

# GEMINI™ STERILIZATION WRAP

## Instructions For Use

### MODELS:

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GEM1 - Light Weight

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GEM2 - Regular Weight

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GEM3 - Medium Weight

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GEM4 - Heavy Weight

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GEM5 - Super Heavy Weight

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Single Use Only  
Disposable

# PRODUCT DESCRIPTION

Gemini Sterilization Wrap is offered to the marketplace as bulk packages of single sheets, where in accordance with standard hospital practices, two sheets are then used to wrap a medical device or a collection of medical devices for sterilization. Gemini Bonded Sterilization Wrap is comprised of two sheets of Gemini Sterilization Wrap ultrasonically sealed on two sides. This allows for convenient wrapping with two sheets simultaneously.

The sheets of sterilization wrap are square or rectangular sheets of fabric produced using multiple layers of SMS (Spunbond-Meltblown-Spunbond) configuration process. The standard blue wrap fabric is made of polypropylene with the addition of less than 2% Phthalocyanine blue pigmentation and less than 0.35% Titanium Dioxide white pigmentation. The blue wrap is available in single and two ply bonded sheet configuration. The two tone wrap is comprised of blue sheet bonded to a pink sheet. The wrap fabric is made of polypropylene with the addition of 2% of Phthalocyanine blue pigmentation, less than 0.5% of Titanium Dioxide white pigmentation and 1.5% of Diazocondensation red pigmentation. The wrap allows for aseptic opening of the sterilized package.

Gemini Sterilization Wraps are available in sizes ranging from 9 in. x 9 in. to 54 in. x 90 in. across five different material weights/models listed in table 1.

**Table 1. Gemini Sterilization Wrap Weights/Models**

Weight	Single Ply	Two Ply Bonded	Two Tone Bonded
Light Weight	GEM11XX (C)	GEM11XXS (C)	GEM11XXT (C)
Regular Weight	GEM21XX (C)	GEM21XXS (C)	GEM21XXT (C)
Medium Weight	GEM31XX (C)	GEM31XXS (C)	GEM31XXT (C)
Heavy Weight	GEM41XX (C)	GEM41XXS (C)	GEM41XXT (C)
Super Heavy Weight	GEM51XX (C)	GEM51XXS (C)	GEM51XXT (C)

# INDICATIONS FOR USE

Gemini Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider; it allows for the sterilization of the enclosed medical device and to maintain sterility of such content until used.

**Pre-vacuum steam at 270°F/132°C for 4 minutes with the following dry times by weight:**

GEM1 – Light Weight	20 Minutes
GEM2 – Regular Weight	20 Minutes
GEM3 – Medium Weight	20 Minutes
GEM4 – Heavy Weight	30 Minutes
GEM5 – Super Heavy Weight	30 Minutes

**Gravity steam at 250°F/121°C for 30 minutes with the following dry times by weight:**

GEM1 – Light Weight	20 Minutes
GEM2 – Regular Weight	20 Minutes
GEM3 – Medium Weight	20 Minutes
GEM4 – Heavy Weight	30 Minutes
GEM5 – Super Heavy Weight	30 Minutes

**Ethylene Oxide (ETO Sterilization)**

60 Minutes exposures to 725mg/L of 100% ETO at 131°F/55°C and 40%-80% relative humidity followed by 12 hours aeration time.

**Table 2. Advanced Sterilization Products STERRAD® Sterilization System – See Appendix –Validated Advanced Sterilization Products (ASP) Cycles**

Gemini Wrap Weight	Gemini Wrap Model	Advanced Sterilization Products STERRAD® Sterilization System Cycles
Light Weight	GEM11XX (C)/ GEM11XXS (C)/ GEM11XXT (C)	STERRAD® 50
Regular Weight	GEM21XX (C)/ GEM21XXS (C)/ GEM21XXT (C)	STERRAD® 100S STERRAD® 200S
Medium Weight	GEM31XX (C)/ GEM31XXS (C)/ GEM31XXT (C)	STERRAD® NX™, (Standard Cycle, Advanced Cycle)
Heavy Weight	GEM41XX (C)/ GEM41XXS (C)/ GEM41XXT (C)	STERRAD® 100NX™, (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle)
Super Heavy Weight	GEM51XX (C)/ GEM51XXS (C)/ GEM51XXT (C)	

