Instructions for Use

External Fixator – Short Bones I

Subtitles of the symbols used on the packaging

REF	Catalogue Number	LOT	Batch Code
STERILE R	Sterile Product - Sterilized by Gamma Radiation		Valid until
	Date of Manufacture		Single-Use Product
	Consult instructions for use		Do not re-sterilize
	Do not use if package is damaged		Fragile, handle with care.
	Keep out of the sun	40 °C	Temperature Limit (40°C);
	Keep Dry		

Features and technical specifications of the product

Technical Name: External fixator for extremities of the skeleton - short bones

Trade Name: External Fixator – Short Bones I

Trade Models:

- External Fixator LineFix
- External Fixator Ulson type

Raw Material:

- Stainless Steel Alloy (ASTM F899: AISI 304/ ASTM F-138)
- Aluminum Alloy (ASTM B221 type 6351 and type 5052)

Validity: 05 years (after sterilization date)

Sterile Product

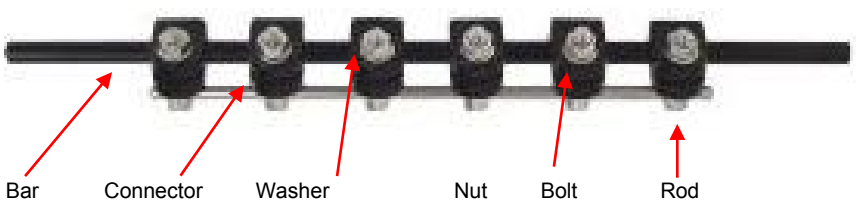
Sterilization Method: Gamma Radiation (dosage of 25 kGy)

Description

External fixators in general were designed to treat open fractures, with a degree of skin lesion and / or soft tissue that make unfeasible or counter indicate the use of gypsum or, internal fixation, due to the risk of infection or exposure of the implant. With the passage of time, indications were extended to unstable fractures, bone transport, stretching and treatment of pseudarthrosis.

The External Fixator – Short Bones I Family is formed by the following business models:

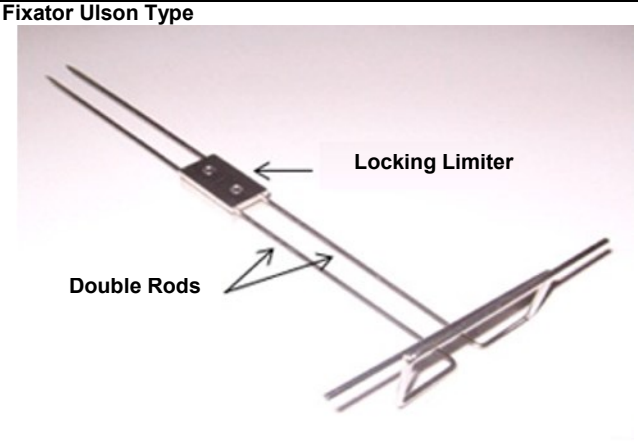
External Fixator LineFix



The External Fixator LineFix is a device formed by: Connectors, Bar, Rod, Nuts, Bolts and Washers which in turn set the pins that will be implanted in the bones to help the fracture healing.

The connectors are gyratory and allow adjustment of the bar, the rod and the pins through the nuts and bolts allowing the linear assembly for fracture fixation.

External Fixator Ulson Type



The External Fixator Ulson type is a device formed by double rods, which are implanted percutaneously in the radius distal portion; this fixator has a Locking Limiter, allowing the alignment of the rods and the limitation of the insertion length of the fixator.

Composition

The External Fixator – Short Bones I Family, which components have a natural metal aspect, are manufactured of Stainless Steel Alloy ASTM F899 (AISI 304) and ASTM - F138; suitable for this purpose because of its resistance to heat, oxidation and to softening at high temperatures.

The anodized components are manufactured of Aluminum alloy ASTM B221 Type 6351 and Type 5052 which have satisfactory mechanical strength, high corrosion resistance and good conformability.

The materials selected for the composition of the product have the properties which are required to achieve the desired performance. Such selection considered factors like biocompatibility and physical, chemical and mechanical properties required for the product.

Indication and Purpose

The External Fixators, in general, were designed to treat open fractures, with an amount of skin lesion and/or soft tissue that make the implant unfeasible or counter indicates the use of gypsum or, internal fixation, due to the risk of infection or exposure of the implant. With the course of time, indications were extended to unstable fractures, bone transport, stretching and treatment of pseudarthrosis.

