Instructions for Use

Schanz Pin

Keys used on packaging and labeling

REF	Reference number (filled with product code)	LOT	Lot Code
STERILE R	Sterile Product - Sterilized by Gamma Radiation		Expiry Date
	Manufacturing Date		Single-use product
	Read instructions for use		Do not re-sterilize
	Do not use if package is damaged		Fragile, handle with care
	Keep protected from sunlight	40 °C	Temperature limit (40 °C)
	Keep dry		

Product features and technical specifications

Technical Name: Non-absorbable hard pin and wire

Trade Name: Schanz Pin

Commercial Model:

- Schanz Pin - Sterile
- Schanz Pin - Conical - Sterile

Raw Material: 18Cr-14Ni-2.5Mo stainless steel alloy - ASTM F138

Validity: 05 years

Sterile Product

Sterilization method: gamma radiation (25 kGy)

Description

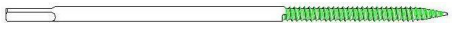
Commercial models making up the Schanz Pin family consist of surgically implantable components for long-term use indicated for osteosynthesis surgical procedures.

The purpose of the implantation of Schanz Pin is the reduction, alignment, stabilization and fixation of bone fragments against rotational forces acting on internal fixations in osteosynthesis procedures of lower and upper limbs. Its purpose is to provide a suitable environment for fracture healing by transfixing pins through the bone in order to apply traction on bone fragments and enable bone healing.

The pins may be used alone or in conjunction with internal fixation systems. They are one of the most versatile and essential synthesis methods available in the orthopedic arsenal for use in fixation of fractures in general, and they permit the application of several osteosynthesis principles and conditions, such as intramedullary internal tutor, assembly of articular fragments as well as in skeletal tractions for conservative treatment of fractures.

The Schanz Pin possesses a cylindrical body with parallel or conical thread, provided with a three-faceted connection to fit into the fixator and nail-like end. The pins are self-tapping and intended to be used with external fixation.

Below follow illustrative images of commercial models that make up the Schanz Pin family:

	
Schanz type Pin - Sterile	**Schanz Conical type Pin - Sterile**

Composition

The materials selected to compose the product have the properties required to achieve its intended performance. Such selection took into account factors like biocompatibility and physical, chemical, and mechanical properties required for the product.

The commercial models that make up the Schanz Pin 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 used to manufacture the product meets the requirements specified by ASTM F138 - *'Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).*

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

Indication and Purpose

Schanz Pins are indicated for reduction, alignment, stabilization, and fixation of bone fragments in osteosynthesis procedures of the lower and upper limbs for use with external fixators.

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 immunocompromised unable to undergo a surgical procedure;
- Patients with sensitivity to foreign bodies, and in such 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 Schanz Pin family are packaged in a double blister type primary packaging system, sealed with surgical grade paper (Tyvek®) or Tyvek® type surgical packaging system, which serves as a barrier for sterilization.

The product is offered for sale under sterile condition and the adopted sterilization method is sterilization by gamma irradiation (25 kGy): a duly qualified outsourced company performs this procedure.

After sterilized, the labeled and primarily packed product is packaged in a cardboard carton (secondary packaging), which contains a leaflet with the information that required for obtaining the instructions for use.

On the primary packaging and the carton a label containing the information required to identify the product is attached.

The Schanz Pin family is presented in the following commercial models, and each of these models is available for sale in the following sizes and quantities:

