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Heat- Sealing Pouch & Reel

Instructions For Use

Introduction:

Sterilization pouches and reels are intended to be used as packing material for the sterilization of medical device.

Preparation for use:

1. Do not fold the pouch to ensure proper penetration of the steam and ethylene oxide (EO).
2. Dimensions of the medical device to sterilize should not exceed ¾ of the pouch space. (Reels: roll out enough length to guarantee sufficient space for the content, the seal and for easy grasping at the opening).
3. Rubber bands, sharp objects (e.g.: paper clips, safety pins or staples) should not be used to secure packages or organize the contents.
4. Before sealing, remove as much air as possible from the pouch to help prevent rupturing in sterilization.

Heat- sealing:

1. Ensure that pouch contents are away from the seal area and will not get caught in the seal.
2. Leave 2 cm space on the outside of the sealing strip. (Reels: leave enough space beyond the seal for easy grasping at opening side).
3. Recommended sealing parameters range:
    - Temperature: 150 – 220 ^{0}C
    - Pressure: 0.2 - 0.6 MPa
    - Time: 0.2 - 3.0 s
4. Verify the seal integrity (e.g.: no folds, wrinkles or air bubbles).

Before sterilization:

1. Be sure to arrange pouches in such a way that there is minimal to no contact between pouches. It is recommended to place sealed pouches into autoclave vertically.
2. The sterilization basket should not be fully packed to leave sufficient space for pouches to expand and ventilate

After sterilization:

1. Check that the pouch is dry and not damaged or discolored.
2. Confirm that the sealing is complete.
3. Verify that sterilization indicator color changed as per specification.

Sterilization indicator:

1. Steam: Blue to Black (after sterilization)
2. Ethylene oxide (EO): Pink to Brown (after sterilization)

Storage condition:

1. Store products in their original packaging in a dust- free environment, away from direct sunlight, UV light sources and excessive humidity.
    - Recommended relative humidity: 30 -60%
    - Recommended Temperature: 10- 40 ^{0}C

2. Outer cartons should be handled with care and kept safe from damage

Shelf life:

3 years

Legal manufacturer:

Global SCP Medical Systems Pte. Ltd., Singapore