

SMART-FOLD*

Sterilization Wrap

H650, Non-Sterile



TECHNICAL DATA SHEET

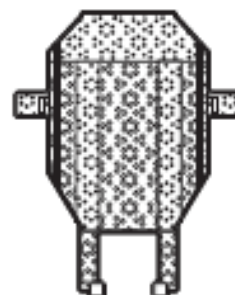
Description

| | | Dimensions |
|-------|--|-----------------|
| 14271 | SMART-FOLD* Sterilization Wrap - H650 | 101 cm x 119 cm |
| 14277 | | 101 cm x 139 cm |
| 14309 | | 121 cm x 154 cm |

Non-Conductive. Single Use.
Treated with an anti-static treatment.

Properties:

Basis weight of inside (white) layer: 62.7 g/m² per application
Basis weight of outside (blue) layer: 87 g/m² per application
Base weight of blue reinforcement strips: 87 g/m²
Base weight of the blue opening pull-tabs: 87 g/m²



Indication

Halyard sterilization wrap is a disposable packaging material intended for use in the sterilization of medical devices and for the maintenance of their sterility until use of the products.

Single use product.

Can be safely incinerated. Under proper combustion conditions, it burns to give water vapour, carbon dioxide and some ash residue. The generated heat is approximately the same as that from home heating oil.

Counter indication

Do not use in the Presence of Flammable Anesthesia.
Do not use wrap in dry heat or radiation sterilization methods.

Main materials

SMS Non-Woven (polypropylene): recycling category #5.

Not formulated with Natural rubber latex.
Does not contain DEHP.

Sterilization

Products are non-sterile.

Compatible with pre-vacuum steam sterilisation,
EO-sterilisation, low temperature hydrogen peroxide sterilisation
and LTFS sterilisation (low temperature formaldehyde sterilisation)

Shelf life

None specified.

Packaging

14271 & 14277: Shipping case of 48 units.

6 units per clip; 2 clips per shrink wrap bundle (12 per bundle)
4 bundles per case (48 count).

14309: Shipping case of 36 units

6 units per clip; 2 clips per shrink wrap bundle (12 per bundle)
3 bundles per case (36 count)

Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

Manufacturing

Processed in Mexico of U.S. Materials.
The manufacturing site's quality system conforms to ISO13485.

Regulatory information

Product CE-marked as per Medical Device Regulation MDR
2017/745. Class of the device: I, non-sterile
This product complies with ISO 11607 and EN 868-2

Storage

Location should be clean, dust free and away from fluorescent or ultraviolet light.

Store in a dry and cool place, away from intense sources of heat.
Keep as much as practicably possible in its shipper box.