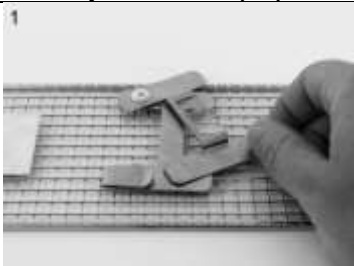
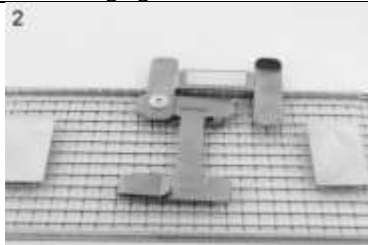
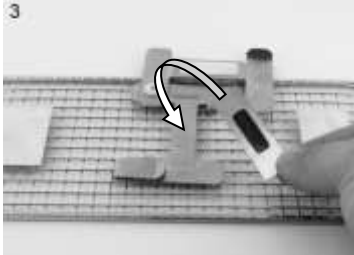
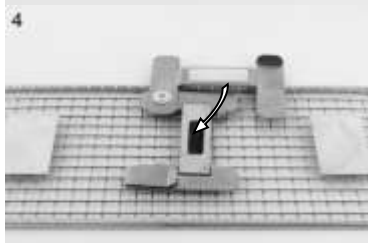

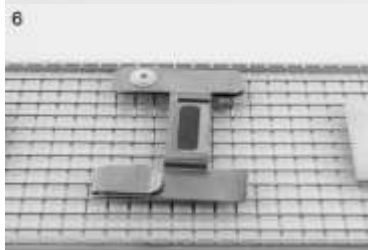


Brand Name of Product	Reusable TOSI®
Generic Name of Product	Test object surgical instrument
Product Code Number(s)	WT-111, WT-112, TOSI® WINDOW
Purpose of Product	To challenge the cleaning efficacy of mechanical cleaning equipment and protolytic detergents. The holder is reusable, keeping the Tosi in place during each testing session.
Range of Applications for Product	<ul style="list-style-type: none"> • Ultrasonic cleaners • Automated instrument washers • Protolytic detergents in a water bath
Key Specifications of Product	<ul style="list-style-type: none"> • Comprised of blood proteins in proportions similar to human blood: <ul style="list-style-type: none"> ○ Water soluble hemoglobin and albumin – 95% ○ Water insoluble fibrin – 5% • Soil on a stainless steel substrate. • In a see-through plastic holder which provides a physical barrier similar to areas of a surgical instrument not exposed to direct spray action, such as the box lock.

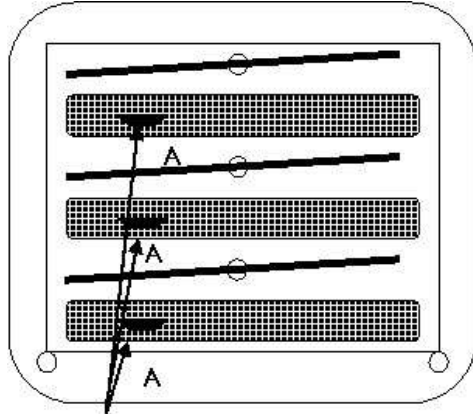
Shipping & Storage

Shipping Conditions & Requirements	
Storage Conditions	<ul style="list-style-type: none"> • Room temperature • Not in direct sunlight.
Packaging Contents	30 TOSI's® per box.
Shelf Life	<ul style="list-style-type: none"> • 18 months from date of manufacturer. • Consult package for expiration date.

Instructions for Using Product

Description of Use (s)	For challenging the cleaning efficacy of mechanical cleaning equipment and protolytic detergents.	
Preparation for Use	<ul style="list-style-type: none"> • TOSI® is designed to clip to a wire mesh basket or rack. If one is not available, use a WT-102 rack. • For routine testing described below, run procedure in an empty washer. • In some facilities, particularly over a weekend, a “dummy” cycle may need to be run prior to the test cycle to insure proper delivery of hot water and cleaning agents. 	
Diagrams (drawings, pictures)	     	

Location



A - Multi-Level Rack

Place one (1) TOSI[®] on each level. Arrange so that TOSI[®] is in the center of the radius of the spinner arm.

