



STERISHEET™ DUO

Sterilization Packaging Materials



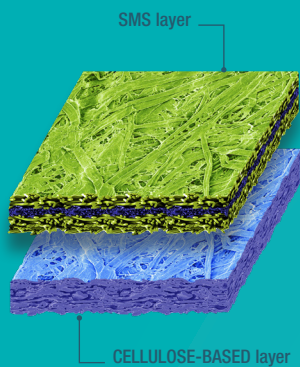
STERISHEET™
by STERIMED



AT STERIMED, WE UNDERSTAND EVERYDAY CHALLENGES IN CSDs

- > Mistakes are unforgivable, time is unmerciful...
- > Surgeons, patients and their relatives all rely on you.
- > Reach out for the best sterilization wraps that bring more confidence to your daily work.

STERISHEET™ DUO A STATE-OF-THE-ART STERILIZATION WRAP:



What is Sterisheet™ Duo?

2 LAYERS THERMALLY SEALED:

Combination of SMS and Cellulose.

The best product features taken from SMS and a cellulose-based wrap combined in one. DUO concept is patented solution provided in 3 different strength levels:

- > Sterisheet™ Duo 1
- > Sterisheet™ Duo 2
- > Sterisheet™ Duo 3



**DID YOU
KNOW?**

STERISHEET™ DUO2 a unique concept only available from STERIMED, combining SMS layer with Reinforced Crepe. Material developed and tested by STERIMED and used in many CSSDs.

MAIN CHARACTERISTICS OF THE PRODUCT



High performance bacterial barrier

Better bacterial filtration thanks to cellulose and high mechanical strength thanks to SMS.



Wet pack prevention

Cellulose helps to reduce or prevent wet pack issues.



Two-layer packaging

Double-layer packaging secures the best possible bacterial barrier.



Time-saving quick folding

Choose envelope, square folding and save half the time for double wrapping.



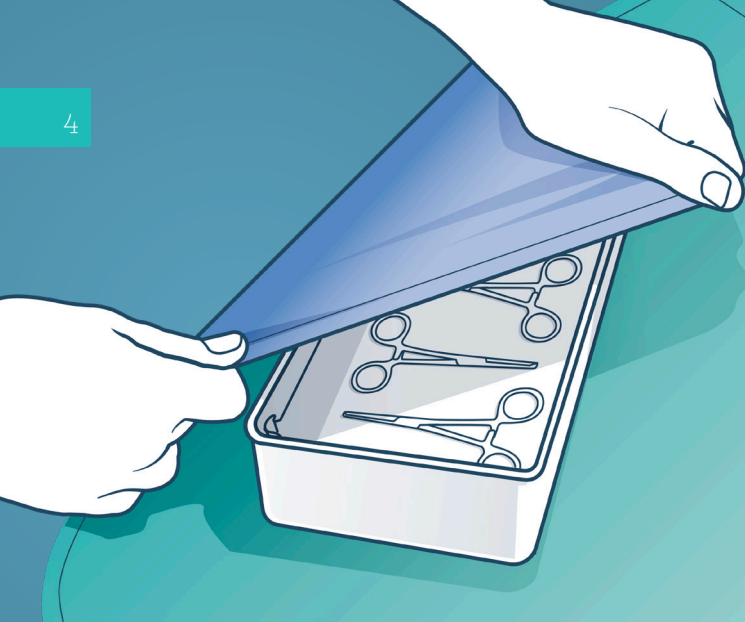
Renewable content

Sterisheet™ Duo consists of one layer of cellulose-based product. With one layer of cellulose-based material the renewable content is increased compare to standard sealed products on the market using 2 SMS layers.



**DID YOU
KNOW?**

For manufacturing of STERISHEET™ DUO, we use only raw materials that meet our highest quality standards (EN 868-2, EN ISO 11607-1).



OUTER LAYER

Sterisheet™ SMS products are made of 100% synthetic polypropylene fibers.

- > Spunbond • Meltblown • Spunbond
- > Spunbond layers consist of endlessly long, strong and thick virgin polypropylene yarns.
- > Meltblown layers are made of short and thin virgin polypropylene microfibers.

Only the meltblown (M-layer) thickness determines barrier properties and not the number of meltblown layers (SMS, SMMS, SMMMS).



DID YOU
KNOW?

For effective barrier properties, Sterisheet™ recommends using a meltblown ratio in SMS of no less than 15%.



INNER LAYER

Our selection of cellulose based materials.

Soft Crepe Paper

> 100% wood pulp material
Original wrapping material, softness and excellent bacterial barrier.

Reinforced 50%

> A Unique material only available from Sterimed
> Wood pulp and synthetic fibers
Higher fluid repellence, drapeability and strength for demanding wrapping.

Nonwoven

> 80% wood pulp and synthetic surface binders
An affordable combination of drapeability and softness with excellent mechanical strength for even more.

