

Foliodrape® Gynaecology and Obstetrics Sets

General Product Description/Intended Purpose

Foliodrape® Gynaecology and Obstetrics 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® Gynaecology and Obstetrics sets are used in different fields of applications in the gynecology discipline. 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 Cesarean section set I, crepe	938 904/2
Foliodrape® Protect Cesarean section set II, crepe	938 918/2
Foliodrape® Protect Cesarean section set III	938 720/3
Foliodrape® Protect Cesarean section set IV, leggings	938 711/3
Foliodrape® Protect Plus Cesarean section set I, leggings	938 736/4
Foliodrape® Protect Delivery set I	936 811/0
Foliodrape® Protect Delivery set III	936 795/0
Foliodrape® Protect Delivery set IV	279 211/4
Foliodrape® Protect Plus Gynecology / Abdomino-Perineal Set I, crepe	938 934/2
Foliodrape® Protect Plus Gynecology / Abdomino-Perineal Set II	938 710/3
Foliodrape® Protect Gynecology / Perineal set I	938 745/2
Foliodrape® Protect Gynecology / Perineal set II	936 786/0
Foliodrape® Protect Gynecology / Perineal set III	938 903/2
Foliodrape® Protect Gynecology / Perineal set IV	936 791/0
Foliodrape® Protect Gynecology / Perineal set V, crepe	936 787/0
Foliodrape® Protect Plus Gynecology / Perineal set I, crepe	938 910/2
Foliodrape® Protect Plus Gynecology / Perineal set II	938 719/3
Foliodrape® Protect Perineal set I, crepe	938 916/2
Foliodrape® Protect Perineal set II	938 725/3
Foliodrape® Protect Perineal set III	938 727/3
Foliodrape® Protect TVT / Perineal Set I, crepe	936 727/0

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.

Foliodrape® Gynaecology and Obstetrics Sets

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.

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

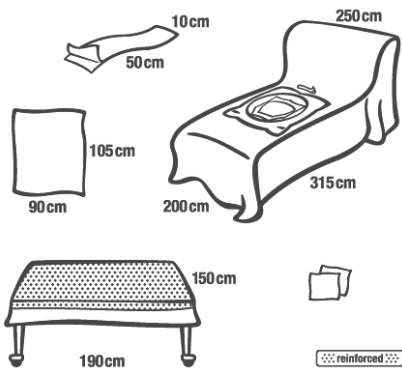
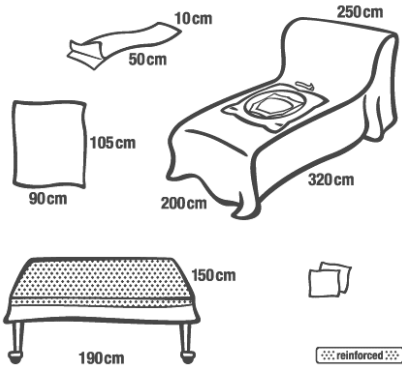
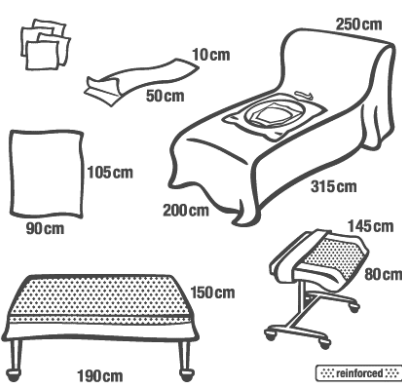
For Performance Indicators, visit individual Technical Data Sheets for components listed below.

Protect	Foliodrape® Protect drapes
Protect Plus	Foliodrape® Protect Plus drapes
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
Baby drape	Foliodrape® Baby drape
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".

