



# Sterilization Reels and Pouches

## User Manual



Sterility™ Sterilization Reels and Pouches are designed to provide the best user experience and meet the requirements of the end users. With this user manual we intend to provide you with the complete and detailed information about our products and the ease of using the same.

Sterility™ Sterilization reels and pouches are compatible with the ISO 11607, part 1 and 2 as well as with part 5 of the EN 868 demonstrating that the packaging for terminally sterilized medical devices meet the international.

Sterility™ Sterilization standard reel packaging is constructed of transparent multilayer CPP film and medical grade paper (60 gsm) in compliance with EN 868-5 along with the chemical process indicators are applied on the paper surface for intended sterilization methods like steam, ethylene oxide and formaldehyde.



### **Sterility™ Manufacturing Process**

Our sterilization packaging are manufactured in the ISO 8 (Class 100,000) Clean room area at Aurangabad, MH, India. The plant is an ISO 13485 certified. As a requirement for certification, the plant has an established Quality System Manual. At SWT we apply the valid Environmental, Health and Safety regulations given by the respective authorities in India. The regulations instructions are followed when processing material, operating machinery and other equipment which is used during the manufacturing of our products and the relevant SOP's have been prepared and updated time to time.

### **The In house QC Testing Lab**

At SWT state-of-the-art in-house laboratory and where we plan to invest in new testing devices to provide best quality product. A wide range of sterilization packaging tests required by related product standards are applied in our new laboratory by specialized and trained personnel.



## **Sterility™ Reel or Pouch Instruction for use**

1. Sterility™ sterilization pouches are ready for use. After unboxing the reels unwrap the wrapped material over the Sterilization reels or pouches.
2. The need to be cut to required length and to be sealed at one end to form a ready to fill pouch.
3. The medical device must be kept in such way that the pouch is not filled more than 75% of its total capacity.
4. The sharp ends need to be taken special care by using protector to avoid puncturing or cutting.
5. A gap of minimum 1.5 cm between the material and each seal edge of the pouch must be left for a smooth airflow.
6. Before sealing, as much air as possible must be removed from the pouch.
7. The filled pouch has to be sealed with a calibrated and validated heat sealer according to the manufacturer's recommendation. The sterilization Paper packaging is suitable for sealing between 180°C up to 190°C while Tyvek should be between 125°C-135°C.
8. Strength of the seal must assure a clean peel and should be free of fibers.
9. When loading into the sterilizer the pouches have to be placed into the basket in a way that film faces film and paper side faces paper side.
10. Sterilization pouches should be put upright in the basket or container and not too tight together so such that a hand can slide in between them.
11. Process the loading should be followed as per the SOP of the Sterilizer supplier.
12. Handle pouches with care when removing from the sterilizer to prevent puncturing or tearing. Store pouches in an area protected from sunlight, water and other liquids.
13. Do not use wet pouches. In case of wet pouches, change the packaging and repeat the sterilization process.
14. To open the pouch, use thumb and index finger to hold plastic side of the pouch and thumb and index finger to pull back the paper side of the pouch. Always open the pouch towards the opening direction. Open the pouch slowly for a clean and aseptic presentation.
15. Do not use the pouch if it is broken from anywhere. Remove the instrument, repack and repeat the sterilization process.



## Medical Grade Paper Specifications-

At SWT we are using a high weighed medical grade Paper -

- Sterility™ uses a 60GSM medical grade paper which is specially imported from Europe.
- For plasma sterilization pouches Tyvek® 1073 B standard, 75 GSM paper is used which is also imported from USA.
- These paper is specially designed to only allow steam and ethylene oxide (ETO) at a specific pressure and temperature.
- The paper is bacteria resistant for one sterilization only.
- These papers have an outstanding resistance to microbial penetration and also significantly reduce the risk of packaging failure.
- These papers used are of international standards ISO 11607-1 and EN 868-3 sheet.

