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TECHNICAL DATA SHEET

PRODUCT: Disposable sterile spinal surgery drape set

Description of Product:

Disposable sterile spinal surgery drape set		
1) 3 pcs.: Mayo-type drape for instrument table 80 x 145cm (± 5cm), reinforced, waterproof, absorbent, 3 layers: 2 layers in the absorbent area 65 x 85cm (± 5cm), of viscose minimum 50g/ml and polyethylene minimum 50 µm, plus a polyethylene layer on the entire surface of minimum 60µm thickness. Absorption capacity in the critical area minimum 2 g/ml (Mayo with hydrophobic area will be excluded). Pictogram for guidance.	80x145 cm	3
2) 2 pcs.: Drapes with adhesive border dimensions 90 x 75cm (± 5cm). Polyamide, minimum 3 layers on the entire surface, reinforced in the critical area a) comfort layer for the patient made of polypropylene; b) waterproof layer of polyethylene minimum 60µm thick; c) absorbent layer of viscose minimum 30g/ml; d) super absorbent layer in the critical area – minimum 70g/ml. Absorbent capacity in the critical area minimum 3.5 g/ml. Adhesive area applied directly to the edge of the field, impregnated in the fabric, without creases. 100% adhesive capacity. Double-sided glue will not be allowed.	90x75 cm	2
3) 2 pcs.: Absorbent cellulose sponges, 20 x 20cm (± 2cm), absorbent sponges, fast-dry, excluding polyester or SMS.	20x25 cm	2
4) 1 pc.: Surgical tape – 10 x 50cm (± 3cm). From 2 layers: a) waterproof polyethylene minimum 20µm thick; b) absorbent polyester minimum 40g/ml, with glue on the entire surface, for film fixation of tubes and instruments during the operation.	10x50 cm	1
5) 1 pc.: Sheet with adhesive border 175 x 175cm (± 10cm). Polyamide, minimum 3 layers on the entire surface, reinforced in the critical area: a) comfort layer for the patient made of polypropylene; b) waterproof layer of polyethylene minimum 40 µm thick; c) absorbent layer of viscose minimum 20g/ml. Adhesive area applied directly to the edge of the field, impregnated in the fabric, without creases. 100% adhesion capacity. Double-sided glue will not be allowed. Pictogram for guidance.	175x175 cm	1
6) 1 pc.: Sterile sheet with adhesive border and absorbent field 240 x 150cm (± 10cm). Polyamide, minimum 3 layers on the entire surface, reinforced in the critical area: a) comfort layer for the patient made of polypropylene; b) waterproof layer of polyethylene at least 40 µm thick; c) absorbent layer of viscose at least 20 g/ml. Adhesive area applied directly to the edge of the field, impregnated in the fabric, without creases. 100% adhesion capacity. Double-sided glue will not be allowed. Pictogram for guidance.	240x150 cm	1
7) 1 pc.: Flat for Bolevo type table 190 x 280 cm (± 10 cm), 100% absorbent area on the entire surface - to be placed first in the set, above the other fields and accessories.	190x280 cm	1
7) Composed of at least 3 layers: a) waterproof, reinforced layer of polyethylene at least 50 µm thick; c) absorbent layer of viscose at least 30 g/ml with absorption capacity at least 3 g/ml.		
8) 1 pc.: Suction catheter 12 CH, at least 0.7 m.	0.5 m	1
9) 20 pcs.: Abrasive sponge for coagulation instruments, 5 x 5cm (± 1cm).	5x5 cm	1
10) 10 pcs.: Syringe 20 ml, Luer lock.	20 mL	3
11) 2 pcs.: Sterile handles for operating lamp.	STD	2
12) 1 pc.: Transparent acetone film, adhesive, dimensions 30 x 26cm (± 2cm), adhesive area 30 x 25cm, made of polyurethane minimum 25 µm thick.	30x26 cm	1
13) 10 pcs.: Neurosurgical absorbent pad, made of non-woven material, fast-dry, hydrophobic, with R-contrast indicator, dimensions 12 x 40mm (± 3mm).	12x40 mm	10
14) 1 pc.: Disposable scalpel N11	N11	1'er adet
14) 1 pc.: Disposable scalpel N22 (N20 or 21)	N22/N20/N21	1 inde 1 adet
15) 2 pcs.: Pocket with adhesive tape for diathermy and suction instruments 11 x 40cm, made of polyethylene minimum 50 µm thick.	35x40 cm	2
16) 1 pc.: Graduated bowl 120 ml for used needles, made of polypropylene, transparent, with thread and hd, minimum height 7cm, inscribed with the label "biohazard"	120 ml	1
17) 1 pc.: C-arm cover 140cm (± 10cm).	140 cm	1
18) 10 pcs.: Microscope cover with three parts, compatible with Pentax 900 microscope. Pictogram for guidance.	ST	1
19) 1 pc.: Disposable forceps with non-stick tip for bipolar coagulator. Straight design, compatible with the cable and the Erbe 200/300 coagulation device provided.	ST	1
20) Gloves 3 pairs: Sterile, powder-free gloves (size: N8.3 – 1 pair, N8.0 – 2 pairs) - made of deproteinized rubber, with low allergenic potential (extractable protein content not more than 0.05g/g), resistant to surgical interventions with the use of metal guides; apertures; tear strength – not less than 100; thickness at the fingers – not less than 0.7mm, coated on the inside with biogel for double protection and tear strength, AQL – not more than 0.65 (AQL – standard for the protection of medical personnel during long term interventions (penetration level for microorganisms and liquids, chemicals – according to the EN 374-2:2014 standard).	N8.5 N8.0	1 çift 2 çift
23) 1 pc.: Skin marker, sterile.	ST	1

Raw Materials:	Triflex / PE + NW / Biflex / Cellulose / PE
Product Colour:	Medical Blue
Reference Code:	SP-05010-24
Weight in Grams:	77 gsm (Triflex) / 28 gsm(SS)+65 mic.(PE) / 56 gsm Biflex / 48 mic (PE) / 60 gsm (Cellulose) / 60 mic (PE)
Package:	Flat Pouch

Product: Medical Device Directive MDR 2017/745 ECC ANNEX XI A ALL VERSIONS. / Products and materials used do not contain metal.
Product Shelf Life - 5 Years

Product Materials

PROPERTIES

Unit / Size	PROPERTIES			
3 NW+PE 80x145 cm				
2 Triflex 90x75 cm				
2 Cellulose 20x25 cm				
1 *** 10x50 cm				
1 Triflex 175x175 cm				
1 Triflex 240x150 cm				
1 Biflex 190x280 cm				
1 *** 0.5 m				
1 *** 5x5 cm				
3 *** 20 mL				
2 PE STD				
1 PE 30x26 cm				
10 *** 12x40 mm				
1 *** N11				
1 *** N22/N20/N21				
2 PE 35x40 cm				
1 *** 120 ml				
1 *** 140 cm				
1 *** ST				
1 *** ST				
1 pair *** N8,5				
2 pair *** N8.0				
1 *** ST				

Tolerances: +/- 2% cm
Measurement: cm

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date

QUALITY CONTROL APPROVAL