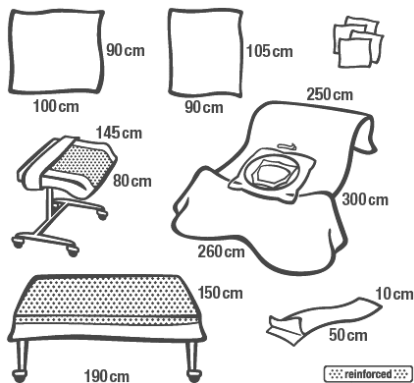
Foliodrape® Gynaecology and Obstetrics Sets

Product Characteristics

Reference Number	Contents Picture	Content Description	Amount
938 904/2		Back table cover (Wrapping) 190 x 150 cm	1
		Cellulose Towels 33 x 30 cm	2
		OR tape adhesive 10 x 50 cm	1
		Baby drape 90 x 105 cm	1
		Protect Caesarean drape 250/200 x 315 cm 24 x 19 cm fenestrated incision foil, integrated collection bag, and hook and loop fastener	1
938 918/2		Back table cover (Wrapping) 190 x 150 cm	1
		Cellulose Towels 33 x 30 cm	2
		OR Tape Adhesive 10 x 50 cm	1
		Baby drape 90 x 105 cm	1
		Protect Caesarean drape 250/200 x 320 cm 29 x 19 integrated incision foil, integrated collection bag, and hook and loop fastener	1
938 720/3		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	1
		Baby drape 90 x 105 cm	1
		Protect Caesarean drape 250/200 x 315 cm 24 x 19 cm fenestrated incision foil, integrated collection bag, and hook and loop fastener	1

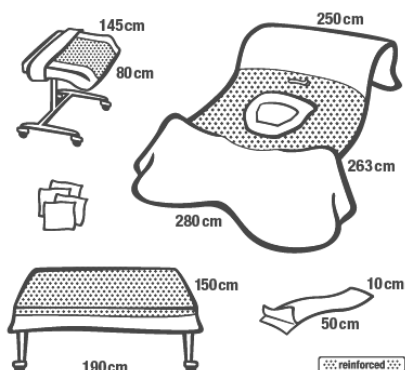
Foliodrape® Gynaecology and Obstetrics Sets

938 711/3



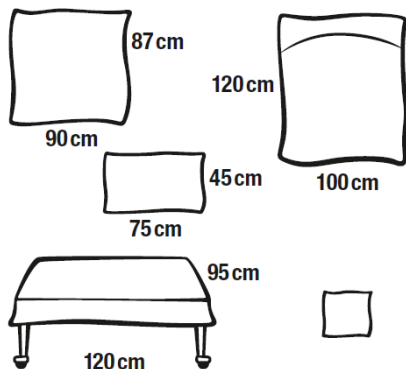
Back table cover (Wrapping)	1
190 x 150 cm	
Instrument table cover	1
80 x 145 cm	
Cellulose Towels	4
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape	1
100 x 90 cm	
Baby drape	1
90 x 105 cm	
Protect Caesarean drape	1
250/260 x 300 cm	
24 x 19 cm fenestrated incision foil, integrated collection bag, leggings, and hook and loop fastener	

938 736/4



Back table cover (Wrapping)	1
190 x 150 cm	
Instrument table cover	1
80 x 145 cm	
Cellulose Towels	4
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Plus Caesarean drape	1
250/280 x 263 cm	
24 x 19 cm fenestrated incision foil, leggings, and hook and loop fastener	

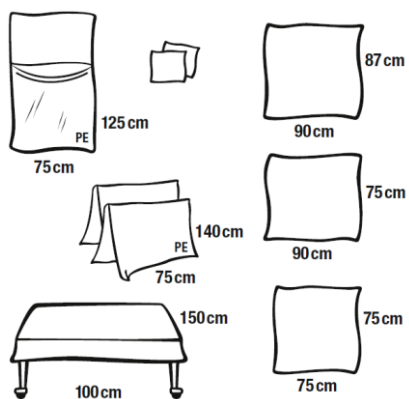
936 811/0



Protect Back table cover (Wrapping)	1
120 x 95 cm	
Cellulose Towel	1
33 x 30 cm	
Baby drape	1
87 x 90 cm	
Protect Surgical drape	1
75 x 45 cm	
Protect Patient Underlay	1
100 x 120 cm	

