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

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

Limitations on Reprocessing

Repeated reprocessing 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 insert prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.

Cautions

If there are any variations between these instructions and either your facility's policies and/or your cleaning/sterilization 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 device for a task other than that for which it is intended will usually result in a damaged or broken device.

Prior to use, inspect device to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or 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 cannula. Lateral pressure on the device during removal can damage the working tip, shaft of the device. Be sure the tips are closed and the device is pulled straight out until completely clear of cannula to avoid catching the valve assemblies in cannulas or dislodging the cannula.

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
1500 Waukegan Road
McGaw Park, IL 60085 U.S.A.

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CareFusion

Pre-processing Instructions

Initiate cleaning of device within 2 hours of use.

Transport devices via the institution's 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.

Manual Cleaning: (Steps 5, 6, 7, 9 and 11 are required for lumen devices only.)

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic / neutral pH detergent solution, utilizing tap water with a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer's instructions.
3. Place device in the open/relaxed position, with flush port open, and completely immerse in the detergent solution and allow device 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 device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas. Note: It is recommended that the detergent solution is 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.
8. Rinse the device by completely immersing in tap 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 tap 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.

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Automatic Cleaning

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

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

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

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.

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Sterilization

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

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

Prevacuum Steam Sterilization Parameters

Minimum Preconditioning Pulses: 3
Minimum Temperature: 132°C (270°F)
Minimum Exposure Time: 3 minutes
Minimum Dry Time: 30 minutes
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Gravity Steam Sterilization Parameters

Minimum Temperature: 132°C (270°F)
Minimum Exposure Time: 15 minutes
Minimum Dry Time (lumens): 45 minutes
Minimum Dry Time (non-lumens): 30 minutes
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Gravity Steam Sterilization Parameters – Non-lumen devices only

Minimum Temperature: 121°C (250°F)
Minimum Exposure Time: 30 minutes
Minimum Dry Time: 30 minutes
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

EO Sterilization Parameters

Sterilizer Cycle: 100% Ethylene Oxide (EO)
Minimum Preconditioning Time: 30 minutes
Minimum EO Gas Concentration: 700 mg/L
Minimum Temperature: 54°C (130°F)
Minimum Humidity: 65%
Minimum Exposure Time: 120 minutes
Minimum Aeration: 8 hours @ 43°C (110°F)
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Storage

After sterilization, devices must 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) 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 charge.

Repair Service

Regardless of age, if any V. Mueller device needs service, return it 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 for use prior to shipment.

Contact Information:

CareFusion
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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