

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	<ul style="list-style-type: none"> • Manufactured of pure cellulose material. • Completely permeable to steam sterilant. • Absorbent paper can help to prevent the 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	Five (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)	N/A
Steps for Use of Product	<ol style="list-style-type: none"> 1. Place item(s) inside the appropriate size bag. (NOTE: The bags can be left open or closed). 2. Chemical indicator should be placed inside each paper bag. (NOTE: Ensure chemical indicator is visible if placing paper bag inside a peel pouch.) 3. Closure – To close, fold over about a ½-inch making a crease in the bag. <p><i>NOTE: Paper Bag alone is not a sterile barrier.</i></p>
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	<p>Compatible with steam and EO sterilization. Follow the IFU for a.) the SBS Mfr., b.) the enclosed device(s)’ Mfr., and c.) the sterilizer Mfr.</p> <p>Steam Cycles:</p> <ul style="list-style-type: none"> • Standard Cycles: <ul style="list-style-type: none"> ○ 121 °C (250 °F) 20 minutes ○ 132 °C (270 °F) 4 minutes

	<ul style="list-style-type: none"> ○ 135 °C (275 °F) 3 minutes. ● Extended Cycle: <ul style="list-style-type: none"> ○ Maximum temperature of 135 °C (275 °F) to a maximum time of 30 minutes.
Storage	N/A
Additional Information	In 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	<p>ANSI/AAMI ST79: 8.2: <i>“Paper-plastic sterilization may be used to protect instruments from damage and/or absorb moisture....”</i></p> <p>ANSI/AAMI ST79 9.5.4: <i>“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.”</i></p>
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