
		Technical Data Sheet	
VivanoTec Exudate Container		Spec.-No.:	D 4.0052
		Department:	CMO-DNP
		Date:	2013-11-25

1. General Product Description

VivanoTec Exudate Container is a single use exudate container for collecting wound exudates during the treatment with negative pressure wound therapy (NPWT). VivanoTec Exudate Container has to be attached to the VivanoTec device.

It is a Polypropylene container with a 1.8 m soft PVC double lumen suction tubing. It also contains the following components:

- fast fitting connector for the fixation with VivanoTec Port
- two hydrophobic bacteria filters, one of them containing activated charcoal
- mini bags containing super-absorbing polymers for wound secretion thickening

Atmos Medizintechnik GmbH is legal manufacturer of VivanoTec Exudate Container. VivanoTec Exudate Container carries the CE-mark according to EU directive 93/42/ EEC for medical devices. The product is classified as a class I sterile medical device. A conformity assessment has been performed for VivanoTec Exudate Container and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of VivanoTec Exudate Container therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Indications

VivanoTec Exudate Container has only to be used in combination with Vivano System.



Application notes

- 1) Carefully remove the sterile secretion canister from the peel package. Make sure that the attached piece of tube does not fall onto an un-sterile surface.
- 2) Place the container attachment at a slightly inclined angle into the guide pins of the device.
- 3) Fold the secretion canister in the direction of the negative pressure unit until it clicks into place.
- 4) Pull gently on the Exudate Container to ensure that it is firmly attached to the device
- 5) Connect the blue male connector to the female connector of VivanoTec Port.

3. Presentations

Article	Article-No.	Peel pouches per dispenser
VivanoTec Exudate Container 300 mL	409 523	3
	409 524	5
	409 525	10
VivanoTec Exudate Container 800 mL	409 520	3
	409 521	5
	409 522	10

VivanoTec Exudate Containers are sterilized by ethylene-oxide gas (EO) according to DIN EN ISO 11135.

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4. Labelling

Lot-No. with 9-digit code:
e.g.: 199800009

Expiry date: 6-digit code

e.g. 2016 06
 year month

shelf life time: 5 years

5. Packaging

VivanoTec Exudate Container are packaged in dispensers which are covered by a shipping carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2013-11-25

PAUL HARTMANN AG
- SM-PDW- Solution Management
- Product Development Wound Management

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Dr. Axel Eckstein