

# Foliodrape® Urology Sets

## General Product Description/Intended Purpose

Foliodrape® Urology Sets sterile are single-use products for short-term use and consists of a variety of products like patient drapes, equipment covers, fixation and collection accessories, commodity products (e.g. towels); included into sterile packages. The Foliodrape® standard sets are intended to be used in different fields of applications/disciplines. Foliodrape® products are 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. These products are placed onto the market sterile and are in Medical Device Class I.

## Application/Indication

The Foliodrape® Urology sets are used in different fields of applications in urology surgery. 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
Foliodrape® Protect Nephroscopy set	938 752/2
Foliodrape® Protect Urology set I	936 726/0
Foliodrape® Protect Urology set II	938 700/3
Foliodrape® Protect Urology set III, crepe	938 908/3
Foliodrape® Protect Urology set IV	936 728/0
Foliodrape® Protect Urology set V	938 750/2
Foliodrape® Protect Urology set VI	938 749/2

## Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

No contraindications known.

## Preparatory Treatment

Sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings.

**Skin and mucosis disinfection prior drape application:** Prepare the surface with antiseptic solution, the solution should remain in contact with the skin as per the instruction on the disinfectant label. Do not make contact with any other area of the patient. Lay the drapes on the patient as per their intended purpose recommended by the product name. Leave uncovered only the operative field and those areas necessary for the maintenance of anesthesia.

## 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.

# Foliodrape® Urology Sets

## 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.).

## Material Characteristics

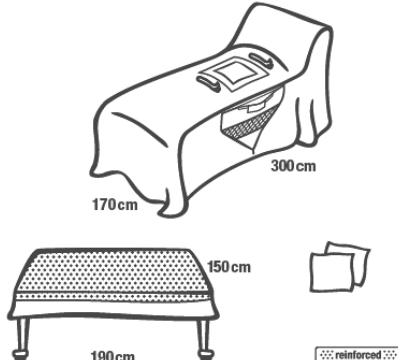
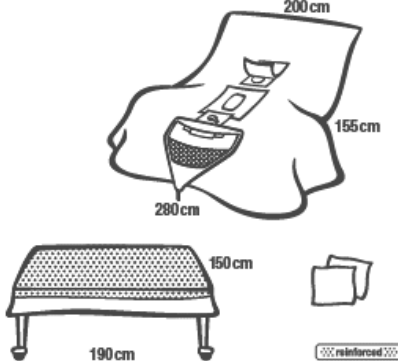
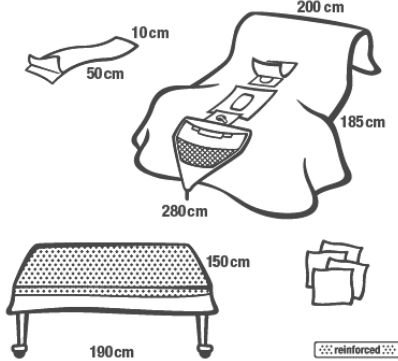
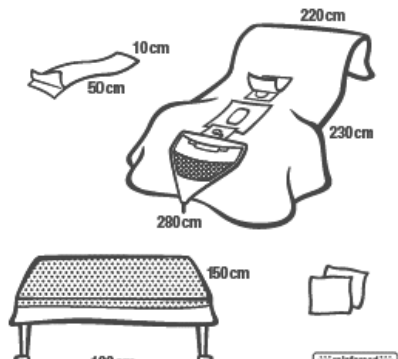
For Performance Indicators, visit individual Technical Data Sheets for components listed below.

Protect	Foliodrape® Protect drapes
Back table cover	Foliodrape® Back table cover reinforced
Instrument table cover	Foliodrape® Instrument table covers
Adhesive bag	Foliodrape® Adhesive bags
Cellulose Towels	Foliodrape® Cellulose Towels
OR tape adhesive	Foliodrape® OR Tape
Leggings	Foliodrape® Leggings
Pouches/Bags on drapes	Foliodrape® Collection Bags

Foliodrape® PROTECT and PROTECT PLUS drapes correspond to all requirements of European standard EN 13795-1:2019 for the highest performance level “High performance, critical area”. Sets are sterilized with ethylene oxide gas according EN 556-1 and EN 11135-1.

