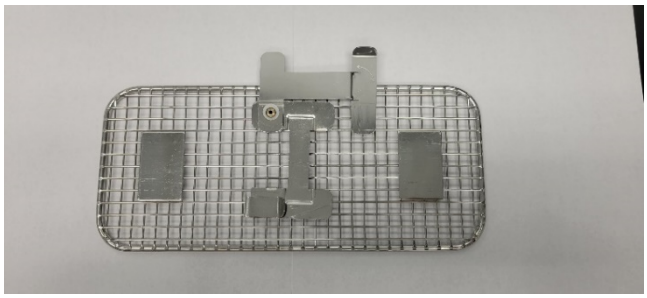
healthmark
INDUSTRIES CO.
health care products
800-521-6224
www.hmark.com

Instructions for Use: Reusable TOSI®

Brand Name of Product	Reusable TOSI®
Generic Name of Product	Test object surgical instrument
Product Code Number(s)	WT-111, WT-112, TOSI® BRACKET
Purpose of Product	To challenge the cleaning efficacy of mechanical cleaning equipment and proteolytic detergents. The holder is reusable, keeping the TOSI® in place during each testing session.
Range of Applications for Product	• Ultrasonic cleaners • Automated instrument washers • Proteolytic detergents in a water bath

Key Specifications of Product	• Comprised of blood proteins in proportions similar to human blood:
	  ○ 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 (e.g., box lock).

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	• Room temperature • Not in direct sunlight
Packaging Contents	Thirty (30) TOSI's® per box.
Shelf Life	• Eighteen (18) months from date of manufacture • Consult package for expiration date.

Instructions for Using Product	
Description of Use(s)	For challenging the cleaning efficacy of mechanical cleaning equipment and proteolytic detergents.
Preparation for Use	• 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 ensure proper delivery of hot water and cleaning agents.
Diagrams (drawings, pictures)	 Figure 1

