Suresafe®

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# Sterilisation Wraps Standard - 47GSM

Sterilisation Wraps are intended to be used to enclose another medical device that is to be sterilised by a healthcare provider. It is intended to allow sterilisation of the enclosed medical device and also to maintain sterility of such content under storage.

Sterilisation Wraps has been validated to preserve sterility and prevent wet packs with intended use in the following sterilisation modes and cycles in the healthcare provider environment using moist heat steriliser (saturated steam).

## INSTRUCTIONS FOR USE

1. The **Suresafe Sterilisation Wrap** has been validated and demonstrated a minimum of 6 months shelf-life for the sterile barrier system's performance.

2. Healthcare facilities (HCF) shall assess the sterile barrier system's shelf life according to AS5369 and their internal policies, procedures, risk assessments, storage and handling of the processed products for event related sterility.

**PRE-VACUUM STEAM CYCLE**
Validated at 270°F/134°C for 4 minutes, dry time 20mins (the dry time is a "minimum", and will need to be adjusted in the real environment.

**GRAVITY STEAM CYCLE**
30 minutes exposure at 250°F/121°C with dry times depending on the weight and items processed per the HCF's validation study.

**ETHYLENE OXIDE**
100% ethylene oxide 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 for EO sterilisation of 8 hours at 55°C or 12 hours at 43.3°C.

**HYDROGEN PEROXIDE ($H_2O_2$) LOW TEMPERATURE**
2 injections at 140°F/60°C using Steriplas 2000 Hydrogen Peroxide Gas Plasma steriliser.

**ASP STERRAD STERILISATION SYSTEM**
- STERRAD 100S
- STERRAD NX [Standard Cycle, Advanced Cycle]
- STERRAD 100NX [Standard, and Duo Cycles]

**STERIS V-PRO LOW TEMPERATURE STERILISATION SYSTEMS**
The wrap was validated to be effectively aerated during the pre-programmed cycles.
-STERIS V-PRO 60 (Lumen, Non-Lumen, and Flexible Cycles)
-STERIS V-PRO 1 (Lumen Cycle)
-STERIS V-PRO1 Plus (Lumen and Non-Lumen Cycle)
-STERIS V-PRO maX (Lumen, Non-Lumen, and Flexible Cycle)
-STERIS V-PRO maX 2 (Lumen, Non-Lumen, and Flexible Cycle)

## PERFORMANCE AND COMPLIANCE

**Suresafe Sterilisation Wraps** are designed to meet the requirements of the following standards:

**- ISO TS 16775** Packaging for terminally sterilised medical devices - Guidance on the application of **ISO 11607-1** and **ISO 11607-2**.

**- EN 868-2** Packaging for terminally sterilised medical devices, sterilisation wrap, requirements, and test methods

**- ISO 11607-1:** Packaging for terminally sterilised medical devices; Requirements for materials, sterile barrier systems and packaging systems.

**- AS5369** Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

## WARNINGS/PRECAUTIONS

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 suspected of mishandling or abuse.

Do not use **Suresafe Sterilisation Wrap** in sterilisation modes or conditions that fall outside the parameters listed in the Instructions for Use section.

**Suresafe Sterilisation Wrap** is not intended for use in the following sterilisation modes or cycles:

- Dry heat sterilisation or Radiation (E.g., Gamma, E-Beam or other)
- Do not use wrap in sterilisation cycles that will exceed 300°F/149°C

If a serious incident has occurred in relation to the device, it should be reported to **Sentry Medical** and the competent authority of the Member State.

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 sterilisation instructions to ensure they are compatible with and sterilisable by the sterilisation modality and cycle listed above in the Instructions for Use.

Certain medical devices may require additional attention for their loading configuration prior to wrapping. See medical device manufacturer IFUs for guidance on loading configurations.

When sterilisation takes place at an external facility, additional care and measures are recommended to protect and secure wrapped packages during transport.

Follow the healthcare facility's policy for transport and handling of sterile packages from an external source.

Do not use wrap in presence of flammable materials. **Suresafe Sterilisation Wrap** is a non-conductive material.

## STORAGE REQUIREMENTS PRIOR TO USE

Location should be:
1. Clean
2. Dust free
3. Away from fluorescent or ultraviolet light

Use first in, first out (FIFO) stock rotation.

**SIZE:** _____ REF

**QTY:** _____ LOT


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RECYCLE ME

At Sentry, we are dedicated to upholding sustainable principles to safeguard our planet, people, and future, and we strive to consistently act responsibly in doing so.

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