

Aesculap® Surgical Instruments Instructions for Use (IFU)

Rx only

Validated Instrument Cleaning & Sterilization Instructions

1. SCOPE

This document serves as Instructions for Use for Aesculap manual surgical instruments and includes information regarding the cleaning, care, maintenance, and sterilization.

Single use items not intended for reprocessing are not covered in this document. Specific assembly and disassembly of instruments can be found at: www.aesculapUSA.com

2. PURPOSE

These Instructions for Use support healthcare facilities in processing Aesculap manual surgical instruments safely.

3. PRODUCT DESCRIPTION

Manual instruments are designed to perform functions; such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing or ligating tissue.

Aesculap manual instruments are supplied **non-sterile** and must be inspected for damage or non-functioning parts, cleaned and sterilized prior to use. Call Aesculap Customer Service 800-282-9000 to report damage.

4. GENERAL INFORMATION

Instructions in this document are based on validation testing by Aesculap in a medical device testing laboratory using worst case soiling methods.

Each facility should verify that their processing system/s provide similar results. Personnel training and competency is required to perform all phases of processing hand held/manual instruments. Equipment, water supply, and practices all contribute to providing an effective reprocessing system and should be monitored by the facility.

Note: Service life of instruments is determined by correct use, maintenance, and processing.

Note: Mixing metal during cleaning or sterilization can result in instrument discoloration or surface damage.

PRECAUTIONS

- Do not apply excessive force at joints. Excessive force may result in misalignment or cracks.
- Only use instruments on the intended type and size of tissues. For example; use micro scissors for delicate soft tissue and osteotomes on bone.
- Only use rongeurs and bone cutting forceps on bone. Do not use on wire.
- Handle delicate instruments gently. Protect tips from damage.
- Remove broken or non-functioning instruments from service and repair or replace them.
- Wear appropriate personal protective equipment when handling contaminated instruments.

CLEANING ACCESSORIES

- Use soft or medium non-metal bristle brush for instrument surfaces.
- For instruments with a tube part or lumen ensure the following points:
 - Syringe tip securely fits into lumen/cannula when flushing.
 - Brush is selected for the size of the inside diameter (ID) and length of the tube/lumen. In order to achieve cleaning action, all inner surfaces need to be in contact with the brush bristles. For example, a 5 mm ID lumen/cannula requires at least a 5 mm brush which extends beyond the tip of tube/lumen.

POINT OF USE CARE

- Remove gross debris with a disposable low or non-linting wipe moistened with water and flush lumens with water.

Note: Use of saline moistened wipes can shorten the service life of the instruments.

- Contain and transport used instruments in a labeled, closed, puncture proof device per facility procedure.
- Transport to processing area as soon as possible.
 - Separate heavy instruments from delicate instruments.
 - Do not put heavy instruments on top of delicate instruments.
 - Keep instruments moist between point of use and decontamination.

CLEANING

- Disassemble while keeping parts together. For specific disassembly instructions go to www.aesculapUSA.com
- Open instruments completely to allow cleaning solution to reach all surfaces.
- Flush lumens as necessary when under water to ensure air is not in lumen during cleaning.
- Move all parts that can be moved during manual cleaning to allow cleaning solution and brushing action to reach all surfaces.
- Prepare cleaning solution per manufacturer's instructions for use.

Note: Validation testing was performed using Prolystica® 2X Concentrate Enzymatic Cleaner (manufactured by Steris). Other medical device cleaning agents may provide similar results.

- Verify cleaning agent performance by using information provided by the manufacturer or by physical testing.

INSPECTION AND LUBRICATION

- Allow the instrument to cool down to room temperature.
- Inspect in a well-lit area and/or use a lighted magnifier.
- Check that the instrument is clean and dry. If not, repeat cleaning and/or drying.
- Lubricate instruments with moving parts as needed; unless otherwise indicated. Use a lubricant intended for use on surgical instruments such as, Aesculap JG598 or JG600.
- Check if instrument is operational and free of damage (e.g. broken insulation or corroded, loose, bent, broken, cracked, worn, or fractured components).
- Remove damaged or inoperative products from service.

Note: Titanium may discolor during processing.

PACKAGING FOR STERILIZATION

- Protect sharp edges for the safety of healthcare workers and to prevent packaging damage.
- Organize instruments in a manner that permits contact with sterilant.
- Use FDA cleared packaging for sterilization according to manufacturer's recommendations.

Note: Validation testing was performed using Aesculap® SterilContainer™ System.

STERILIZATION

Moist heat/steam sterilization is the preferred sterilization method for Aesculap manual instruments.

