Processing Non-Sterile Medical Devices – Implants, Reusable Instruments, and Trays

Purpose & Scope	• These recommendations are for processing non-sterile Vilex implants, reusable instruments, and trays. Facility is responsible for cleaning and steam sterilization. **STERILIZE BEFORE USE**. • Explanted Vilex implants must never be reprocessed and should be handled according to facility protocol upon removal. • Any implant that has not been used, but has become contaminated, should be handled according to facility protocol. Vilex does not recommend the reprocessing of contaminated implants. • All implants and guide wires are **SINGLE USE ONLY**. • These recommendations are to be followed unless otherwise noted on specific product inserts. • Remove all wrapping, shipping materials including plastic wire tubing prior to sterilization.
Cautions	• Vilex implants and instruments are critical devices and must be terminally sterilized prior to use. • All implants, instruments, and trays must be thoroughly cleaned before sterilization. The sterilization parameters are only valid for devices that are adequately cleaned. • Any implant that has not been used, but has become contaminated, should be handled according to facility protocol. Vilex does not recommend the reprocessing of contaminated implants. • Vilex implants should not be lubricated. • Do not use a Vilex implant if the surface has been damaged. • Vilex implants should not be processed or transported with any type of contaminated materials. • Do not use steel wool or abrasive cleaners. • Avoid solutions containing iodine or high chlorine content. • Long, narrow cannulations, blind holes and intricate parts require particular attention during cleaning. • Vilex implants, instruments, and trays should be inspected after processing and should be visually clean. If any soil or residue is visible after cleaning, repeat steps. • In accordance with the CDC, AORN, and AAMI guidelines, Vilex does not recommend or support the flash sterilization of Vilex devices. • The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.
Limits on Reprocessing	• Repeated processing cycles that include manual and mechanical washing and steam sterilization have minimal effects on Vilex implants and instrumentation. • Vilex implants should be inspected for corrosion, damage (such as scratches and notches), debris, discoloration or residue. • Vilex instrumentation and trays should be inspected for functionality before processing. End of life is normally determined by wear and damage due to use. Wear and damage may include but is not limited to: dull edges on cutting instruments, corrosion, fretting, broken or fractured components, bent or deformed components, stuck or galling components, and visible high erosion of material. • pH of detergent/disinfectants should be between 7 and 10. • Damaged implants, instruments, and trays should be returned to Vilex 1-800-521-5002.

Processing Instructions	
Point of Use Care	• Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled. • Minimal handling of implants is necessary to prevent damage to the surface. • Wipe blood and/or debris from reusable devices throughout surgical procedure to prevent it from drying onto the surface. • Flush cannulated reusable devices with sterile water to prevent the drying of soil and/or debris to the inside. • Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. • Soiled, reusable devices should be covered with a towel dampened with purified water to prevent blood and/or debris from drying.
Containment and Transportation	• Soiled devices should be transported separate from non-contaminated devices to avoid contamination. • Implants should not come into contact with contaminated devices and/or equipment. • To avoid contamination, implants should be transported separate from soiled devices.
Preparation for Processing / Decontamination	• Any implant contaminated with blood, tissue and/or bodily fluids/matter should be processed according to the facility's protocol. Vilex does not recommend the reprocessing of contaminated implants. • It is recommended that devices should be reprocessed as soon as is reasonably practical following use. • Disassemble device, if applicable, prior to cleaning. • Open devices with ratchets, box locks or hinges. • Remove sharp devices for manual cleaning or place into a separate tray. • Lumens/cannulas of devices should be manually processed prior to cleaning.

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- Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use a neutral pH enzymatic soak or detergent to soak devices. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality (i.e. pH, hardness) and concentration. Use cool tap water to rinse devices.
- Vilex devices must be cleaned separately from Vilex instrument trays. Lids should be removed for the cleaning process, if applicable. Devices must be thoroughly cleaned to ensure adequate sterilization.

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<tr><td>Cleaning – Manual Method</td><td>

Equipment: Various sized soft-bristled brushes and lumen brushes, syringe, pipettes and/or water jet, Enzol Enzymatic Detergent.

1. Rinse soiled device under running tap water for a minimum of two (2) minutes. Use a soft-bristled brush and appropriately sized lumen brush to assist in the removal of gross soils and debris.
2. Prepare a detergent bath of tap water and Enzol Enzymatic Detergent at a concentration of 1-2 fl oz/gal (7.8 – 15.6 mL/L). Fully immerse the device and soak device in the detergent bath for a minimum of ten (10) minutes.
3. Rinse device with cool tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
4. Prepare a fresh detergent bath of tap water and Enzol Enzymatic Detergent at a concentration of 1-2 fl oz/gal (7.8 – 15.6 mL/L). Fully immerse the device in the detergent bath and manually clean device for a minimum of five (5) minutes. Use a soft-bristled brush and appropriately sized lumen brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to detergent solution. Clean device under water to prevent aerosolization of contaminants. *Note: fresh solution is a newly-made, clean solution.*
5. Rinse device thoroughly with reverse osmosis or distilled water for a minimum of two (2) minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water.
6. Visually inspect device. Repeat the manual cleaning procedure (steps 2-6) until no visible soil remains on device.
7. Dry device using clean compressed air.

