

Foliodrape® ENT / Maxillofacial sets

General Product Description/Intended Purpose

Foliodrape® ENT / Maxillofacial 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 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 or different layers of hydrophobic nonwoven material (SMS) 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® ENT / Maxillofacial sets are used in ear, nose and throat (Otorhinolaryngology or ENT); oral; and maxillofacial 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 ENT / Maxillofacial set I	936 849/0
Foliodrape® Protect ENT / Maxillofacial set I	938 747/2
Foliodrape® Protect ENT / Maxillofacial set II, crepe	938 912/2
Foliodrape® Protect ENT / Maxillofacial set III, crepe	938 746/2
Foliodrape® Protect ENT / Maxillofacial set IV, crepe	936 846/0
Foliodrape® Protect ENT / Maxillofacial set V, crepe	936 850/0
Foliodrape® Protect Plus ENT / Maxillofacial set I	936 848/0
Foliodrape® Protect Plus ENT / Maxillofacial set II	938 735/3
Foliodrape® Protect Plus Head / Neck set, crepe	938 928/2
Foliodrape® Protect Maxillofacial turban set I	936 853/0
Foliodrape® Protect Plus Maxillofacial turban set I	936 847/0
Foliodrape® Protect Plus Maxillofacial turban set II	938 748/2

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.

Foliodrape® ENT / Maxillofacial sets

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.).

Material Characteristics

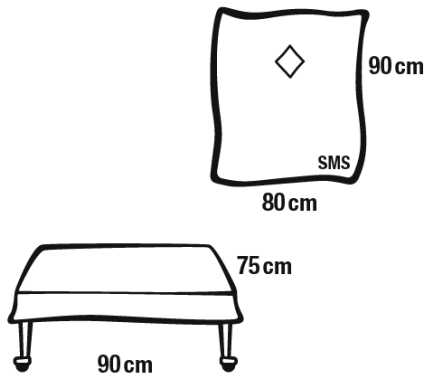
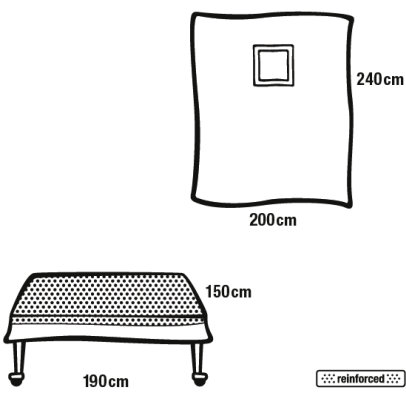
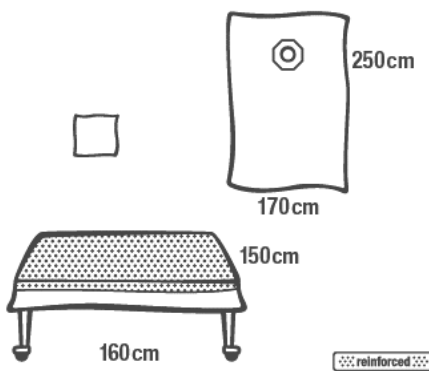
For Performance Indicators, visit individual Technical Data Sheets for components listed below.

Protect	Foliodrape® Protect drapes
Protect Plus	Foliodrape® Protect Plus drapes
SMS drapes	Foliodrape® SMS drapes
Back table cover	Foliodrape® Back table cover reinforced
Instrument table cover	Foliodrape® Instrument table covers
Cellulose Towels	Foliodrape® Cellulose Towels
OR tape adhesive	Foliodrape® OR Tape
Hook and loop fastener	Foliodrape® Hook and loop fastener
Camera Cable Cover	Foliodrape® Camera Cable Cover

