

Foliodrape® Hook and loop fastener

General Product Description/Intended Purpose

Foliodrape® Hook and loop fastener products are single-use products for short-term use in combination with Foliodrape® surgical drapes and equipment covers and consist of Polyamide. The adhesive Hook and Loop fasteners can be fixed on a surgical drape or equipment cover, enabling the fixation of cables and tubes.

According to their intended use, there is no direct contact to the patient. The Foliodrape® fixation 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). The Foliodrape® products are placed on the market sterile and are in Medical Device Class I.

Application/Indication

The Foliodrape® fixation 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.

Foliodrape® products are 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	Reference Number	Size of Product
Foliodrape® Hook and loop fastener, green	258 280/8	2 x 23 cm
Foliodrape® Hook and loop fastener, white	938 858/2	2 x 23 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.

Foliodrape® Hook and loop fastener

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 materials:	Polyamid fabric
	Polyacrylat backing
	Pressure sensitive adhesive on basis of synthetic rubber, latex free
Backing Paper:	Silicon paper
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

Product Characteristics


Product Name	REF number	Size of product	Size of self-adhesive area
Foliodrape® Hook and loop fastener, green	258 280/8	2 x 23 cm	2 x 23 cm
Foliodrape® Hook and loop fastener, white	938 858/2	2 x 23 cm	2 x 23 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
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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





Single use device



Technical Data Sheet


Foliodrape® Hook and loop fastener

Keep dry 

Sterilized using 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




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 **Klettverschluss, grün**
Hook and loop fastener, green

Reference / catalogue number 

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® Hook and loop fastener

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® Hook and loop fastener green	258 280/8	Size: S 133,5 x 290	1	200	Size: M 140 x 300 x 370	4052199509679	4
Foliodrape® Hook and loop fastener, white	938 858/2	Size: M 130 x 290	1	200	Size: M 140 x 300 x 370	4052199249490	4

Latest Date of Revision: 2020-09-07