



GEMINI[®] TITAN[™] STERILIZATION WRAP

Instructions For Use

MODELS:

GEMTITANXXT – Titan Weight

Single Use Only
Disposable

PRODUCT DESCRIPTION

Gemini® Titan™ Sterilization Wrap is offered to the marketplace as bulk, non-sterile packages of two sheets of SMS ultrasonically seamed on two sides. This allows for convenient wrapping with two sheets simultaneously. It is used to wrap a medical device or a collection of medical devices for sterilization.

The two tone wrap is comprised of a blue sheet bonded to a pink sheet. The wrap fabric is made of polypropylene with the addition of less than 1% blue or pink color pigmentation. The wrap allows for aseptic opening of the sterilized package.

Gemini Titan Sterilization Wrap is available in Titan Weight in sizes ranging from 36 in. x 36 in. to 54 in. x 54 in. All sizes are listed in Table 1.

Table 1. GEMINI® TITAN™ Dimensional Specifications, Wrap Weights/Models

Weight	Two Tone Bonded
Titan Weight	GEMTITANXXT - 36 in. x 36 in. - 40 in. x 40 in. - 45 in. x 45 in. - 48 in. x 48 in. - 54 in. x 54 in.

INDICATIONS FOR USE

Gemini Titan Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. Gemini Titan Sterilization Wrap is validated for use in the following pre-vacuum steam sterilization cycle.

Table 2: Steam Pre-Vacuum Sterilization

Wrap Weight	Gemini Titan Model	Sterilization Cycle	Wrap Model Recommendations ¹	
			Intended Load	Maximum Recommended Wrapped Package Content
Titan Weight	GEMTITANXXT	Pre-vacuum steam at 270°F/132°C for 4 minutes with 30 minute dry time	Very heavy weight packages (for example: large orthopedic sets)	25 lbs

The following loads were used in the pre-vacuum steam sterilization Sterility Maintenance Validation Study:

Titan Weight: 5 lb Sterilization Tray (22.8 in. x 11.1 in. x 3.8 in.) was loaded with evenly dispersed instruments and additional medical devices throughout, to achieve a total combined weight, with load and wrap, of twenty-five (25) pounds.

1. 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.

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 Titan Sterilization Wrap.

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 Titan Wrap in sterilization modes or conditions that fall outside the parameters listed in the Indications for Use section.
- Gemini Titan Wrap is not intended for use in the following sterilization modes or cycles:
 - Dry Heat Sterilization
 - Radiation (E.g., Gamma, E-Beam or other)

PRECAUTIONS

The following are general precautions to be aware of relating to Gemini Titan 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 Titan 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 Titan 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*
- *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/packaged.

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.

STERILIZATION PRACTICES

- Gemini Titan Sterilization Wrap is 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 Titan 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 accelerated testing, Gemini Titan 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 (i.e. event related sterility practices).

Table 3: Gemini Titan Wrap Sterility Maintenance

Sterilization Modality	Shelf Life
Pre-Vacuum Steam	2 years

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".



Non sterile



Single use only.



Consult instructions for use.



Not made with Natural Rubber Latex.

www.medline.com

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