method	Cycle	Temperature	Exposition Time
Steam	Pre-Vacuum	132º - 135º C [270º - 275º F]	Minimum 10 minutes

Inspection

- Inspect if the instrument presents signs of wear and damage in all handling stages;
- If any damage is detected, consult the representative of the MDT Indústria Comércio Importação e Exportação de Implantes Ltda., for guidelines.

Risk of Contamination

Considering that the screw come in contact with tissues and corporals fluids there is a biological contamination risk and viral diseases transmission, such as hepatitis and HIV, etc. Therefore, the explanted screws should be treated as contaminant potentially material.

Product Discard

Fall and crushing on hard surfaces can cause damage to the product. Thus, it is necessary an inspection of the product integrity when the packaging is opened, and if any abnormality is observed the product should not be used;

After removal of patient, discard all screws, because they **should not be reused**.

The explanted implants or that by accident are defective should be unusable for use before discard. It is recommended that the parts be cut, twist or filing for its destruction.

To discard the explanted screws, following the legal local procedures of country, for dispose of contaminants potentially products.

Traceability

To ensure the traceability of the implanted product, and comply with the requirements for sanitary surveillance, as a recommendation, the surgeon responsible for implementation should notify the distributor with the following data concerning the implanted product, patient and surgery:

- Surgeon's name;
- Surgery date;
- Name of patient who received the implant;
- Product code;

- Number of batch of the product;

The Screw receives engraving in body with the following information:

- Product code;
- Manufacturing batch;
- Company logo.

Storage

It is recommended dry and airy place, far away of the sunbeam direct incidence.

The implants cannot be stored directly on the floor (minimum height = 20 cm). They cannot stay in high shelves proximate the lamps (for not dry out or delete the package label), cannot be stored in areas where contaminant substances such as insecticides, pesticides or cleaning materials are used.

Transport

Transport with care, avoiding falls and friction that can damage the surface finish. Always observe the packaging integrity.

Keep always the implants in their original packaging until the moment of its use, under the responsibility of medical team designated for this aims.

Manufacturing date, validity term and batch number: see label.

Do not use the product beyond the validity date.

Other Information

Manufactured and distributed by:
MDT – Indústria Comércio Importação e Exportação de Implantes SA
Av. Brasil, nº 2983 – Distrito Industrial
Rio Claro/SP - CEP 13505-600
Phone/Fax: (55-19) 2111-6500
Technical Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

Registration Anvisa #: 10417940027
Review: 01
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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.

MDTImplantes

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