

Brand Name of Product	Protech™ Trays
Generic Name of Product	Instrument sterilization trays
Product Code Number(s)	DDLDP-1123, CYSTO-224B, DDLDP-4113, SDLDP-1130, 51527, 31127 DV, 300605-DVC, 300605-DVA, 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, 4106-H, PIT2715, MIT30251, 1511-4, DT-1218, MIT40301, DT-2136, 1511-7, DT4825, 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, PSST-001, PSST-002, PSST-003, PSST-004, PSST-005, PSST-006, PSST-007, PSST-008, PSST-009, PSST-010, PSST-11, 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, 101525B-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
Intended Use	ProTech™ trays are intended for the protection of items, organization of items, and delivery of items to the point of use.
Range of Applications for Product	For the safe packaging of items for sterilization, transportation and storage. To be used with FDA cleared sterile barrier systems.
Key Specifications of Product	<ul style="list-style-type: none"> Consult the Protech™ Material Compatibility Guide for material composition and compatibility with other forms of sterilization. Secur-It™ instrument holders to provide further protection for contents. For use with FDA cleared sterile barrier systems.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Contents	Sold individually.
Shelf Life	

Instructions for Using Product	
Description of Use(s)	<ul style="list-style-type: none"> To provide protective containment of items during sterilization, transportation and storage. To be used within sterilization packaging as the sterile barrier.
Preparation for Use	<ol style="list-style-type: none"> Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order. Do not overload trays. Trays should be processed according to the IFU of the sterilization packaging manufacturer, the enclosed device(s) manufacturer, and the sterilizer manufacturer.
Diagrams (drawings, pictures)	
Steps for Use of Product	<ul style="list-style-type: none"> Sterilization: Follow the IFU for the sterilization packaging manufacturer, the enclosed device(s) manufacturer and the sterilizer manufacturer.

	<ul style="list-style-type: none"> • DO NOT load trays on their sides or upside down with lid side down. Load trays in barrier system, on cart or shelf so that the lid is always facing upward. Do not nest or crowd trays. • After the sterilization cycle is complete and sterilization carriage is removed, all trays should be allowed to cool to room temperature before handling and dispensing. 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. • Consult the Protech™ Material Compatibility Guide for compatibility with sterilization modalities.
Interpretation of Results	
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	<p>Item codes:</p> <ul style="list-style-type: none"> • 4116-H, 4106H, 41013H, 41116H, 41317H, 41520H- May warp slightly after cleaning and/or sterilization, performance not affected. • Trays are not designed to maintain sterility. They are designed to facilitate the sterilization process when used in conjunction with a sterile barrier system.
Disposal	

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

Maintenance, Inspection, and Testing	<ul style="list-style-type: none"> ● Visual inspection is required to ensure complete removal of soil. If product still shows soil, repeat program. ● Visually inspect to assess for wear and tear and damage due to use. Discard damaged devices.
Reassembly Instructions	
Packaging	Package in FDA cleared sterile barrier system following the IFU of the sterile barrier system manufacturer.
Sterilization	<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"> ● Follow the IFU for the sterilization packaging manufacturer and the sterilizer manufacturer. ● DO NOT load autoclave 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. Do not nest or crowd trays during sterilization. ● Pre-vacuum Sterilizer: Wrapped trays should be exposed to 132° C (4 minutes) to 135° C (3 minutes). Dry for 20 to 40 minutes. ● Gravity Displacement Sterilizer: Wrapped trays should be exposed to 132° C to 135° C for at least 30 minutes, or 121° C to 123° C for at least 55 minutes. Dry for a minimum of 20 minutes. ● 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.
Storage	
Additional Information	

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

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