



**Instructions for Use: Blood Test Soil with Bone**

<b>Brand Name of Product</b>	Blood Test Soil with Bone (BTS-Bone)
<b>Generic Name of Product</b>	Blood Test Soil Bone (BTS-Bone)
<b>Product Code Number(s)</b>	BTS-B-7ML, BTS-B-100ML
<b>Purpose of Product</b>	Blood proteins and bone based standardized test soil.
<b>Range of Applications for Product</b>	For simulated use soiling of medical devices for the purpose of conducting cleaning validations and cleaning verifications
<b>Key specifications of product</b>	Mixture of purified bovine proteins (hemoglobin, albumin) and bone.

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	Store vials with dry test soil at room temperature.
<b>Packaging Conditions</b>	
<b>Shelf Life</b>	18 months: See imprint.

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	
<b>Preparation for Use</b>	
<b>Diagrams (drawings, pictures):</b>	
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Add 6 ML sterile water (room temperature) for a 7 ML size vial, 90 ML sterile water for 100 ML size vial, of the BTS component. Please note: Less water may be used to obtain a thicker soil, yet more time may be needed to dissolve the soil. (Sterile water not provided).</li> <li>2. Add the provided solution A to the hydrated soil.</li> <li>3. Mix the components well by shaking it for ~5 minutes. A laboratory vortex mixer may be used for good homogenization. Use the soil right after hydrating.</li> <li>4. Contaminate the medical device in a manner which reflects real-life soiling from use.</li> </ol> <p>Note: In case of microbiological test, add the microbe-suspension after dissolving of the component. To avoid dilution of the test soil, subtract the amount of suspension from the solvent.</p>
<b>Interpretation of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation</b>	
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• Hazard Information <ul style="list-style-type: none"> <li>○ May be harmful if ingested or inhaled</li> <li>○ May cause skin irritation</li> <li>○ May cause eye irritation</li> <li>○ May be irritant to mucous membranes and upper respiratory tract</li> </ul> </li> <li>• First Aid Measures <ul style="list-style-type: none"> <li>○ After inhalation: Fresh air</li> <li>○ After skin contact: Wash off with plenty of water. Remove contaminated clothing.</li> <li>○ After eye contact: Rinse with plenty of water with the eyelid held wide open. Call an Ophthalmologist.</li> <li>○ After swallowing: Make victim drink plenty of water. Call a physician.</li> </ul> </li> <li>• Accidental release measures</li> </ul>

	○ After spillage. Dilute spilled substance with plenty of water and absorb with absorbent material.
<b>Disposal</b>	Dispose of in accordance with regional and/or national regulations.

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	
<b>Cleaning – Automated:</b>	
<b>Disinfection:</b>	
<b>Drying:</b>	
<b>Maintenance, inspection, and testing:</b>	
<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	
<b>Storage:</b>	
<b>Additional Information:</b>	

<b>Related Healthmark Products</b>	
<b>Other Product Support Documents</b>	
<b>Reference Documents</b>	
<b>Customer Service contact:</b>	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com