

Foliodrape® Protect Plus drapes

General Product Description/Intended Purpose

Foliodrape® surgical drapes and covers consists of a variety of products and materials: different layers of nonwoven material laminated with Polyethylene-film (PE) that are available in different designs, sizes and for different applications. They are single-use sterile patient drapes and covers for short-term use for prevention of infection on humans in clinical environment.

Foliodrape® patient drapes and covers are intended to be used as sterile draping of the patient and dedicated inventory in operating theatres and all other surgical environments (e.g. day surgery, ambulance, doctor's surgery). The main task of drapes consists in the prevention of pathogen entry into the surgical wound. Consequently, the risks of infections and blood-borne diseases are reduced.

Foliodrape® self-adhesive 75 x 75 cm drape can be used as additional reinforcement for the front of a gown, which is added after putting on the gown.

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

Application/Indication

Draping is the perioperative process of covering a patient and surrounding areas in the operating theater with sterile drapes and covers to create and maintain a barrier, which protects the wound from the entry of microorganisms. The microorganisms can originate from the patient's skin, the OR, or the healthcare personnel. The aim of draping is to prevent the passage of pathogens between non-sterile and sterile areas. The different layers of hydrophilic nonwoven material laminated with Polyethylene-film act together as a fluid and bacteria barrier and minimize the transmission of micro-organisms. 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.

Reference Numbers

Name of product	REF number	Size	attributes
Foliodrape® Protect Plus Abdominal / Spinal drape, adhesive	938 825/2	260 x 320 cm	reinforced, with fenestration and hook and loop fastener, wrapped in crepe paper
Foliodrape® Protect Plus Back table cover, crepe	936 339/0	200 x 200 cm	reinforced, wrapped in crepe paper
	936 355/0	250 x 200 cm	reinforced, wrapped in crepe paper
Foliodrape® Protect Plus ENT / Maxillofacial drape, adhesive	938 826/2	225 x 235 cm	reinforced, with fenestration and hook and loop fastener, wrapped in crepe paper
Foliodrape® Protect Plus Extremity drape	936 650/0	200 x 320 cm	reinforced, with fenestration
	938 807/2	200 x 320 cm	reinforced, with fenestration, wrapped in crepe paper
	938 823/2	245 x 320 cm	reinforced, with fenestration, wrapped in crepe paper
	938 824/2	245 x 320 cm	reinforced, with fenestration, wrapped in crepe paper
Foliodrape® Protect Plus Fenestrated drape, adhesive	936 578/0	75 x 90 cm	reinforced, with fenestration
	936 577/0	150 x 120 cm	reinforced, with fenestration
	936 576/0	200 x 300 cm	reinforced, with fenestration, wrapped in crepe paper

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Foliodrape® Protect Plus 936 579/0 170 x 260 cm reinforced, with fenestrated incision foil
Fenestrated drape, fenestrated incision film

Foliodrape® Protect Plus Hand/Foot drape, crepe	938 808/3	245 x 320 cm	reinforced, with fenestration, wrapped in crepe paper
Foliodrape® Protect Plus Patient underlay	938 829/2	100 x 120 cm	reinforced
Foliodrape® Protect Plus Split sheet, adhesive	936 627/0	200 x 150 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 804/2	245 x 150 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 806/2	200 x 260 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 816/2	200 x 260 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 819/2	225 x 280 cm	reinforced, self-adhesive, wrapped in crepe paper
Foliodrape® Protect Plus Split sheet, adhesive	936 628/0	245 x 280 cm	reinforced, self-adhesive, wrapped in crepe paper
Foliodrape® Protect Plus surgical drape, adhesive	938 857/2	75 x 75 cm	reinforced, self-adhesive
	938 855/2	75 x 75 cm	reinforced, self-adhesive
	938 800/3	75 x 90 cm	reinforced, self-adhesive
	938 856/2	75 x 90 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 803/3	90 x 100 cm	reinforced, self-adhesive
	936 527/0	120 x 100 cm	reinforced, self-adhesive
	936 525/1	170 x 175 cm	reinforced, self-adhesive, wrapped in crepe paper
	936 526/1	170 x 200 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 802/3	200 x 200 cm	reinforced, self-adhesive, wrapped in crepe paper
	938 801/3	150 x 240 cm	reinforced, self-adhesive, wrapped in crepe paper
938 805/2	300 x 170 cm	reinforced, self-adhesive, wrapped in crepe paper	

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

No contraindications known.