External Fixator LineFix

It is indicated for the treatment of short bones fractures, wrist and phalanges. It is a fixator that requires the fracture is previously aligned before it is applied. It is a mono-lateral fixator designed for use in the emergency area, with already pre-defined in line assembling.

External Fixator Ulson type

It is indicated for the treatment of fractures in the radius distal portion with the combination of percutaneous fixation methods, that is, the combination of percutaneous intramedullary osteosynthesis and external fixation.

In fractures of the distal radius extremity, corresponding pyramidal fragments are often separated, and even in every comminuted fractures, at least the apexes of these fragments are always present. So they will support double rods that introduced percutaneously will transfix the fragments of the radial styloid and the radius dorse ulnar region.

Contraindications

Relative contraindications for the use of the device are listed below, so that the surgeon in charge, after a thorough study of the case, will indicate the procedures:

- Patients with general or specific active infections that can lead the fixation to complications;
- Patients with impaired general state and/or immune compromised, unable to be submitted to a surgical procedure
- Patients with sensibility to foreign bodies, being that in these cases, tests should be performed;
- Patients with osteoporosis and/or bone affections that may compromise the fixation stability;
- Patients who use narcotic substance, alcohol or smoke.

Forms of Presentation

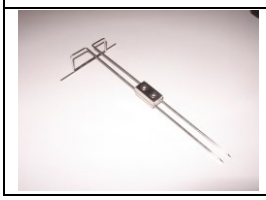
The business models that make up the External Fixator – Short Bones I Family are unitarily packed in a primary packing system which works as sterilization shield.

The product is provided in sterile condition, and the adopted sterilization method is gamma radiation (dosage of 25kGy).

Once sterilized, the components packaged in their primary packaging properly labeled, are packed in a cardboard carton (secondary packaging), in which there is a leaflet with instructions for use of the product.

A label with information necessary for the product identification is glued on the top of the cardboard carton.

The External Fixator – Short Bones I Family are available in the trade models below, and each one are available for commercialization in the following dimensions:

Illustrative Image	Code	Description	Dimension	Made of	Qtty Packed
	04.35.07.00000	Fixator LineFix for wrist	Single	Stainless Steel Alloy (ASTM F-899: AISI 304) + Aluminum Alloy (ASTM B221 types 5052 /6351)	01
	04.35.08.00000	Fixator LineFix for Phalange	Single	Stainless Steel Alloy ASTM F-899: AISI 304) + Aluminum Alloy (ASTM B221 tipos 5052 /6351)	01
	07.35.19.00000	External Fixator Ulson type	Single	Stainless Steel Alloy (ASTM F-899: AISI 304) (ASTM F-138)	01

Ancillary Components:

The ancillary components to the External Fixator – Short Bones I are:

- Schanz Pin
- Conical Schanz Pin

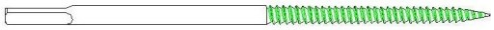
Ancillary implants are manufactured from Stainless steel Alloy (18Cr-14Ni-2.5Mo), which meets the requirements specified by ASTM F-138 – '*Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)'*.

The surgeon in charge of the adopted technique is also responsible for the right choice of the models and sizes of the External Fixator – Short Bones I and its ancillaries to be implanted. He must be familiar with the material, the application method and the adopted surgical procedures.

The consolidation success is linked to the right choice, positioning, and the devices fixation. It is responsibility of the surgeon who evaluates the patient and decides which implants are to be used. Also, it is linked to the strict compliance with postoperative care recommended by the surgeon in charge.

The ancillaries below are not subject of this registration process, and should, therefore, be always purchased separately from the same manufacturer of the implant or from another one the company indicates.

List of ancillaries to the External Fixator – Short Bones I Family

Illustrative Image	Code	Description	Dimensions	Made of
	04.25.10.XXXXX	Schanz Pin	Ø 2,5 – 80, 100 mm Ø 3,0 – 10, 100 mm Ø 3,5 – 80, 100 mm Ø 4,0 – 90, 130, 150, 170 mm Ø 4,8 – 150, 160, 170, 200 mm Ø 5,0 – 160, 200 mm	Stainless Steel Alloy (18Cr-14Ni-2.5Mo) ASTM F138
	04.25.11.XXXXX	Conical Schanz Pin	Ø 4,5 – 160, 200 mm Ø 4,8 – 200 mm Ø 5,0 – 200 mm	Stainless Steel Alloy ASTM F138 (18Cr-14Ni-2.5Mo) ASTM F138

Support Materials

The supporting materials for assembling the External Fixator – Short Bones I Family are the instruments designated for this purpose.