Illustrative image	Code	Description	Sizes	Raw Material	Qty Packed
	04.25.11.45160	Schanz Conical Type Pin Ø 4,5x160 mm - Sterile	**Diameter:** 4.5; 4.8; 5.0 mm **Length:** 160; 200 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F-138	01
	04.25.11.45002	Schanz Conical Type Pin Ø 4,5x160 mm - Sterile (Pack 02)			02
	04.25.11.45004	Schanz Conical Type Pin Ø 4,5x160 mm - Sterile (Pack 04)			04
	04.25.11.45006	Schanz Conical Type Pin Ø 4,5x160 mm - Sterile (Pack 06)			06
	04.25.11.45008	Schanz Conical Type Pin Ø 4,5x160 mm - Sterile (Pack 08)			08
	04.25.11.45200	Schanz Conical Type Pin Ø 4,5x200 mm - Sterile			01
	04.25.11.48200	Schanz Conical Type Pin Ø 4,8x200 mm - Sterile			01
	04.25.11.50200	Schanz Conical Type Pin Ø 5,0x200 mm - Sterile			01
	04.25.11.50002	Schanz Conical Type Pin Ø 5,0x200 mm - Sterile (Pack 02)			02
	04.25.11.50004	Schanz Conical Type Pin Ø 5,0x200 mm - Sterile (Pack 04)			04
	04.25.11.50006	Schanz Conical Type Pin Ø 5,0x200 mm - Sterile (Pack 06)			06
	04.25.11.50008	Schanz Conical Type Pin Ø 5,0x200 mm - Sterile (Pack 08)			08
	04.25.12.25080	Schanz Type Pin Ø 2,5x080 mm - Sterile	**Diameter:** 2.5; 3.0; 4.0; 4.8; 5.0 mm **Length:** 80; 200 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F-138	01
	04.25.12.25002	Schanz Type Pin Ø 2,5x080 mm - Sterile (Pack 02)			02
	04.25.12.25004	Schanz Type Pin Ø 2,5x080 mm - Sterile (Pack 04)			04
	04.25.12.25100	Schanz Type Pin Ø 2,5x100 mm - Sterile			01
	04.25.12.30080	Schanz Type Pin Ø 3,0x080 mm - Sterile			01
	04.25.12.30100	Schanz Type Pin Ø 3,0x100 mm - Sterile			01
	04.25.12.30002	Schanz Type Pin Ø 3,0x100 mm - Sterile (Pack 02)			02
	04.25.12.30004	Schanz Type Pin Ø 3,0x100 mm - Sterile (Pack 04)			04
	04.25.12.30006	Schanz Type Pin Ø 3,0x100 mm - Sterile (Pack 06)			06
	04.25.12.35080	Schanz Type Pin Ø 3,5x080 mm - Sterile			01
	04.25.12.35100	Schanz Type Pin Ø 3,5x100 mm - Sterile			01
	04.25.12.40090	Schanz Type Pin Ø 4,0x090 mm - Sterile			01
	04.25.12.40130	Schanz Type Pin Ø 4,0x130 mm - Sterile			01
	04.25.12.40150	Schanz Type Pin Ø 4,0x150 mm - Sterile			01
	04.25.12.40170	Schanz Type Pin Ø 4,0x170 mm - Sterile			01

	04.25.12.48150	Schanz Type Pin Ø 4,8x150 mm - Sterile			01
	04.25.12.48160	Schanz Type Pin Ø 4,8x160 mm - Sterile			01
	04.25.12.48170	Schanz Type Pin Ø 4,8x170 mm - Sterile			01
	04.25.12.48200	Schanz Type Pin Ø 4,8x200 mm - Sterile			01
	04.25.12.50160	Schanz Type Pin Ø 5,0x160 mm - Sterile			01
	04.25.12.50200	Schanz Type Pin Ø 5,0x200 mm - Sterile			01

Ancillary Components

The ancillary components for the Schanz Pin are the following:

- Minifix Fixator
- Colles type Fixator
- Linefix Fixator (Phalanx, Wrist, Radius, Humerus, Tibia, Femur)
- Tubofix Fixator

Ancillary components are manufactured from 18Cr-14Ni-2.5Mo stainless steel alloy, 6262 Aluminum Alloy and 6351 Aluminum Alloy. Those alloys meet, respectively, the requirements specified by ASTM F138 - *'Standard Specification for Wrought 18 Chromium- 14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673), ASTM 6262 and ASTM 6351*.

