

# Foliodrape® Cellulose towel

## General Product Description/Intended Purpose

Foliodrape® Cellulose towels are disposable single-use absorbent towels for absorption of excessive amounts of disinfectant during skin disinfection procedure in the OR. Towels are made out of cellulose and Vinylacetat/Ethylen-Copolymerisat as a binder. The products are placed on the market as sterile and non-sterile commodities or as part of sterile surgical draping sets (medical device sets). If Foliodrape® cellulose towels are delivered in a non-sterile condition, they must be sterilized before use according to the information provided.

## Application/Indication

The Foliodrape® Cellulose towels may be used in different fields of applications/disciplines, such as general surgery, gynecology, orthopedics, accident surgery, ear, nose and throat (Otorhinolaryngology) (ENT)/oral and maxillofacial surgery, ophthalmology, urology, and cardiothoracic/cardiovascular and neurosurgery. Moreover, as a component in universal sets, they can be used for any type of surgery. They are intended to be used by healthcare professionals for transient use (duration under 60 minutes).

## Reference Numbers

Name of Product	REF Number	Size	Other Information
Foliodrape® Cellulose Towel	258 119/3	33 x 30 cm	Sterile

## Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

No contraindications known.

## Sterile Device

Do not use when sterile packaging or the product are damaged or were unintentionally opened before use.

## 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 Foliodrape® products should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards. All infected waste is recommended to be disposed of by incineration.

Non-contaminated material such as waste paper, packaging and non-sterile but not biologically contaminated materials can be disposed separately. Separate disposal containers should be available where waste is created, so that staff can sort the waste as it is being discarded.

## Product Performance Characteristics

The Foliodrape® range is developed under high-quality standards to ensure safety and infection prevention.

All products are free of CMR/PBT/vPvB substances (substances which are carcinogenic, mutagenic and toxic to reproduction, etc.). There are no added flame-retardants (like polybrominated bi-phenyls, etc.).

## Material Characteristics

Composition	Details
Material composition:	Cellulose and Vinylacetat/Ethylen-Co-polymerisat as binder
Basis weight:	approx. 60 g/m <sup>2</sup>
Absorption capacity (according to DIN 53 923):	4 g/100 cm <sup>2</sup>
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1

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Foliodrape® Cellulose Towel	258 119/3	33 x 30 cm

## Labelling

The Foliodrape® labeling describes the intended purpose of the device as supported by clinical evaluation. Safety information supplied by the legal manufacturer on the labeling are based on the risk management documentation and elaborately present all warnings and precautions according the new requirements of the standards concerning the product.

### Lot-No. with 8-Digit Code

e.g.:

	0 year	12 Week of production	XXXXX for internal purposes only
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### Manufacturing Date

e.g.:

	2020 year	04 month	07 day
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### Use-by-Date

e.g.:

	2025 year	04 month	07 day
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Shelf Life: 5 years

Unique Device Identification (UDI)



Single Sterile Barrier System  Single sterile barrier system

Do not use if the product sterile barrier system or its packaging is compromised



Single use device 

Keep dry 

Sterilized by Ethylene Oxide 

Non-Sterile



Legal manufacturer

 PAUL HARTMANN AG  
Paul-Hartmann-Straße 12  
89522 HEIDENHEIM, GERMANY

Dispose of your waste in an appropriate manner 

Recycling symbols – Corrugated cardboard / Polyethylene Low-Density



# Foliodrape® Cellulose towel

Producer contributes to recycling of packaging 

Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **Zellstofftuch  
Cellulose towel**

Reference / catalogue number **REF**

Pictogram with product look and dimensions 

## Storage and transport conditions

Transport and store in conditions for climatic regions I-IVa according to WHO Technical Report 953, 2009.

## Logistic data

Name of product	REF number	Peel Pouch size [mm]	Products per Peel Pouch	Peel Pouches per dispenser	Dispenser size	EAN of dispenser	Dispensers per carton
Foliodrape® Cellulose Towel	258 119/3	Size: XS 135 x 215	2	25	Size: S 215 x 136 x 185	4049500244060	4

**Latest Date of Revision:** 2020-06-08