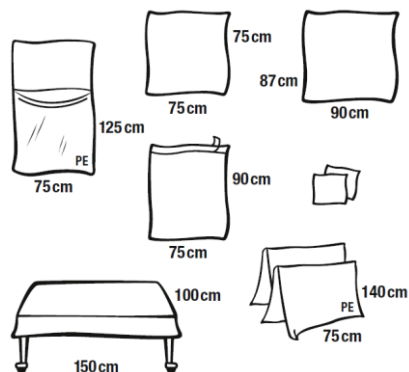
Foliodrape® Gynaecology and Obstetrics Sets

936 795/0



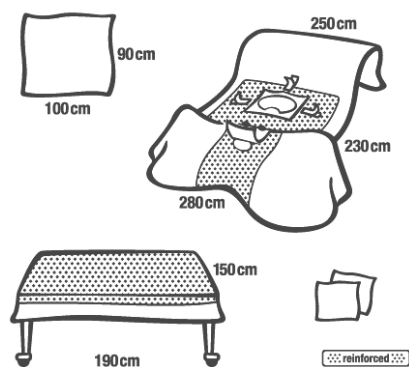
Protect Back table cover (Wrapping) 100 x 150 cm	1
Cellulose Towel 33 x 30 cm	2
Baby drape 87 x 90 cm	1
Protect Surgical drape 75 x 75 cm	1
Protect Surgical drape 90 x 75 cm	1
Protect Patient underlay 75 x 125 cm, with 1 pouch	1
Legging, PE 75 x 140 cm	2

279 211/4



Protect Back table cover (Wrapping) 100 x 150 cm	1
Cellulose Towel 33 x 30 cm	2
Baby drape 87 x 90 cm	1
Protect Surgical drape 75 x 75 cm	1
Protect Surgical drape, adhesive 75 x 90 cm 71 cm adhesive	1
Protect Patient underlay 75 x 125 cm, with 1 pouch	1
Legging, PE 75 x 140 cm	2

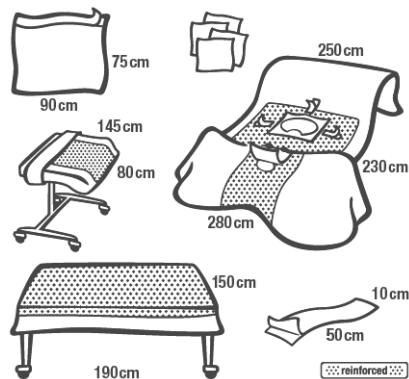
938 934/2



Back table cover (Wrapping) 190 x 150 cm	1
Cellulose Towels 33 x 30 cm	2
Protect Surgical drape 100 x 90 cm	1
Protect Plus Gynaecology / Abdomino-Perineal drape 250/280 x 230 cm 29 x 19 cm fenestrated incision foil, 9 x 12 fenestration, and leggings	1

Foliodrape® Gynaecology and Obstetrics Sets

938 710/3



Back table cover (Wrapping) 1
190 x 150 cm

Instrument table cover 1
80 x 145 cm

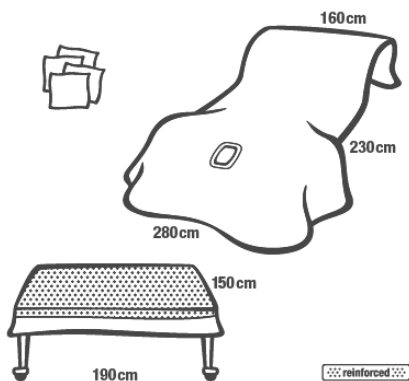
Cellulose Towels 4
33 x 30 cm

OR tape adhesive 1
10 x 50 cm

Protect Surgical drape, adhesive 1
90 x 75 cm
86 cm adhesive

Protect Plus Gynaecology / Abdomino-Perineal drape 1
250/280 x 230 cm
29 x 19 cm fenestrated incision foil,
9 x 12 fenestration, and leggings

