



Instructions for Use: Time Out Sign

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

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Contents	
Shelf Life	

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

Reprocessing Instructions	
Point of Use	Gross soiling should be reduced by wiping down the surfaces.
Preparation for Decontamination	
Disassembly Instructions	
Cleaning – Manual	<ul style="list-style-type: none"> • Manual cleaning is permissible but not recommended. • Equipment: detergent, soft bristle brush, running water. • Rinse excess soil from device. • Apply detergent to all surfaces and use brush to clean all surfaces, ensuring that surface and drainage holes are clean and free from soil. • Thoroughly rinse all surfaces of residual detergent and soil. • Dry with non-linting cloth.
Cleaning – Automated	<ul style="list-style-type: none"> • Machine cleaning is recommended in a washer disinfector in compliance with ISO 15883 series of standards. • Products should be positioned in the washer to allow maximum water penetration and drainage. <ul style="list-style-type: none"> ○ No overlapping - partially covered devices will not be washed properly ○ Bowls and similar devices should be stacked standing on their side to allow complete drainage. • For final rinse, AAMI Critical Water is recommended. <p>The standard program to include:</p> <ol style="list-style-type: none"> 1. Pre-wash with cold water (<38°C) rinse for a minimum of 2 minutes. 2. Washing cycle with enzymatic detergent at temperature recommended by the detergent manufacturer for a minimum for 5 minutes. 3. Washing cycle with neutral pH detergent at the temperature recommended by the detergent manufacturer for a minimum of 2 minutes.

	<ol style="list-style-type: none"> 4. Rinse cycle for a minimum of 1 minute. 5. Thermal disinfection of up to 93°C in compliance with the washer manufacturer recommendations for time and temperature. 6. Drying cycle at temperature not to exceed 116°C. 7. Caution when unloading machine as products will be hot. 8. Visual inspection is required to ensure complete removal of soil. 9. If product still shows soil, repeat program.
Disinfection	
Drying	Drying may be accomplished during the dry cycle of the automated washer and/or with the use of a non-linting, disposable towel.
Maintenance, Inspection, and Testing	<ul style="list-style-type: none"> • Visual inspection is required to ensure complete removal of soil. If product still shows soil, repeat program. • Also, visually inspect to assess for wear and tear and damage due to use. Discard damaged devices.
Reassembly Instructions	
Packaging	Package in FDA cleared sterilization packaging following the IFU of the sterilization packaging manufacturer.
Sterilization	<ul style="list-style-type: none"> • 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"> ○ Pre-vacuum Sterilizer: 132°C for 4 minutes to 135°C for 3 minutes. ○ Gravity Displacement Sterilizer: 132°C to 135°C for 30 minutes, or 121°C to 123°C for 55 minutes. • Materially compatible with EO sterilization • Materially compatible with VH2O2 sterilization
Storage	
Additional Information	

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