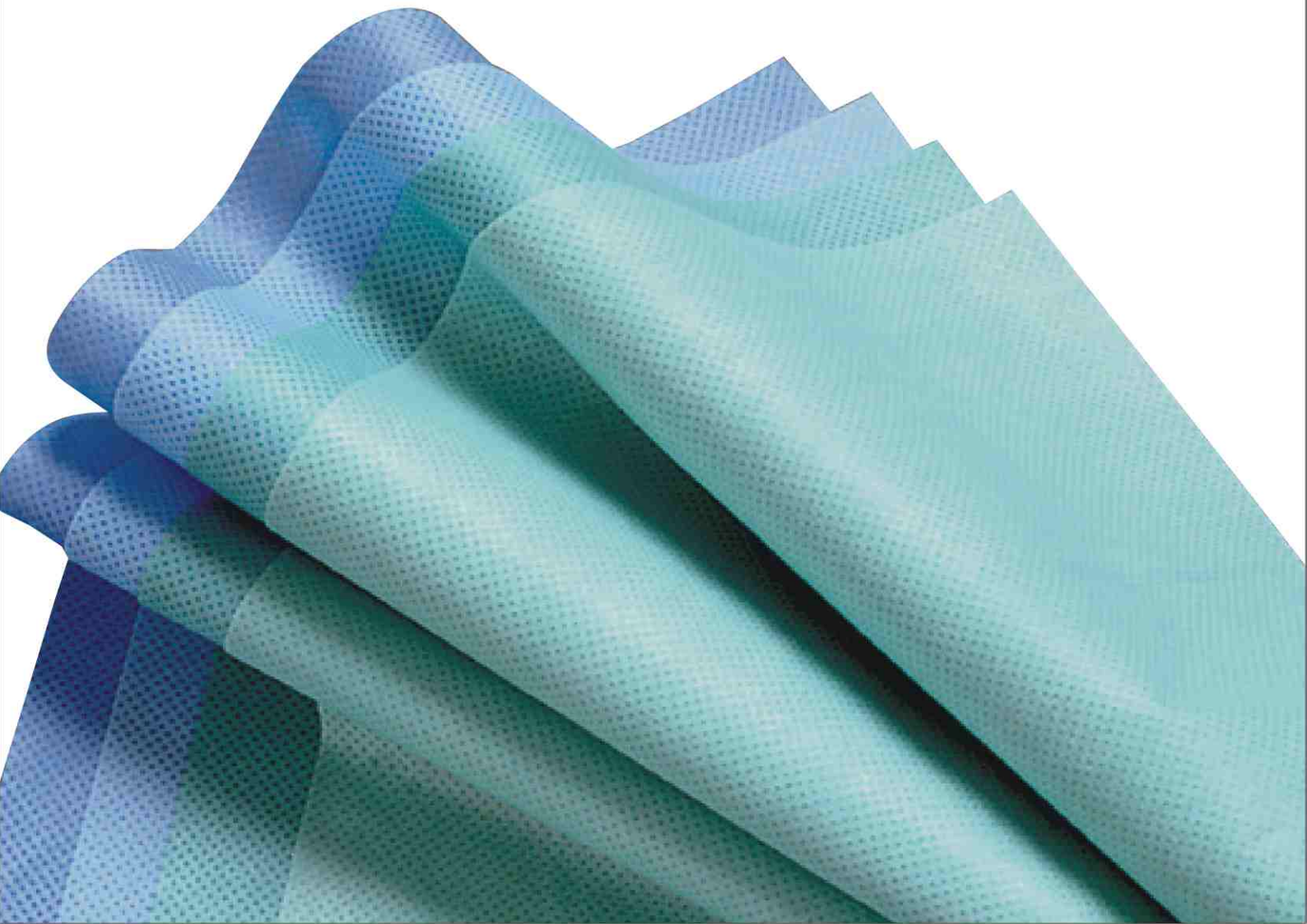
PlaVus

STERILE BARRIER SYSTEM

- STERILIZATION WRAP
- TRAY LINERS
- DUST COVERS



Features of Plavus Wrap

Baterial Barrier

Plavus Wraps are designed to create a tortuous path to prevent migration of micro-organisms.

