Gemini Sterilization Wrap Products

Directions for Use

Models:

- Lightweight
  - GEM11XX
- Regular Weight
  - GEM21XX
- Medium Weight
  - GEM31XX
- Heavy Weight
  - GEM41XX
- Super Heavy Weight
  - GEM51XX

- SINGLE USE ONLY
- DISPOSABLE

Product Description

Gemini Sterilization Wrap is offered to the marketplace as bulk packages of single ply sheets for use by customers in accordance with standard hospital practices which require that two sheets are used each time a medical device or collections of medical devices are wrapped.

Gemini Sterilization Wrap items are square or rectangular sheets of fabric produced using a five-layer SSMMS (spunbond-spunbond-meltblown-meltblown-spunbond) process.

The Standard blue wrap fabric is made of polypropylene with the addition of less than 2% of Phthalocyanine blue pigmentation and less than 0.35% Titanium Dioxide white pigmentation. The wrap allows for aseptic opening of the sterilized package.

Gemini sterilization wrap is available in sizes ranging from 12x12 to 54x72 across the five different material weights/models listed above.

Indications for Use

Gemini Sterilization Wrap has been validated to preserve sterility and prevent wet packs with intended use in the following sterilization modes and cycles when wrapping medical devices in the healthcare provider environment:

- Pre-vacuum steam cycles
  - 4 Minutes Exposure at 270°F/132°C with the following dry times by weight:
    - GEM11XX minimum 20 minutes
    - GEM21XX minimum 20 minutes
    - GEM31XX minimum 20 minutes
    - GEM41XX minimum 20 minutes
    - GEM51XX minimum 20 minutes

- Gravity steam cycles
  - 30 Minutes Exposure at 250°F/121°C with the following dry times by weight:
    - GEM11XX minimum 20 minutes
    - GEM21XX minimum 20 minutes
Gemini Sterilization Wrap – Directions For Use

- GEM31XX minimum 20 minutes
- GEM41XX minimum 20 minutes
- GEM51XX minimum 20 minutes

- Ethylene Oxide (ETO) Sterilization
  - 60 minutes exposure to 725mg/L of 100% ETO at 131°F/55°C and 40-80% relative humidity followed by 12 hours aeration time.

- STERRAD® Sterilization
  - STERRAD® 100NX
    - Flex scope cycle
    - Standard cycle
    - EXPRESS cycle
  - STERRAD® 100S, Standard cycle
  - STERRAD® NX
    - Advanced cycle
    - Standard cycle

Gemini Wrap is intended to allow for sterilization of the enclosed device(s) and to maintain sterility of such content for 180 days following sterilization.

Warnings

- Do not use wrap if damage or external particulates are identified prior to use.
- Do not use wrapped contents if the wrap is torn, wet, dirty or suspect of mishandling or abuse.
- Do not use Gemini Wrap in sterilization modes or conditions that fall outside the parameters listed in the Indications for Use section. Gemini Wrap is not intended for use in the following sterilization modes or cycles:
  - Dry heat sterilization
  - Radiation (E.g., Gamma, E-Beam or other)
  - Do not use wrap in sterilization cycles that will exceed 300°F/149°C

Precautions

The following are general precautions to be aware relating to Gemini Sterilization Wrap.

- Do not open case packaging with sharp knives to avoid creating accidental cuts in the wrap.
- Prior to being wrapped and sterilized, ensure that contents/devices have been deemed compatible for sterilization in the modes of sterilization identified in the above Indications for Use section. Please consult device manufacturer for appropriate sterilization instructions.
- Complex instruments (e.g., air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized in accordance with instrument manufacturer’s instructions.
- Do not use wrap in the presence of flammable materials. Gemini wrap is a non-conductive material.
- If sterilized by an outside third party, please take appropriate measures to cover and secure the wrapped contents so as to protect against contamination during transport.
**Directions for Use**

Gemini Sterilization Wrap should be used in accordance with all preparation, wrapping and sterilization recommendations provided by the following practice standards:

- ANSI/AAMI ST46: Steam Sterilization & Sterility Assurance in Health Care Facilities
- ANSI/AAMI ST41: Ethylene Oxide Sterilization in Health Care Facilities
- ANSI/AAMI ST77: Containment devices for reusable medical device sterilization
- AORN Standards, Recommended Practices, and Guidelines.