- Operate the sterilizer using manufacturer's recommendations.
- Removable instrument parts, such as suction tips, screws, collets, may be sterilized assembled.
 - Threaded parts should not be fully tightened.
- Instruments can be sterilized unratcheted/unlatched OR closed on first ratchet.
- During validations, clamps of the instruments held in closed position by a spring such as vascular bulldog clamps were slightly separated using a piece of tray liner.

STERILE STORAGE

- Store in an area designed to maintain sterile packaged items.

5. DEFINITIONS

Critical water: water that is treated (usually by a multistep treatment process that could include a carbon bed, softening, DI [deionized water], and RO [reversed osmoses] or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or steam generation. (AAMI TIR 34:2014)

Immediate-use steam sterilization (IUSS): Sterilization method that involves the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team. ANSI/AAMI ST79:2017; 2.50

Terminal sterilization: process whereby product is sterilized within its sterile barrier. ANSI/AAMI/ISO TIR11139:2006, 2.52

Utility water: Water as it comes from the tap that might require further treatment to achieve the specifications. This water is mainly used for flushing, washing, and rinsing. (AAMI TIR 34:2014)

6. CLEANING PROCESS USING INSTRUMENT DESIGN

Instruments have design characteristics; such as hinges, joints, lumens, or hidden surfaces. Design characteristics determine the various required and optional cleaning steps. Aesculap has categorized their instruments into instrument groups to promote standardized cleaning processes.

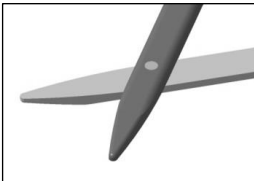
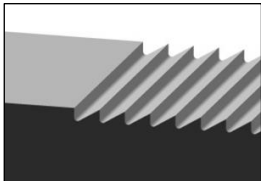
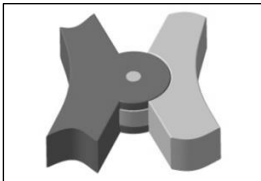
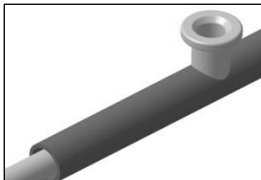
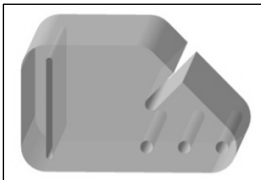
The following table provides a description of the design characteristics for instrument groups and their required cleaning steps.

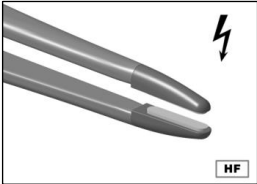
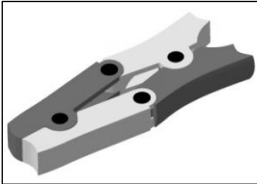
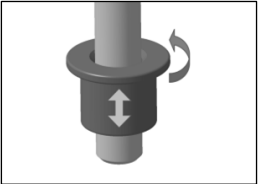
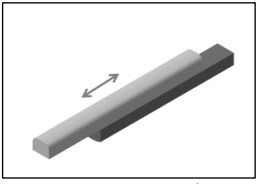
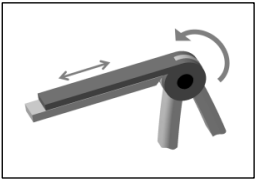
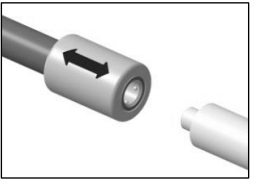
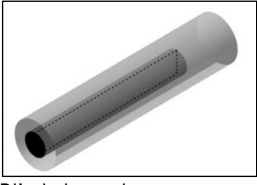
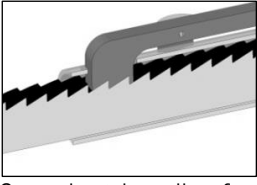
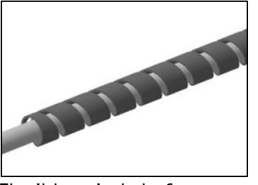
1. Identify the design characteristic of the instrument.
2. Select the instrument group using the table below. If an instrument has design characteristics in multiple groups, use the highest group number.

Note: Column "Required cleaning steps" provides an overview of the cleaning process.

3. Use the tables in section 7 "Manual Cleaning Process Details" and 8 "Automatic Washer Cleaning Process Details" for a complete breakdown of the required cleaning steps for each group of instruments.

