# Foliodrape® C-arm cover

**General Product Description/Intended Purpose**

Foliodrape® C-arm cover consists of transparent Polyethylene-film (PE). It is included into single packed products and into draping sets. Foliodrape® C-arm cover is a non-active device and is a single-use sterile product for short-term use enabling a sterile working environment. The cover is used in operating rooms and all other surgical environments (e.g., ambulance, doctor's surgery). The main task of C-arm covers is the prevention of pathogen entrance 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**

The Foliodrape® C-arm cover can be used in 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 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® C-arm cover, crepe** | 936 332/0 | 95 x 220 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.).

# Foliodrape® C-arm cover

**Material Characteristics**

| Composition | Details |
|---|---|
| **Basis Material:** | Polyethylene film, transparent |
| **Sterilization:** | With ethylene oxide gas according EN 556-1 and EN 11135-1 |

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

Foliodrape® PE drapes and covers correspond to all requirements of European standard EN 13795-1:2019 for the performance level “High performance, critical area”. For more detailed information, please visit PE drapes technical data sheet.

**Product Characteristics**

| Product Name | REF number | Size of drape |
|---|---|---|
| **Foliodrape® C-arm cover, crepe** | 936 332/0 | 95 x 220 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.:

| | | | |
|---|---|---|---|
| LOT | 0<br>year | 12<br>Week of production | XXXXX<br>for internal purposes only |

Manufacturing Date
e.g.:

| | | | |
|---|---|---|---|
|  | 2020<br>year | 04<br>month | 07<br>day |

Use-by-Date
e.g.:

| | | | |
|---|---|---|---|
|  | 2025<br>year | 04<br>month | 07<br>day |

Shelf Life: 5 years

Medical Device MD

Unique Device Identification (UDI)  UDI

Single Sterile Barrier System  Single sterile barrier system

# Foliodrape® C-arm cover

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

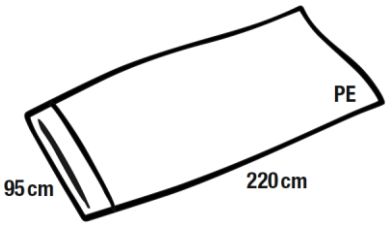
Global trade identification number GTIN

Indication arrow where to open the packaging

Name and intended purpose of the product **C-Bogen-Abdeckung, Kreppeinschlag**
**C-Arm cover, crepe**

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® C-arm cover

**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® C-arm cover, crepe** | 936 332/0 | Size: M<br>266,5 x 360 | 1 | 25 | Size: L<br>368 x 274 x 296 | 4052199516929 | 2 |

**Latest Date of Revision:** 2020-06-02