Use Instructions

Tube Plate

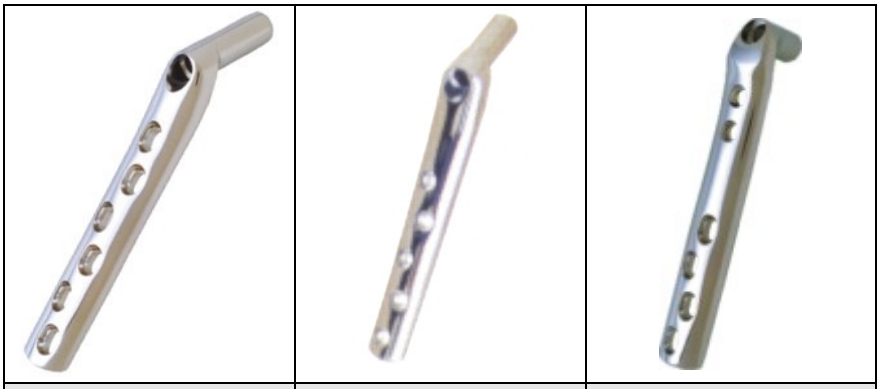
Legends of the symbols used on packaging

REF	Product Code		Avoid exposure to direct sunlight
LOT	Batch Number		Keep protected of humidity
	Read the Use Instructions		Take Care - Fragile
Material SS	Stainless Steel (ASTM F 138)		Do not use if the packaging is violated
DD/MM/YYY	Manufacturing Date		
NON STERILE	Non Sterile		Single Use Product

Description

The tube plates are: tubular, flattened and curved to follow the bone curvature. Are implantable devices used together with the respective sliding screw. They are produced in Stainless Steel type ASTM F 138.

These devices are disposable and should not be reused. The instructions here presented are valid for all tube plates, all models and measures. See models available below:



DHC/DCS	Type Richards	Type Zimmer

The Tube Plates are available in the following presentations:

Code	Description
04.27.10.00002	Tubular Angled Plate type Richards 135° C/S 02 Holes
04.27.10.00003	Tubular Angled Plate type Richards 135° C/S 03 Holes
04.27.10.00004	Tubular Angled Plate type Richards 135° C/S 04 Holes
04.27.10.00005	Tubular Angled Plate type Richards 135° C/S 05 Holes
04.27.10.00006	Tubular Angled Plate type Richards 135° C/S 06 Holes
04.27.10.00007	Tubular Angled Plate type Richards 135° C/S 07 Holes
04.27.10.00008	Tubular Angled Plate type Richards 135° C/S 08 Holes
04.27.10.00009	Tubular Angled Plate type Richards 135° C/S 09 Holes
04.27.10.00010	Tubular Angled Plate type Richards 135° C/S 10 Holes
04.27.10.00011	Tubular Angled Plate type Richards 135° C/S 11 Holes
04.27.10.00012	Tubular Angled Plate type Richards 135° C/S 12 Holes
04.27.10.00013	Tubular Angled Plate type Richards 135° C/S 13 Holes
04.27.10.00014	Tubular Angled Plate type Richards 135° C/S 14 Holes