Repellent to fluids

Plavus Wraps have excellence fluid repellency properties. Repellency minimizes contamination by preventing wicking through wet areas.

Memory free

Plavus Wraps are practically memory-free even after sterilization. This helps to improve aseptic techniques and minimizes the risk of contamination due to spring-back onto the sterile field or contents.

Easy to use / Softness

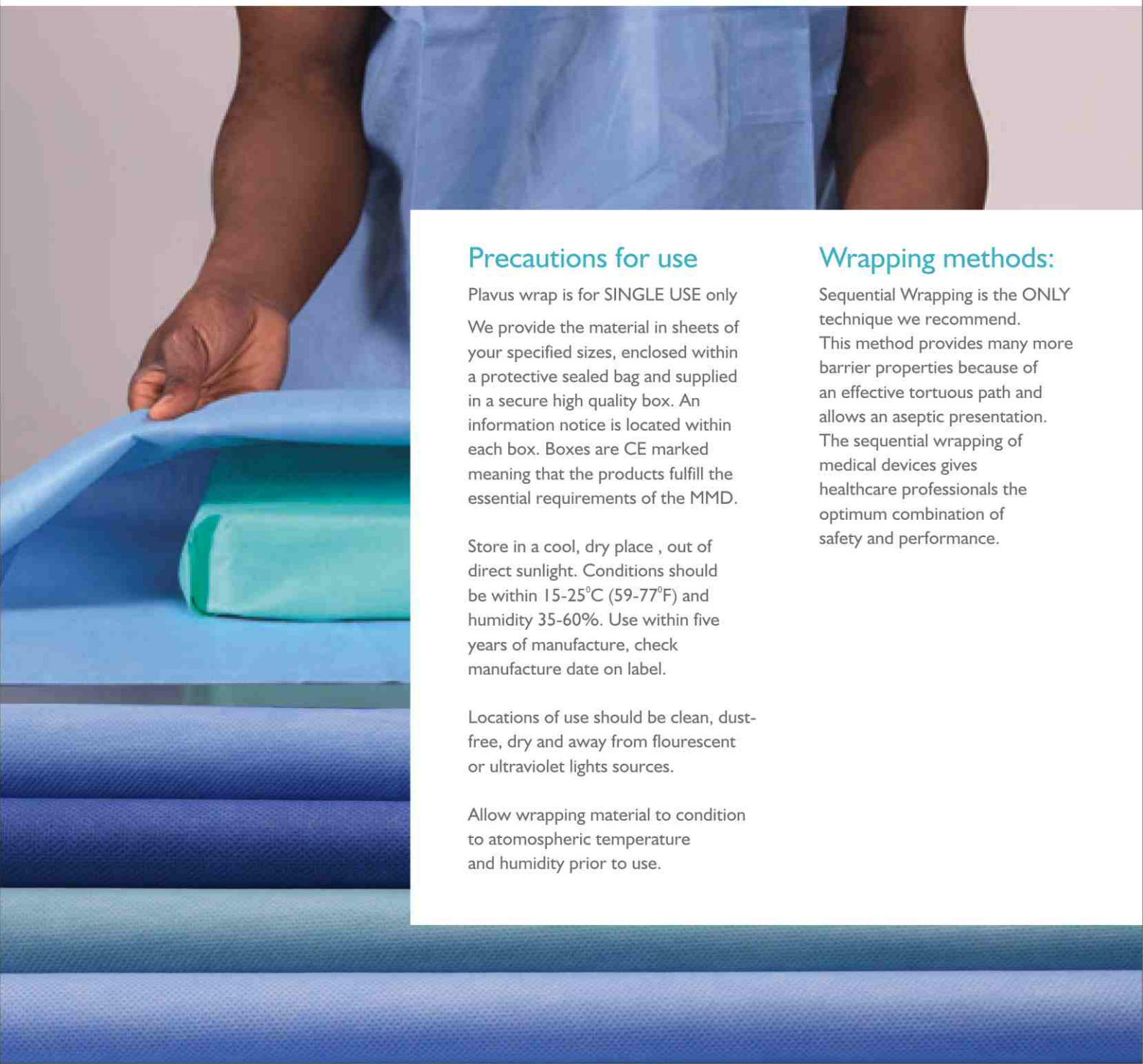
Plavus grades are soft, enabling fast wrapping, saving time and improving efficiency.

