



Recommendations for Processing and  
Sterilization of Orthopedic Instruments and  
Devices



## Purpose of Document

The instructions included herein are to provide guidance for the cleaning, decontamination, care, maintenance, and sterilization of medical devices as manufactured and/or distributed by Shoulder Options, Inc. Such recommendations are provided to assist health care personnel in the safe handling and reprocessing of the aforementioned devices. These instructions have been developed in conjunction with the guidance given in ISO 17664:2004 and Health Technical Memorandum (HTM) 2030. Further, these recommendations were validated for the medical and containment devices using the guidelines and standards as described in AAMI TIR 12:2004 and ANSI/AAMI ST77:2006.

Hospital personnel that are directly involved in the processing and handling of surgical instruments produced and/or distributed by Shoulder Options should be familiar with these instructions to assure the safe and effective processing of such devices so as to prevent damage to the reusable devices while maintaining the highest standards for the benefit of patients.

## General Information

The information contained in this document is applicable to all reusable medical devices manufactured and/or distributed by Shoulder Options, Inc. Additionally, the recommendations apply to single-use medical devices that are supplied in non-sterile form, but are to be utilized in a sterile state (e.g. locking anchor bolts, plates, screws, screwdrivers, etc.). If single use devices that are provided sterile are removed from their sterile packaging and need to be resterilized, the recommendations set forth in this document also apply to reprocessing of such devices.

Devices that cannot be reused should be labeled with the following symbol as set forth by ISO 15223 3.2:



**Do not Reuse**

This information does not apply to single-use devices that are provided sterile and are not intended to be resterilized. Devices that cannot be resterilized should be labeled with the following symbol:



**Do not resterilize**

## Glossary of Terms

<p><b><u>Chemical*</u></b> Includes detergents, washer-disinfectors, rinse aids, enzymatic cleaners, sterilants, etc.</p>	<p>A specific formulation of compound that is intended for use in cleaning/reprocessing and/or disinfecting.</p>
<p><b><u>Detergents</u></b></p>	<p>Cleaning agents, herein requiring a pH range between 6.0 and 8.0. Those detergents with a pH outside of this range can be damaging to the instruments, implants, and trays. The detergents used should be used in concentration ratios recommended by the detergent manufacturer. Some alkaline agents can be safe for medical device reprocessing, but the manufacturer of such agents should be consulted to prevent material damage .</p>
<p><b><u>Cleaning</u></b></p>	<p>Removal of contaminants from an item before further processing. The purpose of cleaning is to remove visible adherent matter and reduce the amount of microorganisms and pyrogens from medical devices. Therefore, cleaning is the most important in preparing a device for reuse and includes both manual and automatic washing/disinfecting procedures described in this manual.</p>
<p><b><u>Contamination</u></b></p>	<p>Having been potentially or actually exposed to contact with microorganisms.</p>
<p><b><u>Decontamination</u></b></p>	<p>To chemically and/or physically remove and/or kill bloodborne pathogens on the surface of medical devices and related instruments and trays to the effect of making such devices incapable of transmitting infectious particles. Thereby, the devices and trays would be considered safe for handling or disposal.</p>
<p><b><u>Disinfection</u></b></p>	<p>The process of reducing/removing the amount of viable microorganisms on a medical device to a level specified as safe for handling or disposal.</p>
<p><b><u>Processing/Reprocessing</u></b></p>	<p>The act of cleaning (manually and/or with an automatic washer), disinfecting, and sterilizing medical devices, instruments, and trays. The action is essential in preparing a new or reusable medical device for its intended use in surgical procedures.</p>
<p><b><u>Sterile</u></b></p>	<p>Free from living germs or microorganisms.</p>
<p><b><u>Sterilization*</u></b></p>	<p>The process, validated by standardized processes, used to kill all forms of microorganisms.</p>
<p><b><u>Reusable Devices</u></b></p>	<p>Devices manufactured with the intent of repeated use on different surgical procedures, with appropriate decontamination and processing between uses.</p>

<b><u>Trays</u></b>	Reusable rigid sterilization container that consists of a lid and a base. Intended to organize system-specific reusable accessories for use in the surgical environment. Trays allow penetration of sterilization agents during cleaning and provide an enclosed environment for sterilization and maintaining sterility.
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*\*When sterile processing is quantified, it is done by quantifying the death of the microorganisms in an exponential function. As such, the chance of a viable microorganism living within the system is expressed by probability. This expressed probability can be very low, but never attain the zero value. The very low probability can only be assured by following a specific validated process.*

## **Attention to Hospitals/End Users**

While the information in this manual is intended to give very thorough and complete information as to the safe processing and handling of Shoulder Options' implants, trays, and instruments, local laws and ordinances should be followed when reprocessing standards are more thorough than those described in this document.

