McKESSON

Sterilization Wraps | **DUAL LAYER**

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The sterilization wrap is single use, non-sterile. It is divided into double layers, with double layer edges closed by ultrasonic suture. The sterilization wrap is made from 100% polypropylene spunbond-meltblown-spunbond (SMS).

It is not made with natural rubber latex.

MODEL AND SPECIFICATIONS

Table 1: Size and specifications of the sterilization wrap

Product Specifications	400 Grade	500 Grade	600 Grade
24 in x 24 in	16-BW3024	16-BW5024	
36 in x 36 in	16-BW3036	16-BW5036	16-BW6036
45 in x 45 in			16-BW6045
48 in x 48 in		16-BW5048	16-BW6048
Basic weight (g/m^2)	65g + 65g	70g + 70g	88g + 88g
Color	Blue + White		
Layer	Dual Layers		

NOTE: The sterilization wrap is a double layer wrap comprised of one sheet of blue pigmented SMS fabric and one sheet of white pigmented SMS fabric that have been ultrasonically sealed on two opposing edges.

INDICATIONS FOR USE

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used up to 365 days post sterilization.

The sterilization wrap is used to enclose another medical device that is to be sterilized by a health care provider using:

a) 100% ethylene oxide (EO) with a concentration of 725 - 735 mg/l at 131°F/55°C and 40% - 80% relative humidity for 60 minutes

b) Exhausting the EO gas vacuum depth: 157 mBar to 160 mBar

c) Aeration time: 12 hours

d) Aeration temperature: 55°C

e) Aeration pressure: 841 mBar to 864 mBar

PACKAGE METHODS

a) Prior to Use

i. Condition wrap at ideal temperature (68°F to 73°F/20°C to 23°C) and relative humidity (20% to 60%) for a minimum of two hours.

ii. Examine wrap and discard if damage or extraneous matter is detected.

iii. Thoroughly clean and dry items to be wrapped.

b) Opening

i. Inspect package for damage, moisture, or any sign of potential contamination prior to opening and again after opening but before use of contents. Do not use contents if these conditions are present, as sterility could be compromised. Reprocess the contents using an unprocessed wrap if any of these conditions are noted.

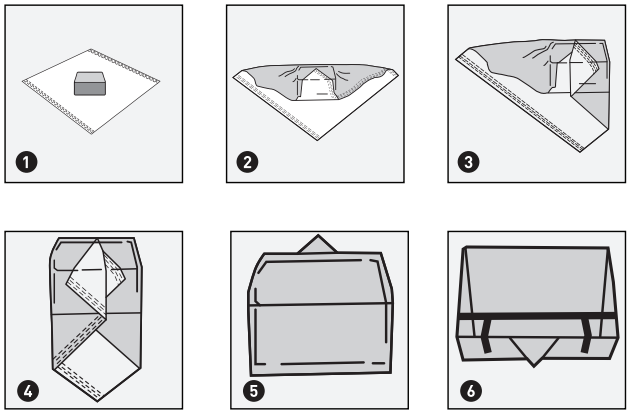
ii. Open packages aseptically in accordance with the health care facility's policy.

c) Secure the wrapped package with sterilization indicator tape or with another closure method suitable for the sterilization method to be used.

d) The closure must allow the sterilant to penetrate the wrapped package, avoid constriction of the package, and maintain package integrity.

e) Label the closure on the wrapped package with the statement "Sequentially Wrapped."

f) The wrapping method is shown in the figure below:



NOTE:

a) After the product packaging is finished, EO sterilization indicator tape is required (Figure 6 shows the sticking position of the sterilization indicator tape).

b) When wrapping, pay attention to the folding angle position gap to ensure that there is no gap in the corner part.

STORAGE CONDITIONS AND METHODS

Store the product in a clean, dust-free location. Keep away from fluorescent or ultraviolet light. Use a first-in, first-out (FIFO) inventory rotation.

STERILIZATION METHODS

a) Suggestions for the packaging content are given in Table 2.