Strength

Plavus Wraps are strong, lowering the risk of puncturing or tearing during wrapping, transport or storing of the more demanding medical devices.

Proven sterilization methods

Plavus Wraps can be sterilized in most of the commonly used processors, i.e. steam, ethylene oxide, radiation, low temperature formaldehyde and gas plasma.



Precautions for use

Plavus wrap is for SINGLE USE only

We provide the material in sheets of your specified sizes, enclosed within a protective sealed bag and supplied in a secure high quality box. An information notice is located within each box. Boxes are CE marked meaning that the products fulfill the essential requirements of the MMD.

Store in a cool, dry place , out of direct sunlight. Conditions should be within 15-25°C (59-77°F) and humidity 35-60%. Use within five years of manufacture, check manufacture date on label.

Locations of use should be clean, dust-free, dry and away from flourescent or ultraviolet lights sources.

Allow wrapping material to condition to atomospheric temperature and humidity prior to use.

Wrapping methods:

Sequential Wrapping is the ONLY technique we recommend. This method provides many more barrier properties because of an effective tortuous path and allows an aseptic presentation. The sequential wrapping of medical devices gives healthcare professionals the optimum combination of safety and performance.

Key Technologies

SMS (Spunbound Meltblown Spunbound)

For the most demanding uses
– inner and / or outer wraps

- **SMMMS**
- **Most advanced technology**
- **High Strength**
- **Fluid repellency**
- **Soft**
- **Drapeability**

Latex Free
For sequential wrapping
Meets ISO 11607-1, Part 1
Pre-vac Steam compatible
STERRAD compatible
Resists tearing or puncture
Non-linting
Flame Resistant
Available in multiple sizes & colors

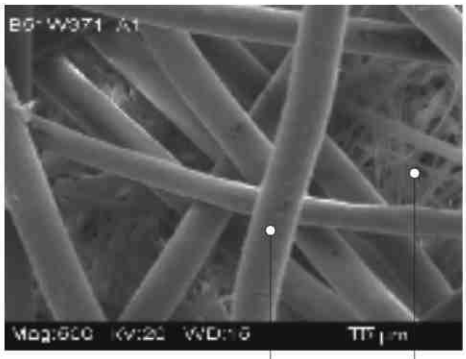
Intended Use

This Sterile Barrier System is for packaging medical devices which can be terminally sterilized by the following methods : steam (121-134°C) ethylene oxide gas, low temperature formaldehyde sterilization and pero gas plasma. We recommend that the end user validates the final packaging system as suitable with the intended sterilization process to comply with national and international regulations.

Meltblown used in SMS is the same as the meltblown used in a surgical facemask and is an excellent filter

General Features

- Newest and most advanced manufacturing equipment
- The key to the barrier protection of the SMMMS is the three "M" layers : three meltblown layers of microscopic fibres, delivering a tortuous path of high barrier. The tortuous path produces a uniform and consistent bacteriological and fluid barrier to maintain sterility.
- The "M" layers are sandwiched between two "S" layers -spunbound fibres, which being larger and stronger, provide exceptional strength as well as tear, burst and abrasion-resistance.



Spunbond fibres
~15 microns in diameter

Meltblown fibres
~2 microns in diameter

SMS range

Plavus SMMMS is 100% polypropylene, antistatic treated to resist static charge build-up. It does not contain natural fibres (cellulose) or synthetic binder. We produce it in four different types to satisfy different user requirements :

SBS - P 430	SBS - P 500	SBS - P 600	SBS - P 700	SBS - P 860
Colors available:	Colors available:	Colors available:	Colors available:	Colors available:







Registrations and declarations:

MDD 93/42/EEC 1993 / 47EC5 2007:
Wrapping materials are considered a Class 1 accessory (self-certification) and complying with the essential requirements 93/42/EEC directive and therefore CE marked.

