healthmark
INDUSTRIES CO.
health care products
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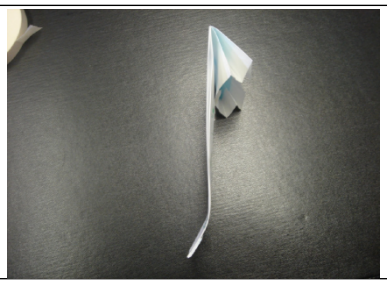
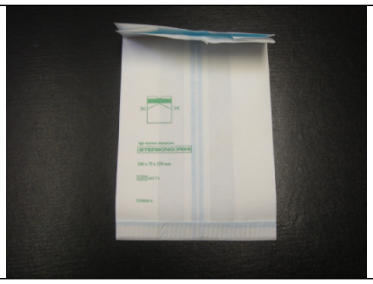
Instructions for Use: Medical Grade Paper Bag

Brand Name of Product	Medical Grade Paper Bag
Generic Name of Product	Medical Grade Paper Bag
Product Code Number(s)	PB1, PB2, PB3, PB4, PB5, PB7, PB8, PB9, PB10, PBR-76, PBTO
Purpose of Product	Hold items in a sterile barrier system
Range of Applications for Product	For use inside a sterile barrier system
Key Specifications of Product	● Manufactured of pure cellulose material. ● Completely permeable to steam sterilant. ● Absorbent paper can help to prevent occurrence of wet pack by wicking away moisture. ● Available in several sizes and configurations

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	N/A
Packaging Conditions	N/A
Shelf Life	5 years from the date of manufacture.

Instructions for Using Product	
Description of Use (s)	Hold items inside a sterile barrier system.
Preparation for Use	N/A
Diagrams (drawings, pictures)	 
Steps for Use of Product	1. Place item(s) inside the appropriate size bag. Item should not protrude out of the bag. 2. Closure – the bags can be left opened or closed depending on your requirements. If closing – fold over about a 1/2 inch making a crease in the bag. 3. A chemical indicator should be placed inside each paper bag. **Note:** Paper bag is not a sterile barrier. **Note:** If using paper bag inside a paper/plastic peel pouch, make sure there is a chemical indicator visible through the plastic side of the pouch.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	Do not seal.
Disposal	Dispose of in compliance with facility policy for sterilization packaging.

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A

Reassembly Instructions	N/A
Packaging	See section "**Steps for Use of Product**" above.
Sterilization	Compatible with steam and EO sterilization. Follow the IFU for a.) the sterilization packaging Mfr., b.) the enclosed device(s)' Mfr., and c.) the sterilizer Mfr. Steam Cycles: ● Standard Cycles: o 121 ºC (250 ºF) 20 minutes o 132 ºC (270 ºF) 4 minutes o 135 ºC (275 ºF) 3 minutes ● Extended Cycle: o Maximum temperature of 135 ºC (275 ºF) to a maximum time of 30 minutes
Storage	N/A
Additional Information	An accordance with ISO 11607

Related Healthmark Products	Time Out Bag, Medical Grade Paper Multi-Pouch Instrument Organizer
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List, Cytotoxicity_Study, Insert for Sample Pack of Paper Bags, Note on Use of Paper Bags in Sterilization Container/Tray, Paper Bag Product Specifications, Paper Bag Sterilization Verification Study (2005), Validation Study for Use of Paper Bags in Trays and Containers
Reference Documents	**ANSI/AAMI ST79: 8.2**: *"Paper-plastic sterilization may be used to protect instruments from damage and/or absorb moisture…"* **ANSI/AAMI ST79 9.5.4**: *"Paper-plastic pouches should not be placed within wrapped set or containment devices unless the practice has been validated by the pouch packaging manufacturer and verified by the product testing in the health carefully"… "Paper-plastic pouches within wrapped sets or containment devices cannot be positioned to ensure adequate air removal, steam contact and drying".*
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