Foliodrape® Equipment covers

General Product Description/Intended Purpose
Foliodrape® Equipment covers consist of transparent Polyethylene-film (PE) and elastic latex-free synthetic rubber band, included into single packed products and sets varying in size, design and application. Foliodrape® Equipment covers are non-active devices and are single-use sterile products for short-term use enabling a sterile working environment. The covers are used in operating rooms and all other surgical environments (e.g., ambulance, doctor's surgery). The main task of equipment covers is the prevention of pathogen entrance into the surgical wound. Consequently, the risks of infections and blood-borne diseases are reduced.
The products are placed on the market sterile and are in Medical Device Class I.

Application/Indication
The Foliodrape® equipment covers 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.
Foliodrape® equipment covers are for short term use* and prevention of infection in humans in a clinical environment. 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	Reference Number	Size of Product
Foliodrape® Multi-purpose Equipment cover, square, crepe	936 342/0	85 x 60 cm
	938 845/2	85 x 150 cm
Foliodrape® Multi-purpose Equipment cover, round	938 846/2	100 x 50 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.

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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
Elastic Band:	Synthetic rubber on base of polyisoprene, latex-free
Sewing Thread:	Polyester thread
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

1.  **1. PE-Film (impermeable for moisture and bacteria)**

Foliodrape® PE drapes and covers correspond to all requirements of European standard EN 13795-1:2019 for the performance level “High performance, critical area”. For more detailed information, please visit page 5.

Product Characteristics

Product Name	REF number	Size of drape	Additional Information
Foliodrape® Multi-purpose Equipment cover, square, crepe	936 342/0	85 x 60 cm	Square, wrapped in crepe paper
	938 845/2	85 x 150 cm	Square, wrapped in crepe paper
Foliodrape® Multi-purpose Equipment cover, round	938 846/2	100 x 50 cm	Round

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.:

LOT	0 year	12 Week of production	XXXXX for internal purposes only

Manufacturing Date

e.g.:		2020 year	04 month	07 day

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Use-by-Date

e.g.:		2025	04	07
		year	month	day

Shelf Life: 5 years

Medical Device MD

Unique Device Identification (UDI) 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 ethylene oxide STERILE EO

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

European Conformity CE 0123

Dispose of your waste in an appropriate manner

Recycling symbols – Corrugated cardboard / Polyethylene Low-Density 20 PAP 04 PE

Producer contributes to recycling of packaging

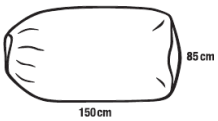
Global trade identification number GTIN

Indication arrow where to open the packaging

Name and intended purpose of the product
Universal-Abdeckhaube, quadratisch, Krepp
Multi-purpose equipment cover, square, crepe

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.

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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[1]
Foliodrape® Multi-purpose Equipment cover, square, crepe	936 342/0	Size: L 265 x 365	1	25	Size: L 275 x 374 x 234	4052199521688	2
	938 845/2	Size: L 265 x 365	1	20	Size: L 275 x 374 x 234	4052199212746	2
Foliodrape® Multi-purpose Equipment cover, round	938 846/2	Size: L 265 x 365	1	25	Size: L 275 x 374 x 234	4052199212784	2

Latest Date of Revision: 2020-09-07

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Foliodrape® PE, base material, testing results according EN 13795-1:2019

Property	Test method	Unit	Product requirement (PR) according EN 13795 -1:2019 for level "High Performance"	Test results[1]
Resistance to microbial penetration - Wet	EN ISO 22610	I_B	Less critical product area: Not required Critical product area: 6.0	6.0 (no penetration)
Cleanliness – microbial	EN ISO 11737-1	CFU/ 100 cm²	Less critical product area: ≤ 300 Critical product area: ≤ 300	Not required[3]
Particle release	EN ISO 9073-10	$\log_{10}$ (lint count)	Less critical product area: ≤ 4,0 Critical product area: ≤ 4,0	M_d =0,0 U_q = 0,9
Resistance to liquid penetration[4]	EN 20811	cm (H_2O)	Less critical product area: ≥ 10 Critical product area: ≥ 100	M_d = 196 L_q = 196
Bursting strength - Dry[5]	EN ISO 13938-1	kPa	Less critical product area: ≥ 40 Critical product area: ≥ 40	M_d = 62,4 L_q = 62,4
Bursting strength - Wet[5]	EN ISO 13938-1	kPa	Less critical product area: Not required Critical product area: ≥ 40	M_d = 61,0 L_q = 61,0
Tensile strength – Dry	EN 29073-3	N/50mm	Less critical product area: ≥ 20 Critical product area: ≥ 20	Longitudinal direction: M_d = 57,5 L_q = 52,6 Lateral direction : M_d = 39,4 L_q = 39,2
Tensile strength – Wet	EN 29073-3	N/50mm	Less critical product area: Not required Critical product area: ≥ 20	Longitudinal direction: M_d = 50,7 L_q = 50,1 Lateral direction: M_d = 40,2 L_q = 39,1

[1] Example REF 938 845 – Lot 699601007, unreinforced part, Test report from independent Testing-Institute is available on request. Abbreviations: L_q = lower quartile value, U_q = upper quartile value and M_d = median value. Product conforms when: Lq ≥ PRmin resp. U_q ≤ PRmax.
[2] Not required when the product fulfill the criteria for high performance in critical product area for resistance to microbial penetration wet (see Annex B7 in EN 13795:2019)
[3] see clause A1.2 in EN 13795-1:2019, Foliodrape® articles are sterile according to EN 556
[4] measured without use of supporting tissue (according to EN 20811),
[5] values after membrane correction (according to EN ISO 13938-1)