



**Instructions for Use: Vertical Soaker**

<b>Brand Name of Product</b>	Vertical Soaker
<b>Generic Name of Product</b>	Soaker
<b>Product Code Number(s)</b>	VS-3520
<b>Intended Use</b>	The vertical soaker is used for lumen devices to ensure that all areas of the lumen have contact with the cleaning solution.
<b>Range of Applications for Product</b>	<ul style="list-style-type: none"> <li>Soaking medical devices in a vertical orientation</li> </ul>
<b>Key specifications of product</b>	

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	
<b>Packaging Conditions</b>	
<b>Shelf Life</b>	

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	
<b>Preparation for Use</b>	The vertical soaker is filled with the medical facilities approved cleaning solution for that specific medical device according to the IFU for the medical device and for the cleaning solution.
<b>Diagrams (drawings, pictures):</b>	
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>Fill vertical soaker to the maximum volume level (2000ml).</li> <li>Place the medical device vertically into the soaker to ensure that the lumen medical device will have contact with the cleaning solution as defined by the medical device manufacturer's IFU.</li> <li>Exposure time of the lumen medical device within the vertical soaker is based on both the medical device and the cleaning solution manufacturers' IFUs.</li> <li>It is important to remember that rinsing of the lumen medical device must take place when removed from the vertical soaker according the medical device and cleaning solutions manufacturers' IFU.</li> </ol>
<b>Interpretation of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation</b>	
<b>Special Warnings and Cautions</b>	Lumen item should be cleaned according to the medical device IFU.
<b>Disposal</b>	

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	<ul style="list-style-type: none"> <li>Do not exceed recommended maximum temperature for each component of the system. See <a href="#">SST Material Compatibility</a> for reprocessing parameter compatibilities for each specific model number and its component parts.</li> <li>Do not use any abrasive powders or metal brushes as these may cause scratching on surfaces.</li> <li>Reprocessing instructions in apply only to an empty Vertical Soaker and its component parts. These instructions are not meant or intended for processing of any reusable medical devices.</li> </ul>
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	<ul style="list-style-type: none"> <li>Manual cleaning is permissible but not recommended.</li> <li>Equipment: detergent, soft bristle brush, running water.</li> <li>Be sure to follow the IFU of the detergent manufacturer.</li> <li>Rinse excess soil from all surfaces.</li> <li>Thoroughly rinse all surfaces of residual detergent and soil.</li> <li>Dry with lint free cloth.</li> </ul>
<b>Cleaning – Automated:</b>	<ul style="list-style-type: none"> <li>Machine cleaning is preferred and using only a washer disinfector cleared by the FDA.</li> <li>Be sure to follow the IFU's of the washer-disinfector and detergent manufacturers.</li> </ul>

	<ul style="list-style-type: none"> <li>• Products should be positioned in the washer to allow maximum water penetration and drainage. <ul style="list-style-type: none"> <li>○ No overlapping of items - partially covered surfaces will not be washed properly.</li> <li>○ Trays, covers and baskets should be stacked standing on their side to allow complete drainage.</li> </ul> </li> <li>• Products can be cleaned with alkaline, acidic and neutral detergents.</li> <li>• For final rinse DI or RO water is preferred.</li> <li>• The standard program to include, always refer to the washer manufacturer's IFU: <ol style="list-style-type: none"> <li>1. Pre-wash with cold water (&lt;100°F) rinse for a minimum of 2 minutes.</li> <li>2. Washing cycle with alkaline or enzymatic detergent at temperature recommended by the detergent manufacturer for a minimum of 5 minutes.</li> <li>3. Washing cycle with neutral pH or neutralizing detergent at temperature recommended by the detergent manufacturer for a minimum of 2 minutes.</li> <li>4. Final rinse cycle for a minimum of 1 minute.</li> <li>5. Thermal disinfection in compliance with the washer manufacturer recommendations for time and temperature but not to exceed the maximum temperature tolerance for the individual Vertical Soaker. See <a href="#">SST Material Compatibility</a> for temperature tolerances for each specific model number and its component parts.</li> <li>6. Drying cycle at temperature not to exceed the maximum temperature tolerance for the Vertical Soaker. See <a href="#">SST Material Compatibility</a> for temperature tolerances for each specific model number and its component parts.</li> <li>7. Caution when unloading machine as products will be hot.</li> <li>8. Visual inspection is required to ensure complete removal of soil.</li> <li>9. If product still shows soil repeat program.</li> </ol> </li> </ul>
<b>Disinfection:</b>	<ul style="list-style-type: none"> <li>• Disinfection may not be required depending upon the clinical use of the Vertical Soaker and the policy of the institution.</li> <li>• Disinfection may be achieved by thermal means as described in the standard wash cycle above, or by use of hospital grade chemical disinfectants. If chemical disinfectants are used, it is recommended that all surfaces be thoroughly rinsed after the required exposure time. Follow the disinfectant manufacturer's instructions for use.</li> </ul>
<b>Drying:</b>	Drying may be accomplished during the dry-cycle of the automated washer and/or with the use of a lint-free, disposable towel.
<b>Maintenance, inspection, and testing:</b>	<ul style="list-style-type: none"> <li>• Visual inspection is required to ensure complete removal of soil. If product still shows soil repeat program.</li> <li>• Visually inspect to assess for wear and tear and damage due to use.</li> </ul>
<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	<ul style="list-style-type: none"> <li>• Terminal sterilization is not required unless the Vertical Soaker will be used in the sterile-field, or some other clinical application requiring a sterile product.</li> <li>• If the Vertical Soaker can tolerate it, a standard hospital steam sterilization cycle is the preferred method.</li> <li>• Follow the IFU of the steam sterilizer manufacturer for the selected cycle.</li> <li>• Depending upon the temperature tolerances of the Vertical Soaker, it may not be able to tolerate steam sterilization, or certain cycles of steam sterilization. See <a href="#">SST Material Compatibility</a> for temperature tolerances and sterilization compatibility for each specific model number and its component parts.</li> <li>• <b>Wrap with FDA cleared sterile barrier wrap in compliance with the IFU of the wrap manufacturer.</b></li> </ul>
<b>Storage:</b>	
<b>Additional Information:</b>	
<b>Related Healthmark Products</b>	
<b>Other Product Support Documents</b>	PPE Brochure, PPE Price List, SST Material Compatibility document
<b>Reference Documents</b>	OSHA Technical Footnote (Item 29 CFR part 1910, 1030 (d) (ii) (E)) from the Federal Register, December 6, 1991):
<b>Customer Service contact:</b>	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026

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2015-04-29 Ralph J Basile