



Sterilization Pouches

Instructions for Use

Select the appropriate pouch according to your sterilizer, steam or EtO and the size of the instrument(s) being sterilized.

Indications for Use

Vital Care™ Paper Sterilization Pouches and Tubing intended use is for placing a medical device inside a single or double peel pouch configuration, which is to be sterilized by a health care provider using:

- Gravity Steam at 121⁰ C (250⁰ F) for 30 minutes: 25-minute dry time.
- Pre-vacuum Steam at 132⁰ C (270⁰ F) for 4 minutes: 20-minute dry time.
- Pre-vacuum Steam at 134⁰ C (273⁰ F) for 33 minutes: 20-minute dry time.
- Pre-vacuum Steam at 135⁰ C (275⁰ F) for 3 minutes: 16-minute dry time.
- Ethylene Oxide (EO) with concentration of 735 mg/L at 55⁰ C (130⁰ F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60⁰ C (140⁰ F).

The external chemical indicators on the pouch/tubing is intended to confirm that the device has been exposed to the Steam or EO sterilization process and to provide visual confirmation of processed or unprocessed medical devices.

Vital Care™ Low Temperature Sterilization Pouch and Tubing (Tyvek®)

Made of high-density polyethylene (HDPE), Tyvek® is extremely stable when exposed to sterilant gases and high-energy sterilization processes. It is compatible with all of the most commonly used sterilization methods, including ethylene oxide (EO), gamma, electron-beam, steam (under controlled conditions) and low-temperature oxidative sterilization processes. This means that no matter which process you use, Tyvek® will retain its color, flexibility and superior protective properties of microbial barrier and strength. (1)

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The pouches are intended to allow sterilization of the enclosed medical device and to maintain sterility (SAL=10⁰). The subject device has been validated to maintain sterility of the enclosed device for 24 months after EO sterilization.

The maximum validated pouch load is 2.64 pounds (1.2kg).

Low temperature (Tyvek®) pouches may be used for medical products with lumens.

¹DuPont, Tyvek®, Protective, Clean Peel Pouches, <https://www.dupont.com/packaging-materials-and-solutions/protective-clean-peel-pouches.html>, Accessed Sept. 27, 2023

Directions for Use

Vital Care™ Sterilization Pouches and Tubing should be used in accordance with the preparation, packaging and sterilization chamber loading recommendations of the following standards.

- ANSI/AMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- ANSI/AAMI ST41: Ethylene Oxide Sterilization in Health Care Facilities.

Packaging

The pouch should contain a maximum of 75% of the packaging volume to allow proper air evacuation and sterilant penetration.

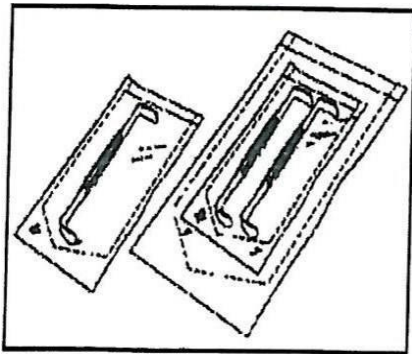
Sealing

Self-Seal Sterilization Pouch

After removing the protective strip, (note the pre-folded flap) seal the pouch by folding the adhesive flap onto the pouch. Apply pressure from the center of the adhesive flap, towards the edges. Repeat the motion an additional time for extra security.

For double pouching, the pouch sizes should be selected so the inner pouch can be placed flat inside the outer pouch without any bending. The inner pouch must also be sealed prior to inserting into larger pouch and the larger pouch must also be sealed after the inner pouch is inside. The paper side of both pouches should face the same way, paper towards paper and film towards film.

Instruments should be placed inside the pouches in accordance with sterile processing policies and procedures. See illustration of single and double packaging of paper-plastic pouches below.



Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities Section 8.3.4/Fig. 8

Heat-Seal Sterilization Pouch

Choose a professional sealing device to ensure proper and consistent seals.

For sterilization tubing, allow for an opening area along the heat-sealed ends of the tubing. The length of the opening

area should be ~ 0.75 to 1.25 in. (~20 to 30mm). If there is any wrinkle in the seal the pouch cannot be used.

If you are double pouching the pouch sizes should be selected so the inner pouch can be placed flat inside the outer pouch without folding. The inner pouch must also be sealed as well as the outer pouch. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.

Seal the pouch with the heat-seal machine according to the appropriate parameters listed in the chart below.

