

Sterilization inspection: visually inspect the implants for damage (holes, staining, tears, non-intact seals, missing security locks), visual change of the external indicators, and moisture.

Do not use hot air, radiation, formaldehyde, ethylene oxide, plasma or peroxide sterilization for products manufactured by Fixier.

Additional information

Fixier used the cleaning agent Aniosyme Synergy 5 © during manual and mechanical validation of this processing recommendation according to ANSI/AAMI ST98, and a 40 kHz ultrasonic washer.

The cleaning and sterilization information is provided in accordance with ISO 17664.

The recommendations provided above have been validated by Fixier in accordance with ANSI/AAMI ST79 and ISO 17665 using the overall test method to a Sterility Assurance Level (SAL) of 10⁻⁶, as being capable of preparing a non-sterile medical implant. It remains the responsibility of the processor to ensure that the processing is actually performed by qualified personal and using adequate equipment and materials in the reprocessing facility. This requires verification and routine monitoring of the process.

STORAGE AND TRANSPORTING



The implants should be stored and transported in a dry environment, protected from dust, direct sunlight, pests and extreme conditions of temperature and humidity. After sterilization always store in the sterile packaging until the surgical procedure. Make use of them according to the First in First out (FIFO) system.

CONTRAINDICATIONS

- Systemic Inflammatory Response Syndrome (SIRS), (to be evaluated by the surgeon)
- Septicemia
- Osteomyelitis
- Patient unable to comply with post-operative care
- Hypersensitivity to the materials (Stainless Steel and Titanium)

SIDE EFFECTS

- Allergic reaction due to incompatibility with the material
- Delay in consolidation due to vascular disorders
- Fatigue fracture due to incorrect selection and/or use of the implant
- Pain caused by the implant

Report suspected adverse incidents by email to tecnovigilancia@fixier.com.mx or by telephone +52 419 688 1191.

TRACEABILITY

Implants are indelibly printed with the batch number, which ensures its traceability. It is important to record the product description and batch number in the patient's record.

IDENTIFICATION / SYMBOLS AND THEIR MEANINGS

 Manufacturer	 Rx Only For prescription use only	 Non-sterile	 Keep dry
 Batch number	 Do not re-use	 Unique device identifier	 Medical device
 Consult instructions or use	 Catalogue number	 Fragile, handle with care	
 Caution	 Date of manufacture	 Protect from heat and radioactive sources	

Manufactured By:
FIXIER S.A. DE C.V.
Carretera Doctor Mora a San Miguel de Allende km 3.4,
C.P. 37967 Comunidad de San Rafael, Doctor Mora,
Guanajuato, México
Tel.: +52 419 688 11 91

www.traufix.com

TRAUFIX
READY TO RUN

INSTRUCTIONS FOR USE



Do not use any implant that is damaged. The surgeon must make the final determination of suitability for use of the implant. Dispose of implants that have been in contact with blood, even if they have not been used.



Implants are provided non-sterile. Traufix implants require thorough cleaning, sterilization, and storage inside a sterile barrier until the moment of implantation



Implants are intended only for single patient use during a single procedure. After implantation, the loads on the implant may cause metal fatigue. In addition, prolonged contact with blood, protein substances and other tissues can cause corrosion. Clinical reuse implies a risk of microbial contamination and mechanical failure. Do not re-use implants.

DEVICE DESCRIPTION

Traufix osteosynthesis medical devices are metal implants (stainless steel per ASTM F138, or ASTM F139, or titanium alloy per ASTM F136) fixed adjacent to the bone for the treatment and consolidation of fractures, osteotomies, and/or joint ossification. The devices include different types and sizes of plates and screws.

Traufix intramedullary nails and screws are metal implants (titanium alloy) locked in the medullary cavity of the bone for the treatment and consolidation of fractures, osteotomies, and/or joint ossification of femur, tibia and humerus. The devices include different types and sizes of nails and screws.

USE WARNINGS

The implants must be implanted by a qualified surgeon and following each product surgical technique.

Fatigue fracture: The development of a fatigue fracture depends on the number of load cycles and the intensity of the load. This means that the fatigue depends on the width of the spaces in the bone, the length of the lever arms and the intensity and duration of the load. An implant that has been selected and implanted under effective and efficient procedures can reduce the risks of a fatigue fracture while the bone consolidation process progresses normally, as the load decreases as the bone supports more load.

Supported loads: The intended use of these implants is not to permanently replace the functionality of a bone, but only to provide support during the consolidation process of the fracture (s), therefore, the perfect bone reduction allows that the implant supports the biomechanical demands of the bone temporarily, restoring the equilibrium of forces again. In this case, there are only relatively small and non-critical loads on the implants, so the complications related to the implants are minimal. However, if the bone has missing fragments, the load forces are not completely balanced or distributed in a balanced manner. The result may be the concentration of bending and torsion stresses on areas of the implant where the bone support is missing. Cyclic loads in these areas increase the risk of fatigue failure in the implant and the area it supports.

Implant selection: Due to the function of the devices as fracture support or fracture fixation support, it is necessary to select the implant appropriate to the patient's bone dimensions and the type of fracture.

