

STERISHEET STERILIZATION WRAPS

STERISHEET 160 SOFT

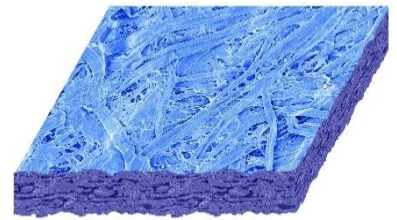


DESCRIPTION

Sterisheet sterilization wraps are high quality Sterile Barrier Systems for CSSDs in hospitals and clinics.

Our production is 100% healthcare dedicated.

STERISHEET CREPE AND SOFT CREPE are original wrapping materials offering the best bacterial barrier and the most cost effective and environmental friendly solution.



COMPOSITION

Belongs to family of products made of > 95 % cellulose

SUITABLE FOR THE FOLLOWING STERILIZATION METHODS:

- Steam
- EO
- Low temperature
- Steam Formaldehyde (LTFS)

APPLICATION

For small and medium-size trays, light packs, instrument kits

Weight: up to 3 kg (for double layer packaging).

Inner wrap for reusable containers.

SIZES AVAILABLE

The following are standard sizes available for all our customers' needs. Choose standard sizes to optimize your costs. Other sizes are also available upon request.

- | | | |
|------------|------------|----------|
| 60x60 cm | 75x75 cm | 90x90 cm |
| 100x100 cm | 120x120 cm | |

RECOMMENDATIONS:

- ✓ Use double wrapping and benefit from color coding
- ✓ Save your time with interleaved products
- ✓ In order to resist weight and handling constrains, use reinforced and nonwoven material as an outer wrap

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COLORS



PRODUCT PROPERTIES:

Mechanical protection and bacterial barrier properties are tested carefully. Our internal laboratory provides complex tests on all of our products. Together with tests conducted by external independent laboratories we secure the best possible results on Sterisheet products.

Mechanical Properties

Preservation of pack integrity from closure till the point of use depends on the materials resistance to tearing, puncturing, breaching stresses generated all along the distribution, handling and storage with the hospital. Any mechanical weaknesses will increase the risks of event related ingress of microorganism into the pack. Excellent mechanical properties will provide you additional safety while using our materials. Optimal strength and resistance provided in every sheet.

Bacterial Properties

Sterilization wraps must prevent microorganisms' ingress inside the package.

To reach this performance, different types of testing have to be performed on the products to reproduce both kind of ingress vehicles possible:

- Airborne ingress
- Waterborne ingress

What are the benefits of Sterisheet Crepe:

- ✓ Excellent bacterial barrier performance
- ✓ High water repellency
- ✓ High environmental scoring
- ✓ The best price – quality ratio

PROPERTIES	TYPICAL
Substance	60 g/m ²
Thickness (Bulky material)	240 µm
Tensile strength MD	2.10 kN/m
Tensile strength CD	1.30 kN/m
Burst Strength	150 kPa
Tearing strength MD	900 mN
Tearing strength CD	1000 mN

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COMPLIANCE TO STANDARDS

Sterisheet products range is classified as a Class I Medical Device according to the European Medical Device Regulation (MDR 2017/745/EU). Its CE marking illustrates the relevant compliance.

Sterisheet products conform with standards below:

EN ISO 11607-1

EN 868-2

OUR WRAPS MANUFACTURING THIRD PART CERTIFICATION

ISO 13485 standard

PACKAGING PRIOR TO USE

Sheet display is optimized by adjusted folding depending on the size and type of the product. We have tested carefully the best solution to ensure the most convenient handling for end users.

- PRIMARY TRANSPORT PACKAGING

Number of sheets is maximized and wrapped in transparent polyethylene bag with quick product ID.

- SECONDARY TRANSPORT PACKAGING

Secondary packaging is a neutral brown color cardboard box providing transportation stress resistance.

LABELLING

Product traceability is fully insured through labelling according to regulations on each transport packaging.

STORAGE CONDITIONS

Sterimed recommends the following storage conditions for best performance of sterilization wraps: Storage in a cool, dry location away from direct exposure to natural light, strong artificial light & UV sources. Cardboard boxes should never be stored in direct contact with the floor. Storage of the products shall be done in areas that are not subject to extreme temperature changes such as in contact with heated objects, vents or cold walls.

As per AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities" recommendations: Before use, holding packaging materials at room temperature (20°C to 23°C) and at a relative humidity ranging from 30% to 60% for a minimum of 2 hours is a good practice for optimum use performances.

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USE BY DATE

Provided the above storage conditions are met, the upper limit of the time interval during which the performance characteristics of the sterilization wrap are demonstrated is 5 years of the manufacturing date.

ENVIRONMENTAL IMPACT & WASTE MANAGEMENT

STERIMED Infection Control is committed to the protection of the environment and the communities it belongs to.

STERISHEET 160 SOFT > 95 % renewable content

Wood pulp used for production is sourced from renewable sustainable well managed forest sources.



Disposal as per local regulations after use.