Substance	DIN 53104	-	g/m <sup>2</sup>	59,8
Thickness	DIN 53105 T1	-	µm	86,6
Tensile strength	DIN 53112 T1	md	N/15mm	72,6
Tensile strength	DIN 53112 T1	cd	N/15mm	40,8
Wet strength	DIN 53112 T2	md	N/15mm	14,0
Wet strength	DIN 53112 T2	cd	N/15mm	7,4
Breaking length	DIN 53112 T1	md	km	8,2
Breaking length	DIN 53112 T1	cd	km	4,6
Plybond resistance	DIN 54516 -IFP	-	kN/m	7,2
Burst strength	DIN 53141- Mullen	-	kPa	253
Roughness	DIN 53108 - Bendtsen	T	ml / min	235
Roughness	DIN 53108 - Bendtsen	R	ml / min	1305
Air permeability	DIN 53120 T1 - Bendtsen	-	ml / min	696
Water absorbency	DIN 53132 - Cobb 60	T	g/m <sup>2</sup>	19
Water absorbency	DIN 53132 - Cobb 60	W	g/m <sup>2</sup>	20,6
Wax pick	Tappi 459	T	Number	16
Wax pick	Tappi 459	W	Number	18
pH - hot-extraktion	DIN 53124	-	-	6,4
pH - online		-	-	5,9
Absolute moisture content	online	-	%	4,1
Brightness	DIN 53145 - R457		%	84,8
ISO 9001; ISO 14001; ISO 50001;REACH;				

## Dupont Tyvek 1073B Specifications-

### SPECIFICATION PROPERTIES OF DUPONT™ TYVEK® (METRIC UNITS)

PROPERTY	COMPARABLE TEST METHOD	UNITS	TYVEK® 1073B	TYVEK® 1059B	TYVEK® 2FS™
Basis Weight	ASTM D3776 <sup>1</sup> EN ISO 536 <sup>1</sup>	(g/m <sup>2</sup> )	74.6 [71.2–78.0]	64.4 [61.7–67.1]	59.5 [56.5–62.5]
Delamination	ASTM D2724 <sup>2</sup>	(N/2.54 cm)	2.3 [1.6–3.1]	2.2 [1.5–2.9]	2.7 [2.1–3.3]
Gurley Hill Porosity	TAPPI T460 <sup>1</sup> ISO 5636-5 <sup>3</sup>	sec/100 cc	22 [8–36]	20 [8–36]	22 [9–35]

## Medical Grade Poly Specifications-

In the whole process of sterilization it is very important to choose the correct film by analyzing its properties because if the film is not strong enough it will not be seal properly to the paper and eventually during the sterilization process it might blow away with the pressure and temperature which will lead to the contamination and thus choosing the right film is very important. Therefore, at SWT we are using a film having following advantages-

- The film used is a 52 micron green tinted/ natural coloured film.
- It is a multilayer film with three very fine layers, which makes it very tough and durable.
- The polyester (PET) outer layer provides high heat resistance.
- The intermediate layers together with the sealing layer of polypropylene (PP) offer advanced sealing and peeling properties with superior tear strength. (Standards- ISO 9001-2008, ISO 22000, HACPP, BRC-IOP)

STRUCTURE :	12 $\mu$ CI PET /38 $\mu$ HST CPP (GREEN)	
PROPERTIES	STANDARDS	OBSERVATION
TOTAL GSM	53.00 $\pm$ 5 %	51.36 - 55.16
BOND STRENGTH 2 PLY	350 GM / 15 MM	365 - 410
SEAL STRENGTH	2.5 KG/15 MM	2.6 - 3.0
COF OF FRICTION	0.15 - 0.25	0.18 - 0.22
UN-WINDING DIRECTION	PET OUTSIDE	PET OUTSIDE
REPEAT LENGTH	N.A	N.A
COIL WIDTH	410 MM	410 MM
PHOTOCELL	N.A	N.A
CORE OD	52 KG	52 KG
CORE ID	76 MM	76 MM
CORE TYPE	PVC	PVC
ODOUR TEST	SHOULD PASS	PASS
REMARK	OK	OK

## Sterilization Process Chemical Indicator Specifications-

At SWT sterilization reels and pouches are imprinted with water based, non-toxic Class 1 chemical process indicators. The indicators are in compliance with ISO 11140-1 and fulfill the requirements of related standard. The standard sterilization packaging is imprinted with steam and ethylene oxide chemical process indicators. Chemical indicator for formaldehyde sterilization method is available upon request.

