



## Instructions for Use: Protech™ Trays

<b>Brand Name of Product</b>	Protech™ Trays
<b>Generic Name of Product</b>	Instrument sterilization trays
<b>Product Code Number(s)</b>	DDL-1123, CYSTO-224B, DDL-4113, SDLP-1130, 51527, 31127 DV, 300605-DVC, 300605-DVC, 300605-H, 30320-H, 31421-H, 31123-T, 31123-T1, 31127-H, 4116-H, 4106H, 41013H, 41116H, 41317H, 41520H, HCO-1309, HCO-1510, HCO-1711, HCO-1912, HDO-0952, HDO-1062, HDO-1272, HDO-1210, HDO-1610, HDO-2012, 184014, 184016, 184019, 184021, 181453, 184453, 181463, 182500, 182062, 182068, 30732-H, 30842-H, 31042-H, 31055-H, 31462-H, 31772-H, 50Z900, 30109HN, 30109CC, 30011KE, 30011CU, 30011RS, 30011BS, 31010-H1, 31010-H2, 31015-H1, 31015-H2, 31020-H, 0278, 02781, 027814, 0625, 062514, 6540, 7540, 754015, 100675, 100615, 100615B, 101525, 101525B, 30126, 30630, 30111-SSC, 30118-SSC, 31042-22, 3-4110, SP-3014, 3-5120, 3-5130, 75.0047.9M, 75.0083.1M, 75.0047.5M, 750083, 72.1400.6, 72.1400.5, 75.0001.7, 31772-22, 261615, 302215, 31462-22, 3-3131, 3-3170, 3-3180, 3-3200, 9326, F41520, PIT2015, DT2525, 4106H, PIT2715, MIT30251, 1511-4, DT2-1218, MIT40301, DT-2136, 1511-7, DT4825, 08881, 08882, 08845, 08846, 7501542, 7501543, 7501544, 7501545, 7501133, 202025, 2-1405, SP2313, SP4622, SP2719, 2-3215, 2-1055, 2-1215, 6-1914, 2-4005, 2111-M, 2-6005, SR10, 101525-M, 101525-M-RP, 101525B-M, 651815-M, 651830-M, 310-M, PSST-001, PSST-002, PSST-003, PSST-004, PSST-005, PSST-006, PSST-007, PSST-008, PSST-009, PSST-010, PSST-011, PSST-012, PSST-013, 18502-INS, 2-2025, 2-3125, 31055-H, 31462, 31772, 6540-M, 7540-M, 0278-M, 0625-M, 100615BM, 100615-M, 30011BP, 30011RS, 30732, 30842, 31042, 31055-H, 100675-M, 100615-M, 100615M, 0625-M, 0278-M, CYSTO-2214B, HCO-1065, HCO-1065-NP, HCO-1309-NP, HCO-1510-NP, HCO-1711-NP, HCO-1912-NP, HCO-2116, HDO-1210-NP, HDO-1272-NP, HDO-1610-NP, HDO-2012-NP, HDO-952-NP, PIT3025, PIT5739, TRI-CUT BRCKT, DINT4825, 2006-4H, 113-1314H, 1015-UB 56-UB, 710-UB, A237591K, A237592K, 237593, A237593K, A237596, A2616901, A2616902, A327593, A327593L, A32759P1, A32759P2, A3875912, A387592, A387593, A387594, A387595, A387595, 314-M, 317-M, 3100-M, 3105-M.
<b>Intended Use</b>	ProTech™ trays are intended for the protection, organization, and delivery of items to the point of use.
<b>Range of Applications for Product</b>	For safe packaging of items for sterilization, transportation, and storage. To be used with FDA cleared sterile barrier systems.
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>Consult the <a href="#">Protech™ Material Compatibility Guide</a> for material composition and compatibility with other forms of sterilization</li> <li>Secur-It™ instrument holders may be used to provide further protection for contents</li> <li>For use with FDA cleared sterile barrier systems.</li> </ul>

Shipping & Storage	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	N/A
<b>Packaging Contents</b>	Sold individually.
<b>Shelf Life</b>	N/A

Instructions for Using Product	
<b>Description of Use(s)</b>	To provide protective containment of items during sterilization, transportation, and storage.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>Always inspect for cleanliness or damage before use.</li> <li>Make sure all latches and handles are secure and in working order</li> <li>Do not overload trays</li> <li>Trays should be processed according to the IFU of the manufacturers of:               <ol style="list-style-type: none"> <li>Sterilization packaging</li> <li>Enclosed device(s)</li> <li>Sterilizer manufacturer</li> </ol> </li> </ol>
<b>Diagrams (drawings, pictures)</b>	N/A

