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Instructions for Use: Protech™ Trays

Brand Name of Product	Protech™ Trays
Generic Name of Product	Instrument sterilization trays
Product Code Number(s)	DDLP-1123, 51527, 31127 DV, 300605-DVA, 300605-DVC, 300605-H, 31421-H , 31123-T, 31123-T1, 31127-H, 41116H BL, 4106H , 41013H-BL, 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-H2, 31020-H, 0278, 02781, 027814, 0625, 062514, 6540, 7540, 754015, 100675, 100615, 100615B, 101525, 101525B, 30630, 30126, 30111-SSC, 30118-SSC, 31042-22, SP-3014, 750083, 72.1400.6, 72.1400.5, 31772-22, 261615, 302215, 31462-22, PIT2015, DT2525, 10PIT2715, MIT30251, 1511-4, DT2-1218, MIT40301, DT2-2136, 1511-7, DT4825, 7501542, 7501544, 7501545, 202025, 101525-M, 101525B-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, 2-3125, 31462, 31772, 6540-M, 7540-M, 0278-M, 0625-M, 100615BM, 100615-M, 30011BP, 30732, 30842, 31042, 100675-M, CYSTO-2214B, HCO-1065, HCO-1309-NP, HCO-1912-NP, HCO-2116, HDO-1272-NP, HDO-1610-NP, 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, 314-M, 317-M, 3100-M, 3105-M
Intended Use	ProTech™ trays are intended for the protection, organization, and delivery of items to the point of use.
Range of Applications for Product	For safe packaging of items for sterilization, transportation, and storage. To be used with FDA cleared sterile barrier systems.
Key Specifications of Product	● Consult the *Protech™ Material Compatibility Guide* for material composition and compatibility with other forms of sterilization. ● Secur-It™ instrument holders may be used to provide further protection for contents. ● For use with FDA cleared sterile barrier systems.

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

Instructions for Using Product	
Description of Use(s)	To provide protective containment of items during sterilization, transportation, and storage.
Preparation for Use	1. Always inspect for cleanliness or damage before use. 2. Make sure all latches and handles are secure and in working order. 3. Do not overload trays. 4. Trays should be processed according to the instructions for use (IFU) of the manufacturers (Mfrs.) of: a. Sterilization packaging. b. Enclosed device(s). c. Sterilizer(s).
Diagrams (drawings, pictures)	N/A
Steps for Use of Product	1. DO NOT nest or crowd trays. 2. *Cooling:* Allow all trays to cool to room temperature before handling and dispensing. a. (NOTE: This should be done after the sterilization cycle is completed and carriage is removed.)

	b. The amount of time required to cool depends on load contents and ambient conditions (i.e., temperature and humidity). c. The potential for condensation may increase if the case is not allowed to cool properly. 3. Consult the *Protech™ Material Compatibility Guide* for compatibility with sterilization modalities.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	• Item codes: 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. • DO NOT nest or crowd trays. • ⚠ CAUTION: Trays will be very HOT after sterilization. Allow to cool before handling.
Disposal	N/A

Reprocessing Instructions	
Point of use	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. (NOTE: Follow facility policy for transportation of contaminated items).
Preparation for Decontamination	N/A
Disassembly Instructions	N/A

Cleaning – Manual	• *Manual cleaning*: Permissible but not recommended.
	• *Equipment:* Detergent, soft bristle brush, and running water.
	• Rinse excess soil from device.
	• *Detergent*: Apply detergent to all surfaces.
	  • Brush to clean all surfaces ensuring surface and drainage holes are clean and free from soil.
	  • Thoroughly rinse all surfaces of residual detergent and soil.
	• *Drying*: Dry with non-linting cloth.

Cleaning – Automated	• Machine cleaning is recommended in a washer disinfector conforming to ISO 15883- 1 & 2.
	• Run on the Instrument Cycle for the Washer-Disinfector.
	  • Consult the *Protech™ Material Compatibility Guide* for the material composition of the Protech™ tray.
	  • Consult the IFU of the detergent Mfr. for material compatibility of the detergent(s) used.

Disinfection	N/A
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	• Visual inspection is required to ensure complete removal of soil. If the product still shows soil, repeat program. • Visually inspect to assess for wear, tear, and damage due to use. • Discard damaged devices.
Reassembly Instructions	N/A
Packaging	Package in FDA cleared sterile barrier system based on the medical device manufacturer's IFU.
Sterilization	When the intention is to sterilize an empty tray without contents, follow the instructions in this section. **For instructions on using these trays as containment devices, see the section above titled *Steps for Use of Product.*** • Follow the IFU for the sterilization packaging Mfr. and the sterilizer Mfr. • Do not nest or crowd trays during sterilization. • Consult the *Protech™ Material Compatibility Guide* for material composition and compatibility with other forms of sterilization.

	● After the sterilizer door is opened, all trays should be allowed to cool to room temperature before handling.
	  ● The amount of time needed depends on load content and ambient conditions (i.e., temperature and humidity).
	  ● The potential for condensation may increase if the case is not allowed to cool properly.
	● Steam sterilization at:
	  ● 132 ℃ (270 ℉) for four (4) minutes.
	  ● 135 ℃ (275 ℉) for three (3) minutes.

Storage	N/A
Additional Information	N/A

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	N/A
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com