

Foliodrape® Adhesive bags

General Product Description/Intended Purpose

Foliodrape® Adhesive bags are single-use products for short-term use in combination with Foliodrape® surgical drapes and equipment covers enabling collection of operating swabs, surgical instruments, tubings/suctions and fluids.

Suction and instrument bags are made of transparent PE film. They have a rectangular shape and consists of 1, 2, or 3 chambers. On the backside, they have a self-adhesive which enables the fixation on the surgical drape or equipment cover.

The Foliodrape® collection products 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).

Foliodrape® collection products are non-active devices. The Products are placed on the market sterile and are in Medical Device Class I.

Application/Indication

The Foliodrape® and HARTMANN 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.

Suction, instrument bags, and fluid collection pouches are fixed on the drape and they are able to collect / store operating swabs, surgical instruments, tubings/suctions, cables and fluids during the surgical procedure. Material and sealings are water-proof, avoiding that fluids drops on the floor.

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	Sterilizaiton
Foliodrape® One-section adhesive bag	258 322/8	Radiation
	258 322/9	Ethylene Oxide
	258 327/3	Radiation
	258 327/4	Ethylene Oxide
Foliodrape® Two-section adhesive bag	258 323/7	Radiation
	258 323/8	Ethylene Oxide
	258 310/3	Radiation
	258 310/4	Ethylene Oxide
Foliodrape® One-section instrument bag	936 340/0	Ethylene Oxide
Foliodrape® Three-section instrument bag	936 329/0	Ethylene Oxide

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

Foliodrape® Adhesive bags

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.).

Material Characteristics

Composition	Details
Basis material:	Polyethylene film, transparent
Self-adhesive:	Synthetic rubber based adhesive, latex-free
Backing paper:	Siliconized paper
Sterilization:	By radiation according to EN ISO 11137-1 or by ethylene oxide gas according EN 556-1 and EN 11135-1

Product Characteristics

Name of product	REF number	size of bag	Size of self-adhesive
Foliodrape® One-section adhesive bag	258 322/8	38 x 43 cm	4,5 x 43 cm
	258 322/9		
	258 327/3	32 x 30 cm	4,5 x 30 cm
	258 327/4		
Foliodrape® Two-section adhesive bag	258 323/7	38 x 43 cm	4,5 x 43 cm
	258 323/8		
	258 310/3	40 x 46 cm	4,5 x 43 cm
	258 310/4		
Foliodrape® One-section instrument bag	936 340/0	55 x 50 cm	13 x 56 cm
Foliodrape® Three-section instrument bag	936 329/0	28 x 48 cm	5,5 x 28 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.

Foliodrape® Adhesive bags


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

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  Do not use if package is damaged

Single use device 


Keep dry 

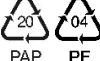
Sterilized using radiation 


Sterilized by Ethylene Oxide 


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

European Conformity 

Dispose of your waste in an appropriate manner 

Recycling symbols – Corrugated cardboard / Polyethylene Low-Density  PAP PE

Producer contributes to recycling of packaging 

Global trade identification number  **GTIN**

Foliodrape® Adhesive bags

Indication arrow where to open the packaging



Name and intended purpose of the product

Einkammer-Saugertasche,
selbstklebend
One-section adhesive bag

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.

Foliodrape® Adhesive bags

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® One-section adhesive bag	258 322/8	Size: XS 135 x 215	1	45	Size: S 218 x 137 x 188	4052199501222	4
	258 322/9	Size: XS 135 x 215	1	30	Size: S 218 x 137 x 188	4052199551654	4
	258 327/3	Size: XS 135 x 215	1	57	Size: S 218 x 137 x 188	4052199500621	4
	258 327/4	Size: XS 135 x 215	1	57	Size: S 218 x 137 x 188	4052199551739	4
Foliodrape® Two-section adhesive bag	258 323/7	Size: XS 135 x 215	1	45	Size: S 218 x 137 x 188	4052199500676	4
	258 323/8	Size: XS 135 x 215	1	45	Size: S 218 x 137 x 188	4052199551692	4
	258 310/3	Size: S 133,5 x 290	1	70	Size: M 300 x 140 x 370	4049500244107	4
	258 310/4	Size: S 133,5 x 290	1	70	Size: M 300 x 140 x 370	4052199551777	4
Foliodrape® One-section instrument bag	936 340/0	Size: S 133,5 x 290	1	25	Size: M 300 x 140 x 370	4052199509822	4
Foliodrape® Three-section instrument bag	936 329/0	Size: XS 135 x 215	1	32	Size: S 215 x 136 x 185	4052199509556	4

Latest Date of Revision: 2020-06-05