

STORAGE AND TRANSPORTATION



Products must be stored and transported in a dry place, protected from dust, direct sunlight, pests, and extreme temperature and humidity conditions. Do not store them in locations where chemicals may emit corrosive fumes or where fluctuating temperatures and humidity may cause vapors to condense on instruments. Always store them in a sterile environment until the surgical procedure. Do not mix sterile and clean materials. Use them according to the FIFO (First In, First Out) system.

REPAIRS AND MAINTENANCE

Fixier offers maintenance and repair services for Traufix instruments.

Any repair or modification of your instruments performed by third parties may result in damage to the product. Furthermore, Fixier will not be liable for any damages that may occur to your instrument after that point.

Fixier is not responsible for damage to its instruments caused by improper use or maintenance. This also applies to repairs that restore or replace the instrument when performed by companies other than Fixier.

IMPORTANT NOTE

Please keep these instructions in a suitable location that is easily accessible to any user.

SYMBOLS AND THEIR MEANINGS

 Manufacturer	 Date of Manufacture
 Lot Number	 Catalog Number
 Fragile, handle with care	 Non-Sterile
 Keep Dry	 Protect from radioactive heat sources
 See instructions for use	 Warnings or Precautions
 Medical Device	 Unique Product Identifier

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TRAUFIX
READY TO RUN

INSTRUCTIONS FOR USE FOR INSTRUMENTS

INTENDED USE

The instruments are indicated for specific use in surgical procedures in orthopedics and traumatology.

Surgical instruments are specifically designed to facilitate the surgical procedure and are used by qualified surgeons. Their purpose is to facilitate the insertion of surgical implants.

DEVICE DESCRIPTION

Traufix reusable instruments include surgical instruments and trays.

The instruments are made of stainless steel (ASTM F899) and the trays are made of aluminum.

WARNINGS AND CAUTIONS



Do not use any instrument that is damaged, replace it.



Instruments are provided non-sterile. Traufix instruments require thorough cleaning, disinfection, sterilization, and storage within a sterile barrier until ready for use.

Surgical instruments are manufactured using established international standards for a variety of uses. All instruments should be used only for their intended purpose. Misuse can damage the instrument. Instruments should only be used by qualified surgeons.

Surface Condition: Traufix instruments will show signs of corrosion if exposed to aggressive substances for prolonged periods of time, so it is essential to follow the processing and sterilization instructions rigorously.

Use in special environments: Incompatibility with magnetic resonance imaging (MRI). Precautions with electrosurgical equipment: avoid contact with uninsulated metal parts.

Condition of use: To ensure Traufix instruments are in optimal condition, they must be inspected and tested before use in the operating room. For use, follow the recommendations outlined in the surgical techniques for each procedure.

Useful life: To ensure Traufix instruments are in optimal condition, they must be inspected and tested before use in the operating room. For use, follow the recommendations outlined in the surgical techniques for each procedure.

Care: Proper instrument processing begins during the surgical procedure itself. Once the instrument has performed its function, it must be cleaned as thoroughly as possible to prevent residues of aggressive substances such as blood, medications, etc., from drying on its surface. This simple step greatly facilitates the task of instrument maintenance.

It is also important to avoid long waiting times between processing steps to prevent these remains from hardening.

Avoid:

- Store the instrument in places not designated for this purpose.
- Prying on instruments not designated for this purpose; these instruments aren't designed for this purpose and may be damaged.
- Falls to the ground.
- Using excessive force.

Functionality test: Instruments should be routinely tested before each use. Attention should be paid to:

- General condition such as cleanliness, absence of corrosion, etc.
- Moving parts, sharp edges, and assembly are in working order.
- No missing components.
- No damage such as dents, cracks, stripped threads, broken parts, etc.

Compatibility: 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.

Consult surgical techniques for compatibility between implants and instruments.

CLEANING AND STERILIZATION

Limitations on reprocessing

Instruments should be washed, disinfected, and sterilized as often as necessary as long as they are undamaged and functional.

Instruments should be inspected for corrosion, damage, or residue before processing. Damaged instruments should be returned for servicing.

Point of use care

- Instruments should remain covered until needed to avoid becoming contaminated with blood, tissue, and/or bodily fluids/matter.
- Only those to be used should be handled.
- Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface.
- Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside.
- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Precautions

Instruments should not be lubricated.

