



Instructions for Use: Sterility Assurance Dust Covers

Brand Name of Product	Sterility Assurance Dust Covers
Generic Name of Product	Dust Covers
Product Code Number(s)	<ul style="list-style-type: none"> • Heat Seal <ul style="list-style-type: none"> ○ SM0610, SM0812, SM1015, SM1220, SM1622, SM1630, SM2430 • Self-Seal <ul style="list-style-type: none"> ○ SE0610, SE812, SE1015, SE1220, SE1622, SE1630, SE2430
Purpose of Product	<ul style="list-style-type: none"> • Protective plastic bag used to protect items from environmental contamination such as moisture, dust and lint.
Range of Applications for Product	<ul style="list-style-type: none"> • Variety of items that require protection after sterilization.
Key specifications of product	<ul style="list-style-type: none"> • Variety of sizes available.

Shipping & Storage	
Shipping Conditions & Requirements	Sterilized packages should be handled as little as possible
Storage Conditions	Sterility maintenance covers (dust covers) may be used to protect and extend the shelf life of properly packaged and sterilized items that could be subjected to environmental challenges or multiple handling before use. Only products specifically labeled as sterility maintenance covers should be used for this purpose. A sterility maintenance cover or dust cover should be clearly designated as such to prevent its being mistaken for a sterile wrap. Sterility maintenance covers are designed to provide protection against outside elements (e.g., dust), not to provide a microbiological barrier.
Packaging Conditions	
Shelf Life	

Instructions for Using Product	
Description of Use (s)	These dust covers are stronger, but easier to open. They are designed to only tear where and when you want.
Preparation for Use	
Diagrams (drawings, pictures):	
Steps for Use of Product	<ul style="list-style-type: none"> • In order to open you simply grab and pull apart or using both thumbs & index (pointer) finger pinch on either side of the point you wish to tear and pull in opposite directions. • Placed sterilized item into dust cover once cooled after sterilization is completed to enhance sterility maintenance. • Dust cover is sealed using either a heat sealer designed to seal plastic to plastic or an alternative method that is similarly effective; a self-sealing cover also may be used (It will take around 3 minutes for the seal to set up.) <ul style="list-style-type: none"> ○ For optimum heat seal of your easy-tear material, a temperature range between 225°F and 230°F works best.

	<ul style="list-style-type: none"> The lot or load control number and expiration statement should be visible through the sterility maintenance cover of the item that is placed with, or an additional label should be used on the dust cover, placed on the outside. IMPORTANT: Proper handling of supplies is important to ensure a sterile usable product. <ul style="list-style-type: none"> Dust covered items should never be carried under the arms. Dust covered items should never be transported/carried by grabbing / holding the end of the bag during transportation (this action can comprise the seal and cause undue stress and tearing). Proper care and handling of dust covered items should be observed at all times. Carry item in both hands is the recommended practice. Once the seal on the edge is broken the bag will easily tear all the way across.
Interpretation of Results	
Contraindications of Test Results	
Documentation	<ul style="list-style-type: none"> 2012 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST79:2010 & A1 & A2 & A3
Special Warnings and Cautions	<ul style="list-style-type: none"> Applying dust covers soon after sterilization enhances sterility maintenance (item must be cool to the touch). However, placing a sterility maintenance cover on a package that is not cool and dry could result in condensation inside the sterility maintenance cover and, because the sterility maintenance cover is not sterile, contaminate the package contents. To be an effective barrier, the sterility maintenance cover has to be sealed. The sterility maintenance cover is only a protective device; the identity and traceability of the package within has to be maintained. Since dust covers are applied after sterilization, the outer surface of the actual packaging material should be considered contaminated for the purposes of sterile presentation. The principals of event related sterility are followed to ensure that the item inside the sterility maintenance is still sterile.
Disposal	

Reprocessing Instructions	
Point of use:	
Preparation for decontamination:	
Disassembly Instructions:	
Cleaning – Manual:	
Cleaning – Automated:	
Disinfection:	
Drying:	
Maintenance, inspection, and testing:	
Reassembly Instructions:	
Packaging:	
Sterilization:	
Storage:	
Additional Information:	

Related Healthmark Products	
Other Product Support Documents	
Reference Documents	Sterilization Packaging Brochure, Sterilization Packing Price List
Customer Service contact:	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com