

Foliodrape® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery Sets

General Product Description/Intended Purpose

Foliodrape® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery Sets 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® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery sets are used in different fields of applications/disciplines, such as 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
Foliodrape® Protect Plus Angiography set I	938 731/3
Foliodrape® Protect Plus Angiography set II, crepe	938 920/2
Foliodrape® Protect Plus Angiography set II	936 861/0
Foliodrape® Protect Plus Cardiovascular Set	938 742/3
Foliodrape® Protect Plus Cardiovascular / Hybrid set, extra reinforced, crepe	936 765/0
Foliodrape® Protect Plus Neurosurgery set I	936 770/0
Foliodrape® Protect Plus Neurosurgery set II	938 741/3
Foliodrape® Protect Plus Radial-Femoral Angiography set I, crepe	938 921/2
Foliodrape® Protect Plus Thorax set I, crepe	936 764/0
Foliodrape® Protect Plus Thorax set II	936 763/0

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.

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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 of 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

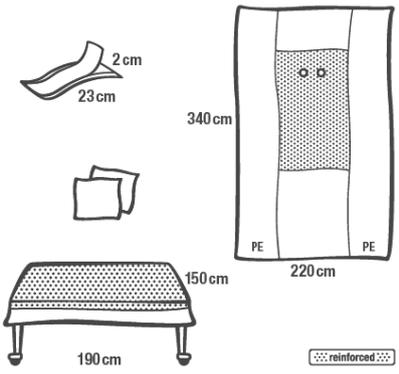
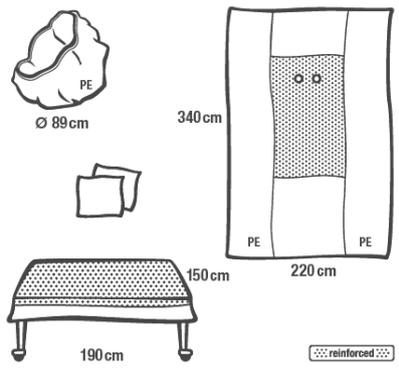
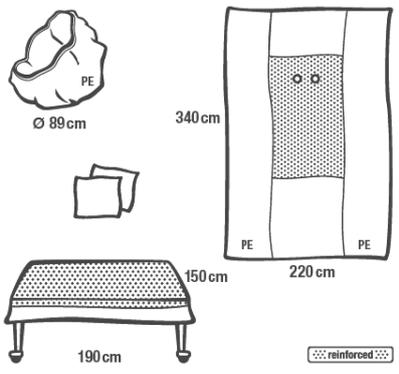
For Performance Indicators, visit individual Technical Data Sheets for components listed below.

Protect	Foliodrape® Protect drapes
Protect Plus	Foliodrape® Protect Plus drapes
PE	Foliodrape® PE drapes
Back table cover	Foliodrape® Back table cover reinforced
Instrument table cover	Foliodrape® Instrument table covers
Equipment Cover	Foliodrape® Equipment covers
Cellulose Towels	Foliodrape® Cellulose Towels
OR tape adhesive	Foliodrape® OR Tape
Hook and loop fastener	Foliodrape® Hook and loop fastener
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".

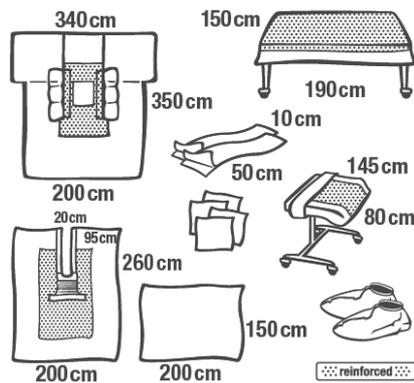
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Product Characteristics

