

TECHNICAL DATA SHEET

PRODUCT: Sterile disposable set for interventions (electrophysiology)

Description of Product:

Sterile disposable set for interventions (electrophysiology)			
1	1 pc. instrument table field, reinforced - 150x150cm (~5cm), absorbent area over the entire surface, 3 layers: absorbent layer of polypropylene at least 30 g/m ² , waterproof layer of polyethylene at least 25 mm thick.	150x150 cm	1
2	1 pc. instrument table field - 150x190cm (~5cm), absorbent area - at least 190x75cm, 2 layers: absorbent layer of viscose at least 20 g/m ² , waterproof layer of polyethylene at least 25 mm thick.	150x190 cm	1
3	1 pc. Mayo field for operating table, reinforced, dimensions 80x145cm (~5cm), absorbent area of viscose at least 25 g/m ² with an absorption area of 65x35cm (~5cm) (Mayo with hydrophobic area will be excluded). Protogram for guidance.	80x145 cm	1
4	4 pcs. hand towels, made of cellulose, minimum 10x25cm.	20x25 cm	5
5	5 pcs. adhesive tape - 10x50cm (~2cm), 2 layers: a) waterproof polyethylene minimum 25mm thick; b) absorbent polyester minimum 40g dm ² ; for fixing tubes.	10x50 cm	1
6	70 pcs. Absorbent viscose polyester pad - dimensions 10x10cm (~3cm), minimum 4 layers, liquid absorption capacity - minimum 100%.	10x10 cm	70
7	1 pc. Angiography field with dimensions 240x330cm (~15cm), integral, 100% waterproof on the entire surface. a) Critical area 90x110cm (~10cm) - reinforced, triple layered, made of viscose minimum 50g/m ² , polyethylene minimum 50mm, polypropylene minimum 10g/m ² , with a high degree of absorption of not less than 3.3 g dm ² , with 2 holes of 5x10cm (~2cm), with an integrated adhesive border around the holes (double-sided glue will not be accepted); b) Absorbent semi-critical area, minimum 100x200cm; c) Transparent side edges, dm. 70x320cm. All areas of the field will ensure 100% tightness, will be heat sealed, will not come off in a dry and/or liquid environment.	240x330 cm	1
8	3 pcs. Surgical gown XL. a) Made of non-woven material, polypropylene fibers, minimum 3 types of fibers - SMS; b) Repellent, SMS material thickness minimum 25 g/m ² ; c) Laser-sewn sleeve to ensure impermeability to microbes and liquids, needle-sewn sleeve will be excluded; d) Sleeve length 60cm (~3cm), gown length (from shoulders to hem) - 130cm (~5cm), gown width in the axillary area 75cm (~5cm).	kol: 60 cm uzunluk: 130 cm geniřlik: 75 cm	3
9	3 pairs. Sterile, powder-free gloves (size: N7.0 - 1 pair, N8.0 - 2 pairs) - made of deproteinized rubber, with low allergenic potential (extractable proteins no more than 50mcg/g), resistant to surgical interventions with the use of metal guides; apyrogenic, breaking strength - not less than 18N, thickness at the fingers - not less than 0.7mm, coated on the inside with biogel for double protection and tear resistance, AQL - no higher than 0.65 (AQL - standard for the protection of medical personnel during long-term interventions) (penetration test for microorganisms and liquids, chemicals - according to standard EN 1213-2:2014).	N7.0 N8.0	1cift 2cift
10	10 pc. surgical lamp handle cover.	ST	1
11	1 pc. cover - 20x30cm (~3cm), transparent.	20x30 cm	1
12	1 pc. circular screen cover - 140cm made of polyethylene, transparent, with elastic.	140 cm	1
13	1 pc. angiography screen cover - 100x100cm (~3cm), transparent.	100x100 cm	1
14	4 pcs. Applicator - length approx. 15cm.	15 cm	4
15	3 pcs. 250ml polypropylene bowl, graduated, transparent.	250 mL	2
16	16 pc. Min. 120ml polypropylene bowl, graduated, transparent, with thread and lid, minimum height 7cm, inscribed with the label "biological risk".	120 mL	1
17	1 pc. Scalpel N11.	7 cm	1
18	2 pcs. Min. 150ml graduated beaker, transparent.	N11	1
19	19 pc. 3 pcs. 3 ml Luer Lock syringe.	150 mL	2
20	20 pc. 1 pc. 20 ml Luer Lock syringe.	5 mL	3
21	21 pc. 2 pcs. 21G syringe needles.	20 mL	1
22	22 pc. 2 pcs. 22G syringe needles.	21 G	2
23	23 pc. 1 pc. PVC extension minimum 180cm, resistant to 500Pa, compatible with all syringes from different manufacturers.	22 G	2
24	24 pc. 5 pairs. White non-woven booties.	180 cm	1
25	25 pc. 5 pcs. 3-layer surgical mask, and antibacterial layer.	ST	5 cift
26	26 pc. 2 pcs. Men's surgical cap.	ST	5
27	27 pc. 2 pcs. Women's surgical cap.	ST	2

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

Product Colour: Medical Blue

Reference Code: SP-05004-67

Weight in Grams: 77 gsm (Triflex) / 35 gsm SMS + 110 gsm (Reinforcement) / 28 gsm(SS)+65 mic.(PE) / 56 gsm Biflex / 48 mic (PE) / 60 gsm (Cellulose) /

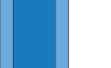
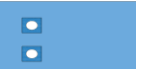
Package: Flat Pouch

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

Unit / Size	1	2	3	4
1 NW+PE 150x150 cm				
1 NW+PE 150x190 cm				
1 NW+PE 80x145 cm				
5 Cellulose 20x25 cm				
1 *** 10x50 cm				
70 *** 10x10 cm				
1 Triflex 240x330 cm				
3 SMS + Reinforcement kol: 60 cm uzunluk: 130				
1 pair *** N7.0				
2 pair *** N8.0				
1 PE ST				
1 PE 20x30 cm				
1 PE 140 cm				
1 PE 100x100 cm				
4 *** 15 cm				
2 *** 250 mL				
1 *** 120 mL				
7 cm				
1 *** N11				
2 *** 150 mL				
3 *** 5 mL				
1 *** 20 mL				
2 *** 21 G				
2 *** 22 G				
1 *** 180 cm				
5 pair *** ST				
5 *** ST				
5 *** ST				
2 *** 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