The correct selection of models and sizes of Schanz Pin, as well as their ancillaries to be implanted, is the surgeon's responsibility. The surgeon is also responsible for the applied surgical technique 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 devices, which is the responsibility of the surgeon who assesses the patient and decides which implants to employ. It is also linked to strict compliance with the post-operative care recommended by the attending surgeon.

Ancillary components listed below 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 commercial models that make up the Schanz Pin family

Illustrative image	Code	Description	Sizes	Material	Qty Packed
	04.35.03.00000	Femoral LineFix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.04.00000	Tibial LineFix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.05.00000	Humerus LineFix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.06.00000	Radius LineFix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.07.00000	Wrist LineFix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.08.00000	Phalange LineFix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.09.00000	Phalange Minifix Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.10.00000	Colles Fracture Fixator	Single	Stainless Steel AISI 304 Aluminum alloy 5052 Aluminum Alloy 6351	01
	04.35.11.00000	Tubofix Fixator - Rod-to-Pin Connector F / T	Single	Aluminum alloy 5052	01
	04.35.11.00001	Tubofix Fixator - Rod-to-Pin Connector U / R	Single	Aluminum alloy 5052	01
	04.35.12.00000	Tubofix Fixator - Rod-to-Pin Connector F / T	Single	Aluminum alloy 5052	01
	04.35.12.00001	Tubofix Fixator - Rod-to-Rod Connector U / R	Single	Aluminum alloy 5052	01
	04.35.13.00000	Fixer Tubofix - Open Connector	Single	Aluminum alloy 5052	01
	04.35.14.00000	Fixer Tubofix - Double Open Connector	Single	Aluminum alloy 5052	01
	04.35.15.00000	Rubber Ring	------	------	01
	04.35.15.95XXX	Tubofix Fixator - Rod	Ø 9.5 mm - 100, 150, 200, 250, 300, 350, 400 mm	Stainless Steel AISI 304	01

Support Materials

Support materials are instruments solely designated solely for the implantation of components that make up the Schanz Pin family and their ancillaries above.

These instruments are manufactured from stainless steel, which provides them high strength and durability, according to requirements specified by ASTM F899 - *'Standard Specification for Stainless Steel for Surgical Instruments'.*

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 the manufacturer or by another manufacturer designated by the former for implantation of the Schanz Pin.

- Instrumental - Linefix Fixator
- Instrumental - Colles type Fixator
- Instrumental - TuboFix Fixator

The instrumental is supplied decontaminated but not sterilized. Inadequate sterilization of surgical instruments can cause infection.

Surgical instruments are subject to wear during normal use and can therefore break. Instruments shall be used only for their intended purposes and shall be inspected regularly to check for possible wear and damage.

For more information about the instruments, consult your representative.

Warnings and Precautions

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

- Schanz Pin shall only be used after a detailed analysis of the surgical procedure to be adopted and reading the product instructions for use;
- The product shall be used by specialized surgical teams, with specific knowledge and capability about osteosynthesis techniques, 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;
- Clinical results and durability of implants are extremely dependent on an accurate surgical technique;
- The surgeon must have extensive knowledge of the local anatomy. Anatomical references are extremely important to define insertion points;
- The insertion of Schanz Pin must be made from the anatomical site of higher risk to the opposite direction;
- Palpate the nearest artery and insert the pin with a minimum distance of 2 cm from it;
- When drilling the flexor muscles the member must be extended. And when drilling the extensor muscles the member must be flexed;
- At medical discretion, the use of bone grafting combined with the product may be required;
- The use in patients with predisposition to disobey medical guidelines and postoperative restrictions, such as children, the elderly, mentally ill and/or chemically addicted people, poses a higher risk of implant failure;
- Risks of implant failure are higher in patients who practice strenuous activities or sports during the postoperative period, contrary to medical restrictions;
- Postoperative complications pose a greater risk when using the product in morbidly obese patients;
- The Schanz Pin and their ancillaries 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;