All Sterisheet™ materials are EN 868-2 and EN ISO 11607-1 certified by independent bodies and third-party laboratories. (Certificates and test reports are available upon request for tender bids.)



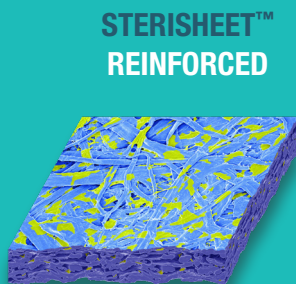
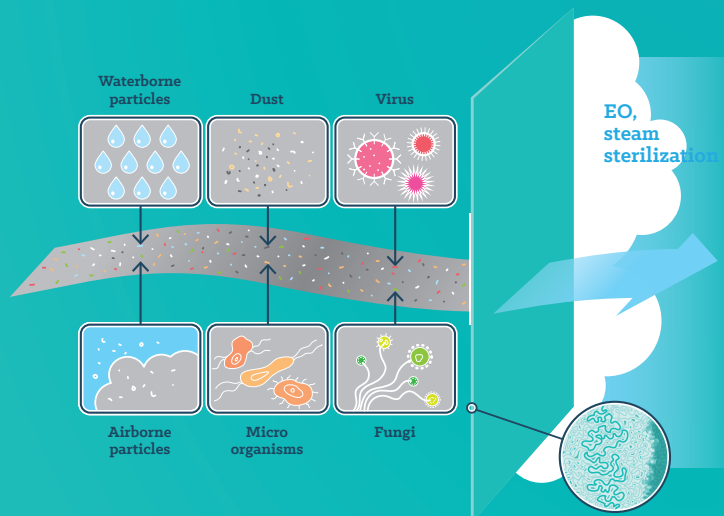
DID YOU
KNOW?

Mechanical and bacterial barrier properties are internally tested on a routine basis according to regulatory requirements & risk management. Combining them with random tests & routine tests conducted by external and accredited laboratories allows Sterimed to guarantee the best performance with Sterisheet™ products.

WHY DO WE RECOMMEND STERISHEET™ DUO?

1 Excellent bacterial barrier properties

Cellulose-based materials provide higher bacterial filtration performance compared to other wrapping materials like those using two SMS layers. The use of SMS as external layer, provides excellent protection to transport and storage constraints in hospital use.



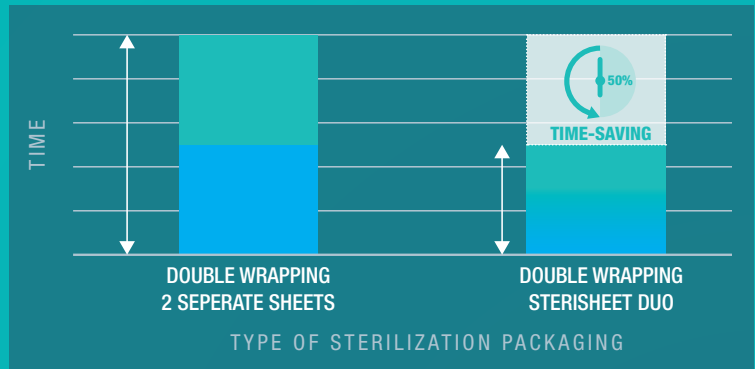
2 Wet pack prevention

Wet pack is one of the main issues in current sterilization packaging practices. Residual water inside the packaging being considered as a potential contamination vector. A layer of cellulose-based material used as an inner wrap is always a better answer to wet packs than two layers of SMS - 100 % Polypropylene. Cellulose based materials facilitate heat exchange, reduce condensation risks, and has structural absorption properties.



3 Bonded products save time during wrapping

With Sterisheet™ DUO you can save significant time during wrapping (and unwrapping). Double wrapping is accomplished in half the time compared to two separate layers.



4 Selection of grades for different strength levels

Choose the right sterilization packaging according to the weight and size of tray to be packed. You should also consider transport and storage conditions and we recommend focusing on worst-case scenario.

Sterisheet™ DUO is available in 3 different versions (110 gsm, 115 gsm and 120 gsm).



DID YOU KNOW?

Higher grammage doesn't mean the best solution for all configurations. If wet pack is a risk, DUO1 and DUO 2 may represent the appropriate answer. If no specific risk with wet packs but loss of sterility risk linked to transport and storage conditions, then DUO 3 will be the right combination.

PRODUCT NAME	DESCRIPTION	GSM
STERISHEET™ DUO 1	160 Soft Green / 340 SMS Blue	100
STERISHEET™ DUO 2	260 Reinforced Blue / 355 SMS Green	115
STERISHEET™ DUO 3	357 NW Green / 363 SMS Blue	120

Note: The higher the number used in the product name (from Duo 1 to Duo 3), the higher the total weight of the product.

