



Sif Medical Manufacturing

Instructions for Use

Name: Sterilization Pouch & reel

Intend Use: The device is intended to be used as packaging for terminally sterilized medical devices indicating the sterilization process is succeeded or not.



Cautions:

1. Do not use if the package is damaged.
2. The device should be used before expiry date.
3. It's for single use only. Reuse may cause cross-contamination.
4. Free from liquid or moisture to prevent contamination

Type of Sterilization the materials are intended for:

The devices are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam or via Ethylene Oxide (ETO).

Type of chemical indicator:

Based on the intended use, the external indicator incorporated with Sterilization Pouch Roll is a Type 1 process indicator with no critical variables as per clause 4.0 of ISO 11140-1 standard that is intended to demonstrate that the device has been exposed to steam or EO sterilization process and to distinguish between processed and unprocessed devices.

Packaging Instructions :

Place items to be sterilized into an appropriate sized pouch. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully press the excess air out of the pouch and ensure there is at least one (1) inch between the adhesive strip and items.



After removing the protective strip, seal the self sealing pouch by folding the adhesive strip onto the pouch. Apply pressure from the center of the adhesive, towards the edges. Repeat this motion an additional time for extra security. Seal the pouch if you are using heat sealing sterilizing pouch. If using roll, then cut it as per required length and heat seal at both the ends. If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.



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Maximum load bearing capacity :

Self Sealing Sterilization Pouch				
Model	Size (mm)	Max Load		
		Gauze	Plastic	Metal
SP 001	57 x 130	4.5 g	13 g	17 g
SP 002	57 x 100	4 g	14 g	18 g
SP 003	50 x 220	8 g	33 g	37 g
SP 004	70 x 260	31 g	36 g	40 g
SP 005	90 x 165	45 g	49 g	54 g
SP 006	90 x 260	50 g	107 g	130 g
SP 007	135 x 280	208 g	213 g	226 g
SP 008	190 x 360	158 g	317 g	353 g
SP 009	190 x 380	174 g	332 g	372 g
SP 010	200 x 320	226 g	320 g	460 g
SP 011	200 x 360	249 g	353 g	510 g
SP 012	230 x 395	265 g	418 g	620 g
SP 013	250 x 400	281 g	580 g	775 g
SP 014	305 x 430	301 g	603 g	689 g
SP 015	400 x 535	492 g	910 g	1070 g
SP 016	500 x 630	724 g	1350 g	1420 g
Heat Sealing Sterilization Pouch				
Model	Size (mm)	Max Load		
		Gauze	Plastic	Metal
SPH 001	75 x 260	31 g	36 g	40 g
SPH 002	100 x 150	40 g	45 g	50 g
SPH 003	100 x 250	50 g	60 g	130 g
SPH 004	150 x 200	60 g	90 g	150 g
SPH 005	200 x 250	115 g	230 g	250 g
SPH 006	300 x 400	276 g	552 g	600 g
SPH 007	300 x 500	345 g	690 g	750 g
SPH 008	300 x 600	414 g	828 g	900 g
SPH 009	200 x 400	184 g	368 g	400 g



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SPH 010	80 x 250	46 g	92 g	100 g
SPH 011	80 x 120	22 g	44 g	48 g
SPH 012	250 x 350	200 g	402 g	437 g
SPH 013	100 x 200	46 g	92 g	100 g

There is no specific length for sterilization roll and it is cut to the length as per user requirement while using. Hence, the above table can be take as reference for the load capacity.

Sterilization Instructions :

Please refer to the following recommendations for Steam and ETO sterilization cycles.

Steam: 4 minutes at 132°C (270°F) - 134°C (273°F); and 20-30 mins at 121°C (250°F)

Ethylene oxide: 8 hours at 50°C; relative humidity between 40%- 60%; ethylene oxide concentration is 600mg/L, 7 days aeration time at 23°C.

The pouch' s external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or ETO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide or steam). Ethylene oxide sterilization indicator color change from pink before sterilization to yellow after sterilization. The steam sterilization indicator color change from blue before sterilization to black/dark green after sterilization.

Loading the sterilizer :

If you are using several pouches at once, when placing pouches in the sterilizer make sure plastic side of sterilization pouch always faces paper side of adjacent pouch to allow proper air evacuation and sterilant penetration. If possible use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.

Sterility Maintenance :

The Self Sealing Sterilization Pouches are made with medical grade paper and medical compound film. The Self Sealing Sterilization Pouch maintains the sterility of the enclosed devices for up to 6 months post Steam or ETO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture.

Storage: The product should be stored in dry place and keep away from acid, heat and direct sunlight during storage and transportation. Maintain Temperature of 25° C ± 2° C before and after use.

Shelf life: 5 years



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List of Models :

Sterilization Pouch

Self Sealing:

SP 001 (57 x 130 mm)	SP 007 (135 x 280 mm)	SP 013 (250 x 400 mm)
SP 002 (57 x 100 mm)	SP 008 (190 x 360 mm)	SP 014 (305 x 430 mm)
SP 003 (50 x 220 mm)	SP 009 (190 x 380 mm)	SP 015 (400 x 535 mm)
SP 004 (70 x 260 mm)	SP 010 (200 x 320 mm)	SP 016 (500 x 630 mm)
SP 005 (90 x 165 mm)	SP 011 (200 x 360 mm)	
SP 006 (90 x 260 mm)	SP 012 (230 x 395 mm)	

Heat Sealing:

SPH 001 (75 x 260 mm)	SPH 006 (300 x 400 mm)	SPH 010 (80 x 250 mm)
SPH 002 (100 x 150 mm)	SPH 007 (300 x 500 mm)	SPH 011 (80 x 120 mm)
SPH 003 (100 x 250 mm)	SPH 008 (300 x 600 mm)	SPH 012 (250 x 350 mm)
SPH 004 (150 x 200 mm)	SPH 009 (200 x 400 mm)	SPH 013 (100 x 200 mm)
SPH 005 (200 x 250 mm)		

Sterilization Reel

SR 001 (55mm x 200m)	SR 006 (250mm x 200m)	SR 011 (350mm x 200m)
SR 002 (75mm x 200m)	SR 007 (300mm x 200m)	SR 012 (400mm x 200m)
SR 003 (100mm x 200m)	SR 008 (50mm x 200m)	SR 013 (450mm x 200m)
SR 004 (150mm x 200m)	SR 009 (120mm x 200m)	SR 014 (500mm x 200m)
SR 005 (200mm x 200m)	SR 010 (125mm x 200m)	SR 015 (600mm x 200m)



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Labels, Packing Logo Design:

Symbol	Introductions	Symbol	Introductions
	Lot Number / Batch Code		Do not reuse" are "single use, "Use only once
	Warnings and Precautions		non-sterile
	medical device		Manufacture Date
	Manufacturer Name & Address		Expiry Date
	Do not use if package is damage		Temperature Limit
	No direct sunlight		Keep dry

Manufacturer Information



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Note : Occurrence of any serious incidents should report to the manufacturer and SFDA (19999) immediately.



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