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

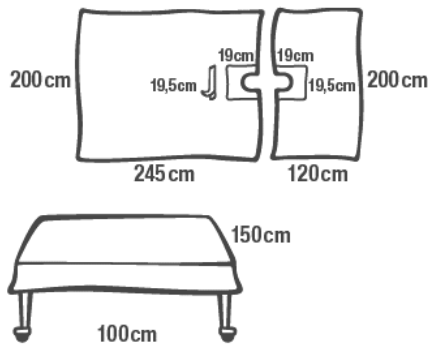
Foliodrape® ENT / Maxillofacial sets

Product Characteristics

Reference Number	Contents Picture	Content Description	Quantity
936 849/0		<p>Protect Back table cover (Wrapping) 90 x 75 cm</p> <hr/> <p>ENT / Maxillofacial Drape, SMS 80 x 90 cm 14 x 16 cm fenestration</p>	<p>1</p> <hr/> <p>1</p>
938 747/2		<p>Back table cover (Wrapping) 190 x 150 cm</p> <hr/> <p>Protect Fenestrated drape, adhesive 200 x 240 cm 10 x 10 cm fenestration, aperature adhesive</p>	<p>1</p> <hr/> <p>1</p>
938 912/2		<p>Back table cover (Wrapping) 160 x 150 cm</p> <hr/> <p>Cellulose Towels 30 x 33 cm</p> <hr/> <p>Protect Fenestrated drape, adhesive 170 x 250 cm Ø10 cm fenestration, aperature adhesive</p>	<p>1</p> <hr/> <p>1</p> <hr/> <p>1</p>

Foliodrape® ENT / Maxillofacial sets

938 746/2

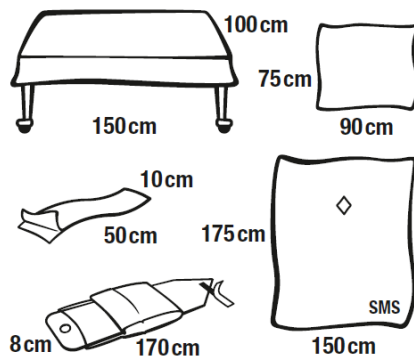


Protect Back table cover (Wrapping) 1
100 x 150 cm

Protect Foot drape, adhesive 1
200 x 245 cm
19 x 19,5 cm split, Variable one-piece, with hook and loop fastener

Protect Anesthetic drape, adhesive 1
200 x 120 cm
19 x 19,5 cm split, Variable one-piece

936 846/0



Protect Back table cover (Wrapping) 1
100 x 150 cm

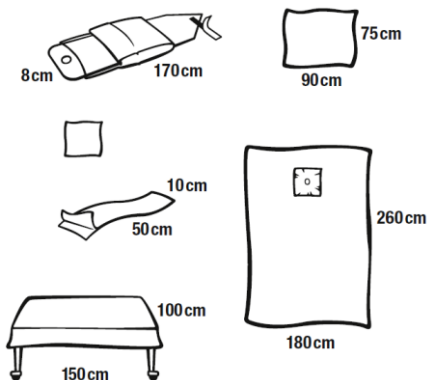
OR tape adhesive 1
10 x 50 cm

Camera Cable Cover 1
8 x 170 cm
Perforation, 2 fixation strips

ENT / Maxillofacial drape SMS 1
150 x 175 cm
10 x 14 cm fenestration

Protect Surgical Drape 1
90 x 75 cm

936 850/0



Protect Back table cover (Wrapping) 1
100 x 150 cm

Cellulose Towel 1
33 x 30 cm

OR tape adhesive 1
10 x 50 cm

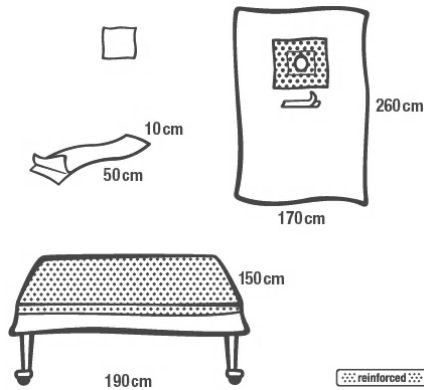
Camera Cable Cover 1
8 x 170 cm
Perforation, 2 fixation strips