Steps for Use of Product

1. Gather appropriate supplies: Reusable TOSI[®] holder, TOSI[®]-plate, Instrument Rack, and Instrument Tray
2. As seen in image 1 above Open the TOSI[®] holder by pushing on the tab in a counterclockwise direction till the position seen in image 2.
3. Remove the TOSI[®]-plate from its protective pouch
4. As seen in image 3 and 4, place the plate into the TOSI[®] holder with the blood soil sample facing up
5. Close the TOSI[®] holder and assure that the TOSI[®]-plate doesn't move by holding down the plate with your finger as seen in image 5. (can touch the plate and blood soil, it's safe)
6. The closed TOSI[®] holder and TOSI[®] -plate should look like image 6.
7. Place the TOSI[®] holder wire rack in the center of an empty instrument tray one TOSI[®] per level of the instrument rack (Position "A" in the diagram below).
8. The empty washer-disinfector is switched on according to the designated program (normal procedure/cycle).
9. After the cycle is complete, remove the wire rack and visually inspect the TOSI[®] -plate through the window and compare the test to the interpretation guide then remove TOSI[®]-plate

	<p>from TOSI[®] holder.</p> <p>10. In case of unsatisfactory results, please refer to the troubleshooting guide.</p> <p>11. Record results on log sheet on hmark.com</p> <p>Routine Monitoring of Washer Performance <i>(for additional test procedures with the TOSI[®], please visit: http://www.hmark.com/tosi.php)</i></p> <ol style="list-style-type: none"> Secure one (1) TOSI[®] per level in the center of an empty tray as depicted in the diagram above. Place one on each shelf. In multiple shelf units follow diagram above and examples: e.g. 3 Shelf Unit, 3 TOSI[®]; 4 Shelf, 4 TOSI[®] or 1 level Tunnel Washer 1 TOSI[®].) Process using your surgical instrument wash cycle. Examine the TOSI[®] for visual cleanliness. Compare the test to the interpretation chart, WT-104, scale (0-5). <p>Record results.</p>
Interpretation of Results	<p>If less than optimal results were obtained (1-5), make adjustments to the equipment utilizing the chart (WT-104) as a guide. Typical failures can be caused by:</p> <ul style="list-style-type: none"> clogged spinner arms worn spray arm bushings insufficient detergent due to empty containers detergent pump failure or clogged delivery tubing poorly functioning water pump incorrect water temperature incorrect cycle settings
Contraindications of Test Results	<ul style="list-style-type: none"> Tiny Red Spot on TOSI[®] Plate: Very rarely, but nonetheless possible, is a slight imperfection in the stainless steel plate which leads to oxidation of the metal. The result is a little red spec which could be confused with the hemoglobin soil on the TOSI[®]. The easiest way to double check for such a thing is to directly employ mechanical action (with a gloved hand, preferably with the aid of an instrument cleaning brush) under water. If the spec remains, then it is definitely not the TOSI[®] blood soil that remains. Ghosting on the TOSI[®] Plate: A whitish stain is observed on the TOSI[®] plate, which can be confused with fibrin protein remaining on the TOSI[®]. This usually happens at a facility that has hard water. If allowed to dry and the TOSI[®] is read at that point, hard water staining may be observed on the TOSI[®] plate. The simplest method is to submerge gently the TOSI[®] plate in a bath of water. If the stain “disappears” when wetted, this indicates a non-test soil residue (likely hard water minerals or detergent) and not the blood soil.
Documentation	Record all changes and adjustments to the washer according to the results found from the TOSI [®] test relative to the chart scale. Utilize the supplied log sheet.
Special Warnings and Cautions	If TOSI [®] WINDOW breaks, call 1-586-774-7600 and we will replace it free of charge.
Disposal	Since the TOSI [®] is run in the mechanical cleaning equipment; there is a chance for contamination. Therefore, it is recommended to dispose of the used TOSI [®] in a biohazard container in compliance with facility protocols.

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	
Cleaning – Manual	
Cleaning – Automated	
Disinfection	
Drying	
Maintenance, Inspection, and Testing	
Reassembly Instructions	
Packaging	
Sterilization	
Storage	
Additional Information	

Related Healthmark Products	Weekly Washer Test Kits
Other Product Support Documents	Automated Washer Technical Bulletin Blood Coagulation Characteristics Evaluation of Cleaning Procedures Instructions for Automated Washer Tests Instructions for Ultrasonic and Lumen Washers Sample Policy for Daily Inspection and Weekly Testing Support for Cleaning Verification with the TOSI TOSI® Glossary of Terms TOSI® Troubleshooting Guide and Log Sheet TOSI® Troubleshooting Wall Chart TOSI® Validation Study Updated Standards and Guidelines Supporting Cleaning Verification
Reference Documents	<ol style="list-style-type: none"> 1. ANSI/AAMI-ST 79 2. Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385 3. Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310 4. OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000
Customer Service Contact	Healthmark Industries Company, Inc 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2020-11-18 Ralph J Basile