Latex Free:
The above products are latex-free-including synthetic late materials or natural rubber materials containing any of the proteins linked to Types I & IV latex allergies.

EN 8682:
packaging material for terminally sterilized medical devices part 2: Sterilization wrap - requirements and tests methods (EN ISO 868-2:2009)

EN ISO 11607-1:
Packaging for terminally sterilized medical devices- part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)

Traceability:
The production system ensures complete traceability of products via a lot number printed on each delivered box, providing information relating to the production cycle. All data needed for effective tracking of single box and identification is contained within the bar code on the box / packaging.

Safety Instructions and disposal:

The product is non-toxic, nonhazardous and considered harmless.

Waste disposal must be in accordance with local and national regulations. Suitable for incineration. Product is not biodegradeable.

The product is combustible in oxygen-rich environments and when a source of ignition is applied to the fabric. Therefore to avoid fire, the product should be kept away from heat, sparks and open flame. If fire does occur it can be extinguished by normal means.

Precautions:
This is a single use product and shall not be re-used.
Do not use sheet if damaged or extraneous matter is detected.

Do not use with sharp instruments These may damage the wrap and compromise barrier properties.

TECHNICAL DATA SHEET
(Sterile Barrier System)

In accordance with EN868 – Part 2: 2009

Chapter	Characteristics	Test Method	Unit	Requirements	Typical Values SBS P 430	Typical Values SBS P 500	Typical Values SBS P 600	Typical Values SBS P 700	Typical Values SBS P 860
4.2	Materials								
4.2.1	General	Visual observation	-	No objections	Conform	Conform	Conform	Conform	Conform
4.2.1.1	Colour	ISO 6588-2	-	No colour shall leach	Conform	Conform	Conform	Conform	Conform
4.2.1.2	Average mass of 1m²	EN ISO 536:1995	g/m²	The average mass shall be within ± 5 % of the nominal value state by the manufacturer	43.0	50	60.0	70.0	86.0
4.2.1.3	pH-value	ISO 6588-2	pH	5 = pH = 8 (hot extraction method)	Conform	Conform	Conform	Conform	Conform
4.2.1.4	Chloride	ISO 9197	%	= 0,05% (NaCl, hot extraction method)	Conform	Conform	Conform	Conform	Conform
4.2.1.5	Sulphate	ISO 9198	%	= 0,25% (Na_2SO_4 hot extraction method)	Conform	Conform	Conform	Conform	Conform
4.2.1.6	Fluorescence	EN 868-2, Annex B	%	No increase in brightness due to the optical brightener of more than 1% and number of spots = 5 ; spots axis > 1mm / 0,01 m²	Conform	Conform	Conform	Conform	Conform
4.2.2.3	Specific requirements for nonwoven								
4.2.2.3.1	Tearing resistance	EN 21974	mN	= 750 in machine direction = 1000 in cross direction	3000 6000	3200 7500	4200 7200	4500 7500	3000 6000
4.2.2.3.2	Bursting strength (dry)	EN ISO 2758	kPa	> 130	150	>200	>200	>200	>150
4.2.2.3.3	Wet bursting strength	ISO 3689	kPa	= 90	150	>200	>200	>200	>150
4.2.2.3.4	Elongation	EN ISO 1924-2	%	= 5 in machine direction = 7 in cross direction	60 65	55 60	45 55	50 50	60 65
4.2.2.3.5	Hydro head test	EN 20811	Mm H^2O	No requirement	550	550	630	650	550
4.2.2.3.6	Tensile strength (dry)	EN ISO 1924-2	kN/m	= 1,00 in machine direction = 0,65 in cross direction	1.80 0.90	2.0 1.0	2.3 1.2	2.5 1.3	1.8 0.9
4.2.2.3.7	Wet tensile strength	ISO 3781	kN/m	= 0,75 in machine direction = 0,50 in cross direction	1.50 0.75	1.9 0.85	2.25 1.10	2.4 1.2	1.5 0.75

