Instructions for Use

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Device name: Foam Dressing

Model

Dressing type	Model	Size		
		Length/cm	Width/cm	Thickness/mm
Foam dressing	Border	1-25	1-50	1-10
	Silicone-Border	1-25	1-50	1-10
	Silicone-Border Lite	1-25	1-50	1-10
	Silicone-Non-Border	1-25	1-50	1-10

Product Describe

Foam dressing is designed for absorbing wound blood/exudates while protecting the wound from external contamination and maintaining a moist internal environment, which help to enhance wound healing and minimize the risk for maceration.

Composition

The foam dressing consists of outer layer, absorption layer, adhesion layer(optional) and protective layer .

The outer layer is a PU film composited nonwoven tape or with or without adhesive. The absorbing layer is either an absorbent pad of PU foam or consisted of PU foam, super absorbent polymer (SAP) produced by polyacrylate and nonwoven. The adhesive layer is a silicone adhesive. The protective layer is a release film or paper.

Indications

Foam dressing, which is a soft and highly absorbent dressing, absorbs wound exudate, maintains a moist wound environment and minimizes the risk for maceration.

Foam Dressing is designed for a wide range of exuding wounds:

- Pressure ulcers
- Leg ulcers
- Foot ulcers

- Traumatic wounds（skin tears）
- Surgical wounds (post-operative, donor site)
- Radiation skin reactions
- Partial thickness burns
- Epidermolysis Bullosa

Foam Dressing can also be used on dry/necrotic wounds in combination with gels.
Foam Dressing may be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcer, postoperative blistering.

Intended Use

This product absorbs and controls wound exudate through foam absorption layer, and is used for covering and nursing chronic wounds with more exudate.

Intended User

Patients requiring wound care and medical staff.

Intended Patient

Adult without contraindications.

Contraindications:

1) Should not be used on third degree burns and surgical implantation.
2) Should not be used on patients with known sensitivity to the dressing or its component.

Warnings and precautions

- Foam dressing is for external use only.
- Do not use if package is damaged or opened prior to use.
- Single-use only and should not be re-used.
- To avoid issues with cross-contamination and sterility, use immediately and discard any unused dressing, the dressing should not be re-used once package is opened.
- Do not use the product in combination with other wound care products without first consulting a healthcare professional.
- If irritation or maceration occurs discontinue use and review the dressing protocol
- Do not use on patients with known sensitivity to the dressing or its component.

- In case of signs of clinical infection, consult a health care professional for adequate infection treatment.
- Do not use foam dressing together with oxidising agents such as hypochlorite solutions or hydrogen peroxide
- The use of foam dressing as part of prophylactic therapy does not preclude the need to continue develop and follow a comprehensive pressure ulcer prevention protocol, e.g. support surfaces, positioning, nutrition, hydration, skin care and mobility.

Directions for use

- Do not cut foam dressing.
- Choose a dressing size that covers the wound.
- Open the pouch and take out foam dressing. Ensure sterility.
- Gently lift one corner, then slowly lift off the dressing.
- Remove release liner.
- Gently secure the dressing to the skin.
- Frequency of dressing change depends on the condition of the wound.
- Clean the wound according to good clinical practice prior to application of a new dressing.
- The single product can be used for up to 7 days depending on the amount of drainage/moisture, the cumulative use does not exceed 28 days.

Storage

This product should be stored in dry conditions at room temperature, below 86°F (30°C). Protect from freezing.

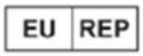
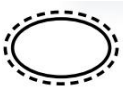
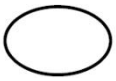
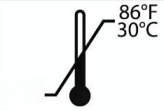
Sterile; do not use if inner packaging is damaged or opened prior to use. Do not re-sterilize.

Incident report

Report any events involving injuries or malfunctions to Jiangsu NewValue Medical Products Co.,Ltd. customer service or your sales representative or competent authority.

Symbol Instruction

	Medical device		Unique device identifier
	Manufacturer		Caution

	Date of manufacture		Use-by date
	Authorized representative in the European Community/European Union		Single sterile barrier system with protec-tive packaging outside
	Batch code		Catalogue number
	Sterilized using ethylene oxide		Do not use if package is damaged
	Single sterile barrier system		Do not re-use
	Temperature limit		Do not resterilize
	Keep dry		Fear of the sun
	Consult instructions for use		CE mark

Packaging mode

1pcs /pack; paper-plastic pouch

Sterilization

Sterilized using ethylene oxide

Sterilization period of validity

3 years

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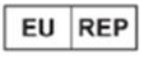

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