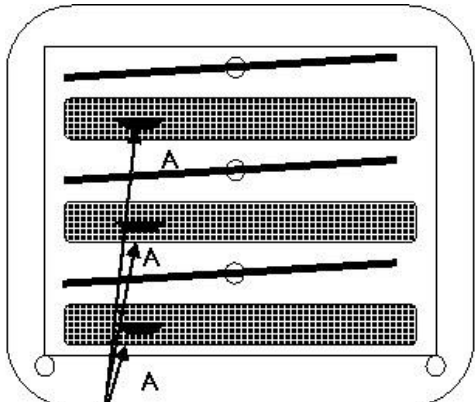


Brand Name of Product	TOSI®
Generic Name of Product	Test object surgical instrument
Product Code Number(s)	WT101, WT101-30, WT102
Purpose of Product	To challenge the cleaning efficacy of mechanical cleaning equipment and proteolytic detergents.
Range of Applications for Product	<ul style="list-style-type: none"> Automated instrument washers Ultrasonic cleaners Proteolytic detergents in a water bath
Key Specifications of Product	<ul style="list-style-type: none"> Comprised of blood proteins in proportionate 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 challenge (i.e., similar to areas of not exposed to direct spray action), such as the box lock.

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	<ul style="list-style-type: none"> Room temperature Not in direct sunlight
Packaging Contents	30 TOSI® coupons per box.
Shelf Life	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> TOSI® is designed to clip to a wire mesh basket. If one is not available, use a WT102 rack and place into a basket For routine testing described below, run procedure in an empty washer To test with a full load, see this document: http://www.healthmark.info/CleaningVerification/TOSI/Example_policy_daily_testing_medical_automatic_washer_with_TOSI_2019-01-31.pdf 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)	 <p style="text-align: center;"><i>Location A - Multi-Level Rack</i></p>

	<p>Place one (1) TOSI® on each level. Arrange so that TOSI® is in the center of the radius of the spinner arm.</p>
Steps for Use of Product	<p>Routine Monitoring of Washer Performance (for additional test procedures with the TOSI®, please visit: http://www.hmark.com/tosi.php)</p> <ol style="list-style-type: none"> 1. Open the TOSI® package by tearing across the precut notch at the top of the TOSI® package; remove the TOSI® coupon from the package 2. Secure one (1) TOSI® per level an empty tray as depicted in the diagram above <ol style="list-style-type: none"> a. Place one on each shelf. b. In multiple shelf units follow diagram above and examples (e.g., 3 Shelf Unit, 3 TOSI®, 4 Shelf Unit, 4 TOSI® or (1) Level Tunnel Washer, 1 TOSI®) 3. Process using the <i>instrument</i> wash cycle 4. Examine the TOSI® for visual cleanliness. Compare the test to the I(Prod Code No. WT-104) TOSI® Interpretation chart, scale (0-5) 5. Record results on a log sheet <p>Sonic & Blood Soil Test</p> <ol style="list-style-type: none"> 1. Make sure the ultrasonic cleaner has been degassed prior to running the test and has the correct amount of cleaning solution in the tank/bath 2. Secure one (1) TOSI® to the middle of the tray 3. TOSI® and SonoCheck™ can be placed in the same tray and run in the same cycle 4. Run the sonic through its normal cycle (record the cycle) 5. Record test results at the end of the cycle
Interpretation of Results	<p>If less than optimal results were obtained (1-5), adjust the equipment utilizing the chart (WT104) 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: Rarely, but possible, a slight imperfection in the stainless-steel plate could oxidize resulting in a little red speck. This could be confused for hemoglobin soil on the TOSI®. The easiest way to check is with mechanical (manual) action (gloved hand, preferably with the aid of an instrument cleaning brush) under water. If the speck remains, then it is not the TOSI® blood soil • Ghosting on the TOSI® Plate: A whitish stain observed on the TOSI® plate could be confused with fibrin protein. This usually happens at a facility having 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 gently submerge 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 • Ultrasonic Cycle: Residual Soil Re-deposited on TOSI® Plate: In ultrasonic washers that do not have a distinct rinsing stage within the same tank (i.e., draining of cleaning solution and filling with a fresh bath of water), it is possible a small amount of TOSI® soil can become trapped underneath the clear plastic holder. This soil can then be redeposited upon the TOSI® coupon. To determine this, simply give a gentle agitation of the TOSI® within a bath. Any soil that was detached during the cycle should be rinsed away. If soil remains attached to the surface of the TOSI® after this rinsing procedure, then this indicates sub-optimal cleaning
Documentation	<ul style="list-style-type: none"> • 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. • Report any unsatisfactory results to the proper management for corrective action according to the policy of your facility.
Special Warnings and Cautions	N/A

Disposal	Since the TOSI® is run in 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	Follow local and national standards for cleaning verification testing frequency and procedures.

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	1. ANSI/AAMI ST79 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

2021-07-30 Ralph J Basile