<b>Steps for Use of Product</b>	<ul style="list-style-type: none"> <li>• Sterilization: follow the IFU for the sterilization packaging manufacturer, the enclosed device(s) manufacturer and the sterilizer manufacturer</li> <li>• DO NOT load trays on their sides or upside down with lid side down</li> <li>• DO NOT nest or crowd trays</li> <li>• Load trays in the barrier system or on a cart or shelf so that the lid is always facing upward. Allow all trays to cool to room temperature before handling and dispensing (this should be done after the sterilization cycle is completed and carriage is removed). <ul style="list-style-type: none"> <li>• The amount of time required depends on load content and ambient conditions (temperature and humidity)</li> <li>• The potential for condensation may increase if the case is not allowed to cool properly</li> </ul> </li> <li>• Consult the Protech™ Material Compatibility Guide for compatibility with sterilization modalities.</li> </ul>
<b>Interpretation of Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	N/A
<b>Special Warnings and Cautions</b>	Item codes: <ul style="list-style-type: none"> <li>• 4116-H, 4106H, 41013H, 41116H, 41317H, 41520H- May warp slightly after cleaning and/or sterilization. Performance not affected</li> <li>• Trays are not designed to maintain sterility. They are designed to facilitate the sterilization process when used in conjunction with a sterile barrier system.</li> </ul>
<b>Disposal</b>	N/A

<b>Reprocessing Instructions</b>	
<b>Point of use</b>	<ol style="list-style-type: none"> <li>1. Gross soiling should be reduced by wiping down the surfaces of the tray prior to transportation</li> <li>2. Trays should be transported in a closed or covered cart (follow facility guidelines for transportation of contaminated items).</li> </ol>
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	<ul style="list-style-type: none"> <li>• Manual cleaning is permissible but not recommended</li> <li>• <i>Equipment:</i> detergent, soft bristle brush, running water</li> <li>• Rinse excess soil from device</li> <li>• Apply detergent to all surfaces and use brush to clean all surfaces ensuring surface and drainage holes are clean and free from soil</li> <li>• Thoroughly rinse all surfaces of residual detergent and soil</li> <li>• Dry with non-linting cloth.</li> </ul>
<b>Cleaning – Automated</b>	<ul style="list-style-type: none"> <li>• Machine cleaning is recommended in a washer disinfectant conforming to ISO 15883- 1 &amp; 2</li> <li>• Products should be positioned in the washer to allow maximum water penetration and drainage. Lids should be open/removed</li> <li>• Products can be cleaned with neutral pH detergents. <ul style="list-style-type: none"> <li>• Consult the Protech™ Material Compatibility Guide: for the material composition of the Protech™ tray</li> <li>• Consult the IFU of the detergent manufacturer for material compatibility of the detergent(s) used</li> </ul> </li> <li>• Final rinse (AAMI TIR34 Critical Water is recommended)</li> <li>• The standard program to include: <ol style="list-style-type: none"> <li>1. Pre-wash with cold water &lt; 38 °C rinse for a minimum of 2 minutes</li> <li>2. Washing cycle with enzymatic detergent at temperature recommended by the detergent manufacturer for a minimum of 4 minutes</li> <li>3. Washing cycle with neutral pH detergent at the temperature recommended by the detergent manufacturer for a minimum of 2 minutes</li> <li>4. Final rinse cycle for a minimum of 1 minute (preferably with AAMI TIR 34 Critical Water)</li> <li>5. Thermal disinfection of up to 93 °C in compliance with the washer manufacturer recommendations for time and temperature</li> <li>6. Drying cycle at temperature not to exceed 115 °C</li> <li>7. <b>CAUTION: products will be hot when unloading the machine</b></li> <li>8. Visual inspection is required to ensure complete removal of soil</li> <li>9. If product still shows soil, repeat program.</li> </ol> </li> </ul>

<b>Disinfection</b>	N/A
<b>Drying</b>	Drying may be accomplished during the dry cycle of the automated washer and/or with the use of a non-linting cloth.
<b>Maintenance, Inspection, and Testing</b>	<ul style="list-style-type: none"> <li>• Visual inspection is required to ensure complete removal of soil. If product still shows soil, repeat program</li> <li>• Visually inspect to assess for wear, tear, and damage due to use. Discard damaged devices</li> </ul>
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	Package in FDA cleared sterile barrier system based on the manufacture's IFU.
<b>Sterilization</b>	<p>For instructions on using these trays as containment devices, see the section above-entitled <i>Steps for Use of Product</i>. The instructions below are for terminal sterilization of empty trays:</p> <ul style="list-style-type: none"> <li>• Follow the IFU for the sterilization packaging manufacturer and the sterilizer manufacturer</li> <li>• DO NOT load autoclave trays on sides or upside down with lid side down on shelf/cart. Load cases on cart or shelf so that the lid is always facing upward. Do not nest or crowd trays during sterilization</li> <li>• Consult the <a href="#">Protech™ Material Compatibility Guide</a> for material composition and compatibility with other forms of sterilization</li> <li>• After the sterilizer door is opened, all trays should be allowed to cool to room temperature before handling <ul style="list-style-type: none"> <li>• The amount of time needed depends on load content and ambient conditions (temperature and humidity)</li> <li>• The potential for condensation may increase if the case is not allowed to cool properly.</li> </ul> </li> </ul>
<b>Storage</b>	N/A
<b>Additional Information</b>	N/A

<b>Related Healthmark Products</b>	Silicone Finger Mats, Protech™, Secur-Its™
<b>Other Product Support Documents</b>	Protech™ Product Brochure, Protech™ Price list, Protech™ Material Compatibility Guide
<b>Reference Documents</b>	N/A
<b>Customer Service Contact</b>	<p>Healthmark Industries Company, Inc.  18600 Malyn Blvd.  Fraser, MI 48026  1-586-774-7600  <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a>  hmark.com</p>

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