04.27.10.00015	Tubular Angled Plate type Richards 135° C/S 15 Holes
04.27.10.00016	Tubular Angled Plate type Richards 135° C/S 16 Holes
04.27.10.00017	Tubular Angled Plate type Richards 135° C/S 17 Holes
04.27.10.00018	Tubular Angled Plate type Richards 135° C/S 18 Holes
04.27.10.00019	Tubular Angled Plate type Richards 135° C/S 19 Holes
04.27.10.00020	Tubular Angled Plate type Richards 135° C/S 20 Holes
04.27.11.00002	Tubular Angled Plate type Richards 90º C/S 02 Holes
04.27.11.00003	Tubular Angled Plate type Richards 90º C/S 03 Holes
04.27.11.00004	Tubular Angled Plate type Richards 90º C/S 04 Holes
04.27.11.00005	Tubular Angled Plate type Richards 90º C/S 05 Holes
04.27.11.00006	Tubular Angled Plate type Richards 90º C/S 06 Holes
04.27.11.00007	Tubular Angled Plate type Richards 90º C/S 07 Holes
04.27.11.00008	Tubular Angled Plate type Richards 90º C/S 08 Holes
04.27.11.00009	Tubular Angled Plate type Richards 90º C/S 09 Holes
04.27.11.00010	Tubular Angled Plate type Richards 90º C/S 10 Holes
04.27.11.00011	Tubular Angled Plate type Richards 90º C/S 11 Holes
04.27.11.00012	Tubular Angled Plate type Richards 90º C/S 12 Holes
04.27.11.00013	Tubular Angled Plate type Richards 90º C/S 13 Holes
04.27.11.00014	Tubular Angled Plate type Richards 90º C/S 14 Holes
04.27.11.00015	Tubular Angled Plate type Richards 90º C/S 15 Holes
04.27.11.00016	Tubular Angled Plate type Richards 90º C/S 16 Holes
04.27.11.00017	Tubular Angled Plate type Richards 90º C/S 17 Holes
04.27.11.00018	Tubular Angled Plate type Richards 90º C/S 18 Holes
04.27.11.00019	Tubular Angled Plate type Richards 90º C/S 19 Holes
04.27.11.00020	Tubular Angled Plate type Richards 90º C/S 20 Holes
04.27.12.00002	Tubular Angled Plate type Zimmer 90° C/S 02 Holes
04.27.12.00003	Tubular Angled Plate type Zimmer 90° C/S 03 Holes
04.27.12.00004	Tubular Angled Plate type Zimmer 90° C/S 04 Holes
04.27.12.00005	Tubular Angled Plate type Zimmer 90° C/S 05 Holes
04.27.12.00006	Tubular Angled Plate type Zimmer 90° C/S 06 Holes
04.27.12.00007	Tubular Angled Plate type Zimmer 90° C/S 07 Holes
04.27.12.00008	Tubular Angled Plate type Zimmer 90° C/S 08 Holes
04.27.12.00009	Tubular Angled Plate type Zimmer 90° C/S 09 Holes
04.27.12.00010	Tubular Angled Plate type Zimmer 90° C/S 10 Holes
04.27.12.00011	Tubular Angled Plate type Zimmer 90° C/S 11 Holes
04.27.12.00012	Tubular Angled Plate type Zimmer 90° C/S 12 Holes
04.27.12.00013	Tubular Angled Plate type Zimmer 90° C/S 13 Holes
04.27.12.00014	Tubular Angled Plate type Zimmer 90° C/S 14 Holes
04.27.12.00015	Tubular Angled Plate type Zimmer 90° C/S 15 Holes
04.27.12.00016	Tubular Angled Plate type Zimmer 90° C/S 16 Holes
04.27.12.00017	Tubular Angled Plate type Zimmer 90° C/S 17 Holes
04.27.12.00018	Tubular Angled Plate type Zimmer 90° C/S 18 Holes
04.27.12.00019	Tubular Angled Plate type Zimmer 90° C/S 19 Holes
04.27.12.00020	Tubular Angled Plate type Zimmer 90° C/S 20 Holes
04.27.13.00002	Tubular Angled Plate type Zimmer 135º C/S 02 Holes
04.27.13.00003	Tubular Angled Plate type Zimmer 135º C/S 03 Holes
04.27.13.00004	Tubular Angled Plate type Zimmer 135º C/S 04 Holes
04.27.13.00005	Tubular Angled Plate type Zimmer 135º C/S 05 Holes
04.27.13.00006	Tubular Angled Plate type Zimmer 135º C/S 06 Holes
04.27.13.00007	Tubular Angled Plate type Zimmer 135º C/S 07 Holes
04.27.13.00008	Tubular Angled Plate type Zimmer 135º C/S 08 Holes

