

# Foliodrape® Absorption pad

## General Product Description/Intended Purpose

Foliodrape® Absorption pads reinforced are single-use products for short-term use in combination with Foliodrape® surgical drapes and equipment covers enabling collection of fluids.

Foliodrape® Absorption pads reinforced are made of 2-layer nonwoven/film laminate.

Foliodrape® Absorption pads reinforced have on the backside a self-adhesive which enables the fixation on the surgical drape. If fixed in that way on a drape it allows the absorbency of bigger amounts of fluids during the surgical procedure. The Foliodrape® Absorption pads are intended to be used in combination with surgical drapes and equipment covers in operating theatres and all other surgical environments (e.g., ambulance, doctor's surgery).

The Products are placed on the market sterile and are in Medical Device Class I.

## Application/Indication

The Foliodrape® collection products can be grouped according to the following fields of application: general surgery; gynecology and obstetrics surgery; orthopedics and accident surgery; ENT, oral, and maxillofacial surgery; urology surgery; ophthalmology surgery; and cardiothoracic, cardiovascular, and neurosurgery.

Depending on the procedure for which they are used, the Foliodrape® products usage time will vary from few minutes to several hours of continuous usage.

\* Definitions according to Reg. (EU) 2017/745 (MDR)

## Reference Numbers

Name of product	REF number	Size
	936 326/1	50 x 50 cm
Foliodrape® Absorption pad, adhesive, extra reinforced	936 327/1	100 x 100 cm
	936 325/1	90 x 75 cm

## 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.

## 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

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

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

# Foliodrape® Absorption pad

## Material Characteristics

Composition	Details
<b>Basis material:</b>	2-layer laminate made of Polyethylene film and viscose nonwoven
<b>Total grammage:</b>	Approx.. 100 g/m <sup>2</sup> ,
<b>Absorbency laminate:</b>	approx. 500 % (≅ approx. 500 ml/m <sup>2</sup> ) according to EN ISO 9073-6
<b>Self-adhesive:</b>	synthetic rubber based adhesive, latex-free
<b>Backing paper:</b>	siliconized paper
<b>Sterilization:</b>	With ethylene oxide gas according to EN 556-1 and EN 11135-1

## Product Characteristics

Name of product	REF number	size of cover	Size self-adhesive area
Foliodrape® Absorption pad, adhesive, extra reinforced	936 326/1	50 x 50 cm	4,5 x 46,5 cm
	936 327/1	100 x 100 cm	4,5 x 100 cm
	936 325/1	90 x 75 cm	4,5 x 86 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
---	-----------	-----------------------------	-------------------------------------

### Manufacturing Date

e.g.:		2020 year	04 month	07 day
-------	---	--------------	-------------	-----------

### Use-by-Date

e.g.:		2025 year	04 month	07 day
-------	---	--------------	-------------	-----------

Shelf Life: 5 years

Medical Device 

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



[www.hartmann.info](http://www.hartmann.info)

Foliodrape® Absorption pad / 100259845 / 2020-09-07

Page 2 of 4

Technical Data Sheet

# Foliodrape® Absorption pad

Single use device 

Keep dry 

Sterilized using ethylene oxide 

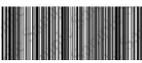
Legal manufacturer  **PAUL HARTMANN AG**  
Paul-Hartmann-Straße 12  
89522 HEIDENHEIM, GERMANY

European Conformity  **CE**  
0 1 2 3

Dispose of your waste in an appropriate manner 

Recycling symbols – Corrugated cardboard / Polyethylene Low-Density 

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 **Selbstklebendes Absorptionspad, extra verstärkt**  
**Absorption pad adhesive, extra reinforced**

Reference / catalogue number 

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.

# Foliodrape® Absorption pad

## 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 <sup>1</sup>
<b>Foliodrape® Absorption pad, adhesive, extra reinforced</b>	936 326/1	Size: S 133,5 x 290	1	60	Size: M 140 x 300 x 370	4052199501796	4
	936 327/1	Size: M 266,5 x 360	1	25	Size: L 274 x 368 x 296	4052199501833	2
	936 325/1	Size: S 133,5 x 290	1	22	Size: M 140 x 300 x 370	4052199501420	4

Latest Date of Revision: 2020-09-07