
		Technical Data Sheet	
VivanoMed Gel Strip			Spec.-No.: D 4.0058
			Department: CMO-DNP
			Date: 2017-03-24

1. General Product Description

A slab of hydrogel adhesive with a central polyester supporting mesh. The dressing is presented between two polyester liners, one of which is printed.

The dressing is packed in heat sealed triple laminate pouch, which is peelable. One side of the pouch is printed with the HARTMANN design and the other with the lot and expiry information. The product is supplied sterile by means of gamma irradiated.

VivanoMed Gel Strip is classified as 1s medical device according to the EU Council Directive 93/42/EEC for medical devices. VivanoMed Gel Strip is CE-marked according to the Council Directive 93/42/EEC for medical devices and legally manufactured by First Water. A conformity assessment process has been performed, demonstrating that VivanoMed Gel Strip is in compliance with all applicable requirements defined in the above mentioned directive. Safety and effectiveness of the VivanoMed Gel Strip is therefore ensured within the limitations of intended use.

2. Application / Indication

Indication

The Vivano®Med Gel Strip is used to fix tubes and to efficiently seal applied wound dressings as part of Negative Pressure Wound Therapy (NPWT), also in anatomically difficult areas, such as in the sacral region.

Application



1. Ensure that the skin on which the gel strip is to be applied is clean and dry.
2. Remove the sterile gel strip from the peel pouch.
3. If necessary, the gel strip can be cut to the required size with sterile scissors.
4. Remove the plastic film backing from both sides before applying the gel strip.
5. Apply the gel strip on the respective area of the skin.

3. Presentations

VivanoMed Gel strip	409 770	5 x P10
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4. Product Characteristics

Hydrogel	70mm Hydrogel – Polyester scrim middle
Liner	125 micron siliconised polyester
Pouch	Peelable paper foil laminate printed with customer supplied artwork and printed with LOT/EXP information in Process Black



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5. Labelling

Peel Pouch:

Each pouch must display at least one full lot and expiry date

- The batch code is made up as follows Lot: 012304, where 01 = Day of Week; 23 = Week of Year; 04 = Year
- The expiry date is three (3) years from the date of manufacture and the format is yyyy-mm
- The variable information is displayed on the reverse of the pouch as follows:

 **LOT** ddwwyy
 yyyy-mm

6. Packaging

- 5 folding boxes (with 10 peel pouches each) in one transport carton

Date: 2017-03-24

PAUL HARTMANN AG
- CMO-DNP Development NPWT

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