Orthopedic surgery inherently results in the soiling of medical instruments, trays, and implants used in the procedures. Instruments and implants are contaminated with blood, tissue, and bone particulates. As such, these medical devices can become contaminated with HIV, hepatitis viruses, and other pathogens. All personnel that may come in contact with these medical devices should be trained in preventing contaminating themselves with infected devices.

It is the responsibility of the hospital to reprocess all Shoulder Options trays and devices in a thorough, safe, and effective manner. Shoulder Options cannot guarantee that all trays shipped to the end user will be completely free of contaminants and sterile. Therefore, it is the responsibility of the hospital to verify upon receipt that any Shoulder Options set is complete, cleaned, and reprocessed by meeting or exceeding the recommendations herein to ensure safety.

Not only is it important to process the Shoulder Options sets in a thorough and consistent manner, equally important is to make sure all warnings and precautions are followed, all instruments are in functioning order, and the storage recommendations are followed. **THE INSTRUCTIONS IN THIS MANUAL MUST BE FOLLOWED (OR EXCEEDED) TO ENSURE THAT THE SETS ATTAIN STERILITY.**

## Warnings and Precautions

THE FOLLOWING INFORMATION ONLY APPLIES TO REUSABLE DEVICES. SINGLE USE DEVICES SHOULD NEVER BE REPROCESSED FOR USE AS THEY MAY MALFUNCTION AND/OR POSE A RISK TO THE HOSPITAL PERSONNEL AND/OR PATIENT IF REUSED.

During the processing of reusable devices standardized universal precautions of handling contaminated devices should be followed to ensure safety of all applicable hospital personnel. Sharp points and cutting edges pose risks to the handler and such personnel are advised to pay careful attention to avoid contaminating themselves. As such, personal protective devices such as gown, mask, eye protection, gloves and shoe covers should be worn at all times.

Although reusable devices are manufactured such that reprocessing has minimal effects on the devices, improper handling and/or cleaning can adversely affect the materials. Therefore, soft-bristled, nylon brushes and pipe cleaners and/or nonabrasive low lint cloths should be used to prevent damage. Low foaming surfactant cleaning/disinfection agents that should be used during manual cleaning to ensure visibility while cleaning instruments below the surface of the cleaning solution (prevent splashing to decrease the chances of contamination). Newly prepared cleaning solutions should be prepared when necessary (excessive amount of contaminants). Cleaning/disinfection agents must be completely rinsed from the device surfaces to prevent accumulation of detergent residue.

DO NOT USE metal brushes during the manual cleaning process. DO NOT USE cleaning/disinfection agents that contain aldehyde, mercury, active chlorine, bromine, bromide, iodine or iodide. These chemicals are corrosive to the materials and should not be used. DO NOT allow contaminated medical devices to dry with contaminants on them prior to reprocessing. DO NOT USE mineral oil or silicone lubricants due to their inherent non-penetrable nature. DO NOT USE descaling agents that include morpholine in steam sterilizers as they can leave a residue that has adverse affects to polymer instruments over time.

The responsibility to ensure that Shoulder Options instrument systems and trays are complete and exhibit proper function lies with the end user which intends to utilize the system in a surgical procedure. Therefore, the hospital should thoroughly inspect instrument and implant sets upon receipt. Contact a Shoulder Options representative with any questions and/or issues found during the thorough inspection.