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Preparatory Treatment

Sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings.

Skin and mucosis disinfection prior drape application: Prepare the surface with antiseptic solution, the solution should remain in contact with the skin as per the instruction on the disinfectant label. Do not make contact with any other area of the patient. Lay the drapes on the patient as per their intended purpose recommended by the product name. Leave uncovered only the operative field and those areas necessary for the maintenance of anesthesia.

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

Foliodrape® PROTECT PLUS offers pleasant usage, as the products are made of skin tolerable, soft material. The products are odor-neutral, and do not make any distracting noises while being handled. Drape design and easy-to-handle folding are developed in cooperation with operating theater staff and surgeons. They offer hygienic and efficient draping that can, in many cases, be done by a single person.

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.).

Because of the hydrophilic nature of the non-woven, the Foliodrape® material itself has antistatic properties, a special antistatic treatment is not necessary.

Foliodrape® PROTECT PLUS drapes reinforced fulfill the requirements for class 1 of flammability standard 16 CFR 1610.

Foliodrape® PROTECT PLUS drapes reinforced meet the highest demand level of EN 13795-1:2019. They fully support patient and OR environment safety.

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Material Characteristics

Composition	Details
Nonwoven:	Hydrophilic PP-spunbond, color: aqua
Reinforcement pad:	Hydrophilic SMS; non woven; color: green; weight: 55 g/m ²
Grammage:	110 g/m ² weight for reinforced zone
Film:	Pore-free polyethylene-film color: aqua
Total Laminate (Nonwoven and Film):	Thermobonded, 55 g/m ²
Adhesive:	Hotmelt on base of synthetic rubber, Latex-free
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-



Foliodrape® PROTECT PLUS drapes correspond to all requirements of European standard EN 13795-1:2019 for the highest performance level “High performance, critical area”. For more detailed information, please visit page 10.

Foliodrape® PROTECT PLUS drapes were tested according to STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES (16 CFR 1610) and belong to class 1.

Product Characteristics

REF number	size of drape	size reinforcement pad	size self-adhesive area	Size of fenestration/ Split
938 825/2	260/200 x 320 cm	40 x 50 cm	20,5 x 32 cm	9 x 22 cm
936 339/0	200 x 200 cm	100 x 198 cm	---	---
936 355/0	250 x 200 cm	100 x 248 cm	---	---
938 826/2	225 x 235 cm	20 x 30 cm	21 x 13 cm	18 x 10 cm
936 650/0	200 x 320 cm	75 x 130 cm	---	5 x 7 cm
938 807/2	200 x 320 cm	75 x 130 cm	---	5 x 7 cm
938 823/2	245 x 320 cm	105 x 150 cm	---	7 x 10 cm
938 824/2	245 x 320 cm	100 x 150 cm	---	3 Ø cm
936 578/0	75 x 90 cm	50 x 50 cm	18 x 20,5 cm	7 Ø cm
936 577/0	150 x 120 cm	50 x 50 cm	17 x 18 cm	7 Ø cm
936 576/0	200 x 300 cm	75 x 75 cm	35 x 35 cm	15 x 15 cm
936 579/0	170 x 260 cm	50 x 50 cm	12 x 14 cm	4 x 6 cm

