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TECHNICAL DATA SHEET

PRODUCT: Sterile disposable surgical set for angiography

Description of Product:

Sterile disposable surgical set for angiography		
1	Angiography field - 240x330cm (+/-5cm), integral, 100% waterproof on the entire surface. a) Critical area - triple-layered reinforced, with a high degree of absorption, minimum dimensions: 240x80cm, with 4 holes: 2 holes of 8x10cm (+/-3cm) and 2 holes of 5x7cm (+/-3cm), with an impregnated adhesive border around the holes (double-sided glue will not be accepted). b) Absorbent semi-critical area, minimum 100x220cm. c) Transparent side edges, dim. 70x220cm. All areas of the field will ensure 100% tightness, will be heat-sealed, will not peel off in a dry and/or liquid environment.	240x330 cm
2	super absorbent field - 35x45cm (+/-5cm), extra-absorbent, multilayered, minimum 6 layers, with adhesive tape, absorption capacity - minimum 500ml liquids.	35x45 cm
3	Field with adhesive board - 50x50cm (+/-5cm). Triple layered on the entire surface: cellulose comfort layer for the patient, waterproof layer, absorbent layer, with impregnated adhesive board (double-sided glue will not be accepted), the adhesive board applied directly to the edge of the field to avoid the accumulation of liquids.	50x50 cm
4	Instrument table field - 150x190cm (+/-5cm), absorbent area - minimum 190x75cm, 2 layers, waterproof.	150x190 cm
5	Hand towels, made of cellulose, minimum 30x40cm.	30x40 cm
6	Surgical gown XL - a) Made of non-woven material, polypropylene fibers, minimum 3 types of fibers - SMS; b) Repellent, SMS material thickness minimum 35 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 (±3cm).	Arm: 60 cm Length: 130 cm Width: 75 cm
7	Sterile, powder-free gloves (sizes: N7.5 - 2 pairs; N8.0 - 1 pair) - made of deproteinized rubber, hypo-allergenic/with low potential to cause allergies, resistant to surgical interventions with the use of metal guides; non-pyrogenic, breaking strength - not less than 18N, thickness at the fingers - not less than 0.27mm; coated on the inside with biogel for double protection and breaking 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)).	N7.5 N8.0
8	Circular screen cover - 140cm made of polyethylene, transparent, with elastic.	140 cm
9	C-arm radiological tube cover, circular, 75cm made of polyethylene, transparent, with elastic.	75 cm
10	120 ml polypropylene bowl, graduated, transparent, with thread and lid, minimum height 7cm, Inscribed with the label “biological risk”.	7 cm
11	Bowl minimum 100 ml made of polypropylene, transparent.	100 mL
12	Bowl minimum 250 ml made of polypropylene, colored.	250 mL
13	Kidney bowl minimum 800 ml.	800 mL
14	Forceps for field fixation - 15cm (+/-3cm).	15 cm
15	Clamp - 10cm (+/-3cm).	10 cm
16	Tray 2500 ml, round, made of polypropylene, colored, with “wings”, minimum height 9cm (+/-1cm) - to ensure the firm position of the metal guide and prevent its slipping.	2500 mL
17	Angio syringe 12 ml with rotator.	12 mL
18	3-way OFF ramp, “wing” valves, resistant to 35 bar integrated with: a) polyurethane contrast system minimum 1800mm; b) polyurethane infusion system minimum 1900mm; c) polyurethane tube, minimum 1500mm.	STD
19	E11 scalpel.	E11
20	Angiographic guide - minimum length 175cm, J3, 0.034-0.036”.	175 cm
21	Gauze pad, absorbent 10x10cm, minimum 8 layers.	10x10 cm
22	Syringe needle 18G.	18G
23	Syringe needle 21G.	21 G
24	Syringe needle 22G.	22G
25	Luer Lock syringe 20 ml.	20 mL
26	Luer Lock syringe 10 ml.	10 mL
27	Luer Lock syringe 5 ml.	5 mL
28	Luer Lock syringe 2 ml.	2 mL
29	Tubing bowl - 30x30cm (+/-3cm).	30x30 cm
30	Sterile field for tubing - 100 x 150cm (+/-3cm).	100x150 cm

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

Product Colour: Medical Blue

Reference Code: SP-05006-161

Weight in Grams: 77 gsm (Triflex) / 35 gsm SMS + 110 gsm (Reinforcement) / 28 gsm(SS)+65 mic.(PE) / 56 gsm Biflex / 48 mic (PE) / 40 gsm (SMS) / 60 gsm (Cellulose) / 60 mic (PE)

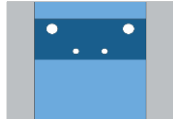
Package: Flat Pouch

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

Unit / Size

PROPERTIES

1	2	3	4
			
5	6	7	8
			
9	10	11	12
			
13	14	15	16

1	***	800 mL				
1	***	15 cm	17	18	19	20
1	***	10 cm				
1	***	2500 mL	21	22	23	24
1	***	10 mL				
1	***	STD	25	26	27	28
1	***	E11				
1	***	175 cm	29	30		
30	***	10x10 cm				
1	***	18G				
2	***	21 G				
1	***	22G				
1	***	20 mL				
1	***	10 mL				
1	***	5 mL				
1	***	2 mL				
1	***	30x30 cm				
1	Biflex	100x150 cm				
Tolerances:			Package Information			
Measurement:			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			