04.27.13.00009	Tubular Angled Plate type Zimmer 135º C/S 09 Holes
04.27.13.00010	Tubular Angled Plate type Zimmer 135º C/S 10 Holes
04.27.13.00011	Tubular Angled Plate type Zimmer 135º C/S 11 Holes
04.27.13.00012	Tubular Angled Plate type Zimmer 135º C/S 12 Holes
04.27.13.00013	Tubular Angled Plate type Zimmer 135º C/S 13 Holes
04.27.13.00014	Tubular Angled Plate type Zimmer 135º C/S 14 Holes
04.27.13.00015	Tubular Angled Plate type Zimmer 135º C/S 15 Holes
04.27.13.00016	Tubular Angled Plate type Zimmer 135º C/S 16 Holes
04.27.13.00017	Tubular Angled Plate type Zimmer 135º C/S 17 Holes
04.27.13.00018	Tubular Angled Plate type Zimmer 135º C/S 18 Holes
04.27.13.00019	Tubular Angled Plate type Zimmer 135º C/S 19 Holes
04.27.13.00020	Tubular Angled Plate type Zimmer 135º C/S 20 Holes
04.27.14.00002	Tubular Angled Plate Type DCS 95° High Compression 02 Holes
04.27.14.00003	Tubular Angled Plate Type DCS 95° High Compression 03 Holes
04.27.14.00004	Tubular Angled Plate Type DCS 95° High Compression 04 Holes
04.27.14.00005	Tubular Angled Plate Type DCS 95° High Compression 05 Holes
04.27.14.00006	Tubular Angled Plate Type DCS 95° High Compression 06 Holes
04.27.14.00007	Tubular Angled Plate Type DCS 95° High Compression 07 Holes
04.27.14.00008	Tubular Angled Plate Type DCS 95° High Compression 08 Holes
04.27.14.00009	Tubular Angled Plate Type DCS 95° High Compression 09 Holes
04.27.14.00010	Tubular Angled Plate Type DCS 95° High Compression 10 Holes
04.27.14.00011	Tubular Angled Plate Type DCS 95° High Compression 11 Holes
04.27.14.00012	Tubular Angled Plate Type DCS 95° High Compression 12 Holes
04.27.14.00013	Tubular Angled Plate Type DCS 95° High Compression 13 Holes
04.27.14.00014	Tubular Angled Plate Type DCS 95° High Compression 14 Holes
04.27.14.00015	Tubular Angled Plate Type DCS 95° High Compression 15 Holes
04.27.14.00016	Tubular Angled Plate Type DCS 95° High Compression 16 Holes
04.27.15.00002	Tubular Angled Plate Type DHS 135° High Compression 02 Holes
04.27.15.00003	Tubular Angled Plate Type DHS 135° High Compression 03 Holes
04.27.15.00004	Tubular Angled Plate Type DHS 135° High Compression 04 Holes
04.27.15.00005	Tubular Angled Plate Type DHS 135° High Compression 05 Holes
04.27.15.00006	Tubular Angled Plate Type DHS 135° High Compression 06 Holes
04.27.15.00007	Tubular Angled Plate Type DHS 135° High Compression 07 Holes
04.27.15.00008	Tubular Angled Plate Type DHS 135° High Compression 08 Holes
04.27.15.00009	Tubular Angled Plate Type DHS 135° High Compression 09 Holes
04.27.15.00010	Tubular Angled Plate Type DHS 135° High Compression 10 Holes
04.27.15.00011	Tubular Angled Plate Type DHS 135° High Compression 11 Holes
04.27.15.00012	Tubular Angled Plate Type DHS 135° High Compression 12 Holes
04.27.15.00013	Tubular Angled Plate Type DHS 135° High Compression 13 Holes
04.27.15.00014	Tubular Angled Plate Type DHS 135° High Compression 14 Holes
04.27.15.00015	Tubular Angled Plate Type DHS 135° High Compression 15 Holes
04.27.15.00016	Tubular Angled Plate Type DHS 135° High Compression 16 Holes
04.27.15.00017	Tubular Angled Plate Type DHS 135° High Compression 17 Holes
04.27.15.00018	Tubular Angled Plate Type DHS 135° High Compression 18 Holes
04.27.15.00019	Tubular Angled Plate Type DHS 135° High Compression 19 Holes
04.27.15.00020	Tubular Angled Plate Type DHS 135° High Compression 20 Holes
04.27.16.00002	Tubular Angled Plate Type DHS 140° High Compression 02 Holes
04.27.16.00003	Tubular Angled Plate Type DHS 140° High Compression 03 Holes
04.27.16.00004	Tubular Angled Plate Type DHS 140° High Compression 04 Holes
04.27.16.00005	Tubular Angled Plate Type DHS 140° High Compression 05 Holes
04.27.16.00006	Tubular Angled Plate Type DHS 140° High Compression 06 Holes