STERILIZATION METHOD	PRE STERILIZATION	POST STERILIZATION
STEAM STERILIZATION	PINK	COCOA/ BLACK
ETO STERILIZATION	BLUE	GOLDEN YELLOW/BROWN
PLASMA STERILIZATION	RED	YELLOW



## The QC Testing of the Final Product-

At SWT the first priority is to meet customer expectations by highest quality and standard conform products. Implemented and applied quality control stages and in-house and/or external laboratory tests help us to ensure high product quality and sustainable production outcome.

Along with the in-process checks during the production we at SWT insist on supplying the material along with the Certificate of Analysis for building the customers confidence in the product. PFA the specimen copy for your reference

CERTIFICATE OF ANALYSIS					
Code : SWTARGR60 -R			Certificate No : SWT- 183		
Product : Sterilization Paper Reel			Date of Inspection : 17.03.2021		
Mfg. Date : 17.03.2021			Batch No : SPS2001703		
Batch Size : 20cm x 200 mtr			Expiry date : 17.02.2024		
MATERIAL DESCRIPTION					
Paper : Medical Grade Paper 60 GSM			Film : Medical Grade Cast Poly Propylene (Green)		
Sr. No	Description of Test	Frequency of Test	Observation	Requirments	Mode of checking
1	Medical Grade Paper GSM	One Reel of every consaginement	60	60 +/- 2 gm	Weighing Balance
2	Medical Grade Paper Thickness		75	75 +/- 2 Micron	Micron Meter
3	CPP Poly GSM		50	50 +/- 2 gm	Weighing Balance
4	CPP Poly Thickness		52	52 +/- 2 Micron	Micron Meter
5	Seal Uniformity	On line check during production	Uniform Sealing	Should be Uniform Sealing	Visual Check
6	Seal Strength	1 hour every lot	R : 3.55N/15mm L : 3.47N/15mm	Above 2.5 N/15mm	Tensile Tester (ASTM D 882-97)
7	Seal Width		10 mm	10mm+/-1mm	Vernier Caliper
8	Air bubble in Sealing Area		No Air bubble observed.	Air bubble should not be present.	Visual Check
9	Skip seal (If any)	On line check during production	Not Applicable	Not Applicable	Not Applicable
10	Sealing Temprature		180 Deg C	180 +/-2 Deg C	Temprature Controller
11	Sealing Pressure		6.0 Kg	6.0 +/-0.5 Kg	Pressure Controller
12	Sealing Time		1.2 Second	1.2 TO 1.5 Sec	Machine Setup
13	Outer Width Size	Every Reel	200mm	200mm +/-2mm	Mesuring Scale
14	Inner Width Size		180mm	180mm +/-2mm	Mesuring Scale
15	Total Length of Reel		200mtr	200mtr +/-1mm	Machine Setup
16	Sterilization Indicator (Steam)	Every consignment	After sterilization Pink turns to Cocca	After sterilization Pink should turns to Cocca/Black	Sterilizer (Steam)
17	Sterilization Indicator (ETO)	Every consignment	After sterilization Blue turns to Golden Yellow/ Brown	After sterilization Blue should turns to Golden Yellow/ Brown	Sterilizer (ETO)
18	Thum Hole (If any)	On line check during production	Holes not observed	Holes should not be observed	Visual Check
19	Printing Text Matter (If any)		Printing as per approved matter	Printing should be as per approved matter	Visual Check

## The Sealing Specifications-

All seals, including closure seal/seals are to be smooth, i.e. without folds, bubbles, or wrinkles. The colored plastic film turns a darker shade where the sealing has taken place, making it easy to check that the seal is intact.

Following things to be considered while heat sealing devices that it must be capable of attaining the sealing conditions suitable for each specific sterile barrier system construction. Correct temperature, pressure and sealing time/speed combination need to be met. Preferably, only sealing devices manufactured and intended for medical use should be used. The sealing temperature for paper shall be in the range of 180°-190°C for medical grade paper and around . For Tyvek 125°– 135°C.

