

TECHNICAL DATA SHEET

PRODUCT: Acute Thoracic Set (Thoracic/Spinal Surgery)

Description of Product:	Acute Thoracic Set (Thoracic/Spinal Surgery)
Raw Materials:	SMS
Product Colour:	Medical Blue
Reference Code:	HP03009001
Weight in Grams:	43 gsm
Package:	Flat Pouch

Product: MDR Manufactured in accordance with (EU) 2017 / 745 Annex XI Part A. Products and materials used do not contain metal.

Technical Documentation

Technical Drawing

CERTIFICATES

EC CERTIFICATE (CE 2696)
ISO 13485:2016
MDR (EU) 2017/745

STANDARDS

EN ISO 13485	EN ISO 10993-10
EN ISO 11135	ISO 11737-1
EN ISO 13795-1	EN ISO 1041
EN ISO 15223-1	EN ISO 11607
EN ISO 14698-1	EN ISO 14001
EN ISO 10993-1	EN ISO 9001
EN ISO 14971:2019	
EN ISO 14698-2	
EN ISO 10993-5	

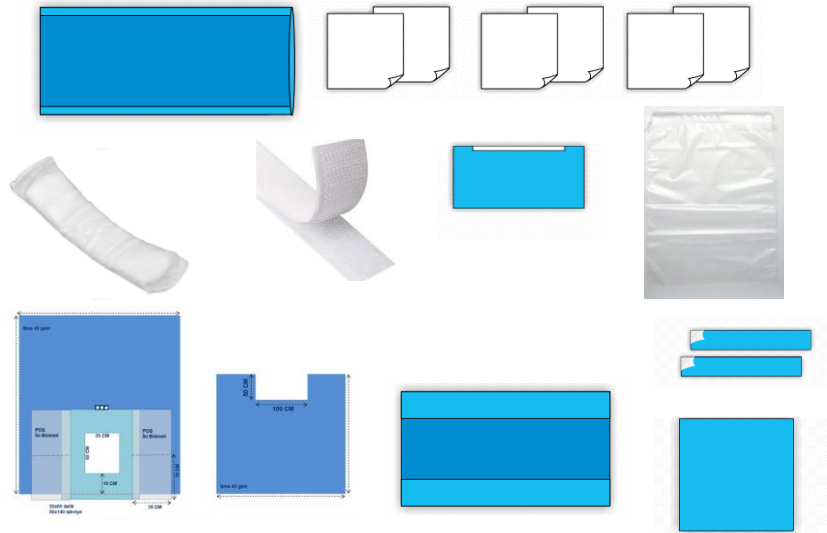
Acute thoracic set (thoracic/spinal surgery)		
1	In the absorbent area 65 x 85 cm (± 5 cm), made of viscose minimum 40g/m ² and polyethylene	80x145 cm
2	polyester or SMS.	20x25 cm
3	1 pc.: Perineal absorbent 20 x 40 cm (± 5cm), waterproof	20x40 cm
4	2 pcs.: Support for velcro tubes 2.5 x 30 cm (± 2cm).	2.5x30 cm
5	1 pc.: Sheet with adhesive border - 75 x 75 cm (± 5 cm). Triple layered on the entire surface: a) comfort layer for the patient, made of cellulose or polypropylene, b) polyethylene waterproof layer at least 40mcn thick, c) viscose absorbent layer at least 20g/m ² , with impregnated adhesive edge (double-sided glue will not be accepted), the adhesive edge applied directly to the edge of the field to avoid accumulation of liquids.	75x75 cm
6	1 pc.: Defibrillator bag, minimum 30 x 40 cm (± 2cm), transparent, with glue, removable	30x40 cm
7	2 pcs.: Surgical ribbons - 10 x 50 cm (± 5 cm). From 2 layers: a) waterproof polyethylene minimum 25mcn thick; b) polyester absorbent minimum 40g/dm ² , with glue all over the surface	10x50 cm
8	1pc.: Chest sheet minimum 200/300 x 330cm (± 2cm), incision area 35 x 65cm (± 2cm). Integral, waterproof, three-layer field on the entire surface, in the critical area 50 x 140 cm (± 5 cm) composed of at least 4 well-defined layers: a) comfort layer for the patient made of viscose at least 20g/m ² ; b) minimum waterproof polyethylene layer 40 mcn thick, c) reinforced polyethylene layer at least 40 mcn; d) super absorbent viscose layer minimum 50g/m ² . Integrated incision film, integrated channels for fixing the tubes, at least 4 resistant polyethylene bags, at least 80mcn thick, integrated with the sheet, with dimensions 30 x 70 cm (± 3 cm). Icons for guidance. Resistant to heavy surgical instruments	200/300x330 cm
9	1 pc.: absorbent table field, dimensions minimum 150 x 240cm (± 2cm), absorbent area minimum 70 x 240cm, composed of at least 2 layers: a) polyethylene layer of at least 50 mcn thickness; b) viscose absorbent layer, minimum 20 g/m ² . *Qualification documents	200x240
10	Sterilization wrap	100x100 cm

INSTRUCTION FOR USAGE

It is used to prevent infections by creating a barrier between sterile and non-sterile areas.

EXPIRY DATE

5 YEAR SHELF LIFE



All sizes have % 2 cm tolerance

Label Information

Package Information

- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Single use,
- CE Mark
- Other customer requests

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into MHK's standard sized carton; dimensions are as follows:
Height = 45 cm; Length = 60 cm ve Width = 40 cm.