V.Mueller® Products and Services
General Surgical Instrument Cleaning and Sterilization Guide

Reusable Devices Instructions for Use

These instructions for use are intended for reusable surgical instruments labeled with the CareFusion, V. Mueller® name. This cleaning and sterilization guide does not replace device-specific instructions for use already included with the device.

How Supplied

Devices are packaged as non-sterile. Cleaning and sterilization of devices must occur prior to use.

Limitations on Reprocessing

Repeated processing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.

Warnings

Devices shall be used in accordance with these Instructions for Use. Read all sections of this IFU prior to use. Improper use of these devices may cause serious injury. In addition, improper care and maintenance of the devices may render the devices non-sterile prior to patient use and may cause serious injury to the health care provider or the patient.

Cautions

If there are any variations between these Instructions for Use and either your facility's policies and/or your cleaning/sterilizing equipment manufacturer's instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.

Use of a device for a task other than what it is intended for will usually result in a damaged or broken device.

Prior to use, inspect devices to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or if they have physical damage.

Avoid mechanical shock or overstressing the devices. Close distal ends prior to insertion or removal through cannulas.

Always use caution when inserting or removing devices through the cannula. Lateral pressure on the device during removal can damage the working tip, and/or shaft of the device. Be sure the tips are closed and the device is pulled straight out until completely clear of the cannula to avoid catching the valve assemblies in cannulas or dislodging the cannula.

Fading of anodized aluminum devices may be accelerated if cleaning and sterilization instructions are not followed.

Only the cleaning and sterilization processes which are defined within these Instructions for Use have been validated.

Use only neutral pH (6-8) detergent solutions.

USA Rx Only

CareFusion
75 North Fairway Drive,
Vernon Hills, IL 60061 U.S.A.

36-4949F • 2013-08

CareFusion

Pre-processing Instructions

Initiate cleaning of device within 2 hours of use.

Transport devices via the institutions established transport procedure.

Remove excess gross soil as soon as possible after use by rinsing or wiping the device.

All devices must be processed in the completely open position (i.e. flushports, jaws, etc.) to allow solution contact of all surfaces.

Note: that applicable device disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.

Manual Cleaning

Manual Cleaning Process - Enzymatic/neutral pH Detergent
Note: Steps 5, 6, 7, 9, and 11 pertain to only devices with lumens.

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic/neutral pH detergent solution, utilizing drinking water with a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer's instructions.
3. Place the device in the open/relaxed position with flush port open. Completely immerse the device in the detergent solution and allow it to soak for a minimum of 5 minutes. Actuate all movable parts during the initiation of the soak time.
4. Using a soft bristled brush, remove all visible soil from the device. Actuate the device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas. Note: It is recommended that the detergent solution be changed when it becomes grossly contaminated (bloody and/or turbid).
5. For lumen devices, use a soft bristled brush with a brush diameter and length that is equivalent to lumen diameter and length. Scrub the lumen (i.e. angulated/nonangulated positions) until no visible soil is detected in the lumen rinsing step below.
6. For lumen devices, place the device into the open/relaxed position with the distal tip pointed down. Flush the device with a minimum of 50 ml of detergent solution utilizing a temperature range of 27°C to 44°C (81°F to 111°F), by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times), ensuring all fluid exiting the lumen is clear of soil.
7. For lumen devices, if visible soil is detected during the final lumen flush, re-perform brushing and flushing of the lumen. **Note:** the final rinse steps (8 and 9) below should be performed with treated water: deionized, distilled or reverse osmosis. If drinking water is used as part of the final rinse, ensure corrosion does not occur.
8. Rinse the device by completely immersing it in treated water with a temperature range of 27°C to 44°C (81°F to 111°F), for a minimum of 30 seconds to remove any residual detergent or debris.
9. For lumen devices, following the rinsing step, place the device into the open/relaxed position with the distal tip pointed down. Flush the device with a minimum of 50 ml of treated water utilizing a temperature range of 27°C to 44°C (81°F to 111°F), by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
10. Dry the device with a clean, lint-free towel.
11. For lumen devices, manipulate the device to allow rinse water to drain from the lumen.
12. Visually examine each device for cleanliness.
13. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.

Automatic Cleaning

Automatic Cleaning Process - Enzymatic/neutral pH Detergent

- Ensure all pre-processing instructions are followed prior to cleaning.
- Clean the devices via the automatic cleaning parameters below.

