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 AAMI TIR30, and a 40 kHz ultrasonic washer.
The cleaning and sterilization information is provided in accordance with ISO 17664 and ANSI/AAMI ST81.
The recommendations provided above have been validated by Fixier in accordance with ANSI/AAMI ST79 and ISO 17665 using the overkill 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 product 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	Do not re-use	Date of manufacture	Consult instructions for use
LOT Batch number	Caution	REF Catalogue number	MD Medical device
Non-sterile	UDI Unique device identifier	Fragile, handle with care	EC REP Representante autorizado en la comunidad europea
Protect from heat and radioactive sources	Keep dry		

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

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OBELIS s.a
Bd. Général Wahis 53
1030 Brussels, BELGIUM
Tel: +(32) 2. 732.59.54
E-Mail : mail@obelis.net

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.

NON STERILE

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.

INDICATIONS FOR USE

Traufix devices are intended for fixation of fractures and osteotomies of various bones including the pelvis, clavicle, scapula, humerus, ulna, radius, femur, tibia, olecranon, and fibula.

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 allergenic 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.

Compatibility: Traufix 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.

The combination with components and instruments from other brands is not recommended, the design, materials and mechanical characteristics are not harmonized. Fixier declines all responsibility for this practice.

Refer to surgical techniques for compatibility between implants and instruments.

MR safety information: Traufix 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 Traufix 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

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. Traufix 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 processing. Damaged implants should be discarded.

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

Cautions

Whenever possible, a mechanical procedure should be used for cleaning.

The implants should not have contact with any type of dirty or contaminated material.

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 aldehydes (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 device), 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 distilled water for the steps of cleaning and subsequent rinsing, prior to sterilization.

Manual processing

1. Rinse the device under running cold tap water for at least two minutes.
2. Soak the products (disassembled) in the cleaning bath with a neutral pH enzymatic or chemical cleaning solution for at least 15 minutes (the products must be completely covered by the solution and the individual components must not be able to damage each other).
3. Rinse the product 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).
4. Manually clean the device for five minutes in a freshly prepared neutral pH enzymatic or chemical cleaning solution using a soft-bristled plastic brush to thoroughly clean the device. Cannulated products (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 product 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 products (drying with medical grade compressed air or a clean, soft, lint-free cloth is recommended).
7. Perform a visual inspection of the products; 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 chemical or 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 device under running cold tap water for at least two minutes.
2. Soak the products (disassembled) in the cleaning bath with a neutral pH enzymatic or chemical cleaning solution for at least 15 minutes (the products must be completely covered by the solution and the individual components must not be able to damage each other).
3. Rinse the product 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).
4. Manually clean the device for five minutes in a freshly prepared neutral pH enzymatic or chemical cleaning solution using a soft-bristled plastic brush to thoroughly clean the device. The cannulated products (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 product 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.

Ultrasonic process
1. Clean the product ultrasonically at least 15 minutes and a bath frequency of minimum 40 kHz using a freshly prepared neutral pH enzymatic or chemical cleaning solution. The products must be completely covered by the solution and the individual components must not be able to damage each other.
2. Rinse the product thoroughly with running 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.
3. Next, thoroughly dry the products (drying with medical grade compressed air or a clean, soft, lint-free cloth is recommended).
4. Perform a visual inspection of the products; 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 chemical or 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 devices in the cleaner.

Fixier is not responsible for the manual or mechanical cleaning.

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 products passing inspection. Implants that become dirty must be cleaned again. Damaged implants should be discarded.

Packaging: Place the cleaned and dried implants in appropriate 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 products 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	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.