

# TECHNICAL DATA SHEET

## Minor Procedure Fenestrated Drape - Sterile, Non- Sterile



### Description

#### Reference

89209: Minor Procedure Fenestrated Drape, Sterile  
79209: Minor Procedure Fenestrated Drape, Non-sterile  
For Manufacturing/Processing/Repacking.  
with Tube Holder/2 holes

#### Dimensions

Drape size: 193 x 315 cm  
Reinforcement size: 51 x 68 cm  
Fenestration: 15 x 15 cm

#### Properties

Basis weight of base material: 44 g/m<sup>2</sup>  
Basis weight of reinforcement: 62 g/m<sup>2</sup>  
High 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

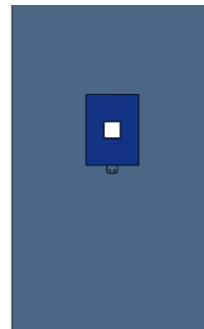
None in particular.

### Main materials

Base material: SMS Fabric (polypropylene), topically treated for alcohol repellency and static dissipation.  
Reinforcement: Control SMF (polypropylene)  
Medical Tape: Acrylate based on a carrier of 76 µm polyethylene film.  
Does not contain Natural rubber latex.  
Does not contain DEHP.

### Sterilisation

89209: Product is sterilized by ethylene oxide (ETO).  
79209: Product is non-sterile.  
Product can be sterilized by ethylene oxide (ETO).



### Packaging

89209: Shipping case of 19 units.  
All units are placed within 1 polyethylene bag.  
Unit packaging: CSR Wrap, FFS (Form/Fill/Seal) peel- bag,  
1 traceability sticker. Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

79209: Shipping case of 23 units.  
All units are placed within 1 polyethylene bag.  
Bar coding: GS1-128 symbology, linear, on shipping case.

### Manufacturing

Processed in China or 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.  
These products are EN 13795 compliant.  
Notified body: BSI (0086)

### 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

89209: 5 years, from date of manufacture.  
79209: None specified.