Foliodrape® Back table cover, reinforced

General Product Description/Intended Purpose

Foliodrape® Back table covers, reinforced consist of a variety of products and materials: different layers of hydrophilic nonwoven material laminated with Polyethylene-film (PE) included into single packed products and sets varying in material type, size, design and application. Foliodrape® equipment covers are non-active devices.
The covers are single-use sterile products for short-term use enabling a sterile working environment. They are used in operating room and all other surgical environments (e.g., ambulance, doctor's surgery).
The main task of Back table covers is the prevention of pathogen entry 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® Back table covers can be grouped according to the following fields of application: general surgery; gynaecology and obstetrics surgery; orthopaedics and accident surgery; ENT, oral, and maxillofacial surgery; urology surgery; ophthalmology surgery; and cardiothoracic, cardiovascular, and neurosurgery.
Foliodrape® equipment covers for short term use* and prevention of infection on 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	REF Number	Size of Product	Size of Reinforcement
Foliodrape® Back table cover, reinforced	938 850/2	150 x 190 cm	75 x 190 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.).

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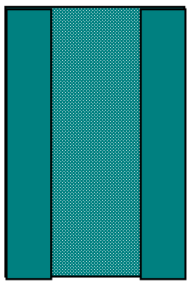
Because of the hydrophilic nature of the non-woven, the Foliodrape® Back table cover, extra-reinforced itself has antistatic properties, a special antistatic treatment is not necessary. Foliodrape® Back table covers meet the demand level “High Performance” of EN 13795-1:2019. They fully support patient and OR environment safety.

Material Characteristics

Composition	Details
Composition:	Non-woven-film-laminate, colour: aqua; total weight 115 g/m², latex-free
Film:	PE-film, colour: aqua, 60 µm, width 150 cm
Non-woven (absorbent):	Hydrophilic Polypropylene non-woven, colour: aqua, 55 g/m², width 75 cm
Adhesive:	Hotmelt on the basis of synthetic rubber
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1



Polypropylene non-woven (absorbent)

Polyethylene-Film (full width)

Foliodrape® Back table cover, reinforced corresponds to all requirements of European standard EN 13795-1:2019 for the performance level “High performance”. For detailed information about the material and test results, please visit page 5.

Product Characteristics

Name of product	REF number	size of cover	Size reinforcement
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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

Use-by-Date

e.g.:	2025 year	04 month	07 day

Foliodrape® Back table cover, reinforced

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 by 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

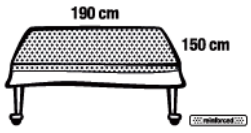
Global trade identification number GTIN

Indication arrow where to open the packaging

Name and intended purpose of the product
Tischabdeckung, verstärkt
Back table cover, reinforced

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® Back table cover, reinforced

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®	938 850/2	Size: M	1	14	Size: L	4052199500713	2
Back table cover, reinforced		266,5 x 360			368 x 274 x 296		

Latest Date of Revision: 2020-05-11

Foliodrape® Back table cover, reinforced

Foliodrape® Back Table Cover, extra-reinforced, 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 -Dry	EN ISO 22612	CFU	Less critical product area: ≤ 300 Critical product area: Not required[2]	**Unreinforced zone:** Not required[2] **Reinforced zone:** Not required[2]
Resistance to microbial penetration – Wet	EN ISO 22610	I_B	Less critical product area: Not required Critical product area: 6.0	**Unreinforced zone:** 6.0 (no penetration) **Reinforced zone:** 6.0 (no penetration)
Cleanliness – microbial	EN ISO 11737-1	CFU/100 cm²	Less critical product area: ≤ 300 Critical product area: ≤ 300	**Unreinforced zone:** Not required[3] **Reinforced zone:** Not required[3]
Particle release	EN ISO 9073-10	$\log_{10}$ (lint count)	Less critical product area: ≤ 4,0 Critical product area: ≤ 4,0	**Unreinforced zone:** M_d = 0,5 and U_q = 0,5 **Reinforced zone:** M_d = 2,2 and U_q = 2,4
Resistance to liquid penetration[4]	EN 20811	cm (H2O)	Less critical product area: ≥ 10 Critical product area: ≥ 100	**Unreinforced zone:** M_d = 172 and L_q = 170 **Reinforced zone:** M_d = 456 and L_q = 446
Bursting strength – Dry[5]	EN ISO 13938-1	kPa	Less critical product area: ≥ 40 Critical product area: ≥ 40	**Unreinforced zone:** M_D = 65 and L_q = 59 **Reinforced zone:** M_d = 250 and L_q = 248
Bursting strength – Wet[5]	EN ISO 13938-1	kPa	Less critical product area: Not required Critical product area: ≥ 40	**Unreinforced zone:** M_d = 82 and L_q = 79 **Reinforced zone:** M_d = 261 and L_q = 261
Tensile strength – Dry	EN 29073-3	N/50mm	Less critical product area: ≥ 20 Critical product area: ≥ 20	**Unreinforced zone:** Longitudinal direction: M_d = 40 and L_q = 38 Lateral direction: M_d = 35 and L_q = 31 **Reinforced zone:** Longitudinal direction: M_d = 174and L_q = 171 Lateral direction: M_d = 119 and L_q = 118
Tensile strength - Wet	EN 29073-3	N/50mm	Less critical product area: Not required Critical product area: ≥ 20	**Unreinforced zone:** Longitudinal direction: M_d = 38 and L_q = 38 Lateral direction: M_d = 33 and L_q = 32 **Reinforced zone:** Longitudinal direction: M_d = 186 and L_q = 184 Lateral direction: M_d = 123 and L_q = 123

[1] Example REF 938 850 – LOT 400114277 , Test report from independent Testing-Institute is available on request. Abbreviation: Lq = lower quartile value, Uq = upper quartile value and Md = median value. Product conforms when: Lq ≥ PRmin resp. Uq ≤ PRmax. Lq = lower quartile value, Uq = upper quartile value and Md = median value

[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)