Note: The user may elect to perform optional cleaning steps for the instrument

Instrument group and design characteristics			Required cleaning steps	
GROUP 1			Manual process	Automated process
			Pre-Rinse ↓ Brushing Et Flushing ↓ Final rinse Et Drying	Pre-Rinse ↓ Automatic washer
Hinges, joints or box locks	Rough textured surfaces	Simple rotating mechanisms		
GROUP 2			Manual process	Automated process
			Pre-Rinse ↓ Brushing Et Flushing ↓ Final rinse Et Drying	Pre-Rinse ↓ Brushing Et Flushing ↓ Automatic washer
Tubes, tubular shafts or lumen	Tubular shafts with flush ports	Not easily exposed surfaces (holes or cavities)		

Instrument group and design characteristics			Required cleaning steps	
GROUP 3  Monopolar or bipolar instruments  Multiple movable joints  Hidden threads or moveable parts with or without spring action			Manual process Pre-Rinse ↓ Soak ↓ Brushing Et Flushing ↓ Final rinse Et Drying	Automated process Pre-Rinse ↓ Soak ↓ Brushing Et Flushing ↓ Automatic washer
GROUP 4  Large sliding surface/s  Moveable mechanism with or without rotation  Quick connector, all surfaces not accessible  Blind channels  Covered notches, all surfaces not accessible  Flexible spiral shaft			Manual process Pre-Rinse ↓ Ultrasound ↓ Brushing Et Flushing ↓ Final rinse Et Drying	Automated process Pre-Rinse ↓ Ultrasound ↓ Brushing Et Flushing ↓ Automatic washer

7. MANUAL CLEANING PROCESS DETAILS

*Note: Required steps **must** be performed. All cleaning steps however can be used for all instruments during the decontamination process if desired by the user.*

Cleaning process steps	Instructions
1. Cleaning Solution	a. Mix cleaning solutions using the manufacturer's label instructions.
2. Pre-Rinse	a. Use unheated utility/tap water to rinse instrument/s (pre-rinse may be part of washer program) for a minimum of 1.5 minutes to remove gross debris. b. Continue rinse with the unheated utility/tap water until gross debris is removed.
3. Soak Required: Group 3 Optional: Groups 1, 2, 4	a. Open, disassemble and/or flush instrument if applicable, so cleaning solution can reach all instrument surfaces. b. Tube (lumen) portion of instrument must be filled with cleaning solution during soak. c. Soak in cleaning solution for a minimum of 4 minutes.
4. Ultrasonic Required: Groups 4 Optional: Group 1, 2, 3	a. Open, disassemble and/or flush instrument if applicable, so cleaning solution can reach all instrument surfaces. b. Place instruments under the surface of the cleaning solution. c. Tube (lumen) portion of instrument must be filled with ultrasonic solution during ultrasonic cleaning. d. Process for a minimum of 5 minutes.
5. Brushing & Flushing Required: all Groups	a. Use unheated utility/tap water for cleaning solution. b. Open, disassemble and/or flush instrument if applicable, so cleaning solution can reach all instrument surfaces. c. Place instruments under the surface of the cleaning solution. d. Use a soft or medium non-metal bristle brush. e. Brush all surfaces until visibly clean. Brush difficult to reach areas such as lumens/cannulas, special rotating areas and hidden surfaces 4 times (back & forth action = 1 time). <i>Note: During validation testing, brush strokes for individual instruments varied from 5 to 75 strokes depending on size and number of surfaces.</i> f. Moving parts should be moved during their cleaning to reach all surfaces. g. Flush lumens 4 times with a minimum of 20cc cleaning solution using a syringe or a jet pistol type flusher. h. Repeat flushing with utility water a minimum of 3 times.
6. Final Rinse	a. Use critical/treated water, see section "5. Definitions". b. Rinse by placing instruments under the water, exposing all surfaces of the device under the water flow for a minimum of 3 times. c. Move parts during the rinsing if needed to expose all surfaces. d. Rinse lumens, tubes, or cannulas 4 times with at least 20cc or critical/treated water using a syringe or pistol type flush device.
7. Dry	a. Use heat or low-linting or non-linting cloth to dry instruments following final rinse.
8. Inspection	a. Visually inspect instruments for remaining soil or cleaning solution. b. Repeat cleaning steps until instrument is free from soil and cleaning solution.

8. AUTOMATIC WASHER CLEANING PROCESS DETAILS

*Note: Required steps **must** be performed. All cleaning steps however can be used for all instruments during the decontamination process if desired by the user.*

