

# Foliodrape® Camera cable covers

## General Product Description/Intended Purpose

Foliodrape® Camera cable covers consist of transparent Polyethylene-film (PE) and 1 or 2 fixation strips, included into single packed products and sets varying in design. Foliodrape® Camera cable covers are non-active devices and are single-use sterile products for short-term use which enable 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 camera cable 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

For single packed products:

| Name of Product                       | Reference Number |
|---------------------------------------|------------------|
| Foliodrape® Camera cable cover, crepe | 258 266/4        |

For Camera cable covers which are part of a set:

| Name of Component  | Set Reference Number(s)             |
|--------------------|-------------------------------------|
| Camera cable cover | 936 741/0, 938 729/2, and 938 702/3 |
| Camera cable cover | 936 846/0 and 936 850/0             |

## 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.

# Foliodrape® Camera cable covers

## 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.).

## Material Characteristics

| Composition:           | Details:  |
|------------------------|---|
| <b>Basis Material:</b> | Polyethylene film, transparent                            |
| <b>Fixation Strip:</b> | Acrylic adhesive, colophony- and latex-free               |
| <b>Sterilization:</b>  | With ethylene oxide gas according EN 556-1 and EN 11135-1 |

1.



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

## Product Characteristics

| Product Name                                 | REF number                                | Size of cover | Additional Information  |
|--|---|---------------|---|
| <b>Foliodrape® Camera cable cover, crepe</b> | 258 266/4                                 | 13 x 250 cm   | Perforation, cardboard introducing support, telescopic folding, 1 fixation strip  |
| <b>Camera cable cover</b>                    | 936 741/0,<br>938 729/2,<br>and 938 702/3 | 13 x 250 cm   | Perforation, cardboard introducing support, telescopic folding, 1 fixation strip  |
| <b>Camera cable cover</b>                    | 936 846/0 and<br>936 850/0                | 8 x 170 cm    | Perforation, cardboard introducing support, telescopic folding, 2 fixation strips |

## 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® Camera cable covers

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

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



Producer contributes to recycling of packaging



Global trade identification number



GTIN

Indication arrow where to open the packaging

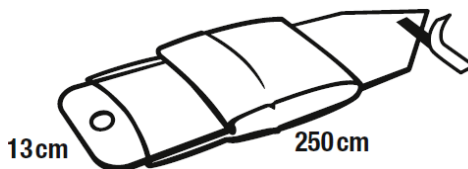


# Foliodrape® Camera cable covers

Kamerakabel-Bezug, Kreppeinschlag  
Camera cable cover, crepe

Name and intended purpose of the product

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

For Single packed Products:

| 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®<br>Camera cable<br>cover, crepe | 258 266/4  | Size: M<br>266,5 x 360 | 1                       | 70                         | Size: L<br>368 x 274 x 296 | 4052199522142    | 2                     |

For logistic details of sets, please visit the related technical data sheet for the set.

Latest Date of Revision: 2020-06-02