# INSTRUCTIONS FOR CLEANING, STERILIZATION, HANDLING AND MAINTENANCE OF RE-USABLE INSTRUMENTS AND TRIALS

**SUMMARY**



## 1. INTRODUCTION

This document is intended to provide detailed instructions for reprocessing and effective maintenance of FX Shoulder Solutions re-usable instruments and trials. It is recommended to follow these instructions for the care, cleaning, disinfection, maintenance and sterilization of reusable surgical instruments and trials manufactured and/or distributed by FX Shoulder Solutions.

Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges. Operating staff must wear permanently appropriate protective equipment.

Upon receipt in the hospital, instrument sets should be inspected for completeness. Many organizing cases have shadow graphs, outlines, instruments references marked on the tray.

Only devices manufactured and/or distributed by FX Shoulder Solutions should be included in FX Shoulder Solutions instruments trays and cases. These validated reprocessing instructions are not applicable to FX Shoulder Solutions trays and cases that include devices that are not manufactured or distributed by FX Shoulder Solutions.

It should be noted that saline solutions and other irrigation fluids such as Ringers solution are often used in large quantities and may cause corrosion of the instruments.

## 2. CLEANING

It is recommended to use a combined manual / automatic cleaning method.

Instrument sets are not sterile and should be thoroughly cleaned and sterilized before use.

Automated cleaning using a washer-disinfector alone may not be effective for complex instruments with cannulas, blind holes, joined surfaces. It is recommended to first conduct a manual cleaning.

FX Shoulder Solutions containers, trays and boxes are not designed for cleaning and disinfection in the fully assembled state. The instruments must be removed from the trays for adequate cleaning results, and trays, boxes and lids must be cleaned separately.

Only use cleaning agents and / or disinfectants specially formulated for cleaning or disinfection of reusable instruments.
Only cleaning agents and / or disinfectants approved (CE marked, FDA approved) should be used.

The instructions provided by the detergent manufacturer on concentrations and temperatures must be observed. If excessive overshoot discoloration or corrosion may occur on some materials. This discoloration or corrosion can also be observed in case of insufficient rinsing after cleaning and / or disinfection.

Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments.

Never use metal brushes or steel wool for cleaning.

**Pre-cleaning / Removal of gross contamination**

The efficiency of subsequent decontamination procedures depends on prior removal of significant dirt during cleaning. Significant dirt must be removed under running water using a soft brush. Avoid splashing and producing aerosols by holding instruments beneath the surface of water in a sink where the water is left to run continuously to drain, being careful not to cause splashing or aerosols. Operating staff must wear protective equipment, including gloves, an apron, safety glasses and a mask. Take care to avoid wounds caused by penetration or cutting. Be particularly careful when removing debris from cannulas and hidden cavities of instruments.

At the point of use, contaminated instruments should be humidified to prevent drying of soils prior to transport to the reprocessing area. Instruments should be cleaned within 30 minutes after use or after removal of the cleaning solution.

Dirty instruments must be removed from metal trays. Do not clean the soiled instruments on the trays. Trays, cases, lids must be cleaned separately.

If cleaning is postponed, place groups of instruments in a covered container with detergent and/or an enzyme solution used by the healthcare establishment to delay drying. Wash all instruments, following protocols validated by the healthcare establishment, whether or not they had been used or if they accidentally came into contact with blood or physiological serum.

During transport to the reprocessing area, prevent damage by ensuring that heavy instruments are not mixed with fragile, do not stack instruments or place heavy instruments on top of delicate instruments.

**Disassembly**

Certain more complex instruments include different components and must be fully disassembled before decontamination. In most cases, the disassembly method is obvious: loosen and/or dismantle the instruments from moving parts.

**Disinfection / Washing**

Decontamination is then performed using automatic washing-disinfection equipment. Only a washer-disinfector whose effectiveness has been proven (CE marked, FDA approved and validated compliant with ISO 15883) must be used.

Compatible detergents and rinse aids can be used according to the recommendations of the automatic washing-disinfection equipment manufacturer. These detergents and / or rinse aids must however be at neutral or nearly neutral pH. Excessively acid or alkaline solutions could corrode instruments and instrument containers.

