

Standard Textile Co., Inc. Processing Procedure Barrier Supreme Sterilization Wrappers

Indication for Use

Barrier Supreme Sterilization Wrappers are intended to be used to enclose another medical device that is to be sterilized by a health care provider. They are intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Barrier Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Barrier Supreme Sterilization Wrappers are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile sterilization wraps that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

Processing Procedures

Important: Reprocessing instructions to be provided to person(s) responsible for reprocessing (laundry and sterilization) cotton and/or cotton/polyester blended surgical fabrics.

- A. Barrier Supreme Sterilization Wrappers must be laundered prior to use.
- B. Launder them separate from other hospital linen to minimize lint accumulation from other products.
- C. Formula:

	<u>OPERATION</u>	<u>TIME</u>	<u>LEVEL</u>	<u>TEMP.</u>	<u>SUPPLIES/100 LB</u>
1.	Flush	3 Minutes	High	100°F	--
2.	Flush	3 Minutes	High	100°F	--
3.	Break	7 Minutes	Low	160°F	8 oz. Detergent & 8 oz. Alkali
4.	Suds	5-7 Minutes	Low	160°F	4 oz. Detergent
5.	Rinse	2 Minutes	High	140°F	--
6.	Rinse	2 Minutes	High	120°F	--
7.	Rinse	2 Minutes	High	100°F	--
8.	Rinse	2 Minutes	High	90°F	--
9.	Sour	5 Minutes	Low	90°F	Sour to pH of 4.5-5.5

- D. Thorough rinsing is essential to properly remove all surfactants.
- E. After washing, tumble dry at an exhaust temperature of 160°F for approximately 15-20 minutes and an appropriate cool down cycle.

Inspection

Visually inspect wrappers over a light table for stains, lint, holes, etc. and to place a mark on the QCM grid. Discard wrappers when the QCM grid is full (75 uses) or if it has stains that have not been removed with repeated cleaning or has holes and/or tears.

Packaging

Pack assembly should follow established folding, assembly and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. A sequential oblong/envelope wrapping method has been validated for use on textile packs. Closure can include autoclave tape and elastomer closures.

Sterilization

Barrier Supreme Sterilization Wrappers can be steam sterilized in prevacuum steam sterilization cycles with a set temperature of 270°F, an exposure time of 4 minutes and dry time of 15 minutes. If visible moisture is present, packs should not be used and the pack broken down and components reprocessed. The maximum pack size validated for use was 0.58 cubic feet with a pack weight of 23.2 pounds – pack density of 40.0 lbs./cu.ft. The maximum chamber loading configuration included 96 pounds of packs in a 9.1 cubic foot chamber – load density of 10.6 lbs./cu.ft. A 15 minute dry time has been validated for use.

For more information on Barrier Supreme Sterilization Wrappers use, performance and/or processing, please contact the Technical Affairs Department.