

Foliodrape® Leggings

General Product Description/Intended Purpose

Foliodrape® Leggings consist of Polyethylene film or of two layers, a nonwoven material laminated with Polyethylene-film (PE) and are available in different 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 a clinical environment.

Foliodrape® Leggings are intended to be used as sterile draping of the patient 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. 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 Polyethylene film or 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	Reference Number	Size of Product
Foliodrape® Protect Legging	938 841/2	75 x 120 cm
	938 840/2	75 x 140 cm
	938 842/2	75 x 140 cm
Foliodrape® Legging PE, crepe	258 969/2	75 x 140 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.

Foliodrape® Leggings

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

For Protect Leggings:

Composition	Details
Nonwoven Material:	Hydrophilic PP-spunbond, 30 g/m ² , color: aqua
Film:	Pore-free polyethylene-film, 25 g/m ² , color: aqua
Total Laminate:	Thermobonded, 55 g/m ² , latex-free
Sterilisation	With ethylene oxide gas according EN 556-1 and EN 11135-1

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|----|--|----------------------------------------------------|
| 1. | | 1. Hydrophilic PP spunbond |
| 2. | | 2. PE-Film (impermeable for moisture and bacteria) |

Foliodrape® PROTECT drapes corresponds to all requirements of European standard EN 13795-1:2019 for the highest performance level “High performance, critical area.” For more information, visit the Foliodrape® Protect drapes technical data sheet.

For PE Leggings:

Composition	Details
Basis material:	PE-film, colour: aqua, 60 µm, width 150 cm
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1

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|----|--|----------------------------------------------------|
| 1. | | 1. PE-Film (impermeable for moisture and bacteria) |
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Foliodrape® PE leggings correspond to all requirements of European standard EN 13795-1:2019 for the performance level “High performance, critical area”. For more detailed material information, please visit Foliodrape® Back table cover technical data sheet.

Product Characteristics

Product Name	REF number	Size of drape	Additional Information
Foliodrape® Protect Leggings	938 841/2	75 x 120 cm	Paired packed
	938 840/2	75 x 140 cm	Single packed
	938 842/2	75 x 140 xm	Paired packed
Foliodrape® Legging PE, crepe	258 969/2	75 x 140 cm	Paired packed, with crepe wrapping

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.

Technical Data Sheet

Foliodrape® Leggings

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 ethylene oxide 


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


European Conformity  0 1 2 3

Dispose of your waste in an appropriate manner 

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

Producer contributes to recycling of packaging 

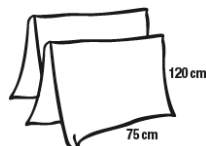
Global trade identification number  GTIN

Indication arrow where to open the packaging 

Name and intended purpose of the product **Beinschützer Legging**

Foliodrape® Leggings

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.

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® Protect Legging	938 841/2	Size: M 266,5 x 360	2	14	Size: L 274 x 368 x 296	4052199517643	2
	938 840/2	Size: M 266,5 x 360	1	22	Size: L 274 x 368 x 296	4052199517681	2
	938 842/2	Size: M 266,5 x 360	2	9	Size: L 274 x 368 x 296	4052199516806	2
Foliodrape® Legging PE, crepe	258 969/2	Size: M 266,5 x 360	2	23	Size: L 274 x 368 x 296	4052199509228	2

Latest Date of Revision: 2020-09-04