



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 for a successful surgery.
Range of Applications for Product	Where surgical procedures are conducted
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 Conditions	
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 for a successful surgery.
Preparation for Use	
Diagrams (drawings, pictures):	
Steps for Use of Product	<ul style="list-style-type: none"> This product is be used according to each facilities policy in following the "Surgical Pause/Time out" outlined in AORN Perioperative Standards and Recommended Practices Check list.
Interpretation of Results	
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	
Disposal	

Reprocessing Instructions	
Point of use:	<ul style="list-style-type: none"> 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 surface 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 lint free cloth.
Cleaning – Automated:	<ul style="list-style-type: none"> Machine cleaning is recommended in a washer disinfector cleared by the FDA. 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, DI or RO water is recommended. The standard program to include: <ol style="list-style-type: none"> Pre-wash with cold water (<100°F) rinse for a minimum of 2 minutes. Washing cycle with enzymatic detergent at temperature recommended by the detergent manufacturer for 5 minutes. Washing cycle with neutral pH detergent at the temperature recommended by the detergent manufacturer for 5 minutes.

	<ol style="list-style-type: none"> 4. Rinse cycle for 2 minutes (preferably with DI or RO water). 5. Thermal disinfection of up to 195°F in compliance with the washer manufacturer recommendations for time and temperature. 6. Drying cycle at temperature not to exceed 240°F. 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 lint-free, 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: Wrapped trays, and instruments, should be exposed to 132° C to 135° C (270° F to 275° F) for at least four minutes. Dry for 20 to 40 minutes. ○ Gravity Displacement Sterilizer: Wrapped trays and instruments should be exposed to 132° C to 135° C (270° F to 275° F) for at least 30 minutes, or 121° C to 123° C (250° F to 254° F) for at least 55 minutes. Dry for 20 to 50 minutes. ○ Immediate Use Steam Sterilization (IUSS): Healthmark recommends strict adherence to both AAMI and AORN guidelines concerning IUSS, as well as the IFU from the device manufacturer. Without the use of sterile packaging, these trays do not provide a sterile barrier and may not be appropriate for IUSS. ○ Proper handling, loading and unloading of trays for steam sterilization: <ol style="list-style-type: none"> 1. DO NOT load trays on their sides or upside down with lid side down on shelf or cart. Load cases on cart or shelf so that the lid is always facing upward. This allows for proper drying. The trays are designed to dry in this position. Do not nest or crowd trays during autoclaving. 2. After the autoclave door is opened, all trays should be allowed to cool to room temperature before handling. The amount of time required depends on load content and ambient conditions (temperature and humidity). The potential for condensation may increase if the case is not allowed to cool properly. 3. If wet spots on the packaging are observed, the contents must be treated as non-sterile and be thoroughly reprocessed. 4. If condensation is observed, check to insure that recommendations 1 and 2 were followed. Also, verify that the steam that is being used for sterilization processing has a quality of more than 97%. Confirm that the sterilizers have been inspected for routine maintenance in accordance with the manufacturer's recommendations. • Materially compatible with EO sterilization • Materially compatible with gas-plasma 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 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com