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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, CYSTO-224B, DDLP-4113, SDLP-1130, 51527, 31127 DV, 250605-DVC, 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, 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
Intended Use	ProTech™ trays are intended for the protection, organization, and delivery to the surgical suite of surgical instruments and/or medical devices.
Range of Applications for Product	For the safe packaging of surgical instruments and other medical devices for sterilization, transportation and storage. To be used with FDA cleared sterilization packaging.
Key specifications of product	• Material compatibility with steam. Consult the Protech™ Material Compatibility Guide for material composition and compatibility with other forms of sterilization. • Optional silicone fingermats and/or Secur-It™ instrument holders can be used to provide further protection for contents. • For use with surgical wrap or sterilization pouches as the sterile barrier.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Conditions	Sold by the each
Shelf Life	

Instructions for Using Product	
Description of Use (s)	• To provide protective containment of surgical instruments and other medical devices during sterilization, transportation and storage. • To be used with sterilization packaging as the sterile barrier.
Preparation for Use	1. Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order. 2. Do not overload trays. 3. Balance contents uniformly within the tray and arrange to allow sterility to come in contact with all objects in the container. 4. 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	• Steam Sterilization: Follow the IFU for the sterilization packaging manufacturer, the enclosed device(s) manufacturer and the sterilizer manufacturer. • Pre-vacuum Sterilizer: Wrapped trays, and instruments, should be exposed to 132º C (270º F) for 4 minutes or 135º C (275º F) at 4 minutes. Dry for 20 to 40 minutes. • Gravity Displacement Sterilizer: Wrapped trays and instruments should be exposed to 132º C to 135º C (270º F to 275º F) for at least 30 minutes, or 121º C to 123º C (250º F to 254º F) for at least 55 minutes. Dry for 20 to 50 minutes. • Immediate Use Steam Sterilization (IUSS): Healthmark recommends strict adherence to both AAMI and AORN guidelines concerning IUSS, as well as the IFU from the device manufacturer. Without the use of sterile packaging, these trays do not provide a sterile barrier and may not be appropriate for IUSS.

	• Proper handling, loading and unloading of trays for steam sterilization: • 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. • After the autoclave 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. • If wet spots on the packaging are observed, the contents must be treated as non-sterile and be thoroughly reprocessed. • If condensation is observed, check to insure that recommendations 1 and 2 were followed. Also, verify that the steam that is being used for sterilization processing has a quality of more than 97%. Confirm that the sterilizers have been inspected for routine maintenance in accordance with the manufacturer's recommendations. • Consult the Protech™ Material Compatibility Guide for compatibility with other forms of sterilization. Follow the IFU for the sterilization packaging manufacturer, the enclosed device(s) manufacturer and the sterilizer manufacturer.
Interpretation of Results	
Contraindications of Test Results	
Documentation	
Special Warnings and Cautions	• Trays are **not** designed to maintain sterility. They are designed to facilitate the sterilization process when used in **conjunction** with sterilization packaging.
Disposal	

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 and transported in a dedicated "dirty" elevator, or marked as "biohazard" if transported outside of the OR/CS areas.
Preparation for decontamination:	
Disassembly Instructions:	
Cleaning – Manual:	• Manual cleaning is permissible but not recommended. • Equipment: detergent, soft bristle brush, running water. • Rinse excess soil from device. • Apply detergent to all surface 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 lint free cloth.

Cleaning – Automated:	• Machine cleaning is recommended in a washer disinfector cleared by the FDA.
	• Products should be positioned in the washer to allow maximum water penetration and drainage.
	  ○ No overlapping - partially covered devices will not be washed properly
	  ○ Bowls and similar devices should be stacked standing on their side to allow complete 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.
	• For final rinse, DI or RO water is recommended.
	• The standard program to include:
	  1. Pre-wash with cold water (<100°F) rinse for a minimum of 2 minutes.
	  2. Washing cycle with enzymatic detergent at temperature recommended by the detergent manufacturer for 5 minutes.
	  3. Washing cycle with neutral pH detergent at the temperature recommended by the detergent manufacturer for 5 minutes.
	  4. Rinse cycle for 2 minutes (preferably with DI or RO water).
	  5. Thermal disinfection of up to 195°F in compliance with the washer manufacturer recommendations for time and temperature.

	6. Drying cycle at temperature not to exceed 240°F. 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 lint-free, disposable towel.
Maintenance, inspection, and testing:	• Visual inspection is required to ensure complete removal of soil. If product still shows soil repeat program. • Also, visually inspect to assess for wear and tear and damage due to use. Discard damaged devices.
Reassembly Instructions:	
Packaging:	Package in FDA cleared sterilization packaging following the IFU of the sterilization packaging manufacturer.
Sterilization:	For instructions on using these trays as containment devices for medical devices, see the section above entitled "*Steps for Use of Product*." The instructions below are for terminal sterilization of empty trays: • Follow the IFU for the sterilization packaging manufacturer and the sterilizer manufacturer. • 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. • Pre-vacuum Sterilizer: Wrapped trays should be exposed to 132º C (4 minutes) to 135º C (3 minutes) (270º F to 275º F). Dry for 20 to 40 minutes. • Gravity Displacement Sterilizer: Wrapped trays should be exposed to 132º C to 135º C (270º F to 275º F) for at least 30 minutes, or 121º C to 123º C (250º F to 254º F) for at least 55 minutes. Dry for 20 to 50 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. • If wet spots on the packaging are observed, the set must be treated as non-sterile and be thoroughly reprocessed.
Storage:	
Additional Information:	

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