The seals need to be strong to withstand the most vigorous sterilization process and handling, yet providing a clean peel. Closing too strongly should be avoided when sealing rolls as one of the seals needs to be opened fiber free. A manual test should be carried out for controlling the seal strength. Closures that compress the package should not be used, (e.g, ropes, strings, elastic bands, paperclips, staples or similar items).

## The LOT No Specifications-

At SWT all the sterilization reel and pouch are provided with a LOT number printed labels have been placed. The LOT number allows the traceability of the product during the manufacturing process.

E.g. SPS2001703 which goes as-

SPO– Sterilization Paper – Sterility™

200– Size in mm,

17– Date when the batch starts

03– Month

**Lot No - SPS2001703**

## The Label for Product Traceability Specifications-

### Sterility™ Sterilization Paper/ Tyvek Reel/ Pouch

Size– 200 mm x 200 Mtr.

Lot No– SPS2001703

Mfg. Date– 03/2021

Exp. Date– 02/2024 ( 3 years from the date of manufacturing).

**Sterility Sterilization Paper Reel**  
Size - 200MM X 200MTR  
Lot No - SPS2001703  
Mfg. Date - 03/2021  
Exp. Date - 02/2024

## The Shipper Label for Product Traceability Specifications-

### Sterility™ Sterilization Paper/ Tyvek Reel/ Pouch

Size– 200 mm x 200 Mtr

Lot No– SPS2001703

Mfg. Date– 03/2021

Exp. Date– 02/2024 (3 years from the date of mfg).

Mfg. By– Sterile World Technologies LLP, India

Contact Details.

**QC APPROVED PRODUCT**  
**STERILITY STERILIZATION PAPER REEL**  
SIZE : 20CM X 200MTR      CODE: SWTARGR60R  
LOT NO : SPS2001703      QTY : 04 Nos  
MFG. DATE: 03/2021      EXP. DATE: 02/2024  
MFG. BY: STERILE WORLD TECHNOLOGIES LLP, INDIA  
Email Id : business@sterilewt.com Contact No : +91 89 7575 5591

## The Storage conditions Specifications-

SWT manufactured sterilization reels and pouches need to be stored under following recommended storage conditions to ensure optimum product quality, microbial properties and expiry date. Storage conditions are printed on each shipping carton labels and are also available at product related instructions for use.

- ⦿ Stored in original packaging
- ⦿ Stored under controlled temperature (max. 35°C)
- ⦿ Stored under controlled humidity (max. %70 Relative Humidity)
- ⦿ Stored protected from direct sunlight, moisture and excessive airflow



Standard Flat Paper / Tyvek Roll (100/ 70 Mtr) Sizes		
50 mmx 200 Mtr	75 mmx 200 Mtr	100 mmx 200 Mtr
125 mmx 200 Mtr	150 mmx 200 Mtr	200 mmx 200 Mtr
250 mmx 200 Mtr	300 mmx 200 Mtr	350 mmx 200 Mtr
380 mmx 200 Mtr	400 mmx 200 Mtr	420 mmx 200 Mtr
450 mmx 200 Mtr	500 mmx 200 Mtr	600 mmx 200 Mtr

Standard Gusseted Paper Roll Sizes		
75 mmx 200 Mtr	100 mmx 200 Mtr	125 mmx 200 Mtr
150 mmx 200 Mtr	200 mmx 200 Mtr	250 mmx 200 Mtr
300 mmx 200 Mtr	350 mmx 200 Mtr	380 mmx 200 Mtr
400 mmx 200 Mtr	420 mmx 200 Mtr	450 mmx 200 Mtr
500 mmx 200 Mtr	600 mmx 200 Mtr	

Medical Grade Paper/ Tyvek Self Seal Pouches		
5cmx27.5cm	20cmx27.5cm	40cmx50cm
7.5cmx27.5cm	25cmx40cm	45cmx50cm
10cmx27.5 cm	30cmx50cm	50cmx60cm
15cmx27.5cm	35cmx50cm	

**All other size of heat seal or self seal pouches can be supplied as per the customer's specifications.**







## STERILE WORLD TECHNOLOGIES LLP

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