

# Foliodrape® Instrument table collection bag

## General Product Description/Intended Purpose

Foliodrape® Instrument table collection bags (drill tube holders) are single-use products for short-term use in combination with instrument table covers enabling collection of operating swabs, surgical instruments, tubings/suctions and fluids. They are made of a nonwoven material laminated with Polyethylene-film (PE). The Foliodrape® collection products are intended to be used in combination with instrument table covers in operating theatres and all other surgical environments (e.g., ambulance, doctor's surgery).

Foliodrape® collection products are non-active devices. The products are placed on the market sterile and are in Medical Device Class I.

## Application/Indication

The Foliodrape® Instrument table collection bags can be grouped according to the following fields of application: general surgery; gynaecology and obstetrics surgery; orthopaedics 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® Instrument table collection bag, crepe	936 333/0	80 x 115 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.).

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## Material Characteristics

Composition	Details
<b>Basis material:</b>	Polyethylene film, transparent
<b>Laminated with:</b>	Hydrophilic Polypropylene non-woven; color: green; weight: 30 g/m <sup>2</sup>
<b>Sterilization:</b>	With ethylene oxide gas according to EN 556-1 and EN 11135-1

## Product Characteristics


Product Name	REF number	Size of drape	Size of reinforcement
Foliodrape® Instrument table collection bag, crepe	936 333/0	80 x 115 cm	60 x 115 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	12	XXXXX
year	Week of production	for internal purposes only	

### Manufacturing Date



e.g.:		2020	04	07
	year	month	day	

### Use-by-Date


e.g.:		2025	04	07
	year	month	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

# Foliodrape® Instrument table collection bag

European Conformity **CE**  
0 1 2 3

Dispose of your waste in an appropriate manner

Recycling symbols – Corrugated cardboard / Polyethylene Low-Density

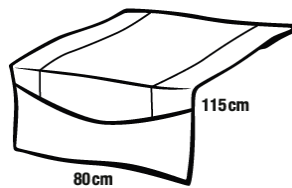
Producer contributes to recycling of packaging

Global trade identification number **GTIN**

Indication arrow where to open the packaging

Name and intended purpose of the product **Instrumententisch-Auffangbeutel, Kreppeinschlag**  
**Instrument table collection bag, 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.

## 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® Instrument table collection bag, crepe	936 333/0	Size: M 266,5 x 360	1	15	Size: L 274 x 368 x 296	4052199510354	2

Latest Date of Revision: 2020-09-04