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938 808/3	245 x 320 cm	100 x 150 cm	---	3 Ø cm
938 829/2	100 x 120 cm	50 x 140 cm	---	---
936 627/0	200 x 150 cm	60 x 70 cm	5 cm around split	6,5 x 65 cm
938 804/2	245 x 150 cm	60 x 70 cm	5 cm around split	6,5 x 65 cm
938 806/2	200 x 260 cm	150 x 160 cm	5 cm around split	6,5 x 95 cm
938 816/2	200 x 260 cm	100 x 175 cm	5 cm around split	20 x 95 cm
938 819/2	225 x 280 cm	150 x 160 cm	5 cm around split	10 x 95 cm
936 628/0	245 x 280 cm	150 x 160 cm	5 cm around split	10 x 95 cm
938 857/2	75 x 75 cm	75 x 37,5 cm	71 x 4,5 cm	---
938 855/2	75 x 75 cm	75 x 37,5 cm	71 x 4,5 cm	---
938 800/3	90 x 75 cm	90 x 37,5 cm	86 x 4,5 cm	---
938 856/2	90 x 75 cm	90 x 37,5 cm	86 x 4,5 cm	---
938 803/3	100 x 90 cm	100 x 37,5 cm	96 x 4,5 cm	---
936 527/0	120 x 100 cm	45 x 75 cm	116 x 5 cm	---
936 525/1	175 x 170 cm	75 x 50 cm	90 x 5 cm	---
936 526/1	200 x 170 cm	75 x 50 cm	90 x 5 cm	---
938 802/3	200 x 200 cm	50 x 75 cm	90 x 5 cm	---
938 801/3	240 x 150 cm	75 x 50 cm	90 x 5 cm	---
938 805/2	300 x 170 cm	50 x 75 cm	100 x 5 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


Technical Data Sheet


Foliodrape® Protect Plus drapes


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**
0 1 2 3

Dispose of your waste in an appropriate manner 

Recycling symbols – Corrugated cardboard / Polyethylene Low-Density 

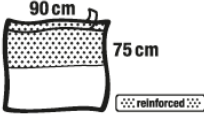
Producer contributes to recycling of packaging 

Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **Abdecktuch, selbstklebend**
Surgical drape, adhesive

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

REF number	Peel Pouch size [mm]	Products per Peel Pouch	Peel Pouches per dispenser	Dispenser size	EAN of dispenser	Dispensers per carton
938 825/2	Size: XL 345 x 510	1	7	Size: XL 374 x 545 x 234	4052199019376	1
936 339/0	Size: M 266,5 x 360	1	7	Size: L 274 x 368 x 296	4052199516325	2
936 355/0	Size: M 266,5 x 360	1	5	Size: L 274 x 368 x 296	4052199570549	2
938 826/2	Size: L 265 x 365	1	8	Size: L 275 x 374 x 234	4052199521794	2
936 650/0	Size: L 360 x 580	1	11	Size: XL 368 x 568 x 300	4052199509884	1
938 807/2	Size: L 360 x 580	1	11	Size: XL 368 x 568 x 300	4052199509440	1
938 823/2	Size: L 360 x 580	1	9	Size: XL 368 x 568 x 300	4052199509532	1
938 824/2	Size: L 360 x 580	1	10	Size: XL 368 x 568 x 300	4052199510729	1
936 578/0	Size: M 266,5 x 360	1	30	Size: L 274 x 368 x 296	4052199523125	2
936 577/0	Size: M 266,5 x 360	1	19	Size: L 274 x 368 x 296	4052199516844	2
936 576/0	Size: L 360 x 580	1	16	Size: XL 368 x 568 x 300	4052199516882	1
936 579/0	Size: L 360 x 580	1	17	Size: XL 368 x 568 x 300	4052199522920	1
938 808/3	Size: L 360 x 580	1	10	Size: XL 368 x 568 x 300	4052199510682	1
938 829/2	Size: L 265 x 365	1	20	Size: L 275 x 374 x 234	4052199521572	2
936 627/0	Size: M 266,5 x 360	1	12	Size: L 274 x 368 x 296	4052199509617	2