**Table 3. STERIS V-PRO® Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles.**

Gemini Wrap Weight	Gemini Wrap Model	STERIS V-PRO® Low Temperature Sterilization Cycles
Light Weight	GEM11XX (C)/ GEM11XXS (C)/ GEM11XXT (C)	V-PRO 60/s2
Regular Weight	GEM21XX (C)/ GEM21XXS (C)/ GEM21XXT (C)	STERIS V-PRO® 1 (Lumen Cycle)
Medium Weight	GEM31XX (C)/ GEM31XXS (C)/ GEM31XXT (C)	STERIS V-PRO® 1 Plus (Lumen and Non-Lumen Cycle)
Heavy Weight	GEM41XX (C)/ GEM41XXS (C)/ GEM41XXT (C)	STERIS V-PRO® maX (Lumen, Non-Lumen, and Flexible Cycle)
Super Heavy Weight	GEM51XX (C)/ GEM51XXS (C)/ GEM51XXT (C)	STERIS V-PRO maX2 (Lumen, Non-Lumen, and Flexible Cycle)

**Table 4. STERIZONE® VP4 Sterilization System – See Appendix – Validated STERIZONE® VP4 Cycles**

Gemini Wrap Weight	Gemini Wrap Model	STERIZONE® VP4 Sterilization System Cycles
Light Weight	GEM11XX (C)/ GEM11XXS (C)/ GEM11XXT (C)	STERIZONE® VP4 Sterilizer single preset sterilization cycle
Regular Weight	GEM21XX (C)/ GEM21XXS (C)/ GEM21XXT (C)	
Medium Weight	GEM31XX (C)/ GEM31XXS (C)/ GEM31XXT (C)	
Heavy Weight	GEM41XX (C)/ GEM41XXS (C)/ GEM41XXT (C)	
Super Heavy Weight	GEM51XX (C)/ GEM51XXS (C)/ GEM51XXT (C)	

## 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 of 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. Consult the sterilization instructions for all devices intended for sterilization. Some medical devices, regardless of the sterilization method and sterilization wrap/container used, may require special consideration in packing configurations to ensure sterilization (refer to ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities).
- Do not use wrap in the presence of flammable materials. The Gemini wrap is non-conductive.
- If sterilization is performed by an outside contract facility, Medline Industries, LP recommends that the wrapped devices should be protected from contamination by an additional covering.

# INSTRUCTIONS FOR USE

Gemini Sterilization Wrap should be used in accordance with all preparation, wrapping, and sterilization chamber loading recommendations of the following standards:

- ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities
- ANSI/AAMI ST41: Ethylene Oxide Sterilization in Healthcare Facilities
- AORN Standards, Recommended Practices, and Guidelines

## GENERAL STORAGE (PRE & POST STERILIZATION)

- Location should be clean, dust free and away from fluorescent or ultraviolet light.
- Use first in, first out (FIFO) stock rotation.
- Refer to ANSI/AAMI and AORN Guidelines for post sterilization storage conditions.

## PRIOR TO USE

- Examine wrap and discard if damage or extraneous matter is detected.
- Thoroughly clean and dry items to be wrapped/packageged.

## COMMON WRAPPING TECHNIQUES

- Place item(s) on wrap using typical aseptic wrapping techniques per ANSI/AAMI ST79: Comprehensive Steam Sterilization and Sterility Assurance in Healthcare Facilities. Recommendations for wrap contents are provided in Table 5.
- If using the simultaneous wrapping technique, ensure the first fold is pulled far enough to cover all package surfaces to ensure sterility maintenance.
- Secure the wrapped packaged with sterilization indicator tape or alternate closure method suitable for the sterilization method to be used.
- Closure must allow the sterilant to penetrate the wrapped package, avoid constriction of the package and maintain package integrity.

