

TECHNICAL DATA SHEET

Description:

88223: ENT Pack III, Sterile

Components:

BACK TABLE COVER 152 x 190 cm	1
MAYO STAND COVER REINFORCED 80 x 144 cm	1
SUTURE BAG	1
HEAD DRAPE 127 x 91 cm	1
EENT SPLIT DRAPE 193 x 314 cm	1

EENT SPLIT DRAPE- with Instrument Pad, Positioning Tapes,
Split 7 x 71 cm, Tube Holder/2 holes

*Properties:*Basis weight of EENT Drape: 44 g/m², Reinforcement: 62 g/m²Basis weight of Head Drape: 47 g/m²Thickness/Basis weight of Mayo: Film 45µm + SMS 47 g/m²Basis weight of BTC: 65 g/m²

EENT Drape: High performance drape as defined by EN 13795:2011.

Test results as per EN13795 available upon request.

Indication:

To create a sterile field around the operative site and to cover areas of the body and operating room equipment that may or may not be involved in the surgical procedure. Single use product.

Counter indication:

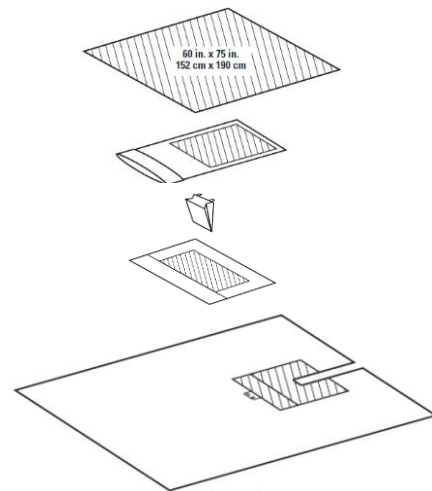
None in particular.

Main materials:

EENT Drape: SMS fabric with Control SMF (polypropylene)
Head Drape: SMS fabric (polypropylene)
Mayo Stand Cover: Film/ SMS (polyethylene/polypropylene)
Back Table Cover (BTC): Spunbond-Film Laminate (polypropylene)
Not formulated with Natural rubber latex.
Not formulated with DEHP.

Sterilization:

Product is sterilized by ethylene oxide (ETO).

**Packaging:**

Shipping case of 6 units.

All units are placed within 1 polyethylene bag.

Unit packaging: Clear Header Bag, 1 traceability sticker.

Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

Manufacturing:

Processed in Mexico of U.S. Materials.

The quality system of the manufacturing sites is ISO 13485 compliant.

Regulatory information:

Product CE marked as per 93/42/EEC Directive on Medical Devices.

Class of the device: I, sterile.

Notified body: BSI (0086).

This product complies with EN 13795:2011.

Storage:

Store in a dry and cool place, away from intense sources of heat.

Keep as much as practicably possible in its shipper box.

Shelf life:

5 years, from the date of manufacture.