938 745/2

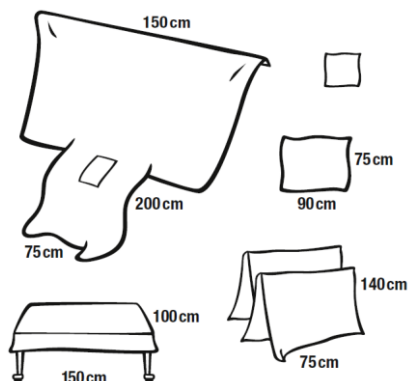


Back table cover (Wrapping) 1
190 x 150 cm

Cellulose Towels 4
33 x 30 cm

Protect Gynaecology / Perineal drape 1
160/280 x 230 cm
7 x 10 cm fenestration and leggings

936 786/0



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

Cellulose Towel 1
33 x 30 cm

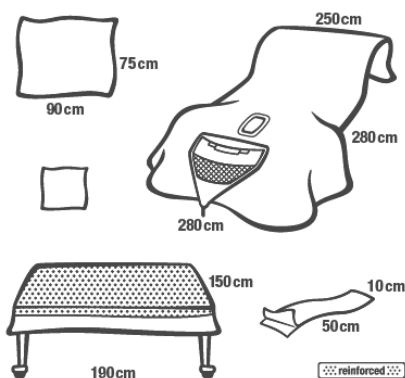
Protect Perineal drape, adhesive 1
150/75 x 200 cm
8 x 15 cm fenestration with adhesive

Protect Surgical drape 1
90 x 75 cm

Protect Legging 2
75 x 140 cm

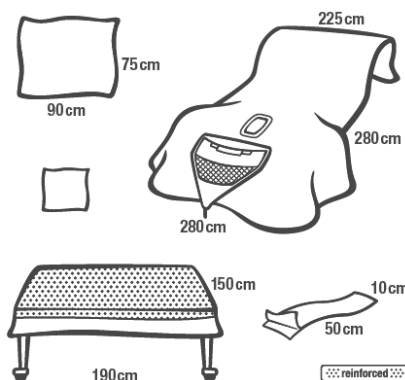
Foliodrape® Gynaecology and Obstetrics Sets

938 903/2



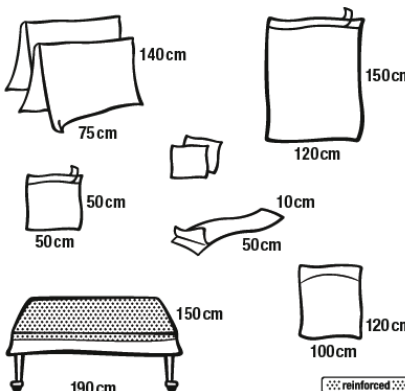
Back table cover (Wrapping)	1
190 x 150 cm	
Cellulose Towel	1
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape	1
90 x 75 cm	
Protect Gynaecology / Perineal drape	1
250/280 x 280 cm	
9 x 12 cm fenestration, with collection bag and leggings	

936 791/0



Back table cover (Wrapping)	1
190 x 150 cm	
Cellulose Towels	1
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape	1
90 x 75 cm	
Protect Gynaecology / Perineal drape	1
225/280 x 280 cm	
14,5/11 x 18 cm fenestration, with collection bag and leggings	

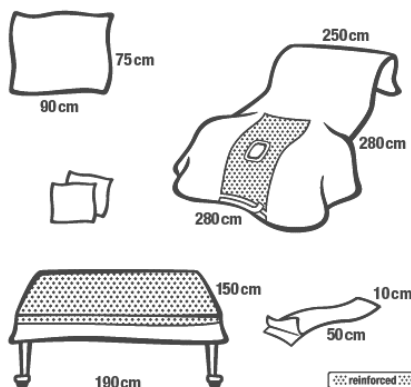
936 787/0



Back table cover (Wrapping)	1
190 x 150 cm	
Cellulose Towels	2
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape, adhesive	1
50 x 50 cm	
46 cm adhesive	
Protect Surgical drape, adhesive	1
120 x 150 cm	
120 cm adhesive	
Protect Patient Underlay	1
100 x 120 cm	
Protect Legging	2
75 x 140 cm	