Protect ENT / Maxillofacial drape 1
180 x 260 cm
9,5 x 11,5 cm fenestration, with 3,5 x 5 cm adhesive

Protect Surgical drape 1
90 x 75 cm

Foliodrape® ENT / Maxillofacial sets

936 848/0



Back table cover (Wrapping) 1

190 x 150 cm

Cellulose Towels 1

30 x 33 cm

OR tape adhesive 1

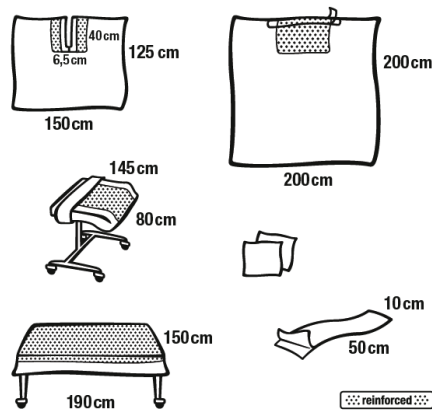
10 x 50 cm

Protect Plus Fenestrated drape 1

170 x 260 cm

4 x 6,5 cm fenestrated incision foil, with hook and loop fastener

938 735/3



Back table cover (Wrapping) 1

190 x 150 cm

Instrument table cover 1

80 x 145 cm

Cellulose Towels 2

30 x 33 cm

OR tape adhesive 1

10 x 50 cm

Protect Plus Split sheet, adhesive 1

150 x 125 cm

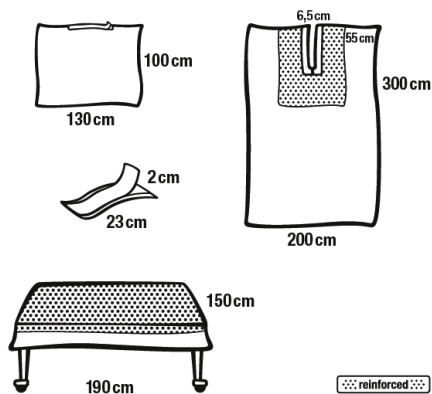
6,5 x 40 cm split

Protect Plus Surgical drape, adhesive 1

200 x 200 cm

With 90 cm adhesive

938 928/2



Back table cover (Wrapping) 1

190 x 150 cm

Hook and loop fastener 1

2 x 23 cm

Protect Plus Split sheet, adhesive 1

200 x 300 cm

6,5 x 55 cm split

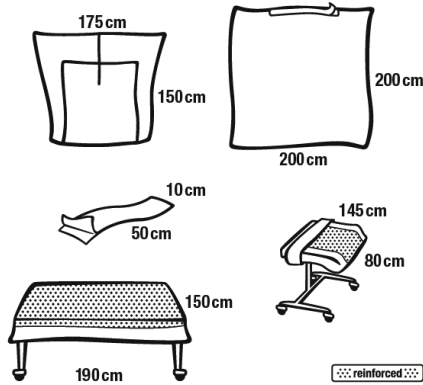
Protect Surgical drape, adhesive 1

130 x 100 cm

With 80 cm adhesive

Foliodrape® ENT / Maxillofacial sets

936 853/0



Back table cover (Wrapping) 1
190 x 150 cm

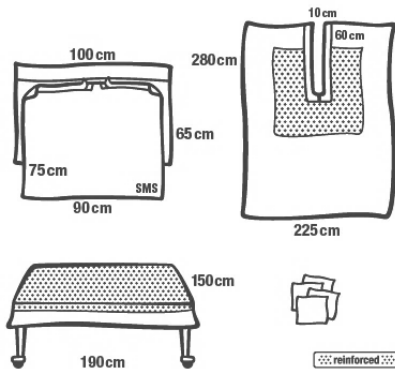
Instrument table cover 1
80 x 145 cm

OR tape adhesive 1
10 x 50 cm

Protect Turban drape 1
175 x 150 cm, 100 x 110 cm
With slit

Protect Surgical drape, adhesive 1
200 x 200 cm
With 100 cm adhesive

936 847/0



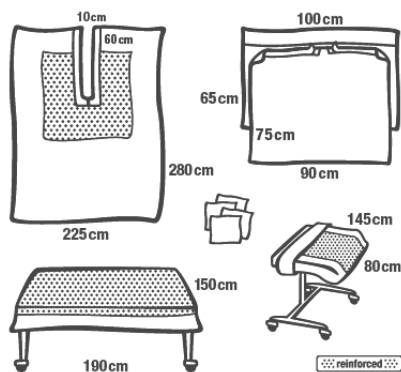
Back table cover (Wrapping) 1
190 x 150 cm

Cellulose Towels 4
30 x 33 cm

Protect Plus Split sheet, adhesive 1
225 x 280 cm
10 x 60 cm split

Protect Turban drape 1
100 x 65 cm, 90 x 75 cm
SMS

938 748/2



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 Plus Split sheet, adhesive 1
225 x 280 cm
10 x 60 cm split

Protect Turban drape 1
100 x 65 cm, 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® ENT / Maxillofacial 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 using 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  