**Table 5: Wrap Model Recommendations<sup>1</sup>**

Gemini Wrap Weight	Gemini Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content <sup>2</sup>				
			Pre-Vacuum, Gravity, and EO	ASP STERRAD® 50, 100S, 200S, NX™, and 100NX™ Cycles	STERIS V-PRO® 1, 1Plus, maX2	STERIS V-PRO® 60 S2	STERI-ZONE® VP4 Sterilizer
Light Weight	GEM11XX (C) GEM11XXS (C) GEM11XXT (C)	Light weight package (for example: standard linen packs)	6 lbs.	10.7 lbs.	6.5 lbs.	6 lbs.	6 lbs.
Regular Weight	GEM21XX (C) GEM21XXS (C) GEM21XXT (C)	Light to moderate weight package (for example: general use medical instruments)	9 lbs.	10.7 lbs.	9 lbs.	9 lbs.	9 lbs.

Medium Weight	GEM31XX (C) GEM31XXS (C) GEM31XXT (C)	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs.	10.7 lbs.	10 lbs.	13 lbs.	13 lbs.
Heavy Weight	GEM41XX (C) GEM41XXS (C) GEM41XXT (C)	Heavy weight package (for example: general use medical instruments)	17 lbs.	10.7 lbs.	10 lbs.	17 lbs.	17 lbs.
Super Heavy Weight	GEM51XX (C) GEM51XXS (C) GEM51XXT (C)	Very heavy weight package (for example: general use medical instruments)	25 lbs.	10.7 lbs.	10 lbs.	25 lbs.	25 lbs.

<sup>1</sup> Individual results may differ due to factors such as variations in handling practices, wrapping techniques and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

<sup>2</sup> It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore is recommended to not exceed the number, weight and sizes of individual content types that were validated for the Gemini Sterilization Wrap.

### The following loads were used in the pre-vacuum steam, gravity, and EO Sterility Maintenance Validation Studies:

- Light Weight: 2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.)
- Regular Weight: 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.). 5 lbs. of metal mass.
- Medium Weight: 4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 11 lbs. of metal mass.
- Heavy Weight: 4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 15 lbs. of metal mass.
- Super Heavy Weight: 4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 20 lbs. of metal mass.

### The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® 50, 100S, 200S, NX™, and 100NX™ Sterility Maintenance Validation Studies:

- Light Weight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Regular Weight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Medium Weight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Heavyweight: 23 in. x 11 in. x 4 in tray containing metal instruments.
- Super Heavyweight: 23 in. x 11 in. x 4 in tray containing metal instruments.

### The following loads were used in the STERIS V-PRO® Sterility Maintenance Validation Studies:

- Light Weight: 2.5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- Regular Weight: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- Medium Weight: 6 lbs. metal mass, 6 forceps,

- STERIS V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- Heavyweight: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (21 in. x 10 in. x 3 ½ in.) at 5 lbs.
- Super Heavyweight: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (21 in. x 10 in. x 3 ½ in.) at 5 lbs

**The following loads were used in STERIS V-PRO® 60/s2 Sterility Maintenance Validation Studies:**

- Lightweight: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.
- Regular Weight: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.
- Medium Weight: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.
- Heavyweight: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.
- Super Heavyweight: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.

**The follow loads were used in STERIZONE® VP4 Sterility Maintenance Validation Studies:**

- Lightweight: Symmetry Medical – MicroPack® Plastic Tray (15 in. x 10 in. x 1.5 in.), metal and non-metal instruments to make final total weight recommended above.
- Regular Weight: Symmetry Medical – MicroPack® Plastic Tray (15 in. x 10 in. x 1.5 in.), metal and non-metal instruments to make final total weight recommended above.
- Medium Weight: SteriPack Metal Tray (23 in. x 11 in. x 5 in.), metal and non-metal instruments to make final total weight tested recommended above.
- Heavyweight: SteriPack Metal Tray (23 in. x 11 in. x 5 in.), metal and non-metal instruments to make final total weight tested recommended above.
- Super Heavyweight: SteriPack Metal Tray (23 in. x 11 in. x 5 in.), metal and non-metal instruments to make final total weight tested recommended above.

# STERILIZATION PRACTICES

- Gemini Sterilization Wraps are intended for use with the common healthcare sterilization parameters listed in the Indications for Use. The sterilizer manufacturer should be consulted for appropriate sterilizer loading configurations.
- If a sterilizer malfunctions or a cycle is aborted before completion, packages should be re-wrapped prior to being placed into another sterilization cycle.
- Sets or items wrapped in Gemini Sterilization Wrap for sterilization should follow the load and stacking configurations identified in ANSI/AAMI ST79: Comprehensive Steam Sterilization and Sterility Assurance in Healthcare Facilities.

