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TECHNICAL DATA SHEET

PRODUCT: Sterile knee implant set

Description of Product:

Sterile knee implant set		
1) 1 pc.: Knee surgery drape 220 x 320cm (± 10cm), with universal elastic opening of 7cm diam. for all sizes, circular, with transparent flexible border for the knee joint, with integrated bag for collecting fluids. Material on the entire surface of at least 3 well-defined layers: a) comfort layer for the patient; b) waterproof layer 100% polyethylene minimum 40 mcm thick on the entire surface; c) absorbent layer of viscose and polyester minimum 30g/m ² ; in the critical area - additional absorbent layer of viscose minimum 20 g/m ² ; "Velcro" type fasteners. Drapes resistant to heavy surgical instruments.	220x320 cm	1
2) 2 pcs.: Drapes with adhesive border dimensions 90 x 75cm (± 5cm). Poly-layered, minimum 3 layers on the entire surface, plus reinforcement in the critical area: a) comfort layer for the patient made of polypropylene; b) waterproof layer made of polyethylene minimum 40mcm thick, c) absorbent layer made of viscose minimum 20g/m ² , d) super absorbent layer in the critical area - minimum 50g/m ² . Absorption capacity in the critical area minimum 3.5 g/dm ² . 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.	90x75 cm	2
3) 2 pcs.: Removable bag, with adhesive tape, transparent, for diathermy and suction instruments 40 x 40cm (± 5cm), made of polyethylene minimum 80 mcm thick.	40x40 cm	2
4) 1 pc.: Incision film made of polyurethane dimensions 30 x 25cm (± 2cm), acrylate-based adhesive.	30x25 cm	1
5) 1 pc.: Mayo drape 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 minimum 40g/m ² and polyethylene minimum 50 mcm; plus a polyethylene layer on the entire surface of minimum 60mcm thickness. Absorbency capacity in the critical area minimum 2 g/dm ² (Mayo with hydrophobic area will be excluded). Pictogram for guidance.	80x145 cm	1
6) 1 pc.: Bobrov-type table drape 190 x 280cm (± 10cm), 100% absorbent area on the entire surface - to be placed first in the set, above the other drapes and accessories. Composed of at least 2 layers: a) waterproof, reinforced layer of polyethylene, minimum 50 mcm thick, c) absorbent layer of viscose, minimum 30g/m ² with minimum absorption capacity of 2g/dm ² .	190x280 cm	1
7) 1 pc.: Stockinet 20 x 75cm (± 5cm), of 1 polyethylene layer and 1 viscose layer, impermeable to liquids.	20x75 cm	1
8) 1 pc.: Skin marker, standard.	ST	1
9) 1 pc.: Container with lid, for taking specimens, minimum volume 500 ml.	500 mL	1
10) 3 pcs.: Astronaut-type surgical cap, with absorbent tape, with ties at the back.	ST	1

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

Product Colour: Medical Blue

Reference Code: SP-07002-27

Weight in Grams: 77 gsm (Triflex) / 28 gsm(SS)+65 mic.(PE) / 56 gsm Biflex / 48 mic (PE)

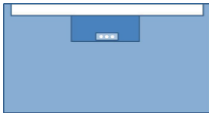
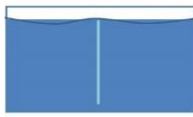
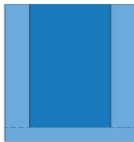
Package: Flat Pouch

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	220x320 cm	
2	Triflex	90x75 cm	
2	PE	40x40 cm	
1	***	30x25 cm	
1	NW+PE	80x145 cm	
1	Biflex	190x280 cm	
1	Biflex	20x75 cm	
1	***	ST	
1	***	500 mL	
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