

Steri-Wrap® I Sterilization Wrap: Instructions for Use

Steri-Wrap® Sterilization wrap is a disposable single layer non-woven fabric used to maintain the sterility of medical instruments after the sterilization process and during storage. Steri-Wrap® is suitable for either double or sequential wrapping. Steri-Wrap® is for single use only.

Dimensions	Steri-Wrap® I	Steri-Wrap® II	Steri-Wrap® III
12 in. x 12 in.	31101200	*	*
15 in. x 15 in.	31101500	31201500	*
18 in. x 18 in.	*	*	31301800
24 in. x 24 in.	31102400	31202400	31302440
30 in. x 30 in.	*	31203040	*
36 in. x 36 in.	31103620	31203620	31303600
48 in. x 48 in.	31104800	*	31304810
54 in. x 54 in.	*	31205400	31305400

Available sizes and Order Numbers for Steri-Wrap ®

* special order, MOQ applies

Indications for Use

Steri-Wrap® is intended for use to enclose instruments, implants or other medical device that is to be sterilized by

- steam
- ethylene oxide
- gamma radiation
- Steri-Wrap[®] is suitable for pre-vacuum cycles at 121-135°C (250°-275°F) and for gravity cycles at 121°C (250°F).

Warnings

- Steri-Wrap[®] is NOT recommend for use in sterilizers employing, dry heat, chemical vapor, hydrogen peroxide
- Do not use Steri-Wrap® if damage is detected prior to use
- Do not use contents wrapped in Steri-Wrap® if wrap is torn, wet or otherwise damaged

Precautions

- Steri-Wrap® is for single use only and should not be re-used
- Do not open Steri-Wrap® packaging with a sharp knife as it can easily cut the wrap.
- Always ensure that all contents of package intended to be wrapped in Steri-Wrap[®] are compatible with intended sterilization modality and that Steri-Wrap[®] is also validated for the sterilization modality. Consult ANSI/AAMI ST-79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities and ST-41 Ethylene Oxide Sterilization in Health Care Facilities as well as the medical device manufacturer's IFU for any question regarding sterilization modality and compatibility.

Shelf Life and Storage Prior to Sterilization

Shelf life: 60 months from date of manufacture, if stored in original polyethylene packaging in a clean, dry environment.

Storage: Store in a cool, dry place and out of direct sunlight. Store at temperatures below 32°C (90°F) and relative humidity below 70%

Instructions for Use

Steri-Wrap® should be used in accordance with user guidelines for the use of disposable wraps provided in

- ANSI/AAMI ST-79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- ANSI/AAMI ST-41:Ethylene Oxide Sterilization in Health Care Facilities
- Department and Hospital Policies and Guidelines

Steri-Wrap® should be conditioned to room temperature and to relative humidity between 30-60% for at least 2 hours prior to use. The appropriate variant and size should be chosen and inspected for any defect prior to use.

Please see "Wrapping Techniques" section for ANSI/AAMI recommended wrapping techniques and be sure to follow hospital protocols when applicable. Wrap should be secured with indicator tape that corresponds to the sterilization method. For the best possible seal, Steri-Wrap® should be partnered with Propper Manufacturing Co indicator tape.

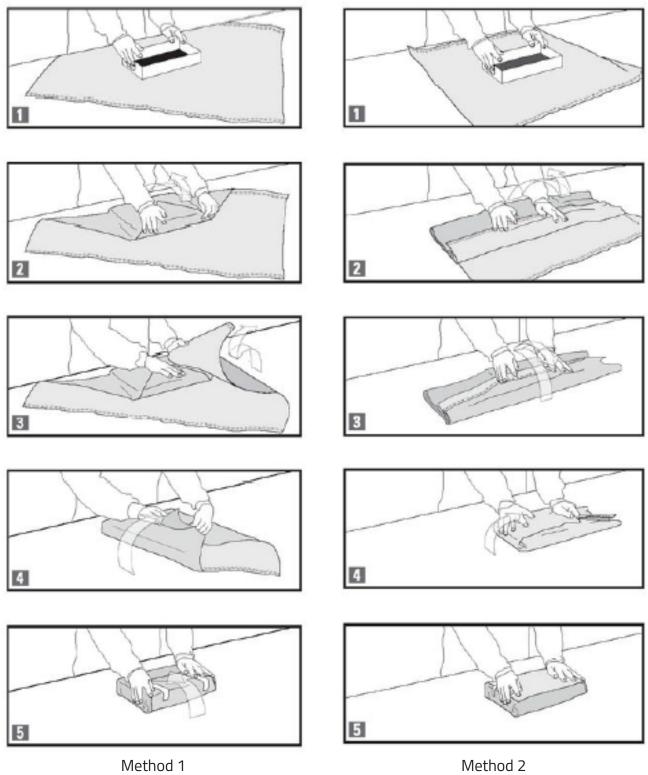
Variants

Variant	Basis Weight (g/m²)	Color	Recommended Use	
Steri-Wrap® I	52	Blue	General use wrap suitable for linen packs, basin sets, instrument and instrument trays	
Steri-Wrap® II	57-58	Green	Softer, more drape-able wrap suitable for large linen packs, basin sets, instruments and instrument trays	
Steri-Wrap® III	59-60	Blue	Strongest wrap, suitable for large linen packs, basin sets, heavy instrument sets and trays.	

Features of Steri-Wrap®

Steri-Wrap[®] is a cellulose based wrap for sterilization in steam, ethylene oxide gas or gamma radiation. All variants of Steri-Wrap[®] provide the following features and benefits.

