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TECHNICAL DATA SHEET

PRODUCT: Disposable sterile brain surgery field set

Description of Product:

Disposable sterile brain surgery field set		
1) 1 pc.: Craniotomy field 230 x 300cm (± 20cm), transparent incision area 20 x 20cm (± 2cm), with liquid collection bag, with tap, super absorbent area in the working area. Polyethylene, minimum 3 layers over the entire surface, reinforced in the critical area: a) comfort layer for the patient made of polypropylene; b) waterproof layer of polyethylene minimum 40 micrometers thick; c) absorbent layer of viscose minimum 20g/m ² . Pictogram for guidance.	230x300 cm	1
2) 4 pcs.: Absorbent field 50 x 50cm (± 5cm). Polyethylene, minimum 3 layers over the entire surface: a) comfort layer for the patient made of polypropylene; b) waterproof layer of polyethylene minimum 40micm thick; c) absorbent layer of viscose minimum 20g/m ² .	50x50 cm	4
3) 2 pcs.: cellulose absorbent wipes 20 x 25cm (± 2cm), absorbent wipes, lint-free, excluding polyester or SMS.	20x25 cm	2
4) 1 pc.: Surgical tape - 10 x 50cm (± 2cm). Made of 2 layers: a) waterproof polyethylene at least 25micm thick; b) absorbent polyester at least 40g/m ² ; with glue on the entire surface, for firm fixation of tubes and instruments during surgery.	10x50 cm	1
5) 1 pc.: Bobber table field 190 x 280cm (± 20cm), 100% absorbent area on the entire surface - to be placed first in the set, above the other fields and accessories. Composed of at least 2 layers: a) waterproof, reinforced layer of polyethylene at least 50 micm thick; c) absorbent layer of viscose at least 30 g/m ² with an absorption capacity of at least 2 g/dm ³ .	190x280 cm	1
6) 2 pcs.: Mayo-type field for instrument table 80 x 145cm (± 10cm), reinforced, waterproof, absorbent, 3 layers: 2 layers in the absorbent area 65 x 85cm (± 5cm), of viscose at least 40g/m ² and polyethylene at least 50 micm; plus a polyethylene layer on the entire surface at least 60 micm thick. Absorption capacity in the critical area at least 2 g/m ² (Mayo with hydrophobic area will be excluded). Pictogram for guidance.	80x145 cm	2
7) 1 pc.: Suction catheter 12 CH, at least 0.5 m.	0.5 m	1
8) 1 pc.: Abrasive sponge for coagulation instruments, 5x 5cm (± 1cm)	5x5 cm	1
9) 3 pcs.: Syringe 20 ml, Luer lock.	20 mL	3
10) 2 pcs.: Light Handle Cover: cover for the handles of the surgical lamp.	STD	2
11) 10 pcs.: Neurosurgical absorbent pad, made of non-woven material, lint-free, hydrophilic, with R-contrast indicator, dimensions 12 x 40mm (± 2mm).	12x40 mm	10
12) 1 pc.: Disposable scalpel N15.	N15	1
13) 1 pc.: Disposable scalpel N22.	N22	1
14) 1 pc.: Pocket with adhesive tape for diathermy and suction instruments 35x40cm, made of polyethylene minimum 80 micm thick.	35x40 cm	1
15) 15) 1 pc.: Graduated bowl 120 ml for used needles, made of polypropylene, transparent, with thread and lid, minimum height 7cm, inscribed with the label "biohazard".	120 ml	1
16) 1 pc.: Microscope case with three ports, compatible with Pentero 900 microscope. Pictogram for guidance.	ST	1
17) 1 pc.: Disposable forceps with non-stick tip for bipolar coagulator. Bayonet design, compatible with the Erbe 200 /300 cable and coagulation device provided.	ST	1
18) 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 50mcg/g), resistant to surgical interventions using metal guides; non-pyrogenic, tear strength - not less than 18N, thickness at the fingers - not less than 0.27mm; coated on the inside with biogel for double protection and tear strength, AQL - not higher than 0.65 (AQL - standard for the protection of medical personnel during long-term interventions (penetration level for microorganisms and liquids, chemicals - according to standard EN 374-2:2014)).	N8.5 N8.0	1 cift 2 cift
19) 1 pc.: Skin marker, sterile.	ST	1

Raw Materials: Triflex / PE + NW / Biflex / Cellulose / PE

Product Colour: Medical Blue

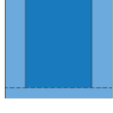
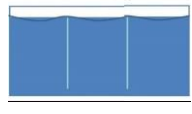
Reference Code: SP-01001-34

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			1	2	3	4
1	Biflex	230x300 cm				
4	Triflex	50x50 cm				
2	Cellulose	20x25 cm				
1	***	10x50 cm				
1	Biflex	190x280 cm				
2	NW+PE	80x145 cm				
1	***	0.5 m				
1	***	5x5 cm				
3	***	20 mL				
2	PE	STD				
10	***	12x40 mm				
1	***	N15				
1	***	N22				
1	PE	35x40 cm				
1	***	120 ml				
1	***	ST				
1	***	ST				
1 pair	***	N8,5				
2 pair	***	N8.0				
1	***	ST				
Tolerances: +/- 2% cm			Package Information			
Measurement: cm			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			