The implants should be considered temporary and are not designed to resist body weight permanently. It is important to consider: the weight, the occupation or physical activity of the patient, the patient's bone quality, habits or addictions, degenerative or congenital diseases and their allergic history at the moment of selecting the dimension and type of implant, as well as following the considerations of recognized Institutions, Organizations and / or Medical Academies to ensure the effectiveness of an osteosynthesis.

Possibility of allergies, infections and faults: It is important to consider the patient's clinical history, addictions, type of activity, hereditary or degenerative diseases, to determine the correct time to perform the surgery, if there is suspicion of foreign body allergy or hypersensitivity to the material, tests must be carried out prior to implantation.

Post-operative care is necessary in order to follow up on the patient regarding load indications, activity level, as well as for the detection of possible indicators of alignment defects, infections, delayed consolidation, surgical wound, and indicators of vascular conditions that the patient might present.

Handling the implant: If it is necessary to mold or set the implant, avoid overfolding, bending it in the opposite direction, damaging it or scratching it. Any manipulation or incorrect use can generate defects in the material and therefore cause its failure.

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Compatibility: Traufox implants have mechanical properties, elasticity, tenacity and resistance to corrosion as well as not being magnetic.

The steel implants are manufactured with stainless steel that complies with ISO 5832-1 and / or ASTM F138/F139. Due to their high content of chromium and nickel, these steels form a protective layer of chromium oxide on the metal surface, called the "passive layer". This passive layer protects the implant against corrosion.

The titanium implants are manufactured with titanium that complies with ASTM F136. They go through an anodizing process in which a titanium oxide layer is formed that increases its surface hardness which translates into an increase in wear resistance. This layer produces a decrease in the release of titanium, aluminum and vanadium ions. This fact reduces the risks of local irritation or long-term metallosis due to the diffusion of metal ions in the surrounding tissues.

Improper or careless handling and chemical, electrochemical or physical aggressions can alter the corrosion resistance. Fixier recommends not mixing implants of different metals, brands or commercial houses since they can generate galvanic corrosion and release of ions. This can cause inflammation, hypersensitivity reactions to metals and long-term adverse systemic effects. In addition, the corrosion process can reduce the mechanical strength of the implant.

Fixier manufactures the following instruments to be used with Fixier's plates. Refer to the surgical techniques for plates and corresponding screws and instrument. The instruments necessary for the placement of intramedullary nails are described in the surgical technique of each product.

Instrument code	Instrument description
128.20X	Drill guide Lionter for 2.0mm drill bit
128.20	Drill guide for 2.0mm drill bit
128.27	Drill guide for 2.7mm drill bit
128.32	Drill guide for 3.2mm drill bit
128.40	Drill guide for 4.0mm drill bit
128.50	Drill guide for 5.0mm drill bit

Other instruments are generic instruments that Fixier recommends to be used. However, Fixier does not recommend any additional instruments to be used because testing was not performed. However, if any hospital or customer chooses to use other instruments proper testing should be performed prior to usage. Otherwise, Fixier declines all responsibilities for this practice.

MR safety information: Traufox implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Traufox devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Removal of the implant: The decision to remove the implant belongs to the attending physician. It is recommended to remove the implant once the consolidation process is complete, provided it is feasible and appropriate for the patient. The implant must be scrapped according to the procedures for disposal of potentially infectious biological waste.

Fixier is not responsible for the misuse of implants.

CLEANING AND STERILIZATION

Cleaning

Whenever possible, a mechanical procedure should be used for cleaning. The implants should not be lubricated.

When selecting cleaning products and equipment, pay attention during all the steps to:

- Suitability for the intended application (e.g., cleaning, ultrasonic cleaning).
- Cleaning products do not contain alcohol (otherwise the remains of blood could be fixed).
- Cleaning products are suitable and compatible with the products. Use detergents with pH from 7 to 9.5, higher pH affects the surface of stainless steel.
- Cleaning products should be low-foaming, free-rinsing (easily removed from the implant), biodegradable, nontoxic, and should rapidly dissolve / disperse soil.
- Consider the following for both mechanical and manual cleaning:
 - Use only clean, lint-free cloths and / or soft brushes (never metal or steel brushes).
 - Use, if necessary, auxiliary means such as cleaning pens, syringes, cannulas or bottle brushes for cannulated or hollow products.
 - During drying, Fixier recommends disposable lint-free paper towels or medical grade compressed air.
- Always handle the product with powder-free gloves and avoid contact with hard objects that can damage the product.

With regard to water quality, Fixier recommends the use of utility water according to ANSI/AAMI ST108 for the intermediate rinse and critical water for final rinse.

Limitations on reprocessing

The implants can be cleaned and sterilized repeatedly when not used in a specific procedure and as long as they have not been in contact with blood, tissues or organic substances. Cleaning and sterilization have a minimal effect on implants. Traufox implants are single-use only and Fixier does not recommend the reprocessing of soiled implants.

The implants should be inspected for corrosion, damage such as scratches, cracks, debris, discoloration or residue before reprocessing. Damaged implants should be discarded.

A discoloration has no adverse effect on titanium alloy implants. The protective oxide layer is fully maintained.