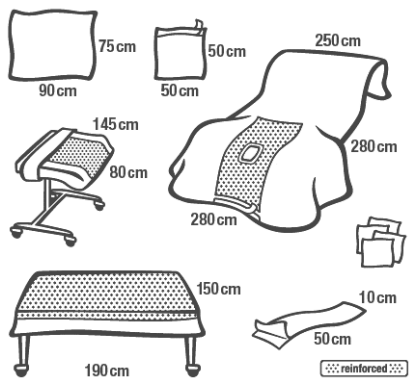
Foliodrape® Gynaecology and Obstetrics Sets

938 910/2



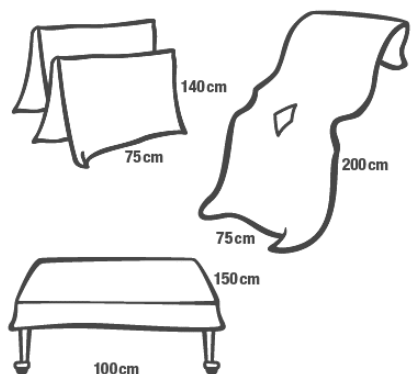
Back table cover (Wrapping)	1
190 x 150 cm	
Cellulose Towels	2
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape	1
90 x 75 cm	
Protect Plus Gynaecology / Perineal drape	1
250/280 x 280 cm	
9 x 12 cm fenestration and leggings	

938 719/3



Back table cover (Wrapping)	1
190 x 150 cm	
Instrument Table Cover	1
80 x 145 cm	
Cellulose Towels	4
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape, adhesive	1
50 x 50 cm	
46 cm adhesive	
Protect Surgical drape	1
90 x 75 cm	
Protect Plus Gynaecology/ Perineal drape	1
250/280 x 280 cm	
9 x 12 cm fenestration and leggings	

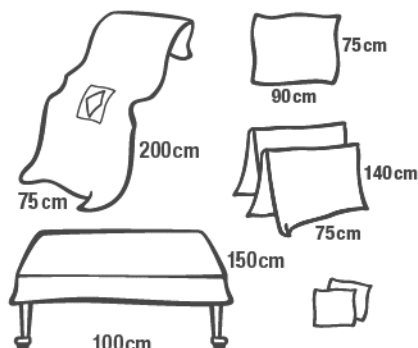
938 916/2



Protect Back table cover (Wrapping)	1
100 x 150 cm	
Protect Perineal drape, adhesive	1
75 x 200 cm	
8 x 12 cm fenestration	
Protect Legging	2
75 x 140 cm	

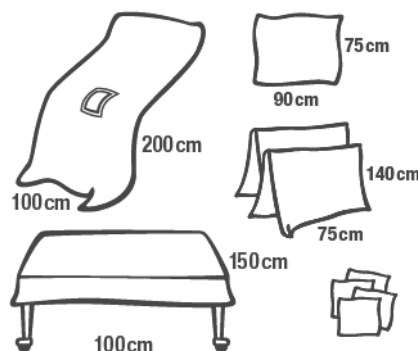
Foliodrape® Gynaecology and Obstetrics Sets

938 725/3



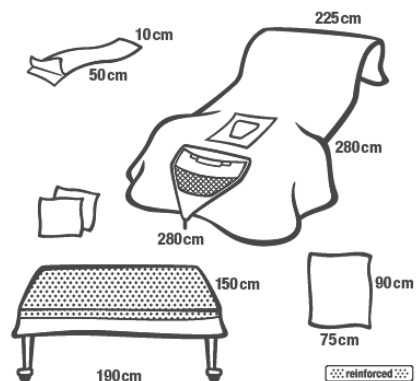
Protect Back table cover (Wrapping)	1
100 x 150 cm	
Cellulose Towels	2
33 x 30 cm	
Protect Perineal drape	1
75 x 200 cm	
8 x 12 cm fenestration	
Protect Surgical drape	1
90 x 75 cm	
Protect Legging	2
75 x 140 cm	

938 727/3



Protect Back table cover (Wrapping)	1
100 x 150 cm	
Cellulose Towels	4
33 x 30 cm	
Protect Perineal drape	1
100 x 200 cm	
7 x 10 cm fenestration	
Protect Surgical drape	1
90 x 75 cm	
Protect Legging	2
75 x 140 cm	

