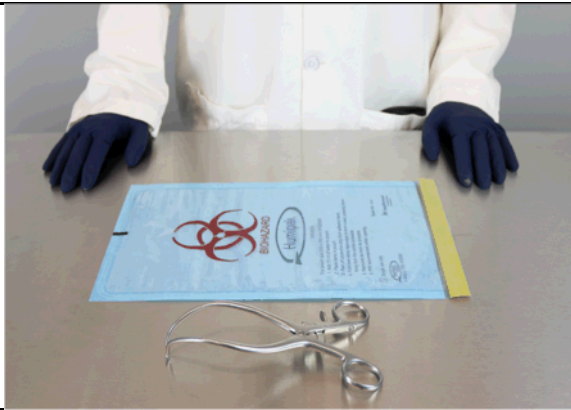


<b>Brand Name of Product</b>	Humipak
<b>Generic Name of Product</b>	Transport pouch
<b>Product Code Number(s)</b>	HPSS2035-25, HPSS2035-100, HPSS4243-25, HPSS4243-100, HPSS4267-25, HPSS4267-100, HPSS6577-10, HPSS6577-50, HPSS2035, HPSS4243, HPSS4267, HPSS6577, HPSSR01-100, HPSSR01-25, HPSSR04-100, HPSSR04-25
<b>Purpose of Product</b>	Provides a humid environment delaying the drying of contaminants (i.e., examples should be put here or say “contaminants and clinical soil on used items/instruments”) during transport <b>prior</b> to required cleaning, disinfection, reprocessing and/or sterilization.
<b>Range of Applications for Product</b>	<p>Holds contaminated items and maintains moisture to stop clinical soils from drying before further processing.</p> <p>The Humipak is <b>NOT</b> intended for:</p> <ul style="list-style-type: none"> <li>○ <i>Patient use</i> (e.g., not to be used in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease).</li> <li>○ <i>Providing any element for cleaning, disinfection, or sterilization of reusable medical devices</i>, which require cleaning, disinfection, or sterilization prior to reuse.</li> <li>○ <i>Sterile barrier packaging</i> for medical devices.</li> </ul>
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• Self-seal strip.</li> <li>• A special absorbent layer (when wet with water) that creates a humid atmosphere within the pouch.</li> <li>• Two layers of transparent film (containing the special absorbent layers) form the pouch.</li> <li>• The transparent film (in addition to maintaining the humid atmosphere) allows the contents to be clearly observed.</li> <li>• Six (6) sizes: <ul style="list-style-type: none"> <li>a. (Item #HPSS2035) Small 200- x 350 mm (7.87- x 13.78 in)</li> <li>b. (Item #HPSS4243) Half-Din 420- x 430mm (16.54- x 16.93 in)</li> <li>c. (Item # HPSS4267) Full-Din 420- x 670 mm (16.54- x 26.38 in)</li> <li>d. (Item # HPSS6577) Double-Din 650- x 770 mm (25.59- x 30.31 in)</li> <li>e. e) Robotic instruments One and Four Arm Configurations (Item codes): <ul style="list-style-type: none"> <li>■ HPSSR01-100</li> <li>■ HPSSR01-25</li> <li>■ HPSSR04-100</li> <li>■ HPSSR04-25</li> </ul> </li> </ul> </li> </ul>

Shipping & Storage	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	Store in a clean, dry place at room temperature (i.e., 20- to 25 °C [68- to 77 °F]).
<b>Packaging Contents</b>	N/A
<b>Shelf Life</b>	Five (5)-year shelf life from the date of manufacture.

Instructions for Using Product	
<b>Description of Use(s)</b>	Placing used items into the Humipak provides a humid environment and will delay drying of contaminants and clinical soil during transport <b>prior</b> to any required cleaning, disinfection, reprocessing, and/or sterilization.
<b>Preparation for Use</b>	Consult the manufacturer’s IFU for pretreatments at the point of use.
<b>Diagrams (drawings, pictures)</b>	