NOTE: Many factors can affect drying time other than sterilization wrap, such as the pack configuration that is used, sterilizer loading, cycle variations, the performance of the sterilizer, temperature, altitude, and ambient environmental conditions. Sterilizers vary widely in design and performance characteristics. As recommended in the ANSI/AAMI guidelines on steam sterilization, the user should consult the sterilizer manufacturer's operator manual for specific drying times.

## POST STERILIZATION COOLING/UNLOADING

- Leave wrapped packages on the sterilizer cart untouched until cool to avoid compromising package sterility.
- Visually inspect wrapped items as they are removed from the cart. Items that are torn, wet, or compressed should not be used.

## STERILITY MAINTENANCE

- Under real time testing, Gemini Wrap is able to maintain package sterility for the following durations in controlled environmental conditions following sterilization. These durations do not prevent users from continuing to practice established healthcare facility protocols.
- The wrap is intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of such content until used.
- A facility will either practice time dating or event-related sterility for a wrapped instrument set, post sterilization. Per ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities the shelf life of facility sterilized items is event-related and should be based on the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount of conditions of handling. Inventory should be rotated on a "first in, first out" basis. The facility policy should be based on the guidance provided in ANSI/AAMI ST79: 2017, 11.1.3. If the facility practices time dating, please reference table 6 below for the appropriate appropriate post sterilization shelf life.

**Table 6: Gemini Wrap Sterility Maintenance**

Sterilization Modality	Shelf Life
Pre-Vacuum & Gravity Steam	2 Years
Ethylene Oxide (ETO)	1 year
STERRAD® 50, 100S, 200S, NX™, and 100NX™ Cycles	1 Year
STERIS V-PRO® 1, 1Plus, maX, V-PRO 60/s2	1 Year
STERIS V-PRO® maX/maX2 (Lumen, Non-Lumen, and Flexible Cycles)	1 Year
STERIS V-PRO® 60/60s (Lumen, Non-Lumen, and Flexible Cycles)	1 Year
STERIZONE® VP4	1 Year

## OPENING

- Inspect package for damage, moisture, or any sign of potential contamination prior to opening and again after opening, but before use of contents. **Caution: Do not use contents if these conditions are present, as sterility could be compromised.** Reprocess the contents using an unprocessed wrap if any of these conditions are noted.
- Open packages aseptically in accordance with the healthcare facility's policy.

## DISPOSAL

- Do not re-use. Medline Industries, LP does not endorse the re-use (re-sterilization) of its sterilization wrap and does not warrant performance if product is re-used.
- Recycle, landfill or incinerate used wrap based upon state and local regulations. Only recycle non-soiled wraps.
- Note that the wrap is composed of polypropylene plastic which has a plastics recycling code of "5".

## APPENDIX:

**Note:** Refer to the User's Guide for complete instructions on load and cycle for each Sterilizer System below. The instructions provided below are not intended to replace the detailed Instructions for Use provide with each sterilizer system.

### Validated Advanced Sterilization Products (ASP) STERRAD® 50, 100S, 200S, STERRAD® NX™, and STERRAD® 100NX™ Cycles

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 50	<p>Reusable metal and non-metal medical devices, including to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>· An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens.</li> <li>· An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.</li> <li>· An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> <li>· An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON®/Polyethylene lumens.</li> </ul> <p>Refer to the STERRAD® 50 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per load).</p>
STERRAD® 100S	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>· An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens.</li> <li>· An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.</li> <li>· An inside diameter of 3mm or larger and length of 400 mm or shorter of single-channel stainless steel lumens.</li> <li>· An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON-Polyethylene lumens.</li> </ul> <p>Refer to the STERRAD® 100 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per load).</p>
STERRAD® 200S	<p>Reusable metal and non-metal medical devices, including to 12 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>· An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens.</li> </ul>