04.27.16.00007	Tubular Angled Plate Type DHS 140° High Compression 07 Holes
04.27.16.00008	Tubular Angled Plate Type DHS 140° High Compression 08 Holes
04.27.16.00009	Tubular Angled Plate Type DHS 140° High Compression 09 Holes
04.27.16.00010	Tubular Angled Plate Type DHS 140° High Compression 10 Holes
04.27.16.00011	Tubular Angled Plate Type DHS 140° High Compression 11 Holes
04.27.16.00012	Tubular Angled Plate Type DHS 140° High Compression 12 Holes
04.27.16.00013	Tubular Angled Plate Type DHS 140° High Compression 13 Holes
04.27.16.00014	Tubular Angled Plate Type DHS 140° High Compression 14 Holes
04.27.16.00015	Tubular Angled Plate Type DHS 140° High Compression 15 Holes
04.27.16.00016	Tubular Angled Plate Type DHS 140° High Compression 16 Holes
04.27.16.00017	Tubular Angled Plate Type DHS 140° High Compression 17 Holes
04.27.16.00018	Tubular Angled Plate Type DHS 140° High Compression 18 Holes
04.27.16.00019	Tubular Angled Plate Type DHS 140° High Compression 19 Holes
04.27.16.00020	Tubular Angled Plate Type DHS 140° High Compression 20 Holes
04.27.17.00002	Tubular Angled Plate Type DHS 145° High Compression 02 Holes
04.27.17.00003	Tubular Angled Plate Type DHS 145° High Compression 03 Holes
04.27.17.00004	Tubular Angled Plate Type DHS 145° High Compression 04 Holes
04.27.17.00005	Tubular Angled Plate Type DHS 145° High Compression 05 Holes
04.27.17.00006	Tubular Angled Plate Type DHS 145° High Compression 06 Holes
04.27.17.00007	Tubular Angled Plate Type DHS 145° High Compression 07 Holes
04.27.17.00008	Tubular Angled Plate Type DHS 145° High Compression 08 Holes
04.27.17.00009	Tubular Angled Plate Type DHS 145° High Compression 09 Holes
04.27.17.00010	Tubular Angled Plate Type DHS 145° High Compression 10 Holes
04.27.17.00011	Tubular Angled Plate Type DHS 145° High Compression 11 Holes
04.27.17.00012	Tubular Angled Plate Type DHS 145° High Compression 12 Holes
04.27.17.00013	Tubular Angled Plate Type DHS 145° High Compression 13 Holes
04.27.17.00014	Tubular Angled Plate Type DHS 145° High Compression 14 Holes
04.27.17.00015	Tubular Angled Plate Type DHS 145° High Compression 15 Holes
04.27.17.00016	Tubular Angled Plate Type DHS 145° High Compression 16 Holes
04.27.17.00011	Tubular Angled Plate Type DHS 145° High Compression 17 Holes
04.27.17.00018	Tubular Angled Plate Type DHS 145° High Compression 18 Holes
04.27.17.00019	Tubular Angled Plate Type DHS 145° High Compression 19 Holes
04.27.17.00020	Tubular Angled Plate Type DHS 145° High Compression 20 Holes
04.27.18.00002	Tubular Angled Plate Type DHS 145° High Compression 02 Holes
04.27.18.00003	Tubular Angled Plate Type DHS 150° High Compression 03 Holes
04.27.18.00004	Tubular Angled Plate Type DHS 150° High Compression 04 Holes
04.27.18.00005	Tubular Angled Plate Type DHS 150° High Compression 05 Holes
04.27.18.00006	Tubular Angled Plate Type DHS 150° High Compression 06 Holes
04.27.18.00007	Tubular Angled Plate Type DHS 150° High Compression 07 Holes
04.27.18.00008	Tubular Angled Plate Type DHS 150° High Compression 08 Holes
04.27.18.00009	Tubular Angled Plate Type DHS 150° High Compression 09 Holes
04.27.18.00010	Tubular Angled Plate Type DHS 150° High Compression 10 Holes
04.27.18.00011	Tubular Angled Plate Type DHS 150° High Compression 11 Holes
04.27.18.00012	Tubular Angled Plate Type DHS 150° High Compression 12 Holes
04.27.18.00013	Tubular Angled Plate Type DHS 150° High Compression 13 Holes
04.27.18.00014	Tubular Angled Plate Type DHS 150° High Compression 14 Holes
04.27.18.00015	Tubular Angled Plate Type DHS 150° High Compression 15 Holes
04.27.18.00016	Tubular Angled Plate Type DHS 150° High Compression 16 Holes
04.27.18.00017	Tubular Angled Plate Type DHS 150° High Compression 17 Holes
04.27.18.00018	Tubular Angled Plate Type DHS 150° High Compression 18 Holes
04.27.18.00019	Tubular Angled Plate Type DHS 150° High Compression 19 Holes

