Reusable Instruments
Instructions for Use

Introduction

Acuitive Technologies manual surgical instruments and instrument cases are generally composed of aluminum, stainless steel, and polymeric materials. The cases are both single and double layered with various internal brackets and trays designed to hold surgical instrumentation in place during handling, sterilization, and storage. The instrument cases are perforated to allow steam to penetrate, which, when placed in a steam autoclave allows sterilization of the contents.

Purpose

This manual is recommended for the care, cleaning, maintenance, and sterilization of reusable Acuitive Technologies manual surgical instruments. All Acuitive Technologies reusable instruments must be cleaned and sterilized to prepare them for use. This document is intended to assist health care personnel in safe handling practices, effective reprocessing, and maintenance of Acuitive Technologies reusable devices.
Hospital personnel, including those in receiving and central sterile supply departments, as well as in the operating room, may be directly involved in handling instruments purchased or consigned from Acuitive Technologies. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

Scope

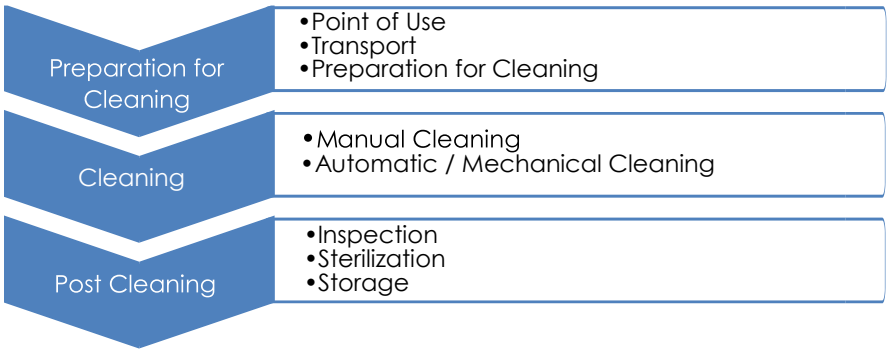
This instruction manual provides information on the care, cleaning, maintenance, and sterilization of manual surgical instruments and is applicable to all reusable medical devices manufactured and distributed by Acuitive Technologies.
These instructions are NOT applicable to any air driven or electrically powered equipment.
These instructions do NOT apply to single use medical devices manufactured or distributed by Acuitive Technologies. Single use devices should not be reused, as they are not designed to perform as intended after the initial use. Devices that cannot be reused may be labeled with the following symbol:

Do not reuse / Single use only

General Warnings and Precautions

- Orthopedic surgery requires instruments which are heavy and have multiple components, articulation or rotating parts, removable handles, plastic replacement parts and series of measuring devices in graduated sizes. Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure.
- During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone chips and marrow. Instruments may also become contaminated with body fluids containing hepatitis virus, HIV or other etiological agents and pathogens. Reference OSHA regulations 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens.
- All health care workers should become familiar with the necessary Universal Precautions of preventing injuries caused by sharp instruments when handling these devices during and after surgical procedures and during reprocessing.
- Personal protective Equipment (PPE) should always be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gowns, masks, goggles or face shields, gloves, and shoe covers.
- Acuitive Technologies has validated the processes provided in these instructions to be capable of being effective. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of cleaning and sterilization processing. The healthcare facility should ensure that the results of selected processing steps and factors are safe and effective.
- Full cycle steam/moist heat is the recommended sterilization method for Acuitive Technologies reusable manual instruments. Immediate-Use steam sterilization (flash sterilization) of individual instruments or inside the instrument case should be avoided. Ethylene Oxide (EO), Gas Plasma, and dry heat sterilization methods are also not recommended.
- Unless otherwise indicated, instrument sets are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.
- Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared sterilization wrap to maintain sterility.
- Repeated processing in accordance to the instructions in this manual has minimal effect on Acuitive Technologies reusable manual instruments. Service life for stainless steel surgical instruments is normally dictated by wear and damage due to intended surgical use and not from reprocessing.
- Saline and other irrigation fluids are often used in copious amounts during surgical procedures and will exert a corroding effect on instruments.
- Mineral oil or silicone lubricants should not be used because they coat microorganisms; prevent direct contact of the surface with steam; and they are difficult to remove.
- The parameters for the sterilization process contained within this instruction manual are applicable within the USA only.

Process Overview



Preparation for Cleaning

Point of Use

After use remove gross soil using absorbent, non-shredding, disposable wipes. Intensive rinsing of the reusable instruments with fluent water or transfer of the medical devices into a bath with a proteolytic enzyme or aldehyde free disinfectant solution is recommended.