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 200S	<ul style="list-style-type: none"> <li>• An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON®/Polyethylene lumens.</li> </ul> <p>Refer to the STERRAD® 200S Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 36.48 lbs. per load).</p>
STERRAD® NX™ Standard Cycle	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> </ul> <p>Refer to the STERRAD® NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs. per load).</p>
STERRAD® NX™ Advanced Cycle	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1 mm or larger and length of 500 mm or shorter of single-channel stainless steel lumens.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• One Single-Channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain:</li> <li>• A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.</li> </ul> <p>Refer to the STERRAD® NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs. per load).</p>
STERRAD® 100NX™ Standard Cycle	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle).</li> </ul> <p>Refer to the STERRAD® 100NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 21.4 lbs. per load).</p>
STERRAD® 100NX™ Flex Cycle	<p>One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain:</p> <ul style="list-style-type: none"> <li>• A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle).</li> </ul> <p>Refer to the STERRAD® 100NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 12.2 lbs. per load).</p>

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 100NX™ Express Cycle	<p>Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaced such as the hinged portion of forceps and scissors, and rigid or semi-rigid endoscopes without lumens.</p> <p>Refer to the STERRAD® 100NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs. per load).</p>
STERRAD® 100NX™ DUO Cycle	<p>One or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain:</p> <ul style="list-style-type: none"> <li>· A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter.</li> <li>· Accessory devices that are normally connected to a flexible endoscope during use.</li> <li>· Flexible endoscopes without lumens.</li> </ul> <p>Refer to the STERRAD® NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs. per load).</p>

## Validated STERIS V-PRO® Low Temperature Sterilization Systems Pre-programmed Cycle

V-PRO Cycle	Intended Load
V-PRO maX/maX2 Flexible Cycle	<ul style="list-style-type: none"> <li>· Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>· Single or dual lumen surgical flexible endoscopes (such as those used in ENT, urology and Surgical Care) and bronchoscopes in either of the two configurations:               <ul style="list-style-type: none"> <li>◦ Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load. The flexible endoscopes may contain single or dual channel lumens that are <math>\geq 1</math> mm ID and <math>\leq 1050</math> mm L</li> <li>◦ One flexible endoscope with a light cord (if not integral to the endoscope) and mat and additional non-lumened instruments. The flexible endoscope may contain single or dual channel lumens that are <math>\geq 1</math> mm ID and <math>\leq 1050</math> mm L                   <ul style="list-style-type: none"> <li>· Additional instruments may include non-lumened medical devices with the following configurations:                       <ul style="list-style-type: none"> <li>· Single, dual or triple channel stainless steel lumen that is <math>\geq 0.48</math> mm ID and <math>\leq 100</math> mm in length.</li> </ul> </li> </ul> </li> </ul> </li> <li>· Refer to the V-PRO maX/maX2 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>
V-PRO maX/maX2 Lumen Cycle	<ul style="list-style-type: none"> <li>· Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>· Medical devices (including single, dual and triple channeled rigid and semirigid endoscopes) with the following configurations:               <ul style="list-style-type: none"> <li>◦ Single, dual or triple channel stainless steel lumen that are:                   <ul style="list-style-type: none"> <li>· <math>\geq 0.77</math> mm ID and <math>\leq 527</math> mm in length</li> <li>· <math>\geq 0.8</math> mm ID and <math>\leq 542</math> mm in length</li> <li>· <math>\geq 0.48</math> mm ID and <math>\leq 100</math> mm in length</li> </ul> </li> <li>◦ Dead end lumen that is <math>\geq 1.3</math> mm ID and <math>\leq 73</math> mm in length</li> <li>◦ Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) that are:                   <ul style="list-style-type: none"> <li>· <math>\geq 3</math> mm ID and <math>\leq 298</math> mm in length</li> <li>· <math>\geq 4</math> mm ID and <math>\leq 424</math> mm in length</li> </ul> </li> </ul> </li> <li>· Refer to the V-PRO maX/maX2 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>


