INSTRUCTION FOR USE

DOUBLE LAYER TWO-COLOR STERILIZATION WRAPS & SINGLE LAYER STERILIZATION WRAPS

Single Use Only & Disposable

Product Description

VIVIT Supply Phoenix Sterilization Wraps are made of high-quality SMS (spunbond-meltblown-spunbond) polypropylene, combining strength and superior filtration capabilities to provide a barrier to protect medical devices from contamination. VIVIT Supply materials offer a smooth finishing pattern to reduce friction on skin and are highly drapeable, allowing for an easy aseptic presentation.

Available in a variety of sizes and types, there is a convenient option to meet various sterilization needs in alignment with standard hospital practices:

- VIVIT Supply Phoenix Single Layer Sterilization Wraps (S) are supplied to the customer as bulk packages of single sheets. Two sheets are then used to wrap a medical device or a collection of medical devices for sterilization.
- VIVIT Supply Phoenix Double Layer Two-color Sterilization Wraps (F2) are made of two sheets in different colours ultrasonically seamed together.

TABLE 1: DIMENSIONAL SPECIFICATIONS OF THE WRAPS

Model*	V100		V200		V300		V400		V500		V600	
Type	F2	S	F2	S	F2	S	F2	S	F2	S	F2	S
12” x 12”	•	•	•	•								
15” x 15”	•	•		•								
18” x 18”	•	•	•	•	•	•	•	•	•	•		
20” x 20”	•	•										
24” x 24”	•	•	•	•	•	•	•	•	•	•		
30” x 30”	•	•	•	•	•	•		•	•	•		
36” x 36”	•	•	•	•	•	•	•	•	•	•	•	•
40” x 40”	•	•	•	•	•	•	•	•			•	•
45” x 45”	•	•			•	•	•	•	•	•	•	•
48” x 48”	•	•		•	•	•	•	•	•	•	•	•
54” x 54”	•	•			•	•	•	•	•	•	•	•
60” x 60”									•			
54” x 72”		•		•	•	•	•		•	•	•	•
54” x 90”	•				•				•		•	

**package is color-coded by model*

VIVIT Supply LLC
200 Continental Dr., Suite 401
Newark, DE 19713 USA

W vivitsupply.com

Indication For Use

The VIVIT Supply Phoenix Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider via the following:

- Pre-Vacuum Steam at 270°F/ 132°C for 4 minutes. The wrap has been validated for dry time of 20 minutes for P100 and P200 and dry time of 30 minutes for P300, P400, P500 and P600.
- 100% Ethylene Oxide Sterilization with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. Validated for aeration times of 8 hours at 55°C or 12 hours at 43.3°C.
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2 and STERIS V-PRO 60/s2 low temperature Sterilization Systems.
- Advanced Sterilization Products STERRAD 100S system.
- Advanced Sterilization Products STERRAD NX [Standard Cycle, Advanced Cycle].
- Advanced Sterilization Products STERRAD 100 NX [Standard Cycle, Flex Cycle, Express, Duo Cycle].

VIVIT Supply Phoenix Sterilization Wraps are available in 6 models and different sizes ranging from 12” X 12” to 54” X 90” and are intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) for a maximum of 180 days or until used. VIVIT Supply Phoenix Sterilization Wraps are validated for use with above listed sterilization systems with the intended loads as described below.

TABLE 2: MAXIMUM RECOMMENDED WRAPPED PACKAGE CONTENTS

Model	Intended Load	Maximum Recommended Wrapped Package Contents		
		Pre-Vacuum Steam and EO	ASP STERRAD® 100S, 100NX, NX	STERIS V-PRO®
V100	Very light weight package. For example, light handle covers or towel packs.	3 lbs	3 lbs	3 lbs
V200	Light weight package. For example, standard linen packs.	6 lbs	6 lbs	6.5 lbs
V300	Light to moderate weight package. For example, general use medical instruments.	9 lbs	9 lbs	9 lbs
V400	Moderate to heavy weight package. For example, general use medical instruments.	13 lbs	10.7 lbs	12 lbs
V500	Heavy weight package. For example, general use medical instruments.	17 lbs	10.7 lbs	12 lbs
V600	Very heavy weight package. For example, general use medical instruments.	25 lbs	10.7 lbs	12 lbs

VIVIT Supply Phoenix Sterilization Wraps are validated for Pre-Vacuum Steam and ETO sterilization with two 3 mm x 400 mm lumen devices as part of the load.

