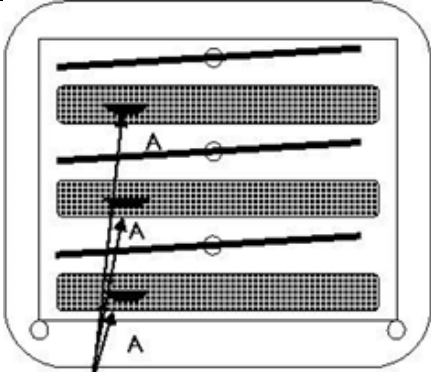

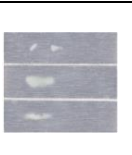
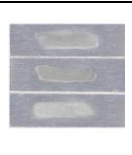
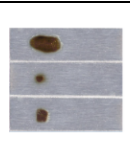
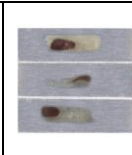


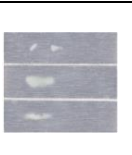
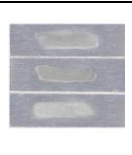
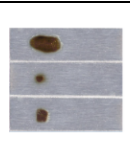
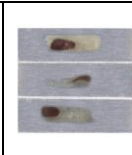


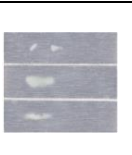
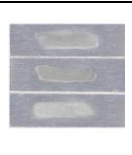
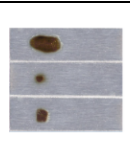
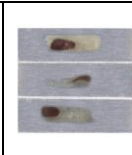



Brand Name of Product	TOSI®
Generic Name of Product	Test object surgical instrument
Product Code Number(s)	WT101, WT102
Purpose of Product	Cleaning challenge for mechanical cleaning equipment and proteolytic detergents.
Range of Applications for Product	<ul style="list-style-type: none"> Automated instrument washers Ultrasonic cleaners Cart Washer on the instrument cycle. Proteolytic detergents in a water bath.
Key Specifications of Product	<ul style="list-style-type: none"> Comprised of blood proteins to stimulate human blood: <ul style="list-style-type: none"> Water soluble hemoglobin and albumin – 95%. Water insoluble fibrin – 5%. Soil on a stainless-steel substrate. Soil loaded inside a transparent, plastic holder, which provides a physical challenge (i.e., areas unexposed 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	Thirty (30) TOSI® coupons per box.
Shelf Life	<ul style="list-style-type: none"> Eighteen (18) months from date of manufacture. Consult package for expiration date.

Instructions for Using Product					
Description of Use(s)	Cleaning challenge for 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 in <i>Steps for Use of Product</i>, run procedure in an empty washer. 				
Diagrams (drawings, pictures)	 <p>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.</p> <p>For Ultrasonic Cleaners:</p> <p>Multi-Level Bays</p> <table border="1" style="margin-left: 20px;"> <tr> <td>Multi-Level Ultrasonic (3)</td> </tr> <tr> <td style="text-align: center;">X</td> </tr> <tr> <td style="text-align: center;">X</td> </tr> <tr> <td style="text-align: center;">X</td> </tr> </table>	Multi-Level Ultrasonic (3)	X	X	X
Multi-Level Ultrasonic (3)					
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	<table border="1"> <tr> <td></td> <td>Multi-Level Dual Tank/Bay (6)</td> <td></td> </tr> <tr> <td>X</td> <td></td> <td>X</td> </tr> <tr> <td>X</td> <td></td> <td>X</td> </tr> <tr> <td>X</td> <td></td> <td>X</td> </tr> </table> <p>Routine Testing (e.g., daily testing)</p>		Multi-Level Dual Tank/Bay (6)		X		X	X		X	X		X									
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X		X																				
X		X																				
X		X																				
Steps for Use of Product	<p>Routine Monitoring of Washer Performance</p> <ol style="list-style-type: none"> Open the TOSI® package by tearing across the precut notch at the top of the TOSI® package; remove the TOSI® coupon from the package Secure one (1)-TOSI® per level in an empty basket and clip the TOSI® inside on the bottom of the wire mesh basket. <ol style="list-style-type: none"> Place one on each shelf. In multiple shelf units, follow the diagram above and examples below: <ol style="list-style-type: none"> Three (3) Shelf Unit = Three (3) TOSI® Four (4) Shelf Unit = Four (4) TOSI® One (1)-Level Tunnel Washer = One (1)-TOSI® Process using the designated program/wash cycle. Examine the TOSI® for visual cleanliness. Record results on a log sheet. <p>Ultrasonic & Blood Soil Test</p> <ol style="list-style-type: none"> Make sure the ultrasonic cleaner has been degassed prior to running the test and has recommended cleaning solution in the tank/bath. <ul style="list-style-type: none"> Place the TOSI® in an empty ultrasonic tray/basket (in the middle of the tray/basket) and place the tray/basket in the ultrasonic cleaner. If using a multi-level ultrasonic, place a minimum of one (1)-TOSI® in each basket on each level of the multi-level ultrasonic, in the middle of the tray/basket. Run the ultrasonic through its designated procedure/cycle. (Note: Record the cycle) Record test results at the end of the cycle. 																					
Interpretation of Results	<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Result</td> <td>Optimum Results No Residue Remaining</td> <td>Visible Fibrin</td> <td>Moderate/High Level Visible Fibrin</td> <td>Visible Hemoglobin</td> <td>Visible Hemoglobin and Visible Fibrin</td> <td>Moderate/High Level of Fibrin and Hemoglobin</td> </tr> <tr> <td>Parameters that may affect TOSI Results:</td> <td></td> <td>Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load</td> <td>Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load</td> <td>Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load Fluid Delivery/Spray</td> <td>Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load Fluid Delivery/Spray</td> <td>Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load Fluid Delivery/Spray</td> </tr> </table>								Result	Optimum Results No Residue Remaining	Visible Fibrin	Moderate/High Level Visible Fibrin	Visible Hemoglobin	Visible Hemoglobin and Visible Fibrin	Moderate/High Level of Fibrin and Hemoglobin	Parameters that may affect TOSI Results:		Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load	Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load	Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load Fluid Delivery/Spray	Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load Fluid Delivery/Spray	Water Temperature Detergent Selection and/or Dosing TOSI Positioning Instrument Load Fluid Delivery/Spray
																						
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Contraindications of Test Results	<ul style="list-style-type: none"> <i>Tiny Red Spot-on TOSI® Plate:</i> 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 (i.e., gloved hand, preferably with the aid of an 																					

	<p>instrument cleaning brush) underwater. If the speck remains, then it is not the TOSI[®] simulated blood soil.</p> <ul style="list-style-type: none"> • <i>Ghosting on the TOSI[®] Plate</i>: 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 simulated blood soil. • <i>Ultrasonic Cycle (Residual Soil Re-deposited on TOSI[®] Plate)</i>: 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 re-deposited 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 on a 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	N/A
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.
Customer Service Contact	<p>Healthmark, A Getinge company 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com</p>