<p>V-PRO maX/maX2 Non-Lumen Cycle</p>	<ul style="list-style-type: none"> <li>· Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>· Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.</li> <li>· Refer to the V-PRO maX/maX2 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>
<p>V-PRO 60/s2 Flexible Cycle</p>	<ul style="list-style-type: none"> <li>· Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>· One surgical flexible endoscope (such as those used in ENT, Urology and Surgical Care) or bronchoscope with light cord (if not integral to the endoscope), mat, and additional load. <ul style="list-style-type: none"> <li>◦ The flexible endoscope may be a single or dual lumen device with lumens that are <math>\geq 1</math> mm ID and <math>\leq 990</math> mm in length</li> </ul> </li> <li>· Additional load, up to 11 lb that can include stainless steel lumens with the following dimensions. <ul style="list-style-type: none"> <li>◦ <math>\geq 0.76</math> mm ID and <math>\leq 233</math> mm L</li> <li>◦ <math>\geq 1.0</math> mm ID and <math>\leq 254</math> mm L</li> <li>◦ <math>\geq 2</math> mm ID and <math>\leq 400</math> mm in L</li> </ul> </li> <li>· Refer to the V-PRO 60/s2 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>
<p>V-PRO 60/s2 Lumen Cycle</p>	<ul style="list-style-type: none"> <li>· Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>· Medical devices (including single, dual and triple channeled rigid and semirigid endoscopes) with the following configurations: <ul style="list-style-type: none"> <li>◦ Single or dual channeled devices with stainless steel lumens that are: <ul style="list-style-type: none"> <li>· <math>\geq 0.77</math> mm ID and <math>\leq 410</math> mm in length</li> </ul> </li> <li>◦ Triple channeled devices with stainless steel lumens that are either: <ul style="list-style-type: none"> <li>· <math>\geq 1.2</math> mm ID and <math>\leq 275</math> mm in length</li> <li>· <math>\geq 1.8</math> mm ID and <math>\leq 310</math> mm in length</li> <li>· <math>\geq 2.8</math> mm ID and <math>\leq 317</math> mm in length</li> </ul> </li> </ul> </li> <li>· Refer to the V-PRO 60/s2 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>
<p>V-PRO 60/s2 Non-Lumen Cycle</p>	<ul style="list-style-type: none"> <li>· Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>· Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.</li> <li>· Refer to the V-PRO 60/s2 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>

STERIS® System and Cycle	Intended Load
STERIS® V-PRO® 60 Lumen Cycle	<p>Reusable metal and non-metal medical devices including instruments with diffusion-restricted spaced (such as the hinged portion of forceps or scissors) and single, dual or trip channeled rigid/semi-rigid endoscopes, with the following configuration:</p> <ul style="list-style-type: none"> <li>· Single or dual channeled devices with stainless steel lumens with <ul style="list-style-type: none"> <li>◦ An inside diameter of 0.77 mm or larger and a length of 410 mm or shorter</li> </ul> </li> <li>· Trip channeled devices with stainless steel lumens with <ul style="list-style-type: none"> <li>◦ An inside diameter of 1.2 mm or larger and a length of 257 mm or shorter</li> <li>◦ An inside diameter of 1.8 mm or larger and a length of 310 mm or shorter or</li> <li>◦ An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter</li> </ul> </li> <li>· Refer to the V-PRO 60 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>
STERIS® V-PRO® 60 Flexible Cycle	<p>Single or dual channeled Flexible Surgical Endoscopes or Bronchoscopes with lumens that have:</p> <ul style="list-style-type: none"> <li>· An inside diameter of 1 mm or larger and a length of 990 mm or shorter</li> <li>· Refer to the V-PRO 60 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</li> </ul>
STERIS® V-PRO® 60 Non-Lumen Cycle	<p>Reusable metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid, and flexible endoscope and medical devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps or scissors. Refer to the V-PRO 60 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions.</p>

## Validated STERIZONE® VP4 Sterilizer Single Preset Sterilization Cycle

STERIZONE® VP4 Sterilizer	Intended Load
STERIZONE® VP4 Sterilizer Single Preset Sterilization Cycle	<p>General medical instruments, representing the following geometries:</p> <ul style="list-style-type: none"> <li>· Gliding mechanism, hinges, and screws, stopcock, instrument with rigid lumen (no dead end)</li> </ul> <p>Single channel flexible endoscopes with:</p> <ul style="list-style-type: none"> <li>· Internal channel diameter of 1 mm or larger and length of 850 mm or shorter</li> </ul> <p>Single/Double Channel rigid endoscopes with:</p> <ul style="list-style-type: none"> <li>· Internal channel diameter of 0.7 mm or larger and length of 500 mm or shorter</li> </ul> <p>Refer to STERIZONE® VP4 Sterilizer User's Guide for complete instructions on load(s), including chamber loading instructions.</p>

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