

## 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 P-1123, CYSTO-224B, DDL P-4113, SDLP-1130, 51527, 31127 DV, 300605-DVC, 300605-DVA, 300605-H, 180502-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, 30011BP, 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, DINT2525, 4106-H, PIT2715, MIT30251, 1511-4, DT-1218, MIT40301, DT-2136, 1511-7, DINT4825, 75.0068.4, 08881, 08882, 08845, 08846, 7501542, 7501543, 7501544, 7501545, 202025, 2-1405, SP2313, SP4622, SP2719, 2-3215, 2-1055, 2-1215, 6-1914, 2-4005, 2111-M, 2-6005, SR10, 101525-M, 310-M.
<b>Intended Use</b>	ProTech™ trays are intended for the protection, organization, and delivery to the surgical suite of items.
<b>Range of Applications for Product</b>	For the safe packaging of items for sterilization, transportation and storage. To be used with FDA cleared sterilization packaging.
<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 to provide further protection for contents.</li> <li>For use with FDA cleared sterile barrier system.</li> </ul>

### Shipping & Storage

<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	
<b>Packaging Contents</b>	Sold by the each
<b>Shelf Life</b>	

### Instructions for Using Product

<b>Description of Use (s)</b>	<ul style="list-style-type: none"> <li>To provide protective containment of items during sterilization, transportation and storage.</li> <li>To be used with sterilization packaging as the sterile barrier.</li> </ul>
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order.</li> <li>Do not overload trays.</li> <li>Balance contents uniformly within the tray and arrange to allow sterility to come in contact with all objects in the container.</li> <li>Trays should be processed according to the IFU of the sterilization packaging manufacturer, the enclosed device(s) manufacturer, and the sterilizer manufacturer.</li> </ol>
<b>Diagrams (drawings, pictures)</b>	
<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 on shelf or cart. Load cases on cart or shelf so that the lid is always facing upward. This allows for proper drying. The trays are designed to dry in this position. Do not nest or crowd trays during autoclaving.</li> <li>After the sterilization cycle is complete and sterilization carriage is removed all tray should be allowed to cool to room temperature before handling and dispensing. The amount of time required depends on load content and ambient</li> </ul>

	<p>conditions (temperature and humidity). The potential for condensation may increase if the case is not allowed to cool properly.</p> <ul style="list-style-type: none"> <li>• If wet spots on the packaging are observed, the contents must be treated as non-sterile and be thoroughly reprocessed.</li> <li>• If condensation is observed, check to ensure that recommendations 1 and 2 were followed. Confirm that the sterilizers have been inspected for routine maintenance in accordance with the manufacturer’s recommendations.</li> <li>• Consult the <a href="#">Protech™ Material Compatibility Guide</a> for compatibility with sterilization modalities.</li> </ul>
<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>• Trays are <b>not</b> designed to maintain sterility. They are designed to facilitate the sterilization process when used in <b>conjunction</b> with sterilization packaging.</li> </ul>
<b>Disposal</b>	

<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 and transported in a dedicated “dirty” elevator or marked as “biohazard” if transported outside of the OR/CS areas.</li> </ol>
<b>Preparation for Decontamination</b>	
<b>Disassembly Instructions</b>	
<b>Cleaning – Manual</b>	<ul style="list-style-type: none"> <li>• Manual cleaning is permissible but not recommended.</li> <li>• Equipment: detergent, soft bristle brush, running water.</li> <li>• Rinse excess soil from device.</li> <li>• Apply detergent to all surface and use brush to clean all surfaces, ensuring that 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 lint free 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. <ul style="list-style-type: none"> <li>○ No overlapping - partially covered devices will not be washed properly</li> <li>○ Bowls and similar devices should be stacked standing on their side to allow complete drainage.</li> <li>○ Lids should be open/removed.</li> </ul> </li> <li>• Products can be cleaned with neutral pH detergents. Consult the <a href="#">Protech™ Material Compatibility Guide</a> for the material composition of the Protech™ tray and consult the IFU of the detergent manufacturer for material compatibility of the detergent(s) used.</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;100°F) 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 199°F in compliance with the washer manufacturer recommendations for time and temperature.</li> <li>6. Drying cycle at temperature not to exceed 240°F.</li> <li>7. Caution when unloading machine as products will be hot.</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>	
<b>Drying</b>	Drying may be accomplished during the dry-cycle of the automated washer and/or with the use of a lint-free, disposable towel.
<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> </ul>

	<ul style="list-style-type: none"> <li>Also, visually inspect to assess for wear and tear and damage due to use. Discard damaged devices.</li> </ul>
<b>Reassembly Instructions</b>	
<b>Packaging</b>	Package in FDA cleared sterilization barrier system following the IFU of the sterilization barrier system manufacturer.
<b>Sterilization</b>	<p>For instructions on using these trays as containment devices for items, 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 trays on sides or upside down with lid side down on shelf or cart. Load cases on cart or shelf so that the lid is always facing upward. This allows for proper drying. The trays are designed to dry in this position. Do not nest or crowd trays during sterilization.</li> <li>Pre-vacuum Sterilizer: Wrapped trays should be exposed to 132° C (4 minutes) to 135° C (3 minutes) (270° F to 275° F). Dry for 20 to 40 minutes.</li> <li>Gravity Displacement Sterilizer: Wrapped trays should be exposed to 132° C to 135° C (270° F to 275° F) for at least 30 minutes, or 121° C to 123° C (250° F to 254° F) for at least 55 minutes. Dry for a minimum of 20 minutes.</li> <li>After the sterilizer door is opened, all trays should be allowed to cool to room temperature before handling. The amount of time required depends on load content and ambient conditions (temperature and humidity). The potential for condensation may increase if the case is not allowed to cool properly.</li> </ul>
<b>Storage</b>	
<b>Additional Information</b>	

<b>Related Healthmark Products</b>	Silicone Finger Mats, Protech™, Secur-Its™
<b>Other Product Support Documents</b>	Protech™ Product Brochure, Price list, Protech™ Material Compatibility Guide
<b>Reference Documents</b>	
<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>