



Endure Sterilization Pouches

INSTRUCTION OF USE & STORAGE GUIDELINES

GENERAL INFORMATION

Peel pouches are ideal for sterilizing, handling, and storing small, lightweight, and compact items securely. When designed and used correctly, these sterilization packages provide effective sterilization, secure handling, and safe storage until needed.

PRODUCT DESCRIPTION

Endure self-sealing sterilization pouches are made from medical-grade plastic film and are sealed on three sides. The fourth side features an adhesive strip for secure sealing. The pouches use medical-grade paper that meets established material standards and is compatible with both steam and ethylene oxide gas sterilization methods. The paper includes Process Indicators Ink, which changes color to indicate successful sterilization when exposed to steam or ethylene oxide.

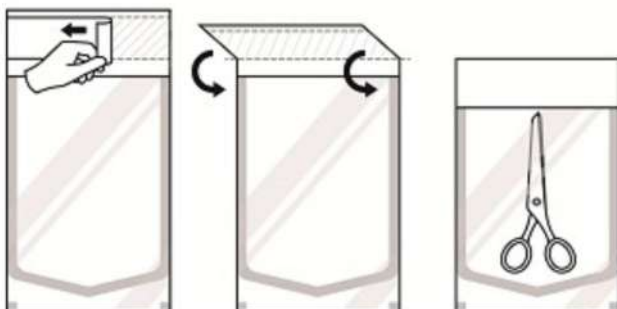
INTENDED USE

Endure sterilization pouches are engineered to help healthcare professionals efficiently prepare items for sterilization using either Steam Sterilizer or Ethylene Oxide (EO) methods. Recommended sterilization cycles include:

- Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 30 minutes.
- Gravity steam at 132°C (270°F) for 15 minutes; Drying time of 30 minutes.
- Gravity steam at 135°C (275°F) for 10 minutes; Drying time of 30 minutes.
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Pre-vacuum steam at 135°C (275°F) for 3 minutes; Drying time of 16 minutes.
- EO sterilization cycle: 4 hours at 55°C (131°F) with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.

INSTRUCTIONS

1. Carefully open the pouch and insert the item.
2. Remove the protective strip from the adhesive band.
3. Fold the paper flap along the perforated line and press firmly from the center outward to seal.





SHELF LIFE

Self-sealing paper pouches can be stored for up to 3 years from the date of manufacture under recommended conditions, prior to sterilization. Healthcare facilities must develop policies to determine the shelf life of sterilized items, considering the quality of packaging material, storage conditions, transport methods, and handling extent. It is advisable to manage inventory on a "first in, first out" basis to ensure efficiency and safety.

MAINTENANCE OF STERILITY

It's imperative for a package to remain sealed to prevent bacterial contamination and enable aseptic presentation of the enclosed product. The sterility of a medical device relies on appropriate packaging, which should be compatible with the device itself, handling procedures, chosen sterilization method, labeling systems, and distribution and storage conditions.

AAMI and AORN recommend event-related rather than time-related sterilization practices. Specific events can compromise the sterility of a package, and these events vary from one facility to another.

Real time aging testing of Endure Sterilization pouches demonstrates that the sterility of the enclosed medical device(s) remains intact for 6 months following steam sterilization and for 36 months following ethylene oxide (EO) sterilization, provided that the integrity of the packaging is preserved. These findings do not suggest that the packaging loses its sterility after the six-month period for steam sterilization or after 36 months for EO sterilization.

LOADING THE AUTOCLAVE/STERILIZER

When placing multiple pouches in the sterilizer, ensure the plastic side of one pouch faces the paper side of the next. This arrangement facilitates proper air evacuation and sterilant penetration. Using a pouch rack is advisable to avoid stacking pouches. Confirm that pouches are dry when removed.

BUILT-IN CHEMICAL INDICATORS - Internal & External

Endure sterilization pouches are equipped with both internal and external chemical indicators. The Class 1 Steam indicators change color from blue to greyish black, while the EO gas indicators shift from pink to yellow. These indicators are stable for up to three years.

While external indicators show that a sterilization cycle has been conducted, they do not guarantee that sterilization has been achieved. Therefore, the CDC advises using an internal chemical indicator in each pack to ensure effective sterilant penetration, a practice implemented in all Endure sterilization pouches.