- Excellent bacterial barrier
- Water and alcohol repellency
- Reversible
- Resistant to linting
- Good drapability
- Latex and Heavy Metal free
- Tested and shown to not cause dermal irritation
- Non-cytotoxic

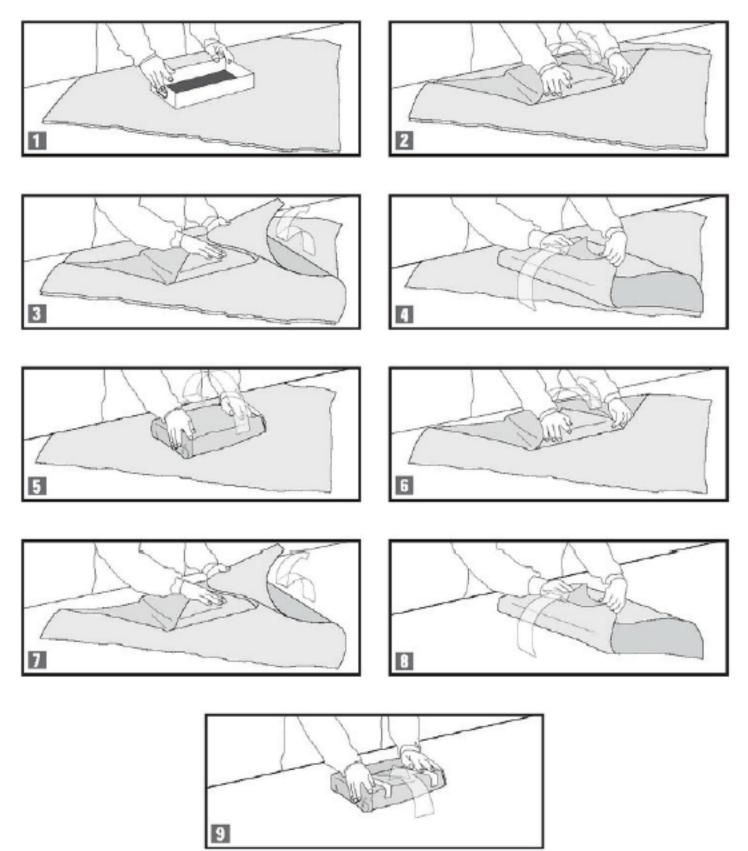


Simultaneous double wrapping: envelope fold

Method 2 Simultaneous double wrapping: square fold

Images obtained from: ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ©2017 Association for the Advancement of Medical Instrumentation, Arlington, VA.

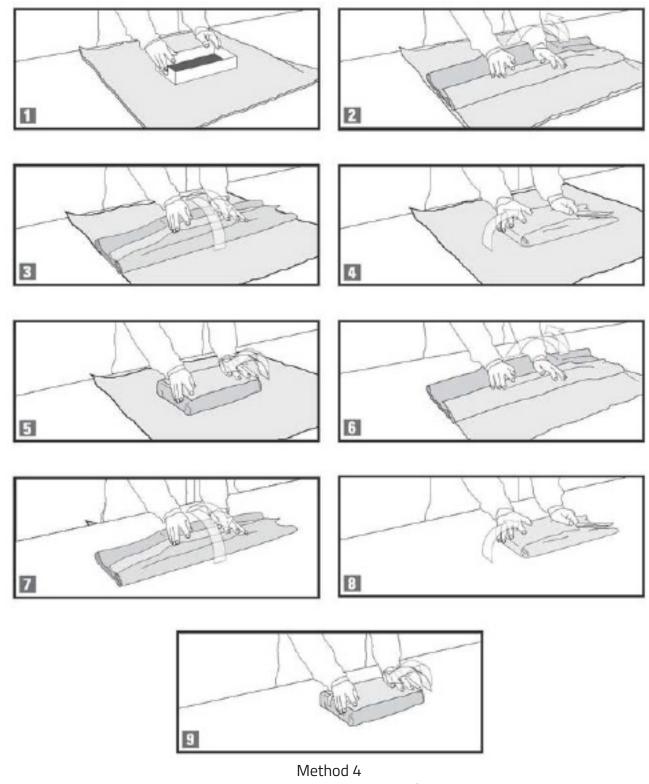
Wrapping Techniques - ANSI/AAMI ST-79: 2017 (continued)



Method 3 Sequential wrapping: envelop method

Images obtained from: ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ©2017 Association for the Advancement of Medical Instrumentation, Arlington, VA.

Wrapping Techniques - ANSI/AAMI ST-79: 2017 (continued)



Sequential wrapping: square fold

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Shelf Life and Storage After Sterilization

As per ANSI/AAMI ST-79, please consult the health care facility policy and procedure for post-sterilization shelf life and storage protocols.

Storage locations should be clean and dust-free and typically follow a first in, first out protocol.

Compliance with International Standards:

Steri-Wrap II, Steri-Wrap III

EN 868-2 Packaging for terminally sterilized medical devices—Part 2: Sterilization wrap- requirements and test methods

ISO 11607-1:2006 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems

Opening and Use of Contents After Sterilization and Storage

Always inspect package for any damage, wetness or tearing prior to using contents to ensure maintenance of sterility. Reprocess the contents prior to use if any sign of damage is identified and sterility could be compromised.

Open packages aseptically in accordance with health care facility policy.

Disposal of wrap

Steri-Wrap® is for single use only and should not be re-used under any circumstances. Steri-Wrap should be disposed of in accordance with facility protocols and state and local guidelines. Steri-Wrap is deemed non-hazardous under the guidelines provided by OSHA Hazard Communication Standard 29 CFR 1910.1200.

Please contact Propper Manufacturing Company if you have any questions:

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