**Storage Conditions Prior to Use**

Prior to being used, Gemini Wrap should be stored in an environment that is:

- Clean
- Dust Free

**Before Use Instructions**

- Wrap should be stored in the following temperature and humidity settings for at least two hours
  - Temperature between 68°F - 73°F / 20ºC - 23ºC
  - Relative Humidity between 30% - 60%
- Visibly inspect wrap sheets for damage or particulates and discard if necessary.
- Ensure that all items being wrapped have been sufficiently cleaned and dried.

**Wrapping Techniques**

Gemini Sterilization Wrap can be used with common wrapping techniques identified in ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. This includes the following methods:

- **Sequential Double Wrapping: Envelope Fold**
  - Make sure to use the appropriate size and material weight.
  - Place item(s) on one sheet and wrap using the above mentioned aseptic wrapping technique.
  - Place this wrapped item on a second sheet and wrap again
  - Seal the wrap in a closed position using the most suitable closure method, most commonly sterilization tape.
  - Appropriately label the package.
  - This wrapping technique allows for sequential opening when items are unwrapped after sterilization.

- **Sequential Double Wrapping: Square Fold**
  - Make sure to use the appropriate size and material weight.
  - Place item(s) on one sheet and wrap using the above mentioned aseptic wrapping technique.
  - Place this wrapped item on a second sheet and wrap again
  - Seal the wrap in a closed position using the most suitable closure method, most commonly sterilization tape.
  - Appropriately label the package.
o This wrapping technique allows for sequential opening when items are unwrapped after sterilization.

o Simultaneous Double Wrapping: Envelope Fold\(^3\)
  o Make sure to use the appropriate size and material weight.
  o Align two sheets of sterilization wrap together.
  o Place item(s) in the middle and wrap both sheets together using above mentioned aseptic wrapping technique.
  o Seal the wrap in a closed position using the most suitable closure method, most commonly sterilization tape.
  o Appropriately label the wrapped items.
  o This wrapping technique allows for items to be opened once when items are unwrapped after sterilization.

o Simultaneous Double Wrapping: Square Fold\(^4\)
  o Make sure to use the appropriate size and material weight.
  o Align two sheets of sterilization wrap together.
  o Place item(s) in the middle and wrap both sheets together using above mentioned aseptic wrapping technique.
  o Seal the wrap in a closed position using the most suitable closure method, most commonly sterilization tape.
  o Appropriately label the wrapped items.
  o This wrapping technique allows for items to be opened once when items are unwrapped after sterilization.

\(^1\)ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Section 8.3.3, Figure 4.

\(^2\)ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Section 8.3.3, Figure 5.

\(^3\)ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Section 8.3.3, Figure 6.

\(^4\)ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Section 8.3.3, Figure 7.
Wrap Selection Recommendations

The below Table 1 identifies the recommended weight that each grade of wrap can support. Please note that all below recommended weights are based on historical usage. Medline recommends that customers follow ANSI/AAMI & AORN practice guidelines which limits overall set weight to a maximum of 25 lbs.

