Technical Data Sheet

Cosmopor® E steril

General Product Description/Intended Purpose

Cosmopor® E steril is a non-active, single-use, self-adhesive, sterile device consisting of an adhesive coated backing material (carrier material) and a woundpad, protected with a silicone paper.

The main constituents of this products is:

- The backing / carrier material: a white non-woven.
- The medical grade adhesive: a transparent synthetic rubber based adhesive / Hotmelt.
- The wound pad has two different layers: a wound contact layer made of a polyethylene net to prevent the wound pad to stick to the wound and an absorbent layer made of viscose for the absorption of wound exudate.
- Silicone paper: protective paper in contact with the adhesive side of the device.

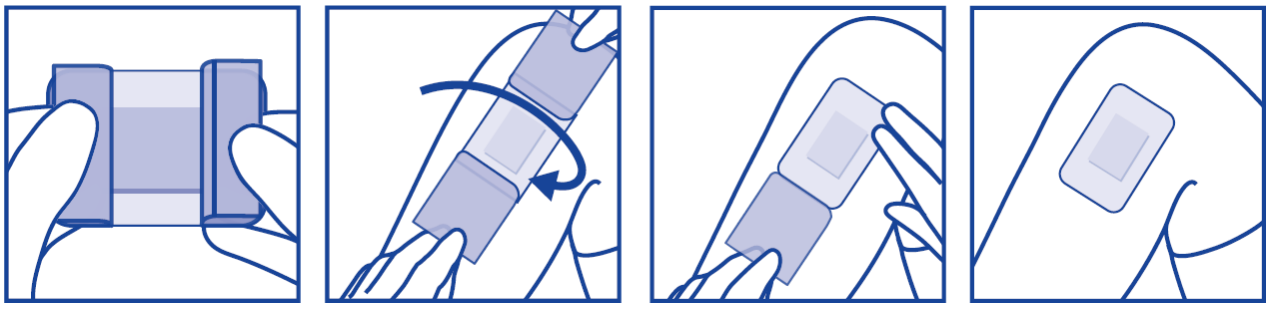
The product does not contain resorbable components, medicinal products / drug substances (derived from human blood or plasma or not), tissues or cells of human or animal origin, radioactive substances, nanomaterials or other hazardous components.

The dressings are sealed individually in peel-pouches and packed in cardboard folding boxes.

Application/Indication

Cosmopor® E steril is a non-active, non-invasive, single-use, sterile self-adhesive dressing consisting of an adhesive coated backing material (carrier material) and a woundpad, protected with a silicone paper, for the protection of postsurgical / primary wounds and absorption of exudate (wounds with a normal exudate production).

The product is intended for humans, without restrictions (in age group, weight range, health status or condition), for use by healthcare professionals and lay-users, in contact with intact skin (healthy skin) and breached skin, and short-term (60 minutes ≤ Duration ≤ 30 days, acc. to MDR) / prolonged use (24 hours < Duration ≤ 30 days, acc. to ISO 10993-1:2018) duration of use.



CP-C2.2-01, Annex 17, Version 2, valid from: 01.03.2020

Cosmopor® E steril

Reference Numbers

Packaging	Dimensions	Reference
P10	7,2 x 5 cm	900 891
	10 x 6 cm	900 892
	10 x 8 cm	900 893
	15 x 8 cm	900 894
	15 x 9 cm	900 899
	20 x 10 cm	900 895
P25	10 x 6 cm	900 871
	10 x 8 cm	900 873
	15 x 6 cm	900 872
	15 x 8 cm	900 874
	20 x 8 cm	900 875
	20 x 10 cm	900 876
	25 x 10 cm	900 877
	35 x 10 cm	900 878
P50	7,2 x 5 cm	900 870

Contraindications

Not indicated to be applied on non-treated infected wounds, ulcers or chronic wounds.

Sterile Device

Prevention symbols added:

Do not use if package is damaged.

Do not resterilize.

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Cosmopor® E steril should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Cosmopor® E steril

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Cosmopor® E steril			
Property	**Test method**	**Unit**	**Specification ***
Peel adhesion – Non-woven adhesion on silk (machine direction).	Evaluation of the peel test based on DIN ISO 6133:2017-04, procedure B.	N/25mm	12 ± 3
Absorption capacity	Method acc. to (DIN) EN 13726-1:2002:06.	g/100cm^2	>12

(*) Specification obtained through internal test results. The tests are performed periodically to ensure that the product meets the specifications

Labelling

Lot-No. with 9-Digit Code

	Eg.:		Eg.:	
LOT	**0**	**XXX**	**03**	**XXX**
	Year	For internal purposes only	Manufacturing week	For internal purposes only

Manufacturing Date

E.g.:	**2025**	**01**	**14**
	Year	Month	Day

Use-by-Date

	Eg.:	Eg.:	
	2025	**01**	**01**
	Year	Month	Day

Shelf Life: **5 years**

Medical Device

MD

Unique Device Indetification (UDI)

UDI

Cosmopor® E steril

Single Sterile Barrier System

Legal Manufacturer

PAUL HARTMANN AG
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www.hartmann.info

Latest Date of Revision: 2020.03.25