Reference Number	Contents Picture	Content Description	Quantity
938 731/3		Back table cover (Wrapping) 190 x 150 cm	1
		Cellulose Towels 33 x 30 cm	2
		Hook and loop fastener 2 x 23 cm	2
		Protect Plus Angiography drape, PE 220 x 340 cm 2 Ø 8 / 16 cm fenestrated incision foil, with measurement desk cover	1
938 920/2		Back table cover (Wrapping) 190 x 150 cm	1
		Cellulose Towels 33 x 30 cm	2
		Multi-purpose equipment cover, round Ø 89 cm	1
		Protect Plus Angiography drape, PE 220 x 340 cm 2 Ø 8 / 16 cm fenestrated incision foil, with measurement desk cover	1
936 861/0		Back table cover (Wrapping) 190 x 150 cm	1
		Cellulose Towels 33 x 30 cm	2
		Multi-purpose equipment cover, round Ø 89 cm	1
		Protect Plus Angiography drape, PE 220 x 340 cm 2 Ø 8 / 16 cm fenestrated incision foil, with measurement desk cover	1

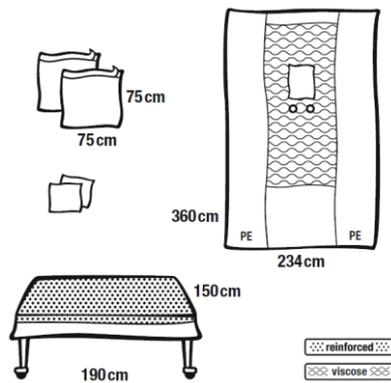
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938 742/3



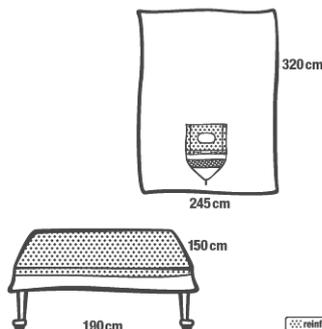
Back table cover (Wrapping) 190 x 150 cm	1
Instrument Table Cover 80 x 145 cm	1
Cellulose Towels 33 x 30 cm	4
OR tape adhesive 10 x 50 cm	2
Protect Plus Thorax drape 340/200 x 350 cm 32 x 38 integrated incision foil, with bilateral suction bags	1
Protect Plus Split sheet, adhesive 200 x 260 cm 20 x 95 cm split, with perineal cover	1
Foot cover PE 23,5 x 40 cm	2
Protect Approach drape 200 x 150 cm	1

936 765/0



Back table cover (Wrapping) 190 x 150 cm	1
Cellulose Towel 33 x 30 cm	2
Protect Surgical drape, adhesive 75 x 75 cm 71 cm adhesive	2
Protect Plus Hybrid drape, extra reinforced 234 x 360 cm 40 x 50 cm integrated incision foil, 2 Ø 8 / 16 cm fenestrations, and measurement desk cover	1

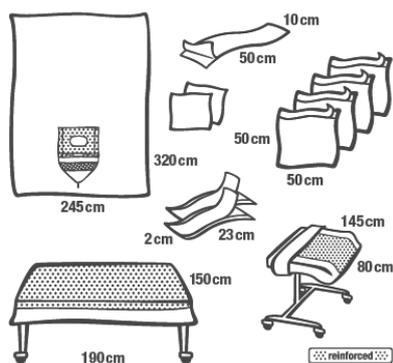
936 770/0



Back table cover (Wrapping) 190 x 150 cm	1
Protect Plus Neuro drape 245 x 320 cm 30 x 19 integrated incision foil, with collection bag	1

Foliodrape® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery Sets

938 741/3



Back table cover (Wrapping) 1
190 x 150 cm

Instrument Table Cover 1
80 x 145 cm

Cellulose Towels 2
33 x 30 cm

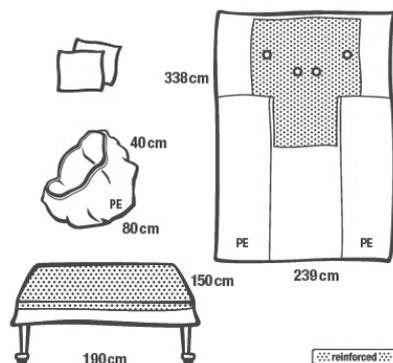
OR tape adhesive 1
10 x 50 cm

Hook and loop fastener 2
2 x 23 cm

Protect Plus Neuro drape 1
245 x 320 cm
30 x 19 cm integrated incision foil, with collection bag