## Limitations and Recommendations

- If using alkaline cleaning agents it is important to make sure that the devices are completely and thoroughly rinsed and neutralized so as to prevent damage to the devices. Particular attention should be paid to sharp and cutting instruments when using alkaline agents to ensure that the cutting edges are not adversely affected by contact with the agent. Additionally, alkaline agents have demonstrated to have an adverse affect on instruments made of titanium or aluminum alloys and should not be used when processing devices with these make-ups.
- Disassembly of devices with multiple components should occur where possible to ensure proper cleaning. If a component is disassembled, it is important to ensure that none of the parts are lost so that the instruments can be reassembled and used effectively during the surgical procedure. If components are lost contact a Shoulder Options representative for a replacement.
- Automated washer-disinfectors alone may not be sufficient for medical devices that are highly soiled or have complex surface features and cannulations. Therefore, a thorough manual, followed by an automated, cleaning process is recommended.
- Reprocessing reusable medical devices usually has minimal affect on the devices and the end of life for these devices is normally determined by wear and damage due to surgical use.
- Instruments **MUST** be removed from the trays that house them for all cleaning procedures. As such, instrument trays and lids should be cleaned separately from the instruments. Non-sterile, single-use plate, screw, and anchor bolt implants are an exception to this rule and can remain in the tray or caddy for reprocessing.
- Polymers used in Shoulder Options trays can experience excessive wear over time and should be replaced if the surfaces turn “chalky” or demonstrate other visible wear.
- Hard water can leave mineral deposits on medical devices and result in ineffective decontamination. Therefore, hard water should be avoided. Softened tap water is recommended for initial rinsing, while purified water should be use for the final rinse to minimize mineral deposits.

- Steam/moist heat is the recommended sterilization method for all Shoulder Options instrument trays. Ethylene Oxide (EO), Gas Plasma and dry heat sterilization ARE NOT RECOMMENDED for Shoulder Options reusable devices.
- Titanium and associated alloy devices can discolor because of steam impurities and residues from detergents. With repeated reprocessing the graduation marks and stamped or etched information on the devices can prove difficult to read. While the device functions are not harmed by this discoloration and residue it may be desirable to remove the discoloration for useful function. Acidic, anti-corrosion agents can accomplish the removal of these impurities from the device surface, but should be used infrequently.

## **Point of Use Recommendations for Reprocessing**

- Reusable devices should be wiped with a non-shedding wipe or brush to clear excess contaminants before being placed in a basin of distilled water to soak. DO NOT allow the contaminants to dry on the surfaces of the medical devices and instruments prior to cleaning.
- Soaking instruments in an enzymatic solution is recommended to break down protein matter and prevent drying.
- Clean instruments within 30 minutes to prevent drying of contaminants on the device surfaces.
- Transport reusable devices to central supply/decontamination department in a closed/covered container to minimize contamination risk to hospital personnel and patients.

## Cleaning/Disinfection Instructions

### A. Manual Cleaning/Disinfection Only\*

**\*NOT RECOMMENDED as the only cleaning method. Manual and automated cleaning recommendations advised except where specifically indicated**

1. Submerge soiled instruments in an enzyme solution for a minimum of 20 minutes. Use non-abrasive brush and/or cloth to remove visible soil, with special attention to devices with complex surface areas. All instruments that can be disassembled should be taken apart prior to soaking. Cavities, cannulations, connectors, and complex surface areas should be cleaned with appropriate cleaning instruments (ex. pipe cleaners).

**Syringe or water jet can improve flushing of difficult to reach surface areas.**

2. After removing from the enzymatic soaking solution, devices should be rinsed with softened or purified water for a minimum of 3 minutes. Again, special attention should be given to adequately flushing complex surface areas.

3. Ultrasonic Cleaners are recommended for devices that have especially difficult to clean surfaces. Ultrasonic cleaners are not intended for disinfection or sterilization, but are effective for cleaning only after gross soil has been removed from the devices. Completely submerge the device in cleaning solution and sonicate at 45-50 kHz for 10 minutes.

4. Rinse device/instrument in warm purified water until there is not visible soil on the item. Special attention should be given to complex surface areas on the devices.

5. Remove excess moisture from instrument with a clean, non-shedding absorbent wipe.

### B. Manual and Automated Cleaning/Disinfection\*

**\*Manual and automated cleaning recommendations are advised except where specifically indicated.**

1. Submerge soiled instruments in an enzyme solution for a minimum of 10 minutes. Use non-abrasive brush and/or cloth to remove visible soil, with special attention to devices with complex surface areas. All instruments that can be disassembled should be taken apart prior to soaking. Cavities, cannulations, connectors, and complex surface areas should be cleaned with appropriate cleaning instruments (ex. pipe cleaners).