Phase	Minimum Recirculation Time	Water Temperature	Detergent Type and Concentration (If applicable)
Pre-wash	15 Seconds	Cold Drinking Water 1°C - 16°C (33°F - 60°F)	N/A
Enzyme Wash	1 Minute	Hot Drinking Water 43°C - 82°C (110°F - 179°F)	• Detergent: pH-neutral/enzymatic • Concentration: Per the detergent manufacturer's recommendations
Wash	2 Minutes	Drinking Water 43°C - 82°C (110°F - 179°F)	• Detergent: pH-neutral cleanser • Concentration: Per the detergent manufacturer's recommendations
Rinse	15 Seconds	Drinking Water 43°C - 82°C (110°F - 179°F)	N/A
Pure Rinse	10 Seconds	Treated Water 43°C - 82°C (110°F - 179°F)	N/A
Drying	N/A	N/A	N/A

- For lumen devices, manipulate the device to allow rinse water to drain from the lumen.
- If visible moisture is present dry the instrument with a clean, lint-free towel.
- Visually examine each instrument for cleanliness.
- If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.

Note: the final rinse step should be performed with treated water: purified, deionized, distilled or reverse osmosis. If drinking water is used as part of the final rinse, ensure corrosion does not occur.

Inspection/Maintenance

Proper care and handling is essential for satisfactory performance of any surgical device. The previous cautions should be taken to ensure long and trouble-free service from all your surgical devices. Inspect devices before each use for broken, cracked, tarnished surfaces, movement of hinges, and chipped or worn parts. If any of these conditions appear, do not use the device. Return devices to an authorized repair service center for repair or replacement.

Before sterilizing, lubricate the device with instrument milk or a steam permeable/ water soluble lubricant, following the lubricant manufacturer's instructions.

Let devices drip dry for three (3) minutes before packaging for sterilization.

Packaging

Devices can be loaded into dedicated packaging systems. Sterilization wrap material must be cleared for the applicable sterilization modality by your country's regulatory body. Use in accordance with packaging manufacturer's sterilization instructions being sure to protect jaws and cutting edges from damage.

Sterilization

All devices must be processed in the completely open position (i.e. flushports, jaws, etc.) to allow sterilant contact of all surfaces. Note that applicable device disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.

All devices with concave surfaces shall be configured so that water pooling does not occur.

Sterilization for United States Market

STANDARD PREVACUUM STEAM STERILIZATION CYCLES

Prevacuum Steam Sterilization Cycle (U.S. "FDA Compliant – WRAPPED")

- Conditioning Pulses: 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

Prevacuum Steam Sterilization Cycle – Immediate Use Steam Sterilization (U.S. "FDA Compliant – WRAPPED")

- Conditioning Pulses: 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

NOTE: Devices must be used immediately and cannot be stored for later use.

Immediate Use Steam Sterilization is not recommended as a routine practice. Refer to ANSI/AAMI ST79 for requirements on when to perform and how to control immediate use steam sterilization.

Reference:ANSI/AAMI ST79: (current revision) Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

STANDARD GRAVITY STEAM STERILIZATION CYCLES

Gravity Steam Sterilization Cycle (U.S. "FDA Compliant – WRAPPED")

- Temperature: 132°C (270°F)
- Exposure Time: 15 minutes
- Dry Time (non lumens): 30 minutes
- Dry Time (lumens): 45 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

Gravity Steam Sterilization Cycle (U.S. "FDA Compliant – WRAPPED")

- Temperature: 121°C (250°F)
- Exposure Time: 30 minutes
- Dry Time (non lumens): 30 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin)

STANDARD ETHYLENE OXIDE (EO) STERILIZATION CYCLES

100% Ethylene Oxide (EO) Sterilization Cycle (U.S. "FDA Compliant –WRAPPED")

- Conditioning Time: 30 minutes
- EO Gas Concentration: 725mg/L
- Relative Humidity: 50-80%
- Temperature: 55°C (130°F)
- Exposure Time: 60 minutes
- Aeration Time: 8 hours @ 43°C (110°F)
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer-1 ply, or 1 layer -2 ply – examples: cellulose, polypropylene, muslin).

Storage

After sterilization, devices should remain in sterilization packaging and be stored in a clean, dry environment.

Warranty

CareFusion offers a lifetime guarantee on every surgical device bearing the V. Mueller brand name (unless otherwise noted). Surgical devices are guaranteed to be free of functional defects in workmanship and materials when used normally for its intended surgical purpose. Any V. Mueller device proving to be defective will be replaced or repaired at no cost to the customer.

Repair Service

Regardless of age, if any V. Mueller device requires service, return the device to an authorized repair service center. For repairs outside the U.S., please contact your local distributor.

Note: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions prior to shipment.

Contact Information

CareFusion
75 North Fairway Drive,
Vernon Hills, IL 60061 U.S.A.
800-323-9088

www.carefusion.com

For domestic inquiries email:
GMB-VMueller-Cust-Support@carefusion.com

For international inquiries email:
GMB-SIT-International-Team@carefusion.com

Other Resources

To learn more about sterilization practices and what is required of manufacturers and end users, visit www.aami.org, www.aorn.org or www.iso.org.