Cleaning process steps	Instructions
1. Cleaning Solution	a. Mix cleaning solutions using the manufacturer's label instructions.
2. Pre-Rinse	a. Use utility/tap water to rinse instrument/s (pre-rinse may be part of washer program) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water. b. Continue rinse with the utility/tap water until gross debris is removed.
9. Soak Required: Group 3 Optional: Groups 1, 2, 4	a. Open, disassemble and/or flush instrument if applicable, so cleaning solution can reach all instrument surfaces. b. Tube (lumen) portion of instrument must be filled with cleaning solution during soak. c. Soak in cleaning solution for a minimum of 4 minutes.
10. Ultrasonic Required: Groups 4 Optional: Group 1, 2, 3	a. Open, disassemble and/or flush instrument if applicable, so cleaning solution can reach all instrument surfaces. b. Place instruments under the surface of the cleaning solution. c. Tube (lumen) portion of instrument must be filled with ultrasonic solution during ultrasonic cleaning. d. Process for a minimum of 5 minutes.
11. Brushing & Flushing Required: Group 2, 3, 4 Optional: Group 1	a. Use unheated utility/tap water for cleaning solution. b. Open, disassemble and/or flush instrument if applicable, so cleaning solution can reach all instrument surfaces. c. Place instruments under the surface of the cleaning solution. d. Use a soft or medium non-metal bristle brush. e. Brush all surfaces until visibly clean. Brush difficult to reach areas such as lumens/cannulas, special rotating areas and hidden surfaces 4 times (back & forth action = 1 time). <i>Note: During validation testing, brush strokes for individual instruments varied from 5 to 75 strokes depending on size and number of surfaces.</i> f. Moving parts should be moved during their cleaning to reach all surfaces. g. Flush lumens 4 times with a minimum of 20cc cleaning solution using a syringe or a jet pistol type flusher. h. Repeat flushing with utility water a minimum of 3 times or connect to flushing mechanism in the washer.
3. Automatic Washer	a. Use cleaning agent instructions for recommended dilution in washer. b. Open or disassemble instrument/s, as needed, to allow cleaning solution to reach all instrument surfaces. c. Use normal washer cycle (see below for specific parameters used during validation). d. Final rinse should be critical/treated water, see section "5. Definitions".
4. Inspection	a. Visually inspect instruments for remaining soil or cleaning solution. b. Repeat cleaning steps until instrument is free from soil and cleaning solution.

Automatic washer validation parameters

- a. Wash cycle – 6 minutes (total time, longer may be used)
- b. Final rinse – Critical/treated water for 2 minutes at 194 °F. (longer time may be used)
- c. Dry – 8 minutes at 194 °F. (longer time and/or higher temperature may be used)

Note: Automatic washer parameters intended for use on medical devices (instruments) that differ from those used during Aesculap's testing, but validated by the washer manufacturer should perform similarly. Verify facility specific equipment by using information provided by the manufacturer and/or by physical testing.

9. STERILIZATION

Steam Sterilization Parameters			
Sterilization Method	Min. temperature	Min. exposure time	Dry time**
Sterilization Dynamic air removal (Pre-Vac), WITH dry time*	270 °F (132 °C)	4 minutes	20 minutes
Sterilization Dynamic air removal (Pre-Vac), WITHOUT dry time*	270 °F (132 °C)	4 minutes	0 minutes

* Definitions for Terminal Sterilization and IUSS can be found on page 2.

** Dry time can vary based on load, sterilizer functionality and other local factors.

Sterilization Validation

- Exposure temperature – 270 °F
- Exposure time – 4 minutes
- Packaged set load – 25 lbs total (container + instruments)

10. DISPOSAL OR RECYCLING

- Dispose of broken instruments following disinfection or sterilization if necessary.
- Follow current local regulations and current facility procedure for the safe handling and disposal of sharps.

11. REFERENCES

Format is based on information found in, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff" issued on March 17, 2015 by the U.S. Food and Drug Administration. Additional resources; ISO 17664-1:2021, AAMI TIR55: 2014, AAMI TIR34: 2014, ANSI/AAMI ST98:2022, AAMI TIR12: 2020.

12. CONTACT INFORMATION

Consult website or call.

www.aesculapUSA.com

800-282-9000

CHANGE HISTORY

<u>RATIONALE SUMMARY</u>			<u>CCR#</u>	CC-202-23
An administrative change was conducted to update an external standard reference. An approvals page will not append to this version and training is not required.				
<u>CHANGE SUMMARY</u>				
<u>SECTION/PAGE</u>		<u>DESCRIPTION</u>		
Section 11/Pg. 7		ISO 17664 was changed to ISO 17664-1:2021. AAMI TIR30:2011 was changed to ANSI/AAMI ST98:2022. AAMI TIR12:2010 was changed to AAMI TIR12:2020.		
Footer		Removed outdated footer.		
<u>SUPPORTING DATA (Y/N)</u>		N	<u>DOCUMENT NAME OF SUPPORTING DATA</u>	N/A
N/A				
<u>ADD / DELETE KEYWORDS FOR THIS DOCUMENT (Y/N)</u>			N	
<u>ADD:</u>		N/A		
<u>DELETE:</u>		N/A		
<u>RELATED DOCUMENTS TO THIS VERSION (Y/N)</u>			N	
<u>DOCUMENT NUMBER</u>	<u>REVISION</u>	<u>TITLE</u>		
N/A	N/A	N/A		