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TECHNICAL DATA SHEET

PRODUCT: Disposable sterile hip and thigh surgery set

Description of Product:

Disposable sterile hip and thigh surgery set			
1) 1 pc: Hip and thigh field dimensions 220/300 x 340cm (± 20cm), with universal elastic opening for all sizes, circular, with flexible edges for the hip and thigh joint 15 x 20cm (± 5cm), with 2 side bags for limb positioning and fluid collection 130 x 75cm (± 2cm), both bags with taps; super absorbent and sharp instrument resistant area with minimum dimensions of 30 x 150cm, with 2 bags for instruments minimum 30 x 20cm, bilateral. Material of at least 3 well delimited layers: a) absorbent layer viscose and polyester minimum 30g/m ² over the entire surface; b) waterproof layer 100% polyethylene minimum 40 mcm thick over the entire surface; c) super absorbent layer of viscose and polyester minimum 50g/m ² in the critical area: "Velcro" type fasteners. Field resistant to heavy surgical instruments.	220/300x340 cm	1	
2) 2 pcs: Sheet with adhesive border – 75 x 75cm (± 5cm). Triple layered on the entire surface: a) comfort layer for the patient, made of cellulose or polypropylene; b) waterproof layer of polyethylene minimum 40 mcm thick; c) absorbent layer of viscose minimum 20g/m ² , with impregnated adhesive border (double-sided glue will not be accepted), the adhesive border applied directly to the edge of the field to avoid the accumulation of fluids.	75x75 cm	2	
3) 2 pcs: Surgical tapes with adhesive layer on the entire surface, dimensions 10 x 50cm (± 5cm); from 2 layers: a) waterproof polyethylene minimum 25 mcm thick; b) absorbent polyester minimum 40g/m ² .	10x50 cm	2	
4) 1 pc: Mayo field for operating table, reinforced in the critical area, dimensions 80 x 145cm (± 5cm); 3 layers: 2 layers in the absorbent area 65 x 85cm (± 5cm), of viscose at least 40g/m ² and polyethylene at least 50mcm; plus a polyethylene layer on the entire surface of at least 60mcm thickness. Absorption capacity in the critical area at least 2 g/m ² (Mayo with hydrophobic area will be excluded). Pictogram for guidance.	80x145 cm	1	
5) 1 pc: Field for table 150 x 190cm (± 5cm), absorbent area 80 x 190cm (± 5cm); Composed of at least 2 layers: a) waterproof layer, of polyethylene at least 55mcm thick; b) absorbent layer of viscose at least 20g/m ² .	175x175 cm	1	
6) 1 pc: Reinforced table field 150x190cm (± 10cm), absorbent area 150 x 190cm (± 10cm) over the entire surface. Composed of at least 2 layers: a) waterproof, reinforced layer of polyethylene minimum 55 mcm thick; b) absorbent layer of polypropylene minimum 30g/m ² .	240x150 cm	1	
7) 1 pc: Stockinet 30 x 120cm (± 2cm), of 1 polyethylene layer and 1 viscose layer, impermeable to liquids.	30x120 cm	1	
8) 1 pc: Incision film made of polyurethane dimensions 40cm x 40cm (± 2cm), on an acrylate basis.	40x40 cm	1	
9) 1 pc: Standard surgical gown size L, made of cellulose non-woven material with polyester 68g/m ² , with polyester cuffs; length from shoulder to hem minimum 120cm; thoracic region minimum 53cm, laser-sewn sleeve.	XL omuzdan eteğe uzunluk 145cm göğüs bölgesi minimum 60cm kol - minimum 40cm	2	
10) 2 pcs: Surgical gown reinforced front and sleeves, size XL, made of SMS non-woven material minimum 40g/m ² , with polyester cuffs; length from shoulder to hem 145cm (± 5cm); chest region minimum 60cm; reinforcement: front – minimum 50 x 100cm, sleeve – minimum 40cm; sleeve sewn with laser.			
11) 1 pc: Skin marker, standard.	ST	1	
12) 2 pcs: Radio-contrast thread mesh, dimensions 50 x 50cm (± 5cm)	50x50 cm	2	
13) 1 pc: Container with lid, for taking specimens, minimum volume 300 ml.	500 mL	1	
14) 1 pc: Cable holder, velcro type with glue minimum 2 x 30cm.	2x30 cm	1	
15) 1 pc: Vicryl Plus 2-0 equivalent suture, length 70cm.	70 cm	1	
16) 1 pc: Vicryl Plus 1 equivalent suture, length 90cm.	90 cm	1	
17) 1 pc: Self-adhesive, absorbent post-operative dressing. Size of the absorption area minimum 10 x 20cm, absorption capacity – minimum 6 g/10cm ² /24 h (according to EN13726 standard).	10x35 cm	1	
18) 2 pcs: Astronaut-type surgical cap, with absorbent tape, with ties at the back.	ST	1	

Raw Materials:

Triflex / SMS + Reinforcement / PE + NW / Biflex / SMS / Cellulose / PE

Product Colour:

Medical Blue

Reference Code:

SP-07004-20

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:

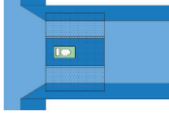
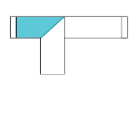
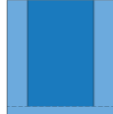
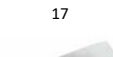
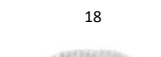
Flat Pouch

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
1	Triflex	220/300x340 cm	
2	Triflex	75x75 cm	
2	***	10x50 cm	
1	NW+PE	80x145 cm	
1	Triflex	175x175 cm	
1	Triflex	240x150 cm	
1	Biflex	30x120 cm	
1	***	40x40 cm	
	***	XL	
2	SMS + Reinforcement	XL	
1	***	ST	
2	***	50x50 cm	
1	***	500 mL	
1	***	2x30 cm	
1	***	70 cm	
1	***	90 cm	
1	***	10x35 cm	
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