The instruments below are not subject of this registration process, and should, therefore, be always purchased separately from the same manufacturer of the implant or from another one the company indicates.

See below a list of the instruments available and provided by the manufacturer or their indication for implanting the External Fixator – Short Bones I:

- 0F.02 – Instrument - Fixator Linefix
- 0F.04 – Instrument - Fixador Ulson type

The instruments are provided decontaminated, but not sterilized. Inappropriate sterilization of the surgical instrument might cause infection.

Surgical instruments are subject to wear and tear during their regular use. Therefore breaking may occur. The instruments should only be used for the purpose they were designed to and should be inspected regularly for possible wear and damage.

For further information concerning the instruments, please consult the dealer.

Warning and Precautions

For the product use, the medical team in charge must consider the following warning and precautions:

- The External Fixator – Short Bones I must only be used after a thorough analysis of the surgical procedure to be adopted and complete reading of these instructions for use;
- The product should only be handled by specialized surgical teams with specific knowledge and capacity building concerning osteosynthesis techniques. The choice and dominance of the adopted technique to be applied are under the responsibility of the surgeon in charge;
- Inappropriate choice and selection of the products to be used, as well as mistakes concerning the indication, handling and application technique might cause excessive stress and tractions on the implant leading to failure due to fatigue, fracture and even looseness;
- Clinical results and the durability of the implants are totally dependent upon a precise surgical technique;
- The surgeon must have extensive knowledge of the local anatomy. It is extremely important the anatomic references for defining the insertion point;
- The use of bone graft may be needed, but it is under medical criteria;
- A greater risk of the implant failure is its use in patients who are predisposed to disobey medical guidelines and postoperative restrictions, such as children, elderly, individuals with neurological changes, or addicted;
- Implant failure risks are greater in patients who practice physical exertion activities or those who practice sports during the postoperative period, contradicting the medical restrictions;

- The patient must be submitted to periodic medical monitoring to check the implant, the bone and the adjacent tissues conditions;
- The External Fixator – Short Bones I and its respective ancillaries should not be used whether there is not an appropriate osseous support that can guarantee the implant stability;
- The pre and perioperative prophylactic antibiotic therapy as well as antibiotic therapy - in cases there is a local and/or systemic predisposition or infections occur – are under medical criteria;
- The correct matching of the External Fixator – Short Bones I and its respective ancillary components is indicated in the “Ancillary Components” topic, and due to the possibility of dimensional and functional incompatibility, it must not be used with other components than the ones indicated by the manufacturer.
- Care of this material is of responsibility of skilled staff, who should follow the normalization and/or any applicable local regulations;
- Only skilled staff for the surgical procedure may open the package;
- Do not use the product if the shelf life is expired or packaging is violated;
- Handle with care;
- Falls or crushing on hard surfaces might damage the product. So, it is necessary the handler to perform inspection of the product to check its integrity while it is unpacked and if there is any abnormality, the product SHOULD NOT be used;
- Single use product – Do not reuse;
- REPROCESSING PROHIBITED;
- Sterile Product – Do Not Re-sterilize;
- Manufacturing date, expiry term and batch number: see label;

Adverse Effects

Every surgical procedure presents some common risks and complication possibilities such as infections, bleeding, allergic drug reactions and anesthetic risks, among others. The following complications and adverse effects can still be associated with the implantation of the product:

- Injuries to the nerves with sensitive or motor harm;
- Absence or delay of bone fusion resulting in the implant breaking;
- Loosening, dismemberment, displacement, twisting or break of the implant;
- Deformation or fracture of the device;
- Pains, discomfort or abnormal sensations due to the product;
- Reaction to foreign body;
- Bone necrosis or adjacent soft tissues;

The decision for the removal due to one of the above adverse effects is made by the surgeon in charge.

Use Instructions

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

- The care of this material is responsibility of the skilled staff, which should follow the standards and/or other local regulations applied;
- The product should be handled with appropriate care in adequate locations (materials center and operating rooms);
- The product should only be used by specialized surgical teams, with specific knowledge and training on techniques for osteosynthesis, and the surgeon in charge is responsible for the choice and dominance of the surgical technique to be performed;
- The insertion should be made from the anatomical site of greatest risk to the opposite direction;
- Palpate the closest artery and insert the pin at a minimum distance of 2 cm from it.
- The limb must be extended for drilling the flexor muscle and it must be flexed for drilling the extensor muscle.