Transport to processing area

Avoid mechanical damage by ensuring that heavy devices do not get mixed with delicate ones. Pay particular attention to cutting edges, both to avoid personal injury and prevent damage to the re-usable instrument. Transport the re-usable instruments to the point where cleaning is to be performed as soon as practical.
Caution: Do not allow contaminated devices to dry prior to reprocessing. If transfer to the processing area is likely to be delayed, consider covering the re-usable instruments with a damp cloth to avoid drying of soil.

Preparation for cleaning

Disassemble instruments as required.

Cleaning

- Two methods of cleaning Acuitive Technologies reusable manual instruments are provided in these instructions, a **manual method** and a mechanical method using an **automated washer disinfector**.
- Whenever possible the automated method should be used. The automated cleaning process is more reproducible, and staff are less exposed to the contaminated devices and the cleaning agents used.

Caution: Automated cleaning using a washer/disinfector *alone* may not be effective for orthopedic instruments with lumens, cannulations, blind holes, mated surfaces, and other complex features.

- A combination of manual and automated cleaning is recommended as described in this manual.
- Whichever method is used, staff should use suitable protective clothing and equipment (PPE) at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.
- Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants.
- The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning is insufficient.
- For cleaning re-usable instruments neutral pH, enzymatic, formulated cleaning agents are recommended and preferred for cleaning Acuitive Technologies reusable manual instruments.
- The quality of the water used for diluting cleaning agents and rinsing re-usable instruments should be carefully considered. Application of freshly prepared purified water is highly recommended for final rinses. Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and decontamination.

Caution: Acuitive Technologies trays and cases are intended for transport, storage, and sterilization of re-usable instruments. They are not designed for cleaning in the fully assembled state. The instruments must be removed from the tray for adequate cleaning results.

Manual cleaning

Equipment required:

- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning
- Nylon Brushes – soft and firm, pipe cleaners, bottle brushes or cleaning wires for cannulations and channels
- Personal protective equipment as recommended by the cleaning agent supplier
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)
- Ultrasonic bath large enough to allow complete immersion of the re-usable instrument. (A frequency of 40-44 kHz is recommended. Do not exceed the temperature stated by the detergent manufacturer.)
- Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment. Do not exceed the concentration specified by the detergent manufacturer.
- Fresh purified water for final rinsing purposes.

Caution: To prevent damage to the instrument surfaces and finishes, *never* use metal brushes or steel wool for cleaning.

Procedure:

1. Remove gross soil using wipes and neutral pH solution of cleaning agent such as Enzol®.
2. Immerse re-usable instrument in solution of enzymatic or cleaning agent and soak for 15 minutes. Ensure that all surfaces are thoroughly wetted. Ensure that air is not trapped within features of the device when immersing in the solution.
3. Manually wash devices a. Use a syringe to ensure that the cleaning solution reaches all parts of cannulations. b. Using suitable soft bristle brushes clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process. c. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches. d. Bend flexible devices in a U-shape and scrub the surface with a firm bristle brush. Repeat bending and brushing at several locations along the length to cover the entire device. e. Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation. f. Operate articulating devices and those with moving parts.
4. Rinse in running water for a minimum of 3 minutes until all traces of cleaning solution are removed. Pay particular attention to cannulations and blind holes, as well as hinges and joints, between mating parts.
5. Visually inspect for any remaining soil and repeat the steps above if necessary.
6. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified by the detergent manufacturer.
7. Immerse the device completely and activate the bath for minimum of 15 minutes.
8. Using suitable brushes or cleaning wires, clean the device paying particular attention to rough surfaces and features that may be shielded from the ultrasonic action.
9. Rinse for at least 3 minutes in running water until all traces of cleaning solution are removed. Pay particular attention to cannulations, blind holes, hinges, and joints between mating parts. Rinse cannulations at least three times with a syringe (volume 1-50ml).
10. If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remains on the device, the cleaning step must be repeated as described above.

Automated/Mechanical cleaning using washer-disinfector

Equipment required:

- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning
- Nylon Brushes – soft and firm, pipe cleaners, bottle brushes or cleaning wires for cannulations and channels
- Personal protective equipment as recommended by the cleaning agent supplier
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)
- Washer-disinfector.
- Cleaning agent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.