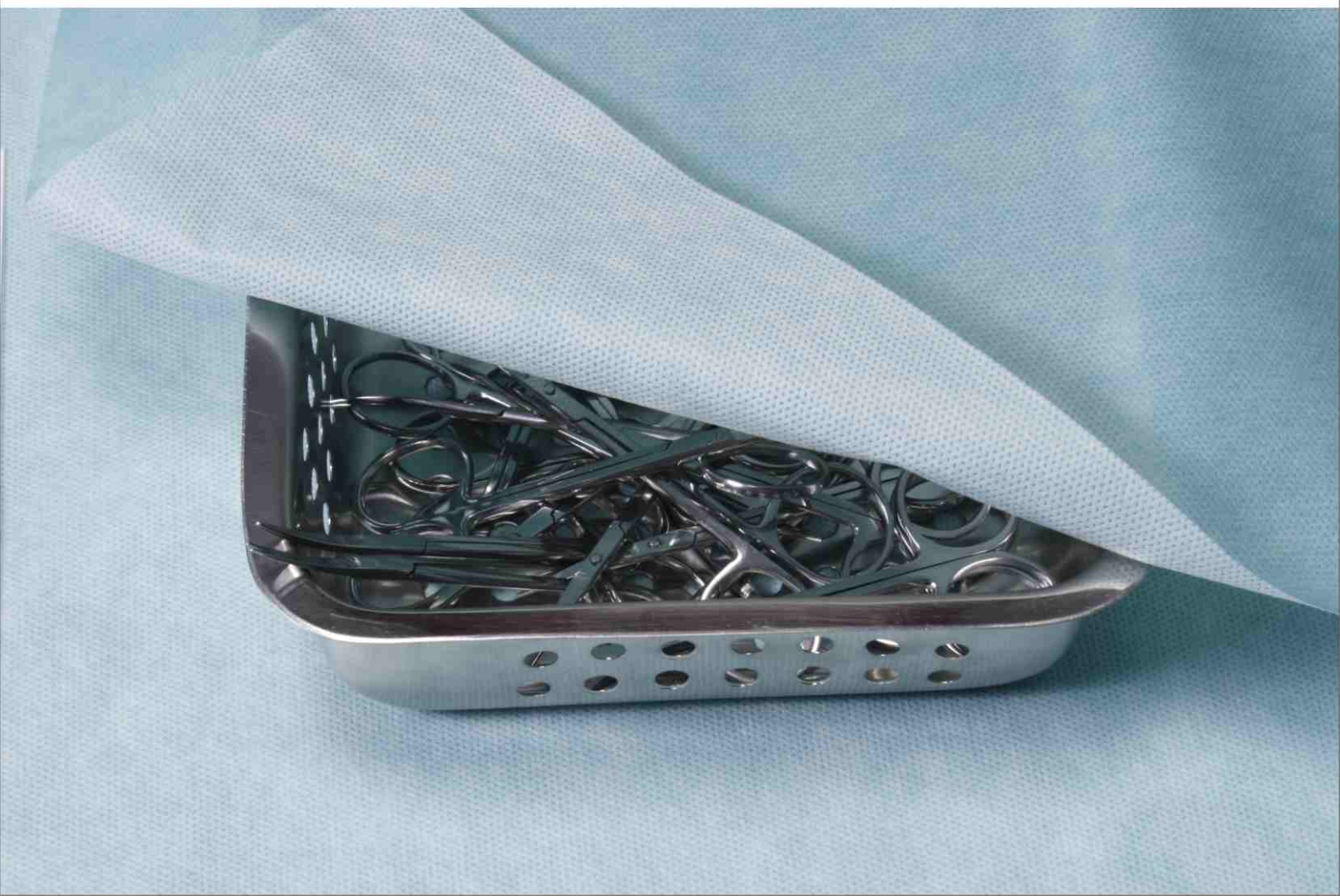
In accordance with ISO 11607 – Part 1: 2009

