

<b>Brand Name of Product</b>	Protech™ Trays
<b>Generic Name of Product</b>	Instrument sterilization trays
<b>Product Code Number(s)</b>	DDLDP-1123, CYSTO-224B, DDLDP-4113, 51527, 31127 DV, 300605-DVC, 300605-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, 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, SP-3014, 75.0047.9M, 75.0047.5M, 750083, 72.1400.6, 72.1400.5, 31772-22, 261615, 302215, 31462-22, F41520, PIT2015, DT2525, 4106H, PIT2715, MIT30251, 1511-4, DT2-1218, MIT40301, DT2-2136, 1511-7, DT4825, 7501542, 7501543, 7501544, 7501545, 7501133, 202025, 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, 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 (Mfr.s) of: <ol style="list-style-type: none"> <li>Sterilization packaging.</li> <li>Enclosed device(s).</li> <li>Sterilizer</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>● <i>Sterilization</i>: follow the IFU for a.) the sterilization packaging Mfr., b.) the enclosed device(s)' Mfr., and c.) the sterilizer Mfr.</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.</li> <li>● Allow all trays to cool to room temperature before handling and dispensing. (NOTE: 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 (i.e., 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 <a href="#">Protech™ Material Compatibility Guide</a> 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 disinfector 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 <a href="#">Protech™ Material Compatibility Guide</a> for the material composition of the Protech™ tray.</li> <li>● Consult the IFU of the detergent Mfr. 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: <ul style="list-style-type: none"> <li>● Prewash with cold-water &lt; 38 °C rinse for a minimum of 2 minutes</li> <li>● Washing cycle with enzymatic detergent at temperature recommended by the detergent Mfr. for a minimum of 4 minutes</li> <li>● Washing cycle with neutral pH detergent at the temperature recommended by the detergent Mfr. for a minimum of 2 minutes</li> <li>● Final rinse cycle for a minimum of 1-minute (preferably with AAMI TIR 34 Critical Water)</li> <li>● Thermal disinfection of up to 93 °C in compliance with the washer Mfr.'s recommendations for time and temperature</li> <li>● Drying cycle at temperature not to exceed 115 °C</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>● <b>CAUTION:</b> products will be hot when unloading the machine</li> <li>● Visual inspection is required to ensure complete removal of soil</li> <li>● If the product still shows soil, repeat program.</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 the 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 Mfr.'s IFU.
<b>Sterilization</b>	<p>When the intention is to sterilize an empty tray without contents follow the instructions in this section.</p> <p><b>For instructions on using these trays as containment devices, see the section above, entitled <i>Steps for Use of Product</i>.</b></p> <ul style="list-style-type: none"> <li>● Follow the IFU for the sterilization packaging Mfr. and the sterilizer Mfr.</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 (i.e., 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>	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