Foliodrape® Collection Bags

General Product Description/Intended Purpose

Foliodrape® Collection bags are single-use products for short-term use in combination with Foliodrape® surgical drapes enabling collection of operating swabs, surgical instruments, tubings/suctions and fluids. Fluid collection products, like urology and arthroscopy pouches, are made of transparent PE film with or without a flexible PE bar or forming foam ring. They have a rectangular or triangular shape and may contain a nylon or Polyethylene filter and a PE tube connector port. The Foliodrape® collection products are intended to be used in combination with surgical drapes 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® collection products 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

For Bags or Pouches that are single packed:

Name of Pouch	Name of Product	Reference Number	Sterilization
Bag for Hip	**Foliodrape® Bag for hip surgery, crepe**	936 330/0	Ethylene Oxide
Collection bag	**Foliodrape® Collection bag, crepe**	936 346/0	Ethylene Oxide
Shoulder Arthroscopy bag U-shaped	**Foliodrape® Shoulder Arthroscopy bag, crepe**	258 128/2	Radiation
Shoulder Arthroscopy bag U-shaped	**Foliodrape® Shoulder Arthroscopy bag, crepe**	258 128/3	Ethylene Oxide

For Bags or Pouches included on a drape or in a set:

Name of Pouch	Name of Component	Set Reference Number(s) Containing Component
Arthroscopy bag with foam	**Protect Arthroscopy drape**	936 734/0
	Protect Knee / Arthroscopy drape	938 909/2
	Protect Knee / Arthroscopy drape	938 703/3
Bag with sieve	**Vertical / Hip drape, PE, extra reinforced**	936 738/0
C-Sectio bag	**Protect Cesarean drape**	938 904/2, 938 720/3, and 938 711/3
	Protect Cesarean drape	938 918/2
Shoulder Arthroscopy bag	**Protect Shoulder / Arthroscopy drape**	936 733/0, 938 726/3, and 936 806/0
Shoulder Arthroscopy bag U-shaped	**Protect Shoulder / Arthroscopy drape**	936 759/0 and 936 756/0

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Suction bag with one chamber	**Ophthalmology drape**	936 817/0
Suction bag with three chambers	**Protect Thorax drape**	936 763/0 and 936 764/0
Urology bag	**Protect Gynecology / Perineal drape**	938 903/2
	Protect Gynecology / Perineal drape	936 791/0
Urology bag	**Protect Gynecology / Perineal drape**	936 727/0
	Protect Urology drape	936 726/0
	Protect Urology drape	938 700/3
	Protect Urology drape	938 908/3
Urology bag small	**Protect Fenestrated / Nephroscopy drape**	938 752/2
	Protect Plus Neuro drape	936 770/0 and 938 741/3
	Vertical drape PE	938 907/2 and 938 705/3
	Vertical drape PE	936 732/0
Urology bag with stripes	**Protect Urology drape**	936 728/0

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.

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
Basis material:	Polyethylene film, transparent
Self-adhesive:	Synthetic rubber based adhesive, latex-free
Backing paper:	Siliconized paper
For some references: thin flexible bar, foam ring, or mesh sieve:	Polyethylene with included metal wire, Polyurethane foam, or Spunbond nylon
Sterilization:	With radiation according to EN ISO 11137-1 or with ethylene oxide gas according to EN 556-1 and EN 11135-1

Product Characteristics

Name of Bag	REF number (s)	Size of Bag	Size of self-adhesive	Other Features
Arthroscopy bag with foam	936 734/0, 938 909/2, and 938 703/3	60 x 94 cm	6,5x60 cm	7x5 cm (Oval) Fenestrated Elastic Cuff, 5x5 cm (Round) Fenestrated Elastic Cuff, Port, 127x2x1 cm Foam Ring
Bag for Hip	936 330/0	117 x 80 cm	5 x 117 cm	2 flexible bars (1,5 x 38 cm each) 2 hook&loop fasteners (2 x 5 cm each)
Bag with sieve	936 738/0	56 x 90 cm	6,5x20 cm And 6,5 x 90 cm	Port, Mesh Sieve, 70x0,8 cm Thin Flexible Bar
C-Sectio bag	938 904/2, 938 720/3, 938 711/3, and 938 918/2	80 x 80 cm	45x40 cm	33x33 cm Fenestration, Incision Film, Ø45 cm Foam Ring
Collection bag	936 346/0	56 x 90 cm	6,5x20 cm And 6,5 x 90 cm	Port, Mesh Sieve, 70x0,8 cm Thin Flexible Bar
Shoulder Arthroscopy bag	936 733/0, 938 726/3, and 936 806/0	73 x 84 cm	2 x 6x33 cm 6x42 cm And 6x70 cm	30x30 cm Fenestration, Port, 190x0,8 cm Thin Flexible Bar
Shoulder Arthroscopy bag U-shaped	258 128/2, 258 128/3, 936 759/0, and 936 756/0	85 x 74 cm	6 cm around slit	2 Ports, 127x2x1 cm Foam Ring
Suction bag with one chamber	936 817/0	28 x 30 cm	5 x 30 cm	15 x 0,8 cm Thin Flexible Bar

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Suction bag with three chambers	936 763/0 and 936 764/0	32 x 110 cm	5 x 110 cm	3 Chambers
Urology bag	938 903/2, 936 791/0, 936 727/0, 936 726/0, 938 700/3, and 938 908/3	56 x 90 cm	6,5x20 cm And 6,5 x 90 cm	Port, Mesh Sieve, 70x0,8 cm Thin Flexible Bar
Urology bag small	938 752/2, 936 770/0, 938 741/3, 938 907/2, 938 705/3, and 936 732/0	47 x 70 cm	6,5x20 cm And 6,5x70 cm	Port, Mesh Sieve, 62x1 cm Thin Flexible Bar
Urology bag with stripes	936 728/0	56 x 90 cm	6,5x90 cm	Port, Mesh Sieve, 2 x 80x4,5 cm Stripes for tying, 70x0,8 cm Thin Flexible Bar

Urology and arthroscopy pouches are intended for better fluid management.
Some of the products are easier to use due to a wider cap for faster liquid discharge than the previous version. They feature an innovative stripe to maintain the pouch open and stable.

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 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 MD

Unique Device Identification (UDI)  UDI

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Single Sterile Barrier System 

Do not use if the product sterile barrier system or its packaging is compromised 

Single use device 

Keep dry 

Sterilized using radiation STERILE R

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 

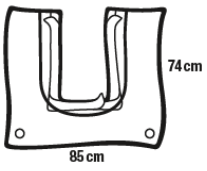
Producer contributes to recycling of packaging 

Global trade identification number  GTIN

Indication arrow where to open the packaging 

Name and intended purpose of the product
Schulter-/Arthroskopie-Beutel, Kreppeinschlag
Shoulder/Arthroscopy 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.

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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® Bag for hip surgery, crepe	936 330/0	Size: M 266,5 x 360	1	25	Size: L 274 x 368 x 296	4052199509495	2
Foliodrape® Collection bag, crepe	936 346/0	Size: M 266,5 x 360	1	25	Size: L 274 x 368 x 296	4052199521879	2
Foliodrape® Shoulder Arthroscopy bag, crepe	258 128/2	Size: M 266,5 x 360	1	10	Size: L 274 x 368 x 296	4052199509792	2
Foliodrape® Shoulder Arthroscopy bag, crepe	258 128/3	Size: M 266,5 x 360	1	10	Size: L 274 x 368 x 296	4052199551920	2

For logistic details of sets, please see the relevant technical data sheet for the set.

Latest Date of Revision: 2020-09-04