Ultrasonic washers can be used with hot water at temperatures recommended by the manufacturer (generally 32-60°C or 90-140°F) and with detergents specially formulated by the manufacturer: follow the manufacturer's recommendations to make up the correctly-formulated cleaning solution specific to ultrasonic washers.

***Combined manual / automated cleaning / disinfection instructions***

1. Completely submerge the instruments in a detergent solution and allow to soak for 20 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner).
2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute if the cycle of washer / disinfector doesn't begin by a rinsing program. Rinse carefully with plenty of water the holes, blind holes and other hard to reach areas.
3. Place instruments in a suitable washer / disinfector basket and process through a standard instrument washer / disinfector cleaning cycle.

**Re-assembly / Assembly and inspection**

After cleaning / disinfection, the disassembled instruments must be reassembled and placed in the right place in the trays and containers of FX Shoulder Solutions instruments. The trays must be replaced in the FX Shoulder Solutions original containers.

All reusable instruments must be inspected. In general, a visual inspection is sufficient for evidence of dirt, corrosion, damage and / or excessive wear.

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning / disinfection process. The proper functioning of the instruments should be continuously monitored. Check the action of the moving parts to ensure the proper functioning. Mating devices should be checked for proper assembly.
The useful life of these devices depends on many factors, including the method and duration of each use. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life. End of life is normally determined by wear and damage in use.

**Packaging**
FX Shoulder Solutions containers with lids must be packaged and taped (materials supplied by the autoclave manufacturer). The tape changes color following exposure to autoclaving, indicating and confirming exposure to a sterilization cycle. Use an FDA cleared sterilization wrap.

The packaging of reusable instruments to be sterilized must satisfy the requirements of ISO 11607-1, be CE marked or FDA approved, suitable for wet steam sterilization, quality suitable for the weight of FX Shoulder Solutions containers.

**3. STERILIZATION**
Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the standards ISO 17665, ANSI/AAMI ST79, AAMI TIR 12.

FX Shoulder Solutions instruments must be sterilized with validated parameters.
FX Shoulder Solutions instruments to be sterilized must be completely dry.
FX Shoulder Solutions instruments can be sterilized by pre-vacuum steam sterilizer and repeatedly autoclave sterilized without being affected, unless otherwise indication.

***Validated Sterilization parameters for USA***

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| Method | Moist heat sterilization according to ANSI/AAMI ST 79 |
| Cycle | Pre-vacuum |
| Temperature | 132°C (270°F) |
| Exposure time | 4 min |
| Drying time | 45 min minimum |

Instruments must not undergo accelerated autoclave sterilization inside the container. Accelerated autoclave sterilization of individual instruments has not been validated by the manufacturer.

The use of other steam sterilization cycles and other sterilization methods have not been validated by FX Shoulder Solutions.

In the event of problems when using instruments or instrument containers, please bring this problem to the attention of the distributor when sending them back. (Returned instruments must be cleaned and sterilized before being sent.)
As the distributor does not know the handling procedures, cleaning methods and the levels of bio-contamination in each hospital, the distributor accepts no responsibility for sterilization of products by a hospital even if the general guidelines given above are followed.

**4. STORAGE**
After sterilization, re-usable instruments should be stored the in the sterilization wrap in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized re-usable instruments before use should be defined by each health care facility.

**5. MAINTAINING AND HANDLING INSTRUMENTS**
Surgical instruments and the instrument container may be damaged for different reasons, including prolonged use, incorrect use, rough or inappropriate handling. Avoid compromising their functional performance. To reduce damage and the risk of injury, proceed as follows:
- inspect the instrument container and instruments for any sign of damage on receipt and after having used and cleaned them. Instruments that are not completely cleaned must be cleaned once again. Damaged instruments must be set aside and replaced.
- use an instrument appropriate to the operative technique.
- be particularly careful when handling cutting instruments to avoid any injury.
In the event of injury, consult an expert in infection control to confirm safety procedures for a blood exposure accident, appropriate to all levels of direct contact with instruments

Comments regarding these products can be addressed to the manufacturer or distributer:

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