VIVIT Supply Phoenix Sterilization Wraps are validated for ASP STERRAD 100 S sterilization with 10 stainless lumens (2 mm ID x 250 mm length) as part of their load.

VIVIT Supply Phoenix Sterilization Wraps are validated for use with STERIS V-PRO cycles and intended loads as listed below (see next page):

V-PRO maX/maX2 Non-Lumen Cycle:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

V-PRO maX/maX2 Lumen Cycle:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Single, dual, or triple channelled stainless steel lumen that are:
  - ≥ 0.77 mm ID and ≤ 527 mm in length.
  - ≥ 0.8 mm ID and ≤ 542 mm in length.
  - ≥ 0.48 mm ID and ≤ 100 mm in length .
- Dead end lumen that is ≥ 1.3 mm ID and ≤ 73 mm in length
- Rigid non-metallic lumen that are:
  - ≥ 3 mm ID and ≤ 298 mm in length.
  - ≥ 4 mm ID and ≤ 424 mm in length.

PRO maX/maX2 Flexible Cycle:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- 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:
  - Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain:
    - Single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length
  - One flexible endoscope with a light cord (if not integral to the endoscope) and mat and additional instruments. The flexible endoscope may contain:
    - Single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length
    - Additional load, up to 24 lbs (11 kg) can include lumened or non-lumened medical devices: single, dual, or triple channel stainless steel lumens ≥ 0.48 mm ID and ≤ 100 mm in length

VPRO 60/s2 Non-Lumen Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

VPRO 60/s2 Lumen Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Medical devices (including single, dual, and triple channelled rigid and semi-rigid endoscopes) with the following configurations:
  - Single or dual channelled devices with stainless steel lumens that are:
    - ≥ 0.77 mm ID and ≤ 410 mm in length
    - ≥ 1.8 mm ID and ≤ 542 mm in length

- Triple channelled devices with stainless steel lumens that are either:
  + ≥ 1.2 mm ID and ≤ 275 mm in length
  + ≥ 1.8 mm ID and ≤ 310 mm in length or
  + ≥ 2.8 mm ID and ≤ 317 mm in length

VII-PRO 60/s2 Flexible Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- 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.
  - The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length
  - Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions:
    + ≥ 0.76 mm ID and ≤ 233 mm in length
    + ≥ 1.0 mm ID and ≤ 254 mm in length
    + ≥ 1.8 mm ID and ≤ 542 mm in length

The VIVIT Supply Phoenix Sterilization Wraps are validated with ASP STERRAD 100 NX and ASP STERRAD NX and ASP STERRAD 100s sterilization cycles and intended loads detailed below:

STERRAD 100NX Standard cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter. (A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle).

STERRAD 100NX Flex Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including most flexible endoscopes, with the following materials and dimensions:
  - Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 1065 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load).

STERRAD 100NX Express Cycle:

- Instruments surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including rigid or semi-rigid endoscopes without lumen.

STERRAD 100NX DUO Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including most flexible endoscopes, with the following materials and dimensions:
  - Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter.
    + Accessory devices that are normally connected to a flexible endoscope during use.
    + Flexible endoscopes without lumens.

STERRAD NX Standard cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors and up to 10 lumens of followings:
  - Single channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 150 mm or shorter.
  - Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 400 mm or shorter.

STERRAD NX Advanced Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Single channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 500 mm or shorter (up to 10 Lumen per load).
- Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscope with an inside diameter of 1 mm or larger and length of 1065 mm or shorter (no additional load).

STERRAD 100s:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Metal and nonmetal lumened instruments with inside diameter of 6 mm or larger and length of 310 mm or shorter.
- A single stainless-steel lumen with an inside diameter of 3 mm or larger and a length of 400 mm or shorter.

General Directions for Use

VIVIT Supply Phoenix Sterilization Wraps are designed to meet the requirements of the following standards:

- ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- ANSI/AAMI ST41: Ethylene Oxide Sterilization in Health Care Facilities
- AORN Standards, Recommended Practices, and Guidelines
- EN 868-2
- ISO 11607-1

Prior to Use

- Store wrap at room temperature and humidity for at least two hours before use.
- Inspect wrap for any irregularity, damage or extraneous particulate. Discard if any of these are detected.
- Ensure devices are adequately cleaned and dried before wrapping.