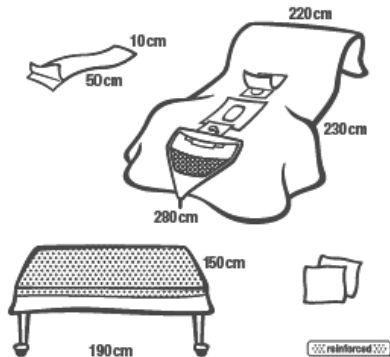
# Foliodrape® Urology Sets

## Product Characteristics

Reference Number	Contents Picture	Content Description	Quantity
938 752/2		<b>Back table cover (Wrapping)</b> 190 x 150 cm <b>Cellulose Towels</b> 30 x 33 cm <b>Protect Fenestrated / Nephroscopy drape</b> 300 x 170 cm 20 x 15 cm fenestration, collection bag, 2 hook and loop fasteners	<b>1</b>  <b>2</b>  <b>1</b>
936 726/0		<b>Back table cover (Wrapping)</b> 190 x 150 cm <b>Cellulose Towels</b> 30 x 33 cm <b>Protect Urology drape</b> 200/280 x 155 cm Pouch with adhesive, 10 x 7 oval and Ø7 round fenestrations, collection bag, finger stall, leggings	<b>1</b>  <b>2</b>  <b>1</b>
938 700/3		<b>Back table cover (Wrapping)</b> 190 x 150 cm <b>Cellulose Towels</b> 30 x 33 cm <b>OR tape adhesive</b> 10 x 50 cm <b>Protect Urology Drape</b> 200/280 x 185 cm 10 x 7 oval and Ø7 round fenestrations, collection bag, finger stall, leggings	<b>1</b>  <b>4</b>  <b>1</b>  <b>1</b>
938 908/3		<b>Back table cover (Wrapping)</b> 190 x 150 cm <b>Cellulose Towels</b> 30 x 33 cm <b>OR tape adhesive</b> 10 x 50 cm <b>Protect Urology drape</b> 220/280 x 230 cm Pouch with adhesive, 10 x 7 oval and Ø7 round fenestrations, collection bag, finger stall, leggings	<b>1</b>  <b>2</b>  <b>1</b>  <b>1</b>

# Foliodrape® Urology Sets

936 728/0



**Back table cover (Wrapping)** 1

190 x 150 cm

**Cellulose Towels** 2

30 x 33 cm

**OR tape adhesive** 1

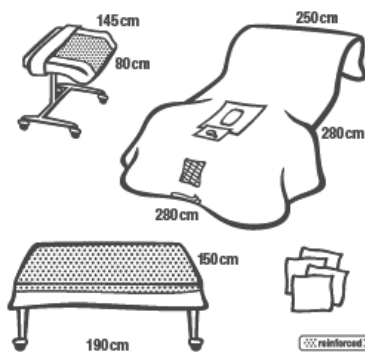
10 x 50 cm

**Protect Urology drape** 1

220/280 x 230 cm

Pouch with strips, 10 x 7 oval and Ø7 round fenestrations, collection bag, finger stall, leggings

938 750/2



**Back table cover (Wrapping)** 1

190 x 150 cm

**Instrument table cover** 1

80 x 145 cm

**Cellulose Towels** 4

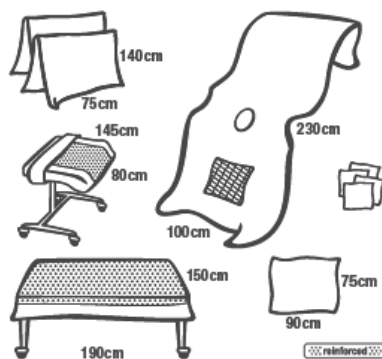
30 x 33 cm

**Protect Urology drape** 1

250/280 x 280 cm

9 x 12 cm fenestration, sieve, finger stall, with leggings

938 749/2



**Back table cover (Wrapping)** 1

190 x 150 cm

**Instrument table cover** 1

80 x 145 cm

**Cellulose Towels** 4

30 x 33 cm

**Protect Urology drape** 1

100 x 230 cm

8 x 12 cm Fenestration, Sieve

**Protect Legging** 2

75 x 140 cm

**Protect Surgical drape** 1

90 x 75 cm

## Labelling

The Foliodrape® labelling describes the intended purpose of the device as supported by clinical evaluation. Safety information supplied by the legal manufacturer on the labelling 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  
year

12  
Week of  
production

XXXXX  
for internal purposes only

Technical Data Sheet

# Foliodrape® Urology Sets

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 **MD**


Unique Device Identification (UDI)  **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 



Keep dry 


Sterilized by Ethylene Oxide **STERILE EO**


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


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 

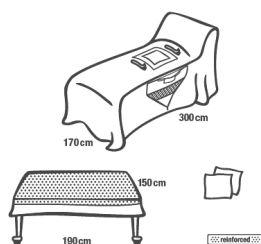
Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **Nephroskopie-Set**  
**Nephroscopy set**

Reference / catalogue number **REF**

# Foliodrape® Urology Sets



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 <sup>1</sup>
<b>Foliodrape® Protect Nephroscopy set</b>	938 752/2	Size: XL 345 x 510	1	7	Size: XL 374 x 545 x 234	4052199522814	1
<b>Foliodrape® Protect Urology set I</b>	936 726/0	Size: XL 345 x 510	1	6	Size: XL 374 x 545 x 234	4052199525648	1
<b>Foliodrape® Protect Urology set II</b>	938 700/3	Size: XL 345 x 510	1	8	Size: XL 374 x 545 x 234	4052199214511	1
<b>Foliodrape® Protect Urology set III, crepe</b>	938 908/3	Size: XL 345 x 510	1	5	Size: XL 374 x 545 x 234	4052199523569	1
<b>Foliodrape® Protect Urology set IV</b>	936 728/0	Size: XL 345 x 510	1	6	Size: XL 374 x 545 x 234	4052199521213	1
<b>Foliodrape® Protect Urology set V</b>	938 750/2	Size: XL 345 x 510	1	4	Size: XL 374 x 545 x 234	4052199523316	1
<b>Foliodrape® Protect Urology set VI</b>	938 749/2	Size: L 265 x 365	1	4	Size: L 275 x 374 x 234	4052199523712	2

Latest Date of Revision: 2020-09-07