Point of use care

Implants should not remain covered until needed to avoid becoming contaminated with blood, tissue, and/or bodily fluids/matter. Only those to be implanted should be handled. Minimal handling of implants is necessary to prevent damage to the surface.

Manual processing

1. Rinse the implant under running cold tap water for at least two minutes.
2. Soak the implants (the implants are delivered individually or in 5 pieces bags, disassembly is not needed) in the cleaning bath with a neutral pH enzymatic cleaning solution for at least 15 minutes (the implants must be completely covered by the solution and the individual components must not be able to damage each other).
3. Rinse the implant thoroughly with running cold water for at least two minutes (you should also rinse the inside of the cannulated implants with suitable syringes and cannulas).
4. Manually clean the implant for five minutes in a freshly prepared neutral pH enzymatic cleaning solution using a soft-bristled plastic brush to thoroughly clean the implant. Cannulated implants (hollow products), must be cleaned with the corresponding pipe cleaner (pipe cleaner diameter should be slightly larger than the lumen to ensure good contact between the cleaner and implant).
5. Rinse the implant thoroughly with running cold water for at least two minutes (you should also rinse the inside of the cannulated products with suitable syringes and cannulas); You can make use of pressure water guns.
6. Next, thoroughly dry the implants (drying with medical grade compressed air or a clean, soft, lint-free cloth is recommended).
7. Perform a visual inspection of the implants; if necessary, repeat the cleaning step until all visible dirt and residual detergent is removed.

NOTE: Follow the manufacturer's instructions for use of the enzymatic detergent in terms of concentration of dilution, temperature, exposure time and water quality as well as the protective equipment. It is recommended to use a freshly prepared solution.

Mechanical processing – Ultrasonic

Pre-cleaning

1. Rinse the implant under running cold tap water for at least two minutes.
 2. Soak the implants (the implants are delivered individually or in 5 pieces bags, disassembly is not needed) in the cleaning bath with a neutral pH enzymatic cleaning solution for at least 15 minutes (the implants must be completely covered by the solution and the individual components must not be able to damage each other).
 3. Rinse the implant thoroughly with running cold water for at least two minutes (you should also rinse the inside of the cannulated implants with suitable syringes and cannulas).
 4. Manually clean the implant for five minutes in a freshly prepared neutral pH enzymatic cleaning solution using a soft-bristled plastic brush to thoroughly clean the implant. The cannulated implants (hollow products), must be cleaned with the corresponding pipe cleaner (pipe cleaner diameter should be slightly larger than the lumen to ensure good contact between the cleaner and implant).
 5. Rinse the implant thoroughly with running cold water for at least two minutes (you should also rinse the inside of the cannulated implants with suitable syringes and cannulas); You can make use of pressure water guns.
- #### Ultrasonic process

1. Clean the implant ultrasonically at least 15 minutes and a bath frequency of minimum 40 kHz using a freshly prepared neutral pH enzymatic cleaning solution. The implants must be completely covered by the solution and the individual components must not be able to damage each other.
2. Rinse the implant thoroughly with running water for at least two minutes (you should also rinse the inside of the cannulated implants with suitable syringes and cannulas); You can make use of pressure water guns.
3. Next, thoroughly dry the implants (drying with medical grade compressed air or a clean, soft, lint-free cloth is recommended).
4. Perform a visual inspection of the implants; if necessary, repeat the cleaning process until all visible dirt and residual detergent is removed.

NOTE: Follow the manufacturer's instructions for use of the enzymatic detergent in terms of concentration of dilution, temperature, exposure time and water quality as well as the protective equipment. It is recommended to use a freshly prepared solution.

NOTE: Follow the ultrasonic cleaner manufacturer's instructions for loading and placement of implants in the cleaner.

Inspection: After cleaning, check the condition of the surfaces. Surfaces must not have scratches and notches, cracks, debris, discoloration, chromatic alterations, chipping, dirt or residues. Surfaces must not show signs of corrosion. Determine if they have been damaged or contaminated and separate them from implants passing inspection. Implants that become dirty must be cleaned again. Damaged implants should be discarded.

Packaging: Place the cleaned and dried implants in appropriate and FDA-cleared sterilization barriers such as wraps, pouches, or containers. Be careful to protect sharp or pointed implants to prevent them from coming in contact with other objects and to prevent damage to the surface of the sterile barrier system.

Steam sterilization: All non-sterile implants can be sterilized with steam (moist heat) in a validated sterilizer that complies to the requirements of ISO 17665. Fixier recommends the following parameters:

Cycle type	Sterilization exposure time	Sterilization exposure temperature	Drying time, minimum
Dynamic air removal (pre-vacuum, minimum three pulses)	4 minutes	132 °C (270° F)	20 – 30 minutes

NOTE: For steam generation, use distilled or deionized water (or equivalent quality) and follow the sterilizer manufacturer's instructions.

NOTE: Follow the instructions for use of the manufacturer of the sterilization equipment when loading to ensure you do not overload the equipment. Overloading the equipment may reduce the effectiveness of the sterilization process. The autoclave must be properly installed, maintained, and calibrated according to the manufacturer instructions.