STORAGE

Store devices at room temperature, ideally not exceeding 24°C (75°F), and maintain humidity between 20-60%, following AORN/AAMI guidelines. AAMI sets a maximum humidity of 60%. ASHE recommends keeping temperatures in sterile storage areas between 22°C to 26°C (72°F to 78°F), with humidity not surpassing 60%.





WRITING ON THE POUCH

AAMI recommends using a non-toxic pen approved for writing on pouches, with all the writing only on the plastic side to prevent contact with the porous paper side, which could compromise the pouch's integrity. While it has been suggested that ink on the paper side may cause leakage, published data on this assertion is minimal or absent.

PEELING METHOD OF STERILIZED POUCH

Open the sterilized pouch slowly and carefully to avoid tearing the material, which could jeopardize the aseptic opening.

Warning - Do not use the contents if the pouch is damaged, moist, or shows signs of potential contamination, as these conditions can compromise sterility.

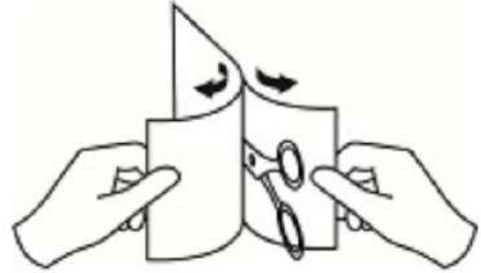


Table 1. Recommended Sterilization Load

Type	Dimension in S.I.	*Content / Max Load (Lbs)		
		Metal	Plastic	Linens & Gauze
Self-Sealing Sterilization Pouches	57 mm x 133 mm	0.11	0.03	0.03
	70 mm x 257 mm	0.39	0.11	0.10
	90 mm x 162 mm	0.30	0.09	0.08
	90 mm x 168 mm	0.32	0.09	0.08
	90 mm x 257 mm	0.57	0.16	0.14
	90 mm x 265 mm	0.59	0.17	0.15
	90 mm x 594 mm	1.35	0.45	0.39
	113 mm x 289 mm	1.00	0.33	0.28
	113 mm x 391 mm	1.43	0.48	0.41
	135 mm x 193 mm	0.67	0.19	0.17
	135 mm x 283 mm	0.99	0.33	0.28
	135 mm x 335 mm	1.20	0.40	0.34
	150 mm x 610 mm	2.08	0.83	0.69
	190 mm x 358 mm	1.75	0.64	0.54
	190 mm x 365 mm	1.79	0.65	0.55
	200 mm x 435 mm	2.00	0.80	0.67
	300 mm x 380 mm	2.48	1.10	0.90
	300 mm x 474 mm	2.63	1.50	1.17
	300 mm x 485 mm	2.70	1.54	1.20
	303 mm x 474 mm	2.66	1.52	1.18
305 mm x 416 mm	2.56	1.28	1.02	
356 mm x 483 mm	2.88	1.92	1.44	
380 mm x 635 mm	3.16	2.53	1.80	
460 mm x 610 mm	3.40	2.83	2.00	





Table 2. Published literature supporting the maintenance of sterility for peel packs is scarce compared to studies conducted on wraps. The table below presents published studies concerning self-seal pouches.

Study Name	Year	Type	Period Tested	Results
Joan, L. S. P., and S. Khor. "Time versus event-related sterility: linen & pouch packaging remain sterile over a year of storage and handling." Singapore Nursing Journal 37.1 (2010).	2010	Steam	12 months	No contamination
Klapes, N. Ariene, et al. "Effect of long-term storage on sterile status of devices in surgical packs." Infection Control & Hospital Epidemiology 8.7 (1987): 289-293.	1987	Steam	12 months	1.6% Contamination
CHOI, Jeong-Sil, and Keun-Soon KIM. "A study for safe storage time and cost analysis for sterilized products." Korean Journal of Nosocomial Infection Control (2004): 131-138.	2004	Steam	6 Month	No contamination
Butt, William E., et al. "Evaluation of the shelf life of sterile instrument packs." Oral surgery, oral medicine, oral pathology 72.6 (1991): 650-654.	1991	Steam	12 months	0.2% Contamination

Fig 1. Seal Description of Self Sealing Pouch