936 727/0



Back table cover (Wrapping)	1
190 x 150 cm	
Cellulose Towels	2
33 x 30 cm	
OR tape adhesive	1
10 x 50 cm	
Protect Surgical drape	1
90 x 75 cm	
Protect Gynaecology / Perineal drape	1
225/280 x 280 cm	
19/11 x 28 cm fenestration, with collection bag and leggings	

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 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	12	XXXXX
	year	Week of production	for internal purposes only

Manufacturing Date

e.g.:

	2020	04	07
	year	month	day


Foliodrape® Gynaecology and Obstetrics Sets

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  Do not use if package is damaged


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 

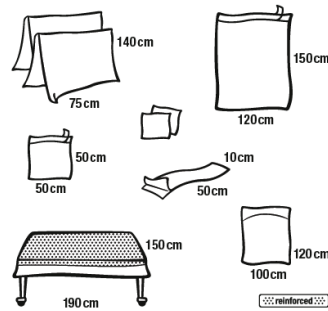
Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **Gynäkologie-/Perineal-Set V, Kreppeinschlag**
Gynecology/Perineal set V, crepe

Reference / catalogue number **REF**

Foliodrape® Gynaecology and Obstetrics 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.

Foliodrape® Gynaecology and Obstetrics 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 Cesarean section set I, crepe	938 904/2	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4049500727785	1
Foliodrape® Protect Cesarean section set II, crepe	938 918/2	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199522517	1
Foliodrape® Protect Cesarean section set III	938 720/3	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199213903	1
Foliodrape® Protect Cesarean section set IV, leggins	938 711/3	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199213866	1
Foliodrape® Protect Plus Cesarean section set I, leggins	938 736/4	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199523682	1
Foliodrape® Protect Delivery set I	936 811/0	Size: M 266,5 x 360	1	12	Size: L 368 x 274 x 296	4052199522333	2
Foliodrape® Protect Delivery set III	936 795/0	Size: L 360 x 580	1	11	Size: XL 568 x 368 x 300	4052199510002	1
Foliodrape® Protect Delivery set IV	279 211/4	Size: L 360 x 580	1	10	Size: XL 568 x 368 x 300	4052199536361	1
Foliodrape® Protect Plus Gynecology / Abdomino- Perineal Set I, crepe	938 934/2	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199523439	1
Foliodrape® Protect Plus Gynecology / Abdomino- Perineal Set II	938 710/3	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199020143	1
Foliodrape® Protect Gynecology / Perineal set I	938 745/2	Size: XL 510 x 345	1	7	Size: XL 545 x 374 x 234	4052199021171	1
Foliodrape® Protect Gynecology / Perineal set II	936 786/0	Size: L 360 x 580	1	10	Size: XL 568 x 368 x 300	4052199530512	1
Foliodrape® Protect Gynecology / Perineal set III	938 903/2	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199523279	1
Foliodrape® Protect Gynecology / Perineal set IV	936 791/0	Size: XL 510 x 345	1	5	Size: XL 545 x 374 x 234	4052199523750	1
Foliodrape® Protect Gynecology / Perineal set V, crepe	936 787/0	Size: L 360 x 580	1	11	Size: XL 568 x 368 x 300	4052199510033	1
Foliodrape® Protect Plus Gynecology / Perineal set I, crepe	938 910/2	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4049500032865	1

Foliodrape® Gynaecology and Obstetrics Sets

Foliodrape® Protect Plus Gynecology / Perineal set II	938 719/3	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199522388	1
Foliodrape® Protect Perineal set I, crepe	938 916/2	Size: L 365 x 265	1	6	Size: L 374 x 275 x 234	4052199525150	2
Foliodrape® Protect Perineal set II	938 725/3	Size: L 365 x 265	1	5	Size: L 374 x 275 x 234	4052199522708	2
Foliodrape® Protect Perineal set III	938 727/3	Size: L 365 x 265	1	5	Size: L 374 x 275 x 234	4052199213781	2
Foliodrape® Protect TVT / Perineal Set I, crepe	936 727/0	Size: XL 510 x 345	1	4	Size: XL 545 x 374 x 234	4052199531526	1

Latest Date of Revision: 2020-06-08