Recommended sealing parameters for;

Paper/Plastic Heat Seal Pouches & Tubing: 225⁰ F – 250⁰ F

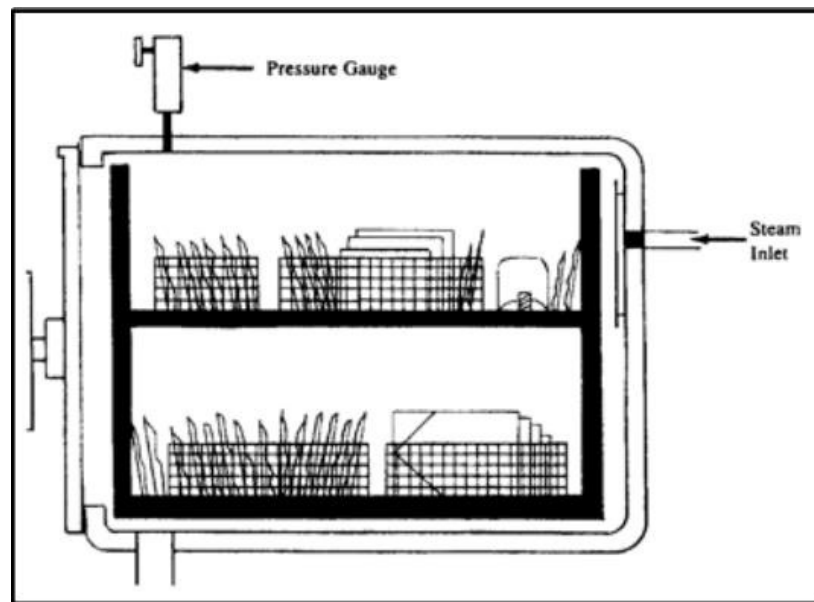
Tyvek™ Heat Seal Pouches/Tubing: 245⁰ F – 270⁰ F

Polyethylene Bags: 225⁰ F – 250⁰ F

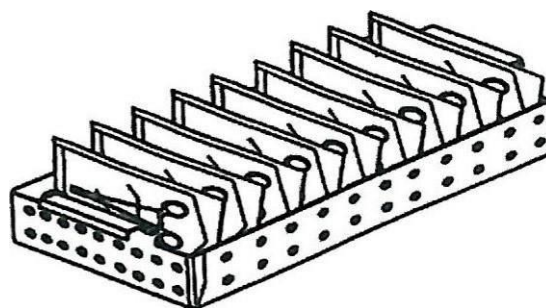
Autopak™ Pouches: 320⁰ F – 340⁰ F

The Rennco Heat Lift Seal™ Heat Sealer automatically makes a 1/2" seal with approximately 30 PSI of consistent sealing pressure. In approximately 2 seconds, the lower safety bar automatically opens for easy removal of the peel pouch.

If sterilizing multiple pouches at once, place pouches in the sterilizer ensuring plastic side of pouch faces paper side of the adjacent pouch. Use pouch racks to prevent stacking of peel pouches. Confirm peel pouches are dry when removed.



Loading paper/plastic peel pouches; wire-type baskets to keep the pouches in place. (Source: ANSIAAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in care facilities 8.5/ Figure 9d)



Paper/plastic peel pouches should be placed on edge (Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Section 8.5/Figure 9e)

Paper Pouch Sterilization Instructions

Sterilizer	Temp	Time	Pressure
Drying Time			
Steam, gravity sterilizer			
25 minutes	250 ⁰ F (121 ⁰ C)	30 minutes	>= 1.2 bar
Steam, pre-vacuum			
20 minutes	270 ⁰ F (132 ⁰ C)	4 minutes	>= 2.1 bar
20 minutes	273 ⁰ F (134 ⁰ C)	3 minutes	>= 2.1 bar
16 minutes	275 ⁰ F (135 ⁰ C)	3 minutes	>= 2.1 bar

After steam sterilization the external indicator changes from pink to brown.

Paper and Low Temperature Pouch EtO Sterilization Instructions

Sterilization Process	Concentration	Temp. Setting	Time
Ethylene Oxide 50% - 80% EO or EtO	735 mg/L	130 ⁰ F (55 ⁰ C)	60 mins.

After EO sterilization the external indicator changes from blue to brown.

Prior to Opening

Inspect package integrity for damage and moisture as well as any potential contamination prior to opening.

Caution: Do not use contents if package integrity has been compromised. Reprocess contents in an unused pouch if the above conditions exist.

Packages should be opened using aseptic technique according to your facility's policy.

Caution

Final sterilization results will vary based on the enclosed instrument's position in the sterilizer. Ensure that all medical devices placed inside Vital Care Sterilization Pouches and Tubing are compatible with and indicated for sterilization using the modality and parameters described in the Instructions for Use. See manufacturer's sterilization instructions of the device to be sterilized.

Some devices may require special packaging configuration or other sterilization considerations. See ANSI/AAMI ST79.

Proper Storage

Storage area should be clean, dust free, and away from fluorescent or ultraviolet light. Room temperature should be 59° F (15° C) to 77° F (25° C) with a relative humidity of 40% to 60%.

The shelf life of a processed pouch is event related upon proper handling and storage conditions.

Pouches stored according to recommended conditions before sterilization have a maximum shelf life of 5 years from the date of manufacture.