

TECHNICAL DATA SHEET

Description

89584: BASICS* Under Buttocks Drape with Graduated Pouch, Sterile
79584: BASICS* Under Buttocks Drape with Graduated Pouch,
Non-sterile, For Manufacturing/Processing/Repacking.

Dimensions

Drape size: 102 x 112 cm
Reinforcement: 40.5 x 51 cm
Pouch: 66 x 71 cm

Properties

Basis weight of base material: 35 g/m²
Basis weight of reinforcement: 60 g/m²
Basis weight of pouch: 80 g/m²
Standard performance fabric 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

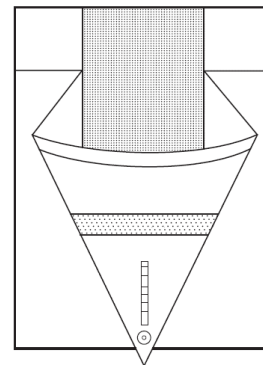
None in particular.

Main materials

Base material: Absorbent Spunbond (polypropylene)
Reinforcement: Bilaminate Absorbent Material (Spunbond/PE film)
Pouch: Clear Film (polyethylene)
Not formulated with Natural rubber latex.
Not formulated with DEHP.

Sterilization

89584: Product is sterilized by ethylene oxide (ETO).
79584: Product is non-sterile. Product can be sterilized by ethylene oxide (ETO).



Packaging

89584: Shipping case of 65 units.
All units are placed within 1 polyethylene bag.
Unit packaging: CSR Wrap, Clear Header Bag, 2 traceability stickers.
Bar coding: GS1-128 symbology, linear on shipping case and unit packaging.

79584: Shipping case of 90 units.
45 units are placed within 1 polyethylene bag and 2 polyethylene bags are placed within the shipping case.
Bar coding: GS1-128 symbology, linear, on shipping case.

Manufacturing

Products are manufactured in China.
The quality system of the manufacturing sites is ISO 13485 compliant.

Regulatory information

Products CE marked as per 93/42/EEC Directive on Medical Devices.
Class of the device: I.
Notified body: BSI (0086).
These products comply 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

89584: 5 years, from date of manufacture.
79584: None specified.