Table 1 – Gemini Wrap Recommended Weight Limits

<table>
<thead>
<tr>
<th>Gemini Wrap Weight</th>
<th>Item number Series</th>
<th>Recommended Use</th>
<th>Max. Recommended Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lightweight</td>
<td>GEM1XXX</td>
<td>Used for light trays, linen packs, small medical devices, and small instruments.</td>
<td>6 Lbs</td>
</tr>
<tr>
<td>Regular Weight</td>
<td>GEM2XXX</td>
<td>Used for packs, light basin sets, instruments, linen packs and trays.</td>
<td>9 Lbs</td>
</tr>
<tr>
<td>Medium Weight</td>
<td>GEM3XXX</td>
<td>Large packs, large medical devices, basin sets, and instruments trays.</td>
<td>13 Lbs</td>
</tr>
<tr>
<td>Heavyweight</td>
<td>GEM4XXX</td>
<td>Heavy instrument sets and multiple basin sets.</td>
<td>17 Lbs</td>
</tr>
<tr>
<td>Super Heavyweight</td>
<td>GEM5XXX</td>
<td>Very large and heavy instrument sets that require extra strength.</td>
<td>25 Lbs</td>
</tr>
</tbody>
</table>

The above recommended weight limits may vary based on facility handling practices, storage conditions, wrapping techniques and sealing methods. Other factors that may cause variance in the above weight limit recommendations are contents of irregular shapes & sizes, sharp edges & areas and sterilizer loading methods. Each facility should establish their own internal practices that identify appropriate wrap use for the intended purposes.

Sterilization Practices

- Gemini Sterilization Wrap is intended for use for the most common sterilization cycle parameters used in healthcare facilities. The Indications for Use section above identifies the parameters that Gemini Wrap has been tested in. Facilities should consult their sterilizer manufacturer to ensure that the equipment is able to regularly achieve such parameters.

- If sterilizer malfunctions or the cycle aborts before completion, devices/contents wrapped in Gemini should be re-wrapped and re-sterilized.

- Sets or items wrapped in Gemini Sterilization Wrap for sterilization should follow the load and stacking configurations identified in ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities."
Post Sterilization Conditioning

- Following completion of a sterilization cycle, it is common for the sterilizer door to be opened slightly and the wrapped contents kept in the sterilizer for up to 30 minutes. Following this, the loading cart should be removed from the sterilizer and be allowed to sit in a controlled environment. Leave the wrapped packages on the cart and do not touch or move them until they cool to room temperature.

- While removing the wrapped packages from the cart, visually inspect them for punctures, tears, wetness or any other irregularities that might compromise package sterility.

- Store wrapped packages in a controlled environment conducive to sterility maintenance.

Shelf Life (Sterility Maintenance)

- Under real time testing, Gemini Wrap is able to maintain package sterility for 180 days in controlled environmental conditions following sterilization. This time point does not prevent users from continuing to practice established healthcare facility protocols.

- Following sterilization, devices/contents wrapped in Gemini Wrap should be stored in environments that are:
  - Clean
  - Dust Free
  - Of temperature between 68ºF - 73ºF / 20ºC - 23ºC
  - Of relative humidity between 30% - 60%

- Medline strongly advises against stacking trays while in post sterilization storage. Such practice can lead to compromising sterility through damage to the wrap material.

- If Sterilization is performed by an outside contract or third party facility, all wrapped devices should be protected from contamination by using an additional covering such as sterility maintenance cover as identified in ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

Opening

- Prior to opening, inspect the wrapped package for damage, wetness or any signs of contamination.
- Open all wrapped packages aseptically in compliance with applicable practice standards such as ANSI/AAMI and AORN practice guidelines.
- Once open, inspect the wrap a second time for damage, wetness or signs of contamination.
- If damaged or contamination is suspected or identified before or after opening, do not use devices/contents of the wrapped package. Reprocess devices/contents in new sheets of wrap.
Disposal

- Gemini Wrap is not intended for re-use. Medline Industries is not responsible for any consequences that may come from re-use of Gemini sterilization wrap after it has already been processed once.
- Facilities should follow the appropriate internal and legal regulation protocols to dispose of soiled wraps after wrapped packages are unwrapped.
- Wrap is made of polypropylene plastic which has a recycling classification code of 5. Do not recycle any soiled wraps. Only clean wraps are eligible for recycling.