- The implant useful life is characterized by the time required for effective bone healing, limited to a maximum period of 01 (one) year. After this period, in case of absence or problems with bone healing, these conditions can represent a risk of implant failure by excessive mechanic stress;
- A revision surgery may be necessary in the case mentioned right above or if loosening of the components is observed.
- It is necessary to use specific instruments for applying the External Fixator – Short Bones I as indicated in the "Supporting Material". Due to the possibility of dimensional and/or functional incompatibility it MUST NOT be used with any other instruments different from the ones indicated by the manufacturer;
- The External Fixator – Short Bones I must not be used with other components than the ones indicated by the manufacturer due to the possibility of dimensional and functional incompatibility.

Guidance to the Patient and/or Legal Representative

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

- The suitable care and restrictions during the postoperative period. The capacity and willingness of patient to follow these guidelines are one of the most important aspects in a surgical procedure;
- The fact that the risks are greater when using in patients with predisposition to disobey the medical guidelines, care and postoperative restrictions, such as children, elderly, individuals with neurological disorders or addicted;
- The fact that the product does not substitute nor does have the same performance of normal bone and therefore can break, deform or loosening due to excessive effort or activities of early load and other situations;
- The need to restrict the effort activities or sportive practice during the postoperative period, whose extension is defined by the surgeon in charge;
- The necessity of use of external supports, aid to ambulate and orthopedic appliances, designed to limit the movement and/or load is under exclusive medical criteria;
- The necessity of periodic medical monitoring to check the conditions of the implant, the bone and the adjacent tissues;
- The fact that the non-performing of the revision surgery in a period longer than 01 (one) year, in cases in which bone fusion (pseudoarthrosis) does not occur, can lead the mechanical failure of the implant;
- The need of review surgery in cases of components loosening;
- The fact that implants can interfere with results of imaging examinations. So, implant users should report this fact when submitted to such examinations;
- The listed information in this topic "Guidance to the patient and/or the Legal Representative" and in the topic "Adverse Effects.

Sterilization

The External Fixator – Short Bones I is provided in the sterile product condition. The adopted sterilization method is by Gamma Radiation (dosage of 25 kGy).

The External Fixator – Short Bones I manufacturing process is done with great care in order to meet the desirable performance of the product. So, the surgical team and all the staff involved must handle all the devices properly in order to reduce the risk of infection.

Sterile Product – Do Not Re-sterilize

Do not use the product if the packaging is violated.

Contamination Risk

As this is an implantable product, in cases in which there is need of explanting the External Fixator – Short Bones I, there are risks of biologic contamination and viral disease transmission.

For minimizing these risks, the explanted External Fixator – Short Bones I components should be treated as potentially contaminant material and should be adopted the standardization and/or other local regulations applied.

Product Discard

The External Fixator – Short Bones I explanted or regarded as inappropriate for use must be discarded. It's highly recommended that before discarding, the product is mischaracterized, and so its parts can be cut, bent or sanded.

The components should be discarded in proper locals, to avoid the environmental contamination and other individuals. It is recommended adoption of local legal regulations for potentially contaminant products.

Single use product – do not reuse.

Traceability

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

- Name of patient who received the implant;
- Surgeon's name;
- Hospital's name;
- Manufacturer's name;
- Supplier's name;
- Surgery date;
- Code of product;
- Number of batch of the product;
- Quantity used;
- Registration product at ANVISA.

The following Information needed for the product traceability is engraved on the piece or may be acquired from the label of the product package:

- Company logotype;
- Manufacturing Batch;
- Code of the piece.

Traceability information is required for notifying the Sanitary Surveillance Agency ANVISA, either by the health service or by the patient him/herself, when serious adverse events occur, so that it helps to drive appropriate investigations.

Storage and Transport

For the storage it is recommended dry and airy place, without exposure to light incidence, humidity or contaminants substances.

The implants cannot be stored directly on the floor. It is recommended the use of shelves with minimal height of 20 cm.

As it is a sterile product, the storage place temperature and humidity must be monitored and kept under 40ºC.

The product should be kept in its original packaging until the moment of its use, being that the surgical packaging opening and handling should be done by trained personal for this procedure.

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

For information about manufacturing date and batch number: see label.

Further 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
Technician Responsible: Miguel Lopes Monte Júnior – CREA 0601150192

ANVISA Registration Nº: 10417940087
Review: 00
Issue: 21/10/2013

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