Table 2: Wrap model recommendations

McKesson MFR Number	Size: Length x Width (in)	Layers of sheet	Color	Basic Weight (g/m^2)	Enclosed Medical Device	Maximum Recommended Wrapped Package Content Weight (lb)
16-BW3024	24 x 24	Dual	White + Blue	65g+65g	Light to moderate weight package (for example: surgical towels, fluid- resistant table cover, general use medical instruments)	7.5
16-BW3036	36 x 36	Dual	White + Blue			9
16-BW5024	24 x 24	Dual	White + Blue	70g+70g	Heavy weight package (for example: tray liners, lumens, general use medical instruments) Maximum two lumens in one pack, each with minimum inner diameter of 3mm ID and maximum length of 400mm.	6
16-BW5036	36 x 36	Dual	White + Blue			9.5
16-BW5048	48 x 48	Dual	White + Blue			17
16-BW6036	36 x 36	Dual	White + Blue	88g+88g	Very heavy weight package (for example: tray liners, lumens, general use medical instruments). Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	10
16-BW6045	45 x 45	Dual	White + Blue			23
16-BW6048	48 x 48	Dual	White + Blue			25

b) Sterilization method

i. 100% ethylene oxide (EO) with a concentration of 725 - 735 mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes.

ii. Exhausting the EO gas vacuum depth: 157 mBar to 160 mBar

iii. Aeration time: 12 hours

iv. Aeration temperature: 55°C

v. Aeration pressure: 841 mBar to 864 mBar

c) Cool/unload after sterilization

i. Place packaged packaging on a sterilizer cart and remain as is before cooling to avoid affecting packaging sterility.

ii. Visually inspect wrapped items as they are removed from the cart. Items that are damaged or wet should not be used.

d) Sterility Maintenance

The wrap supports maintenance of package sterility for 365 days provided package integrity is maintained for ethylene oxide (EO).

VALIDITY

Product shelf life: 5 years

PRECAUTIONS, WARNINGS

a) Do not use it if the packaging is broken, damp, or compressed.

b) Inspect wrap for damage or extraneous matter prior to use. Do not use wrap if a defect is detected.

c) Do not use wrapped contents if wrap is damaged or wet following sterilization.

d) This device has not been approved for reuse. Reuse may result in material degradation which may result in failure of the device to allow sterilization and/or maintenance of sterility of the load.

e) When utilizing a 100% EO sterilization cycle with a concentration of 725 - 735 mg/l at 55°C (131°F) and 40%–80% relative humidity for 60 minutes with the sterilization wrap, do not sterilize at a set point below 55°C (131°F).

f) Do not open boxes or packages with a sharp knife. The knife can be easily cut through to the wrap.

g) Before use, ensure that all the quasi-sterilized medical devices packaged in the sterilization package are compatible and sterilized with the sterilization methods and cycles listed in the instructions. Refer to the sterilization instructions for all the sterilization equipment. Some medical devices, regardless of the sterilization method and sterilization packaging/containers used, may require special consideration in the packaging configuration to ensure sterilization.

h) Do not use it in the presence of flammable anesthetics. The package is not conductive.

i) If sterilization is performed by an external contract facility, it is recommended to use additional covers to protect packaged equipment from contamination.

j) Stacking of wrapped packs should be avoided. Stacking packs can result in damage to the wrap caused by undue pressure from the weight.

k) The sterilization package is suitable for the common medical sterilization parameters listed in the instructions for use. The sterilizer manufacturer should be consulted about the appropriate sterilizer loading configuration.

l) The shelf life of the facility sterilization items is related to the event, and should be based on the quality of the packaging materials, storage conditions, transportation methods and conditions, and the quantity and conditions of handling.

m) Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each health care facility should determine for itself which wrap model is most appropriate for each intended use.

n) It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight and size of individual content types that were validated for the sterilization wrap.

o) If wrapped devices are to be transferred between facilities for sterilization and/or storage, recommends using an additional covering to protect wrapped devices from contamination.

p) The wrap allows for sterile opening and sterile packaging.

q) After use, it is disposed of as medical waste in accordance with local regulations.


Consult instructions for use


Keep dry


Keep away from sunlight

Non-sterile

Do not reuse

Questions? Call 1-800-777-4908

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