5 Bioburden control warranty

At Sterimed level bioburden control gives you additional confidence that you are doing the maximum to protect your patients' and hospital staffs' health.

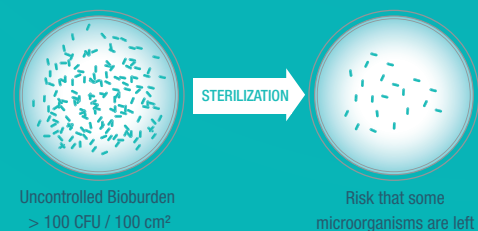


DID YOU KNOW?

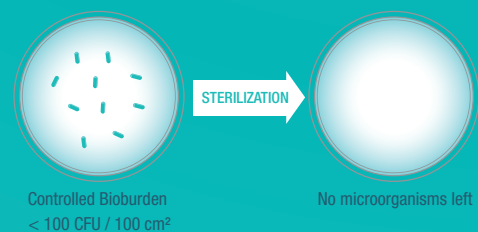
Bioburden is defined as the estimated quantity of viable microorganisms on a medical product before sterilization.

Sterimed has put in place regular bioburden control to reduce to the greatest extent potential contamination from the packaging material and improve the efficiency of the sterilization process.

UNCONTROLLED SHEETING CONDITIONS



STERISHEET™ SHEETING CONDITIONS



6 Event-related sterility maintenance

According to EN ISO 11607-1, the aim of sterilization packaging is to maintain the sterility of medical device until the point of use.

The Sterisheet™ DUO range has been tested and validated in a detailed study at Lille Teaching Hospital (France). Objective of the study was sterility maintenance performance under real hospital conditions including long distance transport and multiple hand lings in storage.

As was also confirmed by the mentioned study Sterisheet™ DUO guarantees a shelf life of at least, minimum 12months after sterilization. The study is available upon request.

WHAT IS ON OUR CHECK LIST WHEN CHOOSING STERILIZATION PACKAGING FOR CSD?

REQUIERMENT	WHAT DOES IT MEAN?	ON MY CHECK LIST	STERISHEET™ PRODUCTS ANSWER THE NEED
CONFORMITY TO NORMS AND STANDARDS	Sterilization packaging as a class 1 medical device must fully comply with all respective norms and regulations. Your supplier is able to provide all necessary certificates and test reports from independent laboratories.	✓	✓
MECHANICAL BARRIER	Resistance to tears, bursts or other mechanical damage in wet and dry conditions.	✓	✓
BACTERIAL BARRIER	Prevention of microorganism ingressio into the pack. Maintain content sterility.	✓	✓
EASY TO USE	Softness, low linting, easy folding and drapeability features.	✓	✓
WET PACK PREVENTION	Wet pack issues are not caused by the type of packaging material. However appropriate sterilization packaging helps with wet pack prevention.	✓	✓
INSTRUCTIONS FOR USE (IFU)	Comprehensive IFU provided by the manufacturer. Clearly states all conditions for storage, usage and handling.	✓	✓
CLINICAL EVALUATION	Sterilization wraps are tested and validated through hospital trials including post sterilization shelf life.	✓	✓

STERIMED, YOUR INFECTION CONTROL PARTNER

- Largest range of sterilization packaging substrates in the world
- Sales in more than 70 countries
- Packaging education programmes for the medical device industry and hospital staff

COMPLIANCE

Our products are compliant with strict regulations and standards, ensuring maximum protection for patients and hospital staff.

Our products conform with:

- EN ISO 11607-1:2017
- EN868-2:2017

We follow:

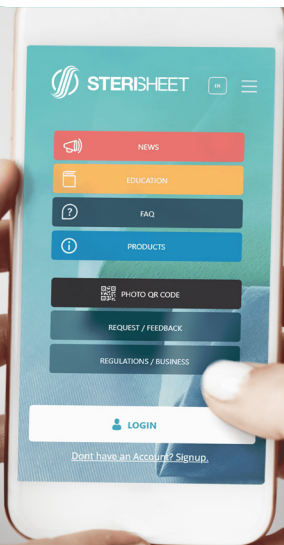
- Risk management
- Quality control
- ISO 13485 standards
- ISO 50001



PATIENT SAFETY FORUM EDUCATIONAL SEMINAR

We help hospital and sterilization centre professionals to share knowledge and gain a better understanding of materials used to sterilize medical instruments in CSSDs.

www.patient-safety-forum.com



GET STERISHEET™ APP

A new platform for education, product selection and communication with STERISHEET™ experts. Direct access to:

- Instruction for use
- Technical data
- Product properties
- Frequently asked questions

Take advantage of online tools for product's replenishment, samples ordering and troubleshooting.



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CONTACT US
contact@sterimed.fr