Procedure:

1. Remove gross soil using wipes and solution of cleaning agent.
2. Immerse re-usable instrument in solution of enzymatic or cleaning agent and soak for 15 minutes. Ensure that all surfaces are thoroughly wetted. Ensure that air is not trapped within features of the device when immersing in the solution.
3. Manually wash devices
   a. Use a syringe to ensure that the cleaning solution reaches all parts of cannulations.
   b. Using suitable soft bristle brushes clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.
   c. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches.
   d. Bend flexible devices in a U-shape and scrub the surface with a firm bristle brush. Repeat bending and brushing at several locations along the length to cover the entire device.
   e. Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation.
   f. Operate articulating devices and those with moving parts.
4. Rinse in running water for a minimum of 3 minutes until all traces of cleaning solution are removed. Pay particular attention to cannulations and blind holes, as well as hinges and joints, between mating parts.
5. Load the re-usable instruments into the washer-disinfector.
   a. Avoid contact between devices as movement during washing could cause damage, and washing action could be obstructed.
   b. Arrange re-usable instruments so that cannulations are not horizontal and blind holes incline downwards to assist drainage. Articulating devices should be in the open position.
6. Operate the washer-disinfector cycle. The following table provides instructions for cleaning re-usable instruments:

Phase	Time	Temperature	Detergent/Concentration
Pre-Wash	2 min	Cold Tap Water	None
Enzyme Wash	1 min	Hot Tap Water	Enzol®/ 1 oz/gal
Wash	2 min	66° C	Renu-Klenz™/ 0.25oz/gal
Rinse	15 sec	Hot Tap Water	None
Pure Water Rinse	10 sec	66° C/Purified Water	None
Drying	7 min	115.5° C	None

7. Upon completion, unload the washer-disinfector. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process. Remaining wetness may be removed with filtered, compressed air or clean, lint-free wipes.

Post Cleaning

Inspection

Before preparing for sterilization, all re-usable instruments should be inspected. Generally un-magnified, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion.

Verifying Cleaning	After cleaning, visually inspect devices under normal lighting for the removal of visible soil

- Inspect soil traps such as mating surfaces, hinges, shafts of flexible drill bits, and recessed features (holes, cannulations)
- Inspect features where soil may be impacted into the device, such as drill flutes adjacent to the cutting tip and sides of teeth on broaches and rasps
- For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood

Functional Checks and Inspections	Visually inspect for damage, wear, and functional anomalies

- Mating devices should be checked for proper assembly
- Check edges of cutting features for distortion or damage. Edges should be sharp and continuous
- Articulating surfaces should be smooth and free of cracks and deep nicks
- Inspect metal surfaces for corrosion and major deformations
- Instruments with moving parts should be operated to check correct operation
- Rotating instruments, such as multiple use drill bits, and reamers, should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface
- Flexible instruments should be checked for damage to the spiral element
- For devices that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.

Note: Acuitive Technologies does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

Sterile Packaging

The packaging for terminally sterilized re-usable instruments should be suitable for steam sterilization and grade appropriate for the weight of the instrument case. Cleaned and checked re-usable instruments should be assembled into the dedicated trays provided. Acuitive Technologies cases/trays should be wrapped during the steam sterilization process using FDA cleared wraps (e.g. KC600 Kimguard® Sterilization Wrap).

Warning: Acuitive Technologies does not recommend the use of rigid containers for steam sterilization. This configuration could limit steam penetration and prevent effective sterilization of the instruments.

Sterilization

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated and maintained in accordance with ISO 17665, and ANSI/AAMI ST79.

Acuitive Technologies has validated an autoclave cycle for sterilization of complete re-usable instrument cases/trays. Instruments shall be sterilized in the assembled state as stored on the tray (i.e.: if the brackets or recessions in the tray are designed to accommodate multi-component instruments in their assembled state, there is no need to disassemble these instruments for sterilization.) The process parameters below are validated and recommended by Acuitive Technologies for sterilization.

Caution: Acuitive Technologies does not recommend the use of 'flash' or immediate use steam sterilization for re-usable instruments.
Warning: Single-use implants and instruments should not be re-sterilized.

USA Parameters for instrument cases up to 25lb (11kg)

Method	Moist heat sterilization according to ANSI/AAMI ST 79
Cycle	Dynamic Air removal Steam Sterilization (Pre-Vac)
Temperature	132°C (270°F)
Exposure Time[1]	4 minutes (minimum)
Drying Time[2]	30 minutes (minimum, in chamber)

[1] Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature.
[2] Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method and material

Storage before Use

After sterilization, re-usable instruments should be stored the in the sterilization wrap in a dry and dust free place to maintain the sterile condition. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, or with handling. The shelf life is dependent on the integrity of the sterile barrier employed, storage manner, environmental conditions and handling.

References

1. AAMI TIR12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
2. AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
3. ANSI/AAMI 35: *Safe handling and biological decontamination of reusable medical devices in healthcare facilities and in nonclinical settings*
4. ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health care Facilities*
5. ANSI/AAMI ST81, *Sterilization of medical devices – Information to be provided by the manufacture for the processing of resterilizable medical devices*
6. ISO 17664: *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices*
7. ISO 17665: *Sterilization of health care products, moist heat*

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PI-002 Rev. 00