Wrap Selection Recommendations

Table 2: Maximum Recommended Wrapped Package Contents (see page 2) outlines the maximum recommended load for each material weight in different sterilization methods. Additional factors such as facility handling practices, storage conditions, wrapping methods, sealing methods, content shape or size, and sterilizer loading may influence the tolerable weight limits. Facilities should develop departmental instructions for use indicating appropriate wraps for each medical device and intended load.

Wrapping Techniques

VIVIT Supply Phoenix Sterilization Wraps are compatible with common wrapping methods. It is recommended to refer to consensus standards such as ANSI/AAMI ST79 Section 19 for wrapping instructions.

Sterilization Practices

- VIVIT Supply Phoenix Sterilization Wraps are intended for use with the common healthcare sterilization cycle parameters. The Indications for Use outlines the parameters VIVIT Supply Phoenix Sterilization Wraps were validated with. It is recommended to consult with the sterilizer manufacturer for appropriate sterilizer loading configurations.
- If a sterilizer malfunctions or a cycle is aborted before completion, wrapped contents should be re-wrapped and re-sterilized.
- The validated drying times with pre-vacuum steam sterilization are 20 minutes for V100 and V200 and 30 minutes for V300 to V600.

Disclaimer: The drying time may be affected by many factors such as device loading configuration, sterilization machine loading configuration, sterilizer performance, variations in cycle, temperature distribution, steam generation, altitude and ambient environmental conditions. See medical device manufacturer and sterilizer manufacturer MIFUs for guidance on dry times.

Post Sterilization Recommendations

- After sterilization, leave packages on the sterilizer cart until they are cooled to room temperature. It is recommended wrapped packages are not touched or moved until cooled.
- As wrapped items are removed from the sterilizer cart, carefully inspect each wrapped package for signs of damage. Any wrap with physical damage or signs of moisture should not be used.
- Special care and attention should be given when removing packages from shelves. It is recommended to use shelf liners for storing wrapped packages.

Sterility Maintenance

- Real time testing with VIVIT Supply Phoenix Sterilization Wraps supports maintenance of package integrity and sterility for 180 days after pre-vacuum steam, EO, STERIS V-PRO and STERRAD sterilization. This shelf life is event related and users should follow established healthcare facility protocols.

Opening

- Follow the health care facility's policy for transport and handling of sterile packages.
- Before opening, examine the package for damage, wetness, or any sign of potential contamination. If these conditions are found, sterility could be compromised and the contents should not be used. Re-sterilize contents with a new wrap.
- Once opened, inspect the wrap again for any damage, wetness or potential contamination. Ensure sterilant penetration was effective by reviewing the internal sterilization indicator.
- Follow the healthcare facility's practices for opening the packages aseptically.

Disposal

- VIVIT Supply Phoenix Sterilization Wraps are single use products and are not intended for re-use. VIVIT Supply is not responsible for any resulting consequences from re-use of VIVIT Supply Phoenix Sterilization Wraps.
- Soiled wraps should be disposed of according to facilities' internal and legal regulations protocols.
- Clean VIVIT Supply Phoenix Sterilization Wraps are eligible for recycling under the recycling classification code of 5 for polypropylene plastic. Soiled wraps are ineligible for recycling.

General Storage Recommendations

- Store unused wraps in a clean, dust free environment and protect from fluorescent or ultraviolet light.
- Use standard first in, first out (FIFO) stock rotation practices.
- For post sterilization storage conditions refer to guidelines in standards such as ANSI/AAMI and AORN.

Warnings

- Do not use wrap if there are signs of damage or external particulates found before use.
- Do not use in the incompatible sterilization methods of dry heat or radiation sterilization.
- Do not use the contents of a wrapped package if it is damaged or mishandled.
- Do not use in the presence of flammable anesthesia or materials. The wrap is anti-static and non-conductive.

Precautions

- It is recommended to avoid the use of sharp knives when opening wrap packaging since knives may cut a wrap.
- Before wrapping, please consult medical device sterilization instructions to ensure they are compatible with and sterilizable by the sterilization modality and cycle listed above in the Indications for Use.
- Certain medical devices may require additional attention for their loading configuration prior to wrapping. See medical device manufacturer MIFUs for guidance on loading configurations.
- When sterilization takes place at an external facility, additional care and measures are recommended to protect and secure wrapped packages during transport. Follow the health care facility's policy for transport and handling of sterile packages from an external source.