

## Instructions for Use: Time Out Sign

<b>Brand Name of Product</b>	Time Out Sign
<b>Generic Name of Product</b>	Time Out Sign
<b>Product Code Number(s)</b>	SS-TO
<b>Purpose of Product</b>	To remind staff to take a few moments and make sure that all conditions are right to proceed.
<b>Range of Applications for Product</b>	Procedure protocol specifying a "time-out."
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>Stainless Steel-Grade 304</li> <li>1" x 5"</li> <li>Washable and sterilizable</li> </ul>

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

Instructions for Using Product	
<b>Description of Use(s)</b>	To remind staff to take a few moments and make sure that all conditions are right to proceed.
<b>Preparation for Use</b>	N/A
<b>Diagrams (drawings, pictures)</b>	N/A
<b>Steps for Use of Product</b>	N/A
<b>Interpretation of Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	N/A
<b>Special Warnings and Cautions</b>	N/A
<b>Disposal</b>	N/A

Reprocessing Instructions	
<b>Point of Use</b>	Gross soiling should be reduced by wiping down the surfaces.
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<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>Rinse excess soil from device.</li> <li>Apply detergent to all surfaces and use brush to clean all surfaces, ensuring that surface and drainage holes are clean and free from soil.</li> <li>Thoroughly rinse all surfaces of residual detergent and soil.</li> <li>Dry with non-linting cloth.</li> </ul>
<b>Cleaning – Automated</b>	<ul style="list-style-type: none"> <li>Machine cleaning is recommended in a washer disinfector in compliance with ISO 15883 series of standards.</li> <li>Products should be positioned in the washer to allow maximum water penetration and drainage. <ul style="list-style-type: none"> <li>No overlapping - partially covered devices will not be washed properly</li> <li>Bowls and similar devices should be stacked standing on their side to allow complete drainage.</li> </ul> </li> <li>For final rinse, AAMI Critical Water is recommended.</li> </ul> <p><b>The standard program to include:</b></p> <ol style="list-style-type: none"> <li>Pre-wash with cold water (&lt;38 °C, 140 °F) rinse for a minimum of 2 minutes.</li> <li>Washing cycle with enzymatic detergent at temperature recommended by the detergent manufacturer for a minimum for 5 minutes.</li> <li>Washing cycle with neutral pH detergent at the temperature recommended by the detergent manufacturer for a minimum of 2 minutes.</li> </ol>

	<ol style="list-style-type: none"> <li>4. Rinse cycle for a minimum of 1 minute.</li> <li>5. Thermal disinfection of up to 93°C (199 °F) in compliance with the washer manufacturer recommendations for time and temperature.</li> <li>6. Drying cycle at temperature not to exceed 116 °C (241 °F).</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>
<b>Disinfection</b>	N/A
<b>Drying</b>	Drying may be accomplished during the dry cycle of the automated washer and/or with the use of a non-linting, 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>• Also, visually inspect to assess for wear and tear and damage due to use. Discard damaged devices.</li> </ul>
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	Package in FDA cleared sterilization packaging following the IFU of the sterilization packaging manufacturer.
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>• Steam Sterilization: Follow the IFU for the sterilization packaging manufacturer, the enclosed device(s) manufacturer, and the sterilizer manufacturer.               <ul style="list-style-type: none"> <li>○ Pre-vacuum Sterilizer: 132 °C (270 °F) for 4 minutes to 135 °C (275 °F) for 3 minutes.</li> <li>○ Gravity Displacement Sterilizer: 132 °C (270 °F) to 135 °C (275 °) for 30 minutes, or 121 °C (252 °F) to 123 °C (253 °F) for 55 minutes.</li> </ul> </li> <li>• Materially compatible with EO sterilization</li> <li>• Materially compatible with VH2O2 sterilization</li> </ul>
<b>Storage</b>	N/A
<b>Additional Information</b>	N/A

<b>Related Healthmark Products</b>	N/A
<b>Other Product Support Documents</b>	Labels Brochure, Labels Price List
<b>Reference Documents</b>	<a href="http://www.aorn.org/Clinical_Practice/ToolKits/Correct_Site_Surgery_Tool_Kit/Comprehensive_checklist.aspx#axzz2DXNe9EVU">http://www.aorn.org/Clinical_Practice/ToolKits/Correct_Site_Surgery_Tool_Kit/Comprehensive_checklist.aspx#axzz2DXNe9EVU</a>
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com