Chapter	Characteristics	Test Method	Unit	Requirements	Typical Value	Typical Value	Typical Value	Typical Value	Typical Value
5.1.6 a)	Germ proofness in moisture	DIN 58 953-6:2010	Nil	Germ- proof	Conform	Conform	Conform	Conform	Conform
	Germ proofness with passage of air	DIN 58 953-6:2010	Nil	Germ- proof	Conform	Conform	Conform	Conform	Conform
5.1.6 b).	Biocompatibility and toxicological attributes, sterile	ISO 10993-1	n/a	Conform to requirements	Conform	Conform	Conform	Conform	Conform
5.1.6 c).	Physical and chemical properties	EN 868-2	n/a	Conform to requirements	Conform	Conform	Conform	Conform	Conform
5.1.6 e).	Compatibility with respect to intended sterilisation processes (Steam (121-134°C), Ethylene Oxide, vapour Hydrogen Peroxide Gas PLASMA	EN 868-2	n/a	Conform to requirements	Conform	Conform	Conform	Conform	Conform
5.1.6 f).	Shelf life limitations Pre sterilisation	EN 868-2	years	Conform to requirements	5 years	5 years	5 years	5 years	5 years

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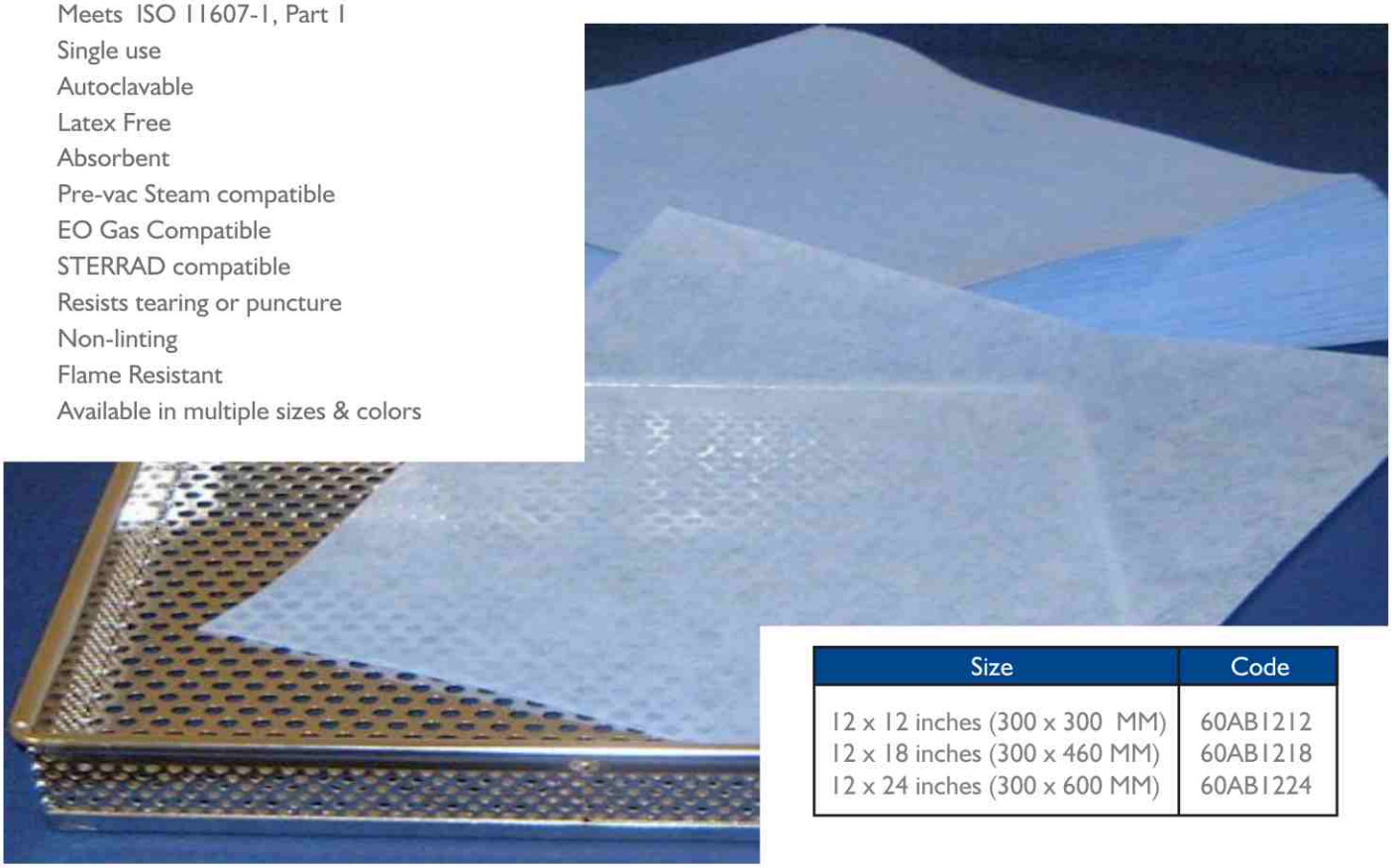
PRODUCT CODES