When selecting cleaning products and equipment, pay attention throughout all steps to ensure that:

- They are suitable for the intended application (e.g., cleaning, ultrasonic cleaning).
- The cleaning products do not contain aldehydes (otherwise, blood residue may stick).
- The cleaning products are suitable and compatible with the products. Use detergents with a pH of 7 to 9.5; higher pH levels affect the stainless steel surface.
- Cleaning products should be low-foaming, easy to rinse (easily removed from the device), biodegradable, non-toxic, and should quickly dissolve/disperse dirt.
- Consider the following for both manual and mechanical cleaning:
 - Use only clean, lint-free cloths and/or soft brushes (never metal or steel brushes).
 - Use, if necessary, auxiliary aids such as cleaning pens, syringes, cannulas, or bottle brushes for cannulated or hollow products.
 - During drying, Fixier recommends disposable lint-free paper towels or clean compressed air.
 - Always handle the product with gloves and avoid contact with hard objects that could 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.



The person in charge of processing the instruments is responsible for ensuring that the process is carried out properly. This usually requires a validation process and routine monitoring of the process to ensure quality.

Preparation for decontamination

Lumens of devices should be manually processed prior to cleaning. Lumens should first be cleared of debris. Lumens should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. After brushing lumens blow clean compressed air through lumen to clear debris, if necessary.

Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use a neutral pH enzymatic detergent to soak devices. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Use cold tap water to rinse devices.

Manual pre-cleaning (Method: Ultrasonic)

1. Disassemble device, if device is able to be disassembled, prior cleaning. (Refer to Surgical Technique for assembly and disassemble instructions).
2. Rinse the instruments with cold tap water for at least two minutes to remove excess dirt.
3. Soak the devices in the cleaning bath with a pH-neutral enzymatic cleaning solution for at least 15 minutes (the devices must be completely covered by the solution and the individual components must not damage each other).
4. Rinse the device thoroughly with cold water for at least two minutes (you must also rinse the inside of cannulated devices with appropriate syringes and cannulas).
5. Manually clean the instruments for five minutes in a freshly prepared pH-neutral enzymatic cleaning solution using a soft-bristled plastic brush to thoroughly clean the device. Cannulated devices (hollow devices) must be cleaned with the appropriate brush (the brush diameter should be slightly larger than the lumen to ensure good contact between the brush and the implant).
6. Rinse the devices with running cold water for at least two minutes.

Ultrasonic Process

1. Clean the product ultrasonically for at least 15 minutes at a minimum bath frequency of 40 kHz using a freshly prepared pH-neutral enzymatic cleaning solution. The products must be completely covered by the solution, and individual components must not damage each other.
2. Rinse the devices with cold running water for at least two minutes. You must also rinse the inside of cannulated products with appropriate syringes and cannulas. Pressurized water guns may be used.
3. Next, dry the products completely (drying with clean, compressed air or a clean, soft, lint-free cloth is recommended).
4. Visually inspect the products. If necessary, repeat the cleaning process until all visible dirt and detergent residue are removed.

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

Automated cleaning and disinfection

Manual precleaning must be performed prior to the automated cleaning and disinfection.

Instruments can be cleaned and disinfected in a qualified washer-disinfector that meets the requirements of ISO 15883. Fixier recommends the following parameters:

Cycle	Minimum time	Minimum temperature	Type of water	Type of detergent
Pre-wash	5 minutes	20°C	Cold tap water	N/A
Wash 1	10 minutes	52°C	Cold to warm tap	Enzymatic detergent (pH 7-9)
Rinse 1	1 minute	20°C	Utility water	Enzymatic detergent (pH 7-9)
Final rinse	1 minute	90°C	Critical water	N/A
Dry	30 minutes	Room temperature	N/A	N/A

Inspection: After cleaning, check the condition of the surfaces. They should be free of scratches, cracks, debris, color changes, chips, or dirt. The surfaces should not show any signs of corrosion. Determine if the instruments have been damaged or contaminated and separate them from products that pass inspection. Instruments that become soiled should be recleaned. Damaged instruments should not be used and should be returned for maintenance.

Packaging: Place the cleaned and dry instruments in their tray and then wrap the tray using an FDA-cleared sterilization barrier.

Steam sterilization: All non-sterile products can be steam sterilized in a qualified autoclave that meets the requirements of ISO 17665. Fixier recommends the following parameters:

Type of cycle	Exposure time	Exposure Temperature	Drying time , minimum
Dynamic air removal (Minimum 3 pulses for vacuum)	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 sterilization equipment manufacturer's operating instructions during loading to ensure the equipment is not overloaded. Overloading the equipment can reduce the effectiveness of the sterilization process. The autoclave must be properly installed, maintained, and calibrated according to the manufacturer's instructions.



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Sterilization inspection: Visually inspect the sterile barrier for damage (holes, stains, tears, broken seals, missing tamper-evident closures), visual changes in 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 Triple-Zyme during manual and automated validation of this processing recommendation.

The cleaning, disinfection, and sterilization information was validated and is provided in accordance with ISO 17664, ISO 15883, ANSI/AAMI ST98, AAMI TIR12, and ISO 17665.

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile Traulux medical devices. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires verification and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.