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TECHNICAL DATA SHEET

PRODUCT: Sterile Knee Arthroscopy Set

Description of Product:

Knee arthroscopy Set			
1	1) 1 pc.: Knee surgery drape 220 x 320cm (± 10cm), with universal elastic hole diam. 7cm, 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) 100% waterproof layer of polyethylene minimum 40 micm 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) 2 pcs.: Drapes with adhesive border dimensions 90 x 75cm (± 2cm). 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 40micm 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	3) 2 pcs.: Transparent removable bag, with adhesive tape, for diathermy and suction instruments 40 x 40cm (± 5cm), made of polyethylene minimum 80 micm thick.	40x40 cm	2
4	4) 1 pc.: Incision film made of polyurethane dimensions 30 x 25cm (± 2cm), acrylate-based adhesive.	30x25 cm	1
5	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 50micm; plus a polyethylene layer on the entire surface of minimum 60micm 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	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 at least 50micm thick; c) absorbent layer of viscose at least 30g/m ² with absorption capacity at least 2g/dm ² - 1 pc.	190x280 cm	1
7	7) 1 pc.: Stockinet 20 x 75cm (± 5cm), of 1 polyethylene layer and 1 viscose layer, impermeable to liquids.	20x75 cm	1
8	8) 2 pairs: N8.0 powder-free surgical gloves, made of deproteinized rubber, with low allergenic potential (extractable proteins not more than 20 mcg/g), resistant to surgical interventions with the use of heavy instruments; 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.	N8.0	2 pair
9	9) 1 pc.: Skin marker, standard.	ST	1
10	10) 1 pc.: Cover for endoscopic video camera, minimum dimensions 18 x 250cm, made of transparent polyethylene of at least 55 micm, with glue for fixation at both ends.	18x250 cm	1
11	11) 1 pc.: Astronaut-type surgical cap, with ties at the back.	ST	1

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

Product Colour: Medical Blue

Reference Code: SP-07002-10

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.

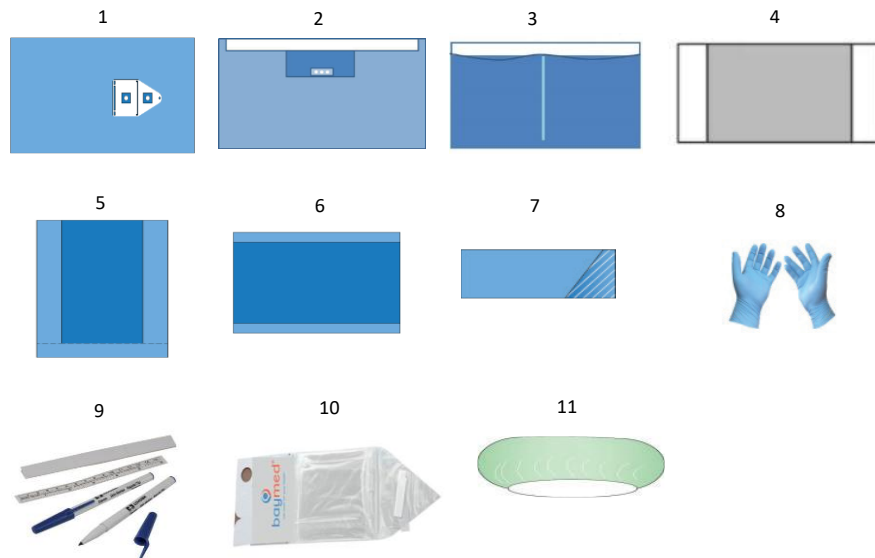
Product Shelf Life - 5 Years

Product Materials

Unit / Size

PROPERTIES

1	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
2 pair	***	N8.0
1	***	ST
1	PE	18x250 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