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<tr><td>Pre-Cleaning – Automated Method</td><td>

Equipment: Washer/disinfector, Various sized soft-bristled brushes and lumen brushes, syringe, pipettes and/or water jet, Enzol Enzymatic Detergent, and Valsure Neutral Detergent.

Pre-clean method (Pre-clean method must be performed prior to mechanical method listed below.)

1. Rinse soiled device under running cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristled brush, appropriately sized lumen brush, or soft, lint-free cloth.
2. Prepare a detergent bath of tap water and Enzol Enzymatic Detergent at a concentration of 1-2 fl oz/gal (7.8 – 15.6 mL/L). Fully immerse the device and soak the device in the detergent bath a minimum of ten (10) minutes.
3. Rinse the device with cool tap water for a minimum of two (2) minutes. Use a syringe, pipette or water jet to flush lumens, channels and other hard to reach areas.
4. Prepare a fresh detergent bath of tap water and Enzol Enzymatic Detergent at a concentration of 1-2 fl oz/gal (7.8 – 15.6 mL/L). Fully immerse the device in the detergent bath and manually clean device for a minimum of five (5) minutes. Use a soft-bristled brush and appropriately sized lumen brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to detergent solution. Clean device under water to prevent aerosolization of contaminants. *Note: fresh solution is a newly-made, clean solution.*
5. Rinse device thoroughly with reverse osmosis or distilled water for a minimum of two (2) minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water.
6. Visually inspect device. Repeat steps 2-6 until no visible soil remains on device.
7. Place the devices in the tray and follow the Processing – Automated Method steps below.

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<tr><td>Cleaning – Automated Method</td><td>

Place the tray in an automated washer and use the following cycle parameters with high motor speed:

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<tr><th>Cycle</th><th>Time (minutes)</th><th>Water / Temperature</th><th>Type of Detergent / Concentration</th></tr>
<tr><td>Pre-wash</td><td>2</td><td>Cold tap water</td><td>N/A</td></tr>
<tr><td>Enzyme Wash</td><td>2</td><td>Hot tap water</td><td>Enzol Enzymatic,
1 - 2 fl oz/gal
(7.8 – 15.6 mL/L)</td></tr>
<tr><td>Wash 1</td><td>5</td><td>Hot tap water (60°C)</td><td>Valsure Neutral,
½ - 1 fl oz/gal
(3.9 – 7.8 mL/L)</td></tr>
<tr><td>Rinse</td><td>2</td><td>Hot reverse osmosis or distilled water (60°C)</td><td>N/A</td></tr>
<tr><td>Thermal Disinfection</td><td>5</td><td>Hot reverse osmosis or distilled water (90°C)</td><td>N/A</td></tr>
<tr><td>Dry</td><td>15</td><td>90°C</td><td>N/A</td></tr>
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Drying	If a dry cycle is not included in the mechanical washer or if the device is not processed in a mechanical washer: • Dry each device thoroughly with clean compressed air inside and out to prevent rusting and malfunction. • Pay special attention to threads, ratchets and hinges or areas where fluid can accumulate. • Open and close devices so that all areas are reached.
Inspection	• Vilex implants, instruments, and trays should be inspected after processing, prior to sterilization. • If any device is determined not to be visually clean at the end of the cleaning step, then repeat the relevant previous cleaning steps or safely dispose of the device. Visibly soiled devices should not be used. • Any implant with corrosion, discoloration, scratches, flaws, residue or debris should be returned to Vilex 1-800-521-5002. • Removal of residual soil ensures the effectiveness of sterilization processes and reduces the risk of infection to patients.
Sterilization	• After Manual or Automated Cleaning, each Vilex implant, instrument, and tray must be steam sterilized prior to use. • Refer to the system Instructions for Use (IFU) for steam sterilization parameters. • Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, implant materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. • USE FDA-Cleared sterilization wraps. • Ensure steam quality is in accordance with AAMI ST79. • Prevacuum is dynamic-air-removal steam sterilization.
Additional Information	• The cleaning and sterilization information is provided in accordance with AAMI ST79, ISO 17664-1, and AAMI TIR12. The parameters have been validated for use with the Vilex devices per ISO 17665 and ANSI / AAMI ST98. • It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences. • All users should be qualified personnel with documented expertise, competency and training. Users should be trained on facility policies and procedures along with current applicable guidelines and standards. • Users should wear appropriate personal protective equipment (PPE) when processing implants.
Manufacturer Contact	For further information, contact Vilex Customer Service Department at Phone: 1-800-521-5002, Fax: 1-855-748-7437, Email: customerservice@vilex.com or Physical Address: Vilex, LLC, 111 Moffitt Street, McMinnville, TN, USA 37110