SIZE	SBS-P430	SBS-P500	SBS-P600	SBS-P700	SBS-P860D
30 x 30 Cms. (12" x 12 ")	43003030	50003030	60003030	70003030	86003030
38 x 38 Cms. (15" x 15")	43003838	50003838	60003838	70003838	86003838
45 x 45 Cms. (18" x 18")	43004545	50004545	60004545	70004545	86004545
50 x 50 Cms. (20" x 20")	43005050	50005050	60005050	70005050	86005050
60 x 60 Cms. (24" x 24")	43006060	50006060	60006060	70006060	86006060
75 x 75 Cms. (30" x 30")	43007575	50007575	60007575	70007575	86007575
90 x 90 Cms. (36" x 36")	43009090	50009090	60009090	70009090	86009090
100 x 100 Cms. (40" x 40")	43100100	50100100	60100100	70100100	86100100
100 x 140 Cms. (40" x 56")	43100140	50100140	60100140	70100140	86100140
120 x 120 Cms. (48" x 48")	43120120	50120120	60120120	70120120	86120120
135 x 135 Cms. (54" x 54")	43135135	50135135	60135135	70135135	86135135
135 x 180 Cms. (54" x 72")	43135180	50135180	60135180	70135180	86135180
135 x 220 Cms. (54" x 88")	43135220	50135220	60135220	70135220	86135220
150 x 150 Cms. (60" x 60")	43150150	50150150	60150150	70150150	86150150
150 x 200 Cms. (60" x 80")	43150200	50150200	60150200	70150200	86150200



INSTRUMENT TRAY LINER

Meets ISO 11607-1, Part 1
Single use
Autoclavable
Latex Free
Absorbent
Pre-vac Steam compatible
EO Gas Compatible
STERRAD compatible
Resists tearing or puncture
Non-linting
Flame Resistant
Available in multiple sizes & colors



Size	Code
12 x 12 inches (300 x 300 MM)	60AB1212
12 x 18 inches (300 x 460 MM)	60AB1218
12 x 24 inches (300 x 600 MM)	60AB1224

DUST / TRANSPORTATION COVER



Size	Plastic	Non Woven
10 x 12 INCHES (250 x 300 MM)	50PL1012	50NW1012
10 x 15 INCHES (250 x 375 MM)	50PL1015	50NW1015
12 x 15 INCHES (300 x 375 MM)	50PL1215	50NW1215
12 x 20 INCHES (300 x 500 MM)	50PL1220	50NW1220
16 x 22 INCHES (400 x 550 MM)	50PL1622	50NW1622
16 x 28 INCHES (400 x 700 MM)	50PL1628	50NW1628
16 x 30 INCHES (400 x 750 MM)	50PL1630	50NW1630
24 x 28 INCHES (600 x 700 MM)	50PL2428	50NW2428
24 x 30 INCHES (600 x 750 MM)	50PL2430	50NW2430
30 x 36 INCHES (750 x 900 MM)	50PL3036	50NW3036



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