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 packed as non-stereile. Cleaning and sterilization of devices must occur prior to use.

Limitations in 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 use and maintenance of the devices may render the devices non-stereile 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 void any warranty. 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 function or if they have physical damage.

Devices must be used in accordance with these Instructions for Use. Devices shall be used in accordance with device-specific instructions for use already included with the device.

Note: Steps 5, 6, 7, 9, and 11 pertain to only devices with lumens.

Manual Cleaning

Manual Cleaning Process - Enzymatic/neutral pH Detergent

Pre-processing Instructions

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.

Pre-processing Instructions

Ensure all pre-processing instructions are followed prior to cleaning.

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 specified position with the distal 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, recesses and other difficult-to-clean areas. Note: It is recommended that the detergent solution is changed when it becomes grossly contaminated (already and/or turbid).

5. For lumens, 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/triangularized positions) until no visible soil is evident in the lumen rinsing step below.

6. For lumens, place the device into the open/relaxed position with the distal tip pointed down. Flush the device with a minimum of 2 liters of drinking water (27°C to 44°C (81°F to 111°F)), by using the flushing port located on the handlehaft. 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 lumens, 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 lumens, following the rinsing steps, place the device into the open/relaxed position with the distal tip pointed down. Flush the device with a minimum of 2 liters 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 handlehaft. 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 lumens, manipulate the device to allow rinse water to drain from the lumens.

12. Visually examine each device for cleanliness.

13. If stable soil remains, repeat cleaning procedure until the device is thoroughly clean.

Pre-processing Instructions

Initiate cleaning of device within 2 hours of use. Transport devices via the institution’s established transport procedures. Remove excess gross soil as soon as possible after use by rinsing or drying the device.

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

Note: that applicable device disassembly should not require any mechanical tooling (i.e. screwdrivers, pins 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 specified position with the distal 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, recesses and other difficult-to-clean areas. Note: It is recommended that the detergent solution is changed when it becomes grossly contaminated (already and/or turbid).

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10. Dry the device with a clean, lint-free towel.

11. For lumens, manipulate the device to allow rinse water to drain from the lumens.

12. Visually examine each device for cleanliness.

13. If stable soil remains, repeat cleaning procedure until the device is thoroughly clean.

Pre-processing Instructions

Initiate cleaning of device within 2 hours of use. Transport devices via the institution’s established transport procedures. Remove excess gross soil as soon as possible after use by rinsing or drying the device.

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Manual Cleaning

Manual Cleaning Process - Enzymatic/neutral pH Detergent

Note: Steps 5, 6, 7, 9, and 11 pertain to only devices with lumens.
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.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Minimum Recondition Time</th>
<th>Water Temperature</th>
<th>Detergent Type and Concentration (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rinse</td>
<td>10 Seconds</td>
<td>Cold Drinking Water (40°F - 60°F)</td>
<td>NA</td>
</tr>
<tr>
<td>Wash</td>
<td>2 Minutes</td>
<td>Soaking Water (117°F - 179°F)</td>
<td>Polypropylene, muslin</td>
</tr>
<tr>
<td>Brine</td>
<td>10 Seconds</td>
<td>Soaking Water (117°F - 179°F)</td>
<td>Polypropylene, muslin</td>
</tr>
<tr>
<td>Drying</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

• For human devices, manipulate the device to allow rinse water to drain from the lumens.
• If visible moisture is present dry the instrument with a clean, lint-free towel.
• Visually examine each instrument for cleanliness.
• If visible wet 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.

Pre-wash
Cold Drinking Water (40°F - 60°F)

Wash
Soaking Water (117°F - 179°F)

Brine
Soaking Water (117°F - 179°F)

Rinse
Cold Drinking Water (117°F - 179°F)

Drying
NA
NA
NA

• Contamination: 3
• Exposure Temperature: 121°C (250°F)
• Exposure Time: 30 minutes
• Conditioning Pulses: 3
• Conditioning 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)
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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 warranted 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 it to the 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: GMHR-V-Mueller-Cust-Support@carefusion.com
For international inquiries email: GMHR-V-Mueller-Cust-Support@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.

