



Instruction For Use

PRODUCT NAME :

PMSSteripack Crepe Papers and SMMS Wrapping Papers (Standard, non woven, soft, smms)

PRODUCT DESCRIPTION :

PMSSteripack Crepe Papers and SMMS Wrapping Papers; Crepe papers are separated into 3 groups, namely; standard, soft and nonwoven. Standard and soft crepes content cellulose whereas nonwoven products content both cellulose and synthetic fiber. SMS wrapping papers are made of 100% polypropylene material, and are used by the end users in customized sizes . These products are in compliance with standards TS EN ISO 11607 and TS EN 868-2.

INTENDED USE:

It is intended to be used as sterilization packaging for other medical devices to be sterilized by healthcare professionals.

PRODUCT	DIMENSION(cm)	NO of BOXES
Wrapping Paper (Blue, Green, White)	30 X 30	2.000
Wrapping Paper (Blue, Green, White)	40 X 40	1.000
Wrapping Paper (Blue, Green, White)	45 X 45	1.000
Wrapping Paper (Blue, Green, White)	50 X 50	1.000
Wrapping Paper (Blue, Green, White)	60 X 60	500
Wrapping Paper (Blue, Green, White)	75 X 75	250
Wrapping Paper (Blue, Green, White)	90 X 90	250
Wrapping Paper (Blue, Green, White)	100 X 100	250
Wrapping Paper (Blue, Green, White)	120 X 120	100

INSTRUCTION FOR USE:

- 1- Appropriate size of wrapping paper is used depending on the size of the material to be sterilized.
- 2- Type of wrapping paper shall be determined regarding the weight and kind of the material. (Figure-1)
- 3- In order to prevent microorganism penetration and for safer, firmly packaging, two fold wrapping shall be done.
- 4- Packing shall be carried out as specified in Figure-2.
- 5- Cover sharp ends of instruments with an instrument protector, to prevent puncturing or tearing.
- 6- Autoclave tapes with indicators shall be preferred in packing operation.
- 7- Indicator strips shall be placed into the packages to verify whether the sterilization process is carried out or not.



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- 8- Wrapping papers are resistant to steam sterilization at 121°C and 134°C.
- 9- Wrapping papers are suitable for steam, ethylene oxide, formaldehyde, plasma (no cellulose content) and gamma sterilization.
- 10- Wrapping papers are for single use. In case of repeating the sterilization operation, packing material must be changed.
- 11- After sterilization, care must be taken to prevent the packages from damaging.
- 12- Sterilized packs shall be stored in special rooms, kept on shelves.
- 13- Packs shall be kept away from direct sunlight, humidity and the places having contamination risk.
- 14- Sterilized packs (Standard, non woven, soft, sms) preserve bacterial barrier properties during 6 months when stored at recommended conditions.
- 15- In case of using the packages, outer wrapping shall be removed first out of the working environment. Then, inner wrapping shall be removed in working place.

LOT NUMBER:

Each PMSSteripack Crepe Papers and SMMS Wrapping Papers; is provided with a LOT number printed on the inner pack label and the shipping carton label. The LOT number allows the traceability of the product during the manufacturing process. If there is any complaint or feedback, you must store the LOT number and provide picture of it.

STORAGE CONDITIONS:

PMSSteripack Crepe Papers and SMMS Wrapping Papers; must be stored in their original packaging at max. +35°C and max. 70% RH humidity. Wrapping papers should be protected from direct light, moisture and excess humidity. If wrapping paper is wet, do not use it anymore and dispose it as specified.

SHELF LIFE / EXPIRY DATE:

- 1- The shelf life (pre-sterilization use) of PMSSteripack Crepe Papers and SMMS Wrapping Papers; are 5 (five) years after manufacture date under recommended storage and handling conditions. The product must be used within 5 years from date of manufacture. The expiry date, as well as the manufacture date is printed on the inner pack label and the shipping carton label.
- 2- Sterilized packs (Standard, non woven, soft, sms) preserve bacterial barrier properties during 6 months when stored at recommended conditions.

It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

If any serious incident has occurred in relation to the product, user must inform to the manufacturer and has right to report to the competent authority of the member state in which user and/or patient established.

DISPOSAL INSTRUCTION:

Throw used or damaged wrapping papers into the autoclavable biohazard bags, not into the regular waste bags.



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Figure-1






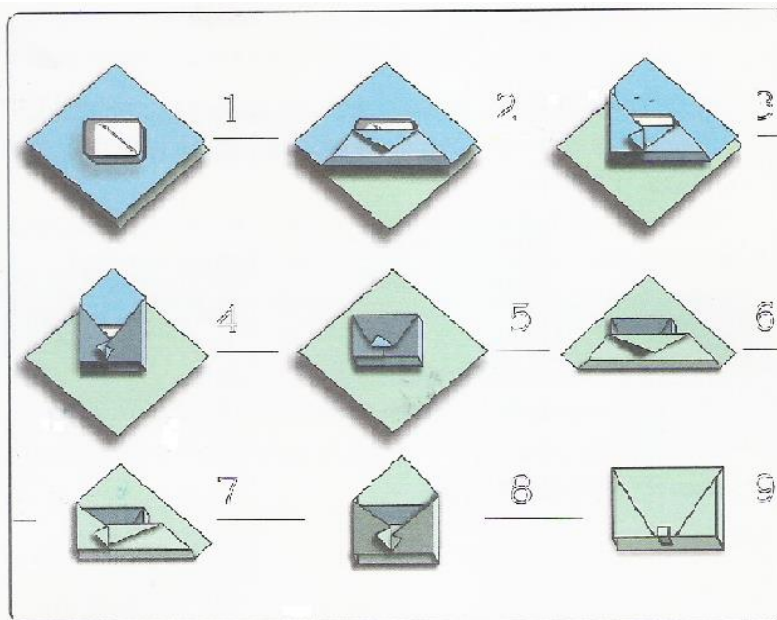
Crepe		<ul style="list-style-type: none"> - Weight up to 3 kg (for double layer packaging) - Small and medium-size trays, light packs, instruments
Reinforced Crepe		<ul style="list-style-type: none"> - Weight up to 6 kg (for double packs) - Small surgical trays - Small surgical packs of medium size and weight
Nonwoven		<ul style="list-style-type: none"> - Weight up to 12 kg (for double packs) - Surgical instrument trays, orthopedic trays and packs, heavy and large-size packs
Interleaved		<ul style="list-style-type: none"> - Combination of various grades and colours to suit every type of application
Interleaved SMS / Nonwoven		<ul style="list-style-type: none"> - Weight up to 15 kg (for double packs) - Orthopedic trays and packs, very heavy packs

Figure-2



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