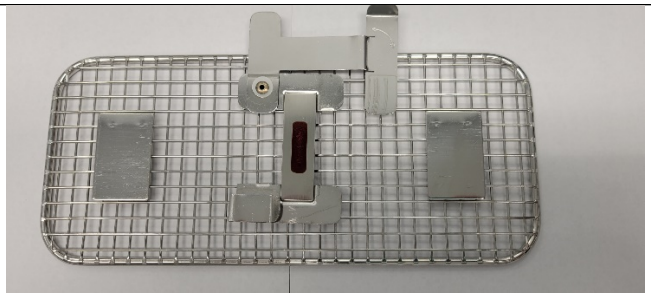


Figure 2

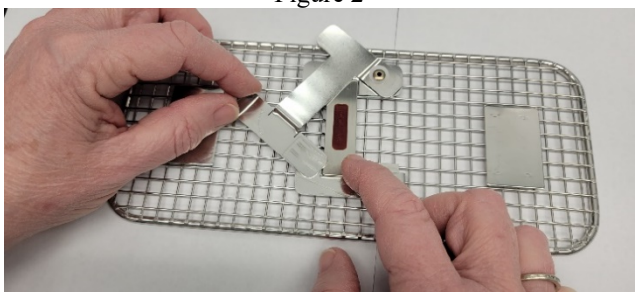


Figure 3

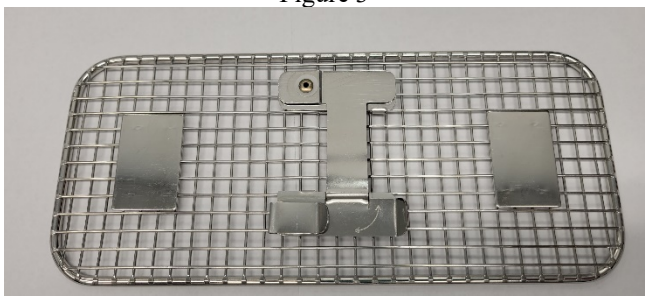


Figure 4

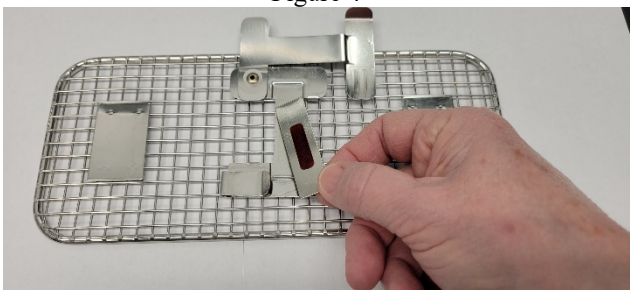


Figure 5

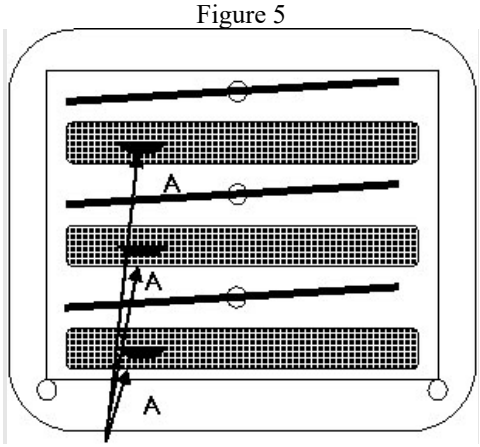


Figure 6

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 a. Reusable TOSI® holder

	b. TOSI®-plate c. Instrument Rack d. Instrument Tray 2. Open the TOSI® holder by pushing on the tab in a counterclockwise direction until the position seen in (Fig. 1). 3. Remove the TOSI®-plate from its protective pouch. 4. As seen in (Fig. 2, place the plate into the TOSI® holder with the blood soil sample facing up. 5. Close the TOSI® holder and ensure the TOSI®-plate doesn't move by holding down the plate with your finger as seen in (Fig. 3). (NOTE: It is safe to touch the plate and blood soil.) 6. The closed TOSI® holder and TOSI® -plate should look like (Fig. 4). 7. Place the TOSI® holder wire rack in the center of an empty instrument tray one (1)-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 a. Remove the wire rack b. Open the TOSI holder to visually inspect the TOSI plate. (Fig. 5) c. Compare the test to the interpretation guide d. Remove TOSI®-plate from TOSI® holder. 10. In case of unsatisfactory results, please refer to the troubleshooting guide 11. Record results on log sheet on hmark.com. **Routine Monitoring of Washer Performance** (*For additional test procedures with the TOSI®, please visit http://www.hmark.com/tosi.php*) 1. Secure one (1) TOSI® per level in the center of an empty tray as depicted in the diagram above in Figure 6. 2. 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® as shown in (Fig. 6). 3. Process using your surgical instrument wash cycle. 4. Examine the TOSI® for visual cleanliness. Compare the test to the interpretation chart, WT-104, scale (0-5). 5. Record results.
Interpretation of Results	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: • 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	• **Tiny Red Spot-on TOSI® Plate**: Though rare, but possible, a slight imperfection in the stainless-steel plate could lead to oxidation of the metal. The result is a little red speck, which could be confused with the hemoglobin soil on the TOSI®. o Double check by employing mechanical action (with a gloved hand, preferably with the aid of an instrument cleaning brush) under water. o If the speck remains, then it is not the TOSI® blood soil but rust. • **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®. Hard water is the usual cause. If allowed to dry, and then the TOSI® is read, hard water staining may be observed on the TOSI® plate. o Double check by gently submerging 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 Healthmark 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	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	N/A
Storage	N/A
Additional Information	N/A

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	AAMI. (2017). *ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Association for the Advancement of Medical Instrumentation (AAMI). Pfeifer, M. (1998). Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection. *Zentr Steril*, 6(6), 381-385. Pfeifer, M. (1998). Standardized Test Soil Blood 1: Composition, Preparation, Application. *Zentr Steril*, 6(6), 304-310. Fushimi, Ryo. (2000). *OSAKA REPORT: Importance of the cleaning test*. University of Osaka, Department of Medicine.
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com