Automatic Cleaning Process - Enzymatic/neutral pH Detergent

• Contamination: 3
• Exposure Temperature: 121°C (250°F)
• Exposure Time: 30 minutes
• Conditioning Pulses: 3
• Conditioning 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)

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

• Temperature: 132°C (270°F)
• Temperature: 121°C (250°F)
• Temperature: 121°C (250°F)
• Temperature: 121°C (250°F)
• Temperature: 121°C (250°F)
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• Temperature: 121°C (250°F)

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

• Conditioning Time: 30 minutes
• EO Gas Concentration: 750mg/L
• Relative Humidity: 50-80%
• Temperature: 55°C (130°F)
• Temperature: 55°C (130°F)
• Temperature: 55°C (130°F)
• Temperature: 55°C (130°F)
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**Automatic Cleaning**

**Automatic Cleaning Process - Enzymatic/neutral pH Detergent**

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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Minimum Recondition Time</th>
<th>Water Temperature</th>
<th>Detergent Type and Concentration (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rinse 1</td>
<td>10 Seconds</td>
<td>Cold Drinking Water (41°F - 44°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash 1</td>
<td>3 Minutes</td>
<td>Cold Drinking Water (41°F - 44°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash 2</td>
<td>3 Minutes</td>
<td>Cold Drinking Water (41°F - 44°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Rinse 2</td>
<td>10 Seconds</td>
<td>Cold Drinking Water (41°F - 44°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Drying</td>
<td>N/A</td>
<td>Cold Drinking Water (41°F - 44°F)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- For human devices, manipulate the device to allow rinse water to drain from the lumens.
- If visible moisture is present dry the instrument with a clean, lint-free towel.
- Visually examine each instrument for cleanliness.

**Inspection/Maintenance**

Proper care and handling is essential for satisfactory performance of any surgical device. The previous cautions shall 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 device to an authorized repair service center for repair or replacement.

Before sterilizing, lubricate the device with instrument milk or a steam sterilization wrap material must be cleared for the applicable sterilization modality (i.e. screw driver, pliers etc.) unless otherwise indicated.

For lumens devices, manipulate the device to allow rinse water to drain from the lumens.

**For United States Market**

**STANDARD PREVACUUM STEAM STERILIZATION CYCLES**

**PreVacuum Steam Sterilization Cycle (U.S. "FDA Complaint - WRAPPED")**

- Conditioning Pulse(s): 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 11 minutes
- Sterilization Configuration: FDA-Cleared Sterilization Wrap (2 lap-1 ply; or 3 lap-2 ply – examples: cellulose, polypropylene, maxil

**PreVacuum Steam Sterilization Cycle - Immediate Use Steam Sterilization (U.S. "FDA Complaint – WRAPPED")**

- Conditioning Pulse(s): 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 11 minutes
- Sterilization Configuration: FDA-Cleared Sterilization Wrap (2 lap-1 ply; or 3 lap-2 ply – examples: cellulose, polypropylene, maxil

**PreVacuum Steam Sterilization Cycle **

- Conditioning Pulse(s): 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 11 minutes
- Sterilization Configuration: FDA-Cleared Sterilization Wrap (2 lap-1 ply; or 3 lap-2 ply – examples: cellulose, polypropylene, maxil

**Steam Sterilization Cycle (U.S. "FDA Complaint – WRAPPED")**

- Conditioning Pulse(s): 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 11 minutes
- Sterilization Configuration: FDA-Cleared Sterilization Wrap (2 lap-1 ply; or 3 lap-2 ply – examples: cellulose, polypropylene, maxil

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

- Conditioning Pulse(s): 3
- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 11 minutes
- Sterilization Configuration: FDA-Cleared Sterilization Wrap (2 lap-1 ply; or 3 lap-2 ply – examples: cellulose, polypropylene, maxil

**Vacuum Steam Sterilization Cycle (U.S. "FDA Complaint – WRAPPED")**

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- Exposure Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 11 minutes
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**100% Ethylene Oxide (EO) Sterilization Cycle (U.S. "FDA Complaint – WRAPPED")**

- Conditioning Time: 30 minutes
- EO Gas Concentration: 750mL/L
- Relative Humidity: 50-80%
- Temperature: 55°C (131°F)
- Exposure Time: 30 minutes
- Loading: 0 hours 01 minutes 43 degrees F (119°F)
- Sterilization Configuration: FDA-Cleared Sterilization Wrap (2 lap-1 ply; or 1 lap-2 ply – examples: cellulose, polypropylene, maxil

**STORAGE**

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

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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.

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**Contact Information**

CareFusion
75 North Firstage Drive
Vernon Hills, IL 60061 U.S.A.
800-323-8889
www.carefusion.com
For domestic inquiries email: GMX-V-Mueller-Cust-Support@carefusion.com
For international inquiries email: GMX-501-international@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.