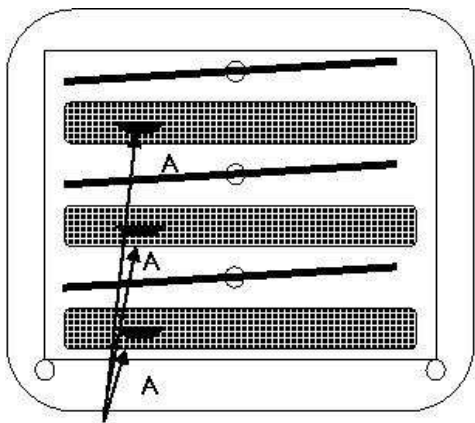


Brand Name of Product	TOSI®
Generic Name of Product	Test object surgical instrument
Product Code Number(s)	WT101, WT102
Purpose of Product	To challenge the cleaning efficacy of mechanical cleaning equipment and proteolytic detergents.
Range of Applications for Product	<ul style="list-style-type: none"> • Ultrasonic cleaners • Automated instrument washers • Proteolytic 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 Conditions	30 TOSIs 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 or rack. If one is not available, use a WT102 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)	 <p style="text-align: center;"><i>Location A - Multi-Level Rack</i> 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	Routine Monitoring of Washer Performance

	<p>(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 in the center of an empty tray as depicted in the diagram above. 3. 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[®].) 4. Process using your surgical instrument wash cycle. 5. Examine the TOSI[®] for visual cleanliness. Compare the test to the interpretation chart, WT104, scale (0-5). 6. Record results on log sheet on www.hmark.com. <p>Sonic & Blood Soil Test</p> <ol style="list-style-type: none"> 1. Make sure that the ultrasonic cleaner has been degassed prior to running the test and has the correct amount of cleaning solution in the tank/bath. 2. The number of SonoChecks placed in the tank will be dependent on the volume of the tanks (see routine testing). 3. Place the correct amount of SonoChecks in the appropriate tray for testing according to tank size. 4. Secure one (1) TOSI[®] to the middle of the tray. 5. TOSI[®] and SonoCheck[™] can be placed in the same tray. 6. Run the Sonic through its normal cycle (record the cycle). 7. Record both the SonoCheck[™] and TOSI[®] results at the end of the cycle.
<p>Interpretation of Results</p>	<p>If less than optimal results were obtained (1-5), make adjustments to 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
<p>Contraindications of Test Results</p>	<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 speck 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 speck 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 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 (draining of cleaning solution and filling with a fresh bath of water), it is possible that a small amount of TOSI[®] soil can become trapped underneath the clear plastic holder and that soil is then redeposited upon the coupon. To determine if that is the case, 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 still remains attached to the surface of the TOSI[®] after this rinsing procedure, then this indicates sub-optimal cleaning.
<p>Documentation</p>	<p>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.</p>
<p>Special Warnings and Cautions</p>	
<p>Disposal</p>	<p>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.</p>

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 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
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