04.27.18.00020	Tubular Angled Plate Type DHS 150° High Compression 20 Holes

Composition

The Tube Plates are manufactured in Stainless Steel according to with the specification ASTM F-138 - Standard Specification for Wrought 18 Chromium -14 Nickel - 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants.

Purpose

It is indicated for fixation in fractures of femur colon, condylar fractures and knee.

IMPORTANT:

The Tube Plates are used together with the Sliding Screws for its implantation and is need the use of specific instrumental that should be acquired separately of plates.

The instrumental for implant of Tube Plate is registered by Anvisa under nº. 10417940035.

The Sliding Screws are registered by Anvisa under nº. 10417940027.

Consult its representative MDT for more information about the instrumental and screws.

The instrumental for implant of Tube Plate is consists of the following items:

For DHS/DCS

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 to Tube Plate
02.11.12.00002	Long Centralizer Handle
02.11.12.00001	Short Centralizer Handle
02.11.13.00000	Handle in “T” for Angled Guide
07.08.07.25230	Steinmann Type Wire Ø2,5 x 230 mm
02.05.00.24070	Depth Gauge 70 mm
02.31.01.16185	Scale measuring cannulated 160 mm
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	Ø4,5 x 1,75 Cortical Tap
02.03.02.65275	Cancellous Tap Ø 6.5 x 2,75 Passo
02.02.04.32031	Double Guide with Removes Tip Ø 3,2 mm
02.02.02.45047	Simple Serrated Guide for Drill Ø4,5 mm
02.02.01.32037	Simple Guide for Drill 3,2 mm
02.02.19.00095	95º Angled Guide – DCS
02.02.19.00135	135" Angled Guide

For Richard’s

Code	Description
02.01.01.35235	Hexagonal Key 3,5 mm
02.05.00.24070	Depth Gauge 70 mm
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
02.02.01.32037	Simple Guide for Drill Ø 3,2 mm
02.03.01.45175	Ø4,5 x 1,75 Cortical Tap

02.03.02.65275	Cancellous Tap Ø 6.5 x 2,75 Passo
02.14.05.00001	Impactor to Tube Plate
02.06.01.24210	Hohmann Retractor 24 x 210 mm
02.08.01.00063	Screw Tweezer
02.25.06.00001	Introducer of Sliding Screw Richard's
02.68.01.00001	Extender of Sliding Screw Richard's
02.11.20.00001	Handle in “T” for Screw Richard's
02.15.03.00002	Combined Reamer Richard's
02.20.03.25300	Calibrate Wire Ø 2,5 x 300 mm
02.02.42.00001	Richard´s Assistant Guide
02.31.01.20250	Cannulated Measure Scale 200 mm
02.02.37.00002	Mobile Graduated Guide
02.03.04.12275	Tap for Sliding Screw Richard's
02.63.01.00030	Box with Lid for Packaging of Tube Plate Richard´s
02.63.05.00030	Tray for Tube Plate Richard's

The instrumentals should be acquired separately and always from the same manufacturer of the implant. The instrumentals are provided decontaminated, but not sterilized.