- At medical discretion, pre- and perioperative antibiotic prophylaxis, as well as antibiotic therapy, may be adopted in cases of local and / or systemic predisposition or occurrence of infections;
- For the application of the Schanz Pin and their ancillary components it is necessary to use specific instrumentation, as indicated in item "Support Material", and, because of the possibility of dimensional and / or functional incompatibility, the product shall not be used with instruments other than those indicated by the manufacturer;
- The right combination for the Schanz Pin and their respective ancillary components is indicated under item "Ancillary Components", and because of the possibility of dimensional and functional incompatibility it should not be used with components other than those indicated by the manufacturer. Caring for this material is responsibility of the qualified personnel, which should follow the applicable standards and/or other local regulations;
- Falls or crushing on hard surfaces can cause damage to the product. Therefore, it is necessary that the operator performs an inspection of the product for its integrity when the package is opened, and if any abnormality is observed the product shall not be used;
- 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;
- REPROCESSING PROHIBITED;
- Sterile product - Do not re-sterilize.
- 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:

- Risk of vascular, visceral, and nerve injuries;
- Absent or delayed bone healing, which results in implant rupture;
- 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;
- Breakage of the implant, which can make its removal difficult or impractical.

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 on osteosynthesis techniques, being the responsibility of the surgeon the choice and mastery over the technique to be applied;
- The insertion must be performed from the anatomical site of higher risk to the opposite direction;
- Palpate the artery closest to the pin and insert it to a minimum distance of 2 cm from it;
- When drilling the flexor muscle the member must be extended. And when drilling the extensor muscle the member must be flexed;

- The product lifespan is characterized by the time required for the completion of bone healing, limited to a maximum of 01 (one) year. After that, in case of failure or problems with bone healing, these conditions may pose risk of implant failure due to excessive mechanical demand;
- It may be necessary to perform a revision surgery in the case mentioned above or if looseness of components is observed;
- For the application of the Schanz Pin it is necessary to use specific instrumentation, as indicated in item "Support Material", and, because of the possibility of dimensional and / or functional incompatibility, the product shall not be used with instruments other than those indicated by the manufacturer;
- Schanz Pin shall not be used with different components than those indicated by the manufacturer, because of the possibility of dimensional and functional incompatibility.

Guidelines to patient and / or legal representative

The attending surgical team shall instruct the patient and / 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 osteosynthesis;
- The fact that risks are greater in patients predisposed to not comply to medical guidelines, care, and postoperative restrictions, such as children, the elderly, subjects with neurological disorders or drug addicts;
- 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 restriction of strenuous physical activities or sports during the postoperative period, which extension is defined by the attending surgeon;
- The increased risk of postoperative complications in morbidly obese patients;
- The need to use, exclusively at medical discretion, external support, walking aid, and orthopedic devices designed to range of movement and / or load;
- 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

Schanz pin is supplied in sterile condition. The adopted sterilization method is sterilization by gamma irradiation (25 kGy).

The manufacturing of components is carefully carried out in order to meet the product's intended performance. Thus, the surgical team and others involved shall handle the devices properly so that infection risks are minimized.

Sterile product - Do not re-sterilize.

Do not use the product if packaging is violated.

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 devices that were explanted or regarded as inappropriate for use must be discarded. It is highly recommended that before discarded, the parts are cut, bent or sanded.

The implants shall be discarded in proper sites, to avoid environmental and other individuals' contamination. The adoption of local regulations for discarding potentially contaminant products is recommended.

Single-use product - Dot not reuse.

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 receiving 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 required for the traceability of the product, then, can be found on the product or can be obtained from the label contained in its packaging:

- Company logo;
- Product lot number;
- Product code;

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 transport

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.

Since it is a sterile product, temperature and humidity at the storage site shall be monitored and kept below 40 ºC.

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 date of manufacturing, 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: 10417940053
Review: 04
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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 CAP (Customer Service Department) manufacturer, as following:

Customer Service Department – CAP:
Telephone: +55 19 2111.6500
FAX: +55 19 2111.6500
http://www.mdt.com.br/contato
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.