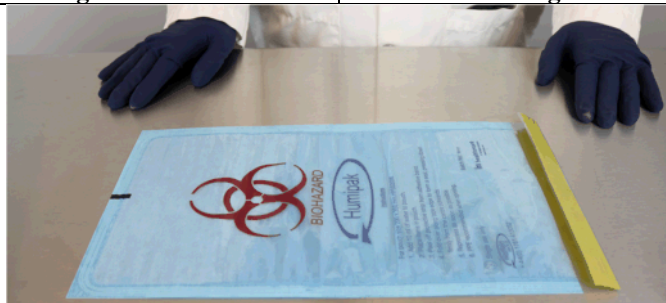
**Figure 1**



**Figure 2**



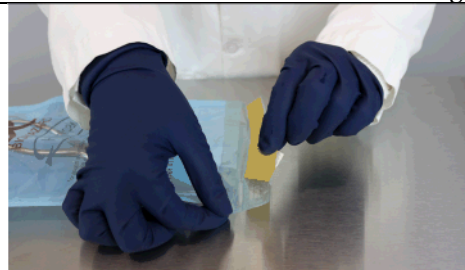
**Figure 2a**



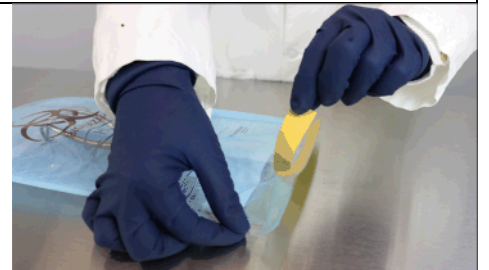
**Figure 3**



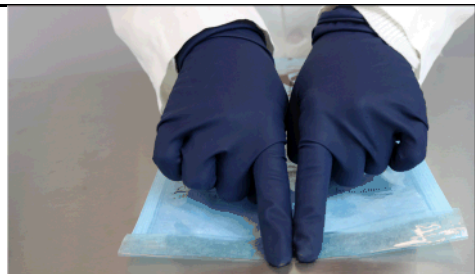




**Figure 4**






**Figure 5**



**Figure 5A**

	<div data-bbox="565 92 1036 363">  </div> <div data-bbox="743 363 846 394"> <p><b>Figure 6</b></p> </div> <div data-bbox="1044 92 1510 363">  </div> <div data-bbox="1214 363 1330 394"> <p><b>Figure 6a</b></p> </div> <div data-bbox="748 394 1317 800">  </div> <div data-bbox="976 800 1091 831"> <p><b>Figure 6b</b></p> </div> <div data-bbox="565 831 1036 1102">  </div> <div data-bbox="743 1102 846 1134"> <p><b>Figure 7</b></p> </div> <div data-bbox="1044 831 1510 1102">  </div> <div data-bbox="1214 1102 1330 1134"> <p><b>Figure 7b</b></p> </div>
<p><b>Steps for Use of Product</b></p>	<ol style="list-style-type: none"> <li>1. Pick the correct size of Humipak pouch for items to be kept moist until reprocessing. <b>(Fig. 1).</b></li> <li>2. Add the specified amount of water per the directions found on the Humipak pouch. <b>(Fig. 2, 2a).</b></li> <li>3. Water will wick and be absorbed throughout the Humipak pouch because of the special absorbent layer between the transparent films. <b>(Fig. 3).</b></li> <li>4. Place item(s) in the pouch. <b>(Fig.4).</b></li> <li>5. Peel off the protective strip from the adhesive band. <b>(Fig. 5, 5a).</b></li> <li>6. Fold over the adhesive strip and press down firmly from the center outwards to ensure a watertight seal. <b>(Fig. 6, 6a, 6b).</b></li> <li>7. Send sealed Humipak to the appropriate area for reprocessing to begin as soon as possible.</li> <li>8. Cut open—preferably cutting along the side or end farthest away from the body to avoid direct contact with air expelled from the pouch. <b>(Fig. 7, 7b).</b></li> <li>9. Ensure controlled environmental conditions within the decontamination area to minimize the spread of airborne organisms.</li> </ol>
<p><b>Interpretation of Results</b></p>	<p>N/A</p>
<p><b>Contraindications of Test Results</b></p>	<p>N/A</p>
<p><b>Documentation</b></p>	<p>N/A</p>
<p><b>Special Warnings and Cautions</b></p>	<ul style="list-style-type: none"> <li>• Items placed in the Humipak should be reprocessed as soon as possible.</li> <li>• Single use only.</li> <li>• Humipak is NOT: <ul style="list-style-type: none"> <li>○ A sharps container.</li> <li>○ Puncture proof.</li> </ul> </li> <li>• ⚠ Do NOT reuse or sterilize the Humipak.</li> <li>• ⚠ Use proper PPE when opening the Humipak.</li> </ul>

	<ul style="list-style-type: none"> <li>•  Treat used Humipak(s) as biohazardous.</li> <li>•  Follow your facility's policy for handling contaminated reusable sharps in compliance with OSHA Guidelines.</li> </ul>
<b>Disposal</b>	Treat used Humipak as a  biohazard and dispose of in accordance with facility's policy for contaminated items.

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	N/A
<b>Additional Information</b>	N/A

<b>Related Healthmark Products</b>	SST
<b>Other Product Support Documents</b>	SST Instrument Retrieval Brochure, SST Instrument Retrieval Price List, Humipak Pocket Brochure
<b>Reference Documents</b>	N/A
<b>Customer Service Contact</b>	Healthmark, A Getinge company 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com