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938 804/2	Size: M 266,5 x 360	1	8	Size: L 274 x 368 x 296	4052199510453	2
938 806/2	Size: L 360 x 580	1	11	Size: XL 368 x 568 x 300	4052199509204	1
938 816/2	Size: L 360 x 580	1	12	Size: XL 368 x 568 x 300	4052199509358	1
938 819/2	Size: L 360 x 580	1	9	Size: XL 368 x 568 x 300	4052199509402	1
936 628/0	Size: L 360 x 580	1	10	Size: XL 368 x 568 x 300	4052199509648	1
938 857/2	Size: S 133,5 x 290	1	30	Size: M 140 x 300 x 370	4052199229041	4
938 855/2	Size: S 133,5 x 290	2	16	Size: M 140 x 300 x 370	4052199228976	4
938 800/3	Size: S 133,5 x 290	1	28	Size: M 140 x 300 x 370	4052199219561	4
938 856/2	Size: M 266,5 x 360	2	20	Size: L 274 x 368 x 296	4052199500997	2
938 803/3	Size: S 133,5 x 290	1	17	Size: M 140 x 300 x 370	4052199219608	4
936 527/0	Size: S 133,5 x 290	1	15	Size: M 140 x 300 x 370	4052199510415	4
936 525/1	Size: M 266,5 x 360	1	16	Size: L 274 x 368 x 296	4052199501468	2
936 526/1	Size: M 266,5 x 360	1	13	Size: L 274 x 368 x 296	4052199501710	2
938 802/3	Size: M 266,5 x 360	1	12	Size: L 274 x 368 x 296	4052199509310	2
938 801/3	Size: M 266,5 x 360	1	11	Size: L 274 x 368 x 296	4052199500584	2
938 805/2	Size: M 266,5 x 360	1	9	Size: L 274 x 368 x 296	4052199509372	2

Latest Date of Revision: 2020-09-04

Foliodrape® Protect Plus drapes

Foliodrape® Protect Plus, 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	l _g	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 cm ²	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 = 2,2 and U _q = 2,3 Reinforced zone: M _d = 1,8 and U _q = 2,0
Resistance to liquid penetration ⁴	EN 20811	cm (H2O)	Less critical product area: ≥ 10 Critical product area: ≥ 100	Unreinforced zone: M _d = 150 and L _q = 155 Reinforced zone: M _d = 204 and L _q = 174
Bursting strength – Dry ⁵	EN ISO 13938-1	kPa	Less critical product area: ≥ 40 Critical product area: ≥ 40	Unreinforced zone: M _D = 134 and L _q = 125 Reinforced zone: M _d = 339 and L _q = 335
Bursting strength – Wet ⁵	EN ISO 13938-1	kPa	Less critical product area: Not required Critical product area: ≥ 40	Unreinforced zone: M _d = 132 and L _q = 129 Reinforced zone: M _d = 353 and L _q = 339
Tensile strength – Dry	EN 29073-3	N/50mm	Less critical product area: ≥ 20 Critical product area: ≥ 20	Unreinforced zone: Longitudinal direction: M _d = 78,5 and L _q = 75,1 Lateral direction: M _d = 46,3 and L _q = 45,6 Reinforced zone: Longitudinal direction: M _d = 190 and L _q = 188 Lateral direction: M _d = 128 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 = 82,2 and L _q = 81,5 Lateral direction: M _d = 46,8 and L _q = 46,2 Reinforced zone: Longitudinal direction: M _d = 202 and L _q = 200 Lateral direction: M _d = 135 and L _q = 127
Absorbency (laminat)	EN ISO 9073-6	%	No normative requirement	Unreinforced zone: 285 (± approx. 156 ml/m ²) Reinforced zone: 350 (± approx. 386 ml/m ²)

¹ Example REF 938 707 – Lot 400114277, 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: L_q ≥ 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)