PAP PE

Producer contributes to recycling of packaging 

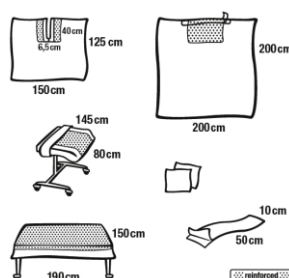
Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **HNO-/MKG-Set II**
ENT/Maxillofacial set II

Reference / catalogue number **REF**

Foliodrape® ENT / Maxillofacial 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	Disensers per carton
Foliodrape® Protect ENT / Maxillofacial set I	936 849/0	Size: M 266,5 x 360	1	26	Size: L 368 x 274 x 296	4052199510569	2
Foliodrape® Protect ENT / Maxillofacial set I	938 747/2	Size: L 360 x 580	1	12	Size: XL 568 x 368 x 300	4052199510279	1
Foliodrape® Protect ENT / Maxillofacial set II, crepe	938 912/2	Size: L 365 x 265	1	5	Size: L 374 x 275 x 234	4052199523798	2
Foliodrape® Protect ENT / Maxillofacial set III, crepe	938 746/2	Size: L 365 x 265	1	6	Size: L 374 x 275 x 234	4052199522418	2
Foliodrape® Protect ENT / Maxillofacial set IV, crepe	936 846/0	Size: M 266,5 x 360	1	9	Size: L 368 x 274 x 296	4052199510231	2
Foliodrape® Protect ENT / Maxillofacial set V, crepe	936 850/0	Size: L 360 x 580	1	9	Size: XL 568 x 368 x 300	4052199522296	1
Foliodrape® Protect Plus ENT / Maxillofacial set I	936 848/0	Size: XL 510 x 345	1	10	Size: XL 545 x 374 x 234	4052199521411	1
Foliodrape® Protect Plus ENT / Maxillofacial set II	938 735/3	Size: L 360 x 580	1	8	Size: XL 568 x 368 x 300	4052199510187	1
Foliodrape® Protect Plus Head / Neck set, crepe	938 928/2	Size: L 360 x 580	1	8	Size: XL 568 x 368 x 300	4052199510637	1

Foliodrape® ENT / Maxillofacial sets

Foliodrape® Protect Maxillofacial turban set I	936 853/0	Size: L 360 x 580	1	8	Size: XL 568 x 368 x 300	4052199509914	1
Foliodrape® Protect Plus Maxillofacial turban set I	936 847/0	Size: XL 510 x 345	1	6	Size: XL 545 x 374 x 234	4052199525563	1
Foliodrape® Protect Plus Maxillofacial turban set II	938 748/2	Size: XL 510 x 345	1	6	Size: XL 545 x 374 x 234	4052199522852	1

Latest Date of Revision: 2020-06-02