Protect Surgical drape, adhesive 1
50 x 50 cm
46 cm adhesive

938 921/2



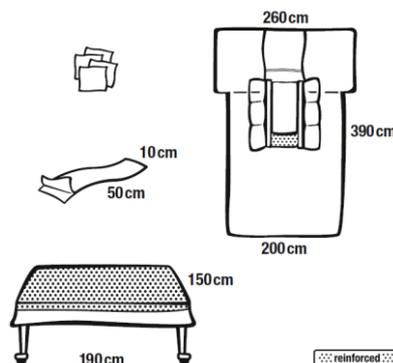
Back table cover (Wrapping) 1
190 x 150 cm

Cellulose Towels 2
33 x 30 cm

Multi-purpose equipment cover, round 1
40 x 80 cm

Protect Plus Angiography drape, PE 1
239 x 338 cm
2 Ø 8 / 16 cm fenestrated incision foils, 2 7x12 cm (oval) cm fenestrations, with measurement desk cover

936 764/0



Back table cover (Wrapping) 1
190 x 150 cm

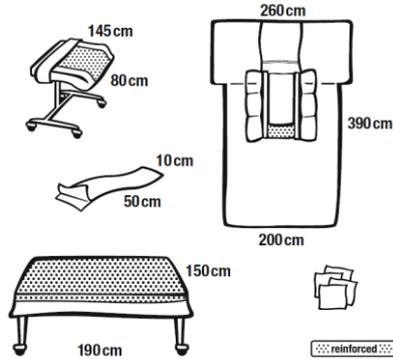
Cellulose Towels 4
33 x 30 cm

OR tape adhesive 1
10 x 50 cm

Protect Thorax drape 1
260/200 x 390 cm
40 x 95 cm integrated incision foil, with integrated collection bag

Foliodrape® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery Sets

936 763/0



Back table cover (Wrapping) 190 x 150 cm	1
Instrument Table Cover 80 x 145 cm	1
Cellulose Towels 33 x 30 cm	4
OR tape adhesive 10 x 50 cm	1
Protect Thorax drape 260/200 x 390 cm 40 x 95 cm integrated incision foil, with integrated collection bag	1

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
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Manufacturing Date

e.g.:

	2020 year	04 month	07 day
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Use-by-Date

e.g.:

	2025 year	04 month	07 day
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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 using ethylene oxide **STERILE EO**

Foliodrape® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery Sets

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 

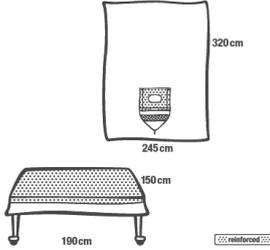
Producer contributes to recycling of packaging 

Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **Neurochirurgie-Set I
Neurosurgery set I**

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® Cardiac-, Thoracic-, Vascular-, and Neuro-Surgery Sets

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® Protect Plus Angiography set I	938 731/3	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199214665	1
Foliodrape® Protect Plus Angiography set II, crepe	938 920/2	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4049500043403	1
Foliodrape® Protect Plus Angiography set II	936 861/0	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199521176	1
Foliodrape® Protect Plus Cardiovascular Set	938 742/3	Size: XL 510 x 345	1	3	Size: XL 545 x 374 x 234	4052199214627	1
Foliodrape® Protect Plus Cardiovascular / Hybrid set, extra reinforced, crepe	936 765/0	Size: L 360 x 580	1	7	Size: XL 568 x 368 x 300	4052199530185	1
Foliodrape® Protect Plus Neurosurgery set I	936 770/0	Size: XL 510 x 345	1	6	Size: XL 545 x 374 x 234	4052199521299	1
Foliodrape® Protect Plus Neurosurgery set II	938 741/3	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199214887	1
Foliodrape® Protect Plus Radial-Femoral Angiography set I, crepe	938 921/2	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199522463	1
Foliodrape® Protect Plus Thorax set I, crepe	936 764/0	Size: L 360 x 580	1	6	Size: XL 568 x 368 x 300	4052199530109	1
Foliodrape® Protect Plus Thorax set II	936 763/0	Size: L 360 x 580	1	5	Size: XL 568 x 368 x 300	4052199530062	1

Latest Date of Revision: 2020-05-07