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

The instrumentals should be acquired separately and always from the same manufacturer of the implant.

The instrumentals are provided decontaminated, but not sterilized. Receiving engrave 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.

Following, 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), for this is need that the fracture, if 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 an average term of 3 to 4 months, can lead to osteosynthesis failure with breaks and loosening of material;
- In cases when there is instability for bone failure by comminution or bone loss it is recommended the use of adequate implants in the serious cases or use of autologous grafting for mild and moderate cases;
- Osteoporosis leading material loosening. In cases of tube plates can have colon and head fractures with loss reduction, or blade extrusion into joint;
- 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 in 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, if relevant, the achievement of surgery;
- 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 alloy 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;
- With dementia problems or neurological changes of lower limbs;
- 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 Tube Plate, 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 Tube Plates 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 (as metallic debris or of 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 alloy 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 use of the tube plates before complete reading these use instructions. Additionally should be used tube plates as well as its instrumentals, at specialized environment (ambulatory or operating rooms). The medical team should verify the plates and instrumentals integrity at end of the sterilization process and before the use.**
- The use of prophylactic antibioticterapy in cases where there is local predisposition or systemic to occurrence of infections is recommended;
- The Tube Plate was designed to be implanted through the use of instrumental, specifically developed for this aim. Any improvisations with different instrumentals or inaccurate surgical technique can compromise the fixation quality 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 already described in specific literature, like risk factors;
- **SINGLE USE PRODUCT – DO NOT REUSE;**
- **The Tube Plate is supplied non sterile;**
- Discard and **DO NOT USE** opened or damaged devices. Use only devices that are packaged in closed packages and undamaged;

The patient should be informed about:

- All the postoperative restrictions, especially those related to sports and occupational activities;
- The patient should be adequately oriented about the postoperative 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 device, 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 validity expired or with the packaging violated. 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 legislation;
- 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;
- Handle 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.

Use Instructions

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 surgery results.

The tube plates are indicated for use only by professionals.

The torque to be applied in the screw 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 are extremely dependents on a 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;

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

Cleaning and Sterilization

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

After the cleaning, the products must be rinsed 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

1) Inspect if the instrument presents signs of wear and damage in all handling stages;

2) 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 plate 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 plates 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 plates, because they **must 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 avoid reuse - intentional or not – of product.

To discard the explanted plates, 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 plate receives engraving in body with the following information:

- Company Name;
- Manufacturing batch;

Storage and Transport:

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

To avoid falls and friction on hard surfaces to avoiding damage to the product.

Avoid falls and friction on hard surfaces to prevent damage to the product.
Manufacturing date, validity term and batch number: see label.

Outras informações

Fabricado e distribuído por:
MDT – Indústria Comércio Importação e Exportação de Implantes SA
Avenida Brasil, 2983 – Distrito Industrial – CEP 13505-600
Rio Claro/SP – Brasil
Fone/Fax: (55-19) 2111-6500
Technical Responsible: Engº. Miguel Lopes Monte Júnior – CREA 0601150192

Review: 01

Issued: February 06th 2006

Registration ANVISA Nº: 10417940029

ALERT
INSTRUCTIONS FOR USE

These INSTRUCTIONS FOR USE are not available in printed form, they are available at the web-site 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

MDT® - INDÚSTRIA COMÉRCIO IMPORT. E EXPORT. DE IMPLANTES SA
Av. Brasil, 2983 - Dt. Industrial | 13505-600 - Rio Claro / SP - Brasil
Tel./Fax. +55 (19) 2111.6500 | www.mdt.com.br