**Syringe or water jet can improve flushing of difficult to reach surface areas.**

2. Although not required, the use of an ultrasonic cleaner at 45-50 kHz will assist in sufficiently cleaning devices.
3. Rinse device/instrument in warm purified water until there is not visible soil on the item. Special attention should be given to complex surface areas on the devices.
4. Place device/instrument in a washer/disinfector basket and process in a standard automated/disinfector washer cleaning cycle. The minimum requirements for cleaning/disinfection of Shoulder Options' devices, instruments, and trays are as follows\*:

*\*Washer/disinfector manufacturer's instructions should be strictly observed*

- A. 2 minute cold prewash
- B. 15 second cold water rinse (X2)
- C. 2 minutes detergent wash with hot water (63-68°C/145-154°F)
- D. 15 second hot water rinse
- E. 2 minute thermal rinse (80-93°C/176-200°F)
- F. 7-30 minute hot air dry (100°C/212°F)

#### **C. Automated Cleaning/Disinfection Only\***

**\*NOT RECOMMENDED as the only cleaning method. Manual and automated cleaning recommendations advised except where specifically indicated**

Only simple instruments without complex surfaces, or those with cannulations and/or requiring disassembly should be solely cleaned by the automated means recommended above.

## **Inspection and Function Testing**

All devices should be visually inspected to ensure that contamination is not present on all medical devices and trays. If contamination is observed the cleaning/disinfection process should be repeated. Again, observation is made to make sure no functional damage or incomplete components are found. If components are missing, or otherwise dysfunctional, contact a Shoulder Options representative with any questions and/or issues found during the thorough inspection process.

## **End User Sterile Packaging**

### **Sterile Packaging of Individual Instruments**

There are commercially available medical grade steam sterilization pouches (i.e. paper, Tyvek™ or equivalent) that can be used in a double package form to sterilize individual instruments. The end user must make sure that the inner pouch is large enough to contain the instrument/device without straining the seals or puncturing the packaging. The inner pouch containing the instrument must be small enough to be placed in a secondary package without compromising the integrity of the combined package. Special attention should be made to making sure any sharp or cutting surfaces are protected from penetrating the packaging.

Standard medical grade steam sterilization wrap can be used to encase individual medical devices and instruments. Such wrapping should be done utilizing the AAMI double wrap or equivalent method.

### **Providing Sterile Instruments/Devices in Rigid Trays with Lids**

The combined weight of a wrapped instrument system (tray) should not exceed 11.4 kg/25 lbs. If placed in an approved sterilization container with a gasket lid, the combined weight should not exceed 16 kg/35 lbs.

Trays with lids should be wrapped in standard medical grade, steam sterilization wrap utilizing the AAMI double wrap or equivalent method.

Medical devices can also be processed in an approved sterilization container with a gasket lid for sterilization. Manufacturer's instructions for use and sterilization of these containers should be followed accordingly.

### **Instrument/Device Trays with Defined Layouts**

The trays provided for Shoulder Options' instruments and implants should only contain those devices specified and intended within the tray layout. Optional instruments should only be added to the preconfigured trays if a universal/miscellaneous compartment has been designated for such additional instruments.

Only devices manufactured or distributed by Shoulder Options should be included in the Shoulder Options instrument trays. The validated processes set hereto fore are NOT APPLICABLE to devices which are not manufactured/distributed by Shoulder Options.

## **Storage Recommendations**

Sterile, packaged instruments are to be stored in a designated area that is well ventilated, traffic is kept to a minimum, and is protected from dust, moisture, insects and vermin. The sterile items should not be exposed to extreme temperatures or humidity.

It is imperative that all packages are thoroughly inspected to ensure that the sterile barrier has not been compromised before transferring to the sterile field. If a sterile wrap is perforated, torn, or appears to have been compromised in any way the instruments/devices should be repackaged and resterilized.

## **Contact Information**

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**A copy of this manual can be found at [www.shoulderoptions.com](http://www.shoulderoptions.com) under the "Downloads" tab.**

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