Femoral Angiography

Surgical Drape

TECHNICAL DATA SHEET

CE

Description

Reference
89716: Femoral Angiography Drape with Dual Windows, Sterile
79716: Femoral Angiography Drape with Dual Windows, Non-sterile, For Manufacturing/Processing/Repacking.

Dimensions
Drape size: 224 x 292 cm
Reinforcement: 81 x 122 cm
Fenestration: 12 cm diameter (incise of 7 cm diameter)
Windows: 71 x 292 cm

Properties
Basis weight of base material: 47 g/m^2
Basis weight of reinforcement: 99 g/m^2
Thickness of polyethylene film: 38µm
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

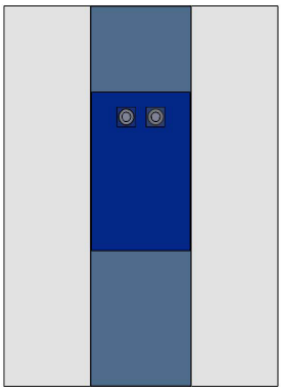
None in particular.

Main material

Base material: SMS Fabric (polypropylene), topically treated for alcohol repellency and static dissipation.
Reinforcement: Control Plus SMF (polypropylene)
Windows: Clear Film (polyethylene)
Not formulated with Natural rubber latex.
Not formulated with DEHP.

Sterilization

89716: Product is sterilized by ethylene oxide (ETO).
79716: Product is non-sterile. Product can be sterilized by ethylene oxide (ETO).



Packaging

89716: Shipping case of 18 units.
All units are placed within 1 polyethylene bag.
Unit packaging: CSR Wrap, Clear Header Bag, 1 traceability sticker. Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

79716: Shipping case (HANDI BIN) of 200 units.
10 units are placed within 1 polyethylene bag and 20 polyethylene bags are placed within the HANDI BIN.
Bar coding: GS1-128 symbology, linear, on shipping case and bags.

Manufacturing

Products are manufactured in China.
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.
Notified body for sterile product: BSI 2797
These products are EN 13795 compliant.
High performance fabric as defined by EN 13795

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

89716: 5 years, from date of manufacture.
79716: None specified.

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Created 31-Mar-2015, version 0

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.