Universal Spine Drape

TECHNICAL DATA SHEET

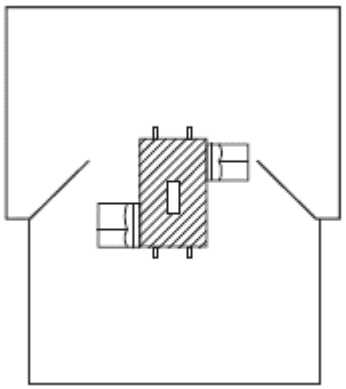
CE 0086

Description

29221: Universal Spine Drape, Sterile
29224NS: Universal Spine Drape, Non-sterile,
For Manufacturing/Processing/Repacking.

With 2x Instrument Pouches, 4x Fasteners,
Positioning Tapes around fenestration.

Dimensions:
- Drape size: 284 x 251 x length 350 cm
- Reinforcement: 46 x 91 cm
- Fenestration: 10 x 30 cm, Medical tape width: 2.5 cm
- Pouches: 18 x 30 cm



Properties:
- Basis weight of base material: 47 g/m^2
- Basis weight of reinforcement: 99 g/m^2
- Thickness of polyethylene film: 76µm
- 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 Plus SMF (polypropylene)
Pouches: Clear Film (polyethylene)
Does not contain Natural rubber latex.
Does not contain DEHP.

Sterilization

29221: Product is sterilized by ethylene oxide (ETO).
29224NS: Product is non-sterile.
Product can be sterilized by ethylene oxide (ETO).

Packaging

29221: Shipping case of 8 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.

29224NS: Shipping case of 9 units.
All units are placed within 1 polyethylene bag.
Bar coding: GS1-128 symbology, linear, on shipping case.

Manufacturing

Processed in Mexico of U.S. Materials.
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.
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

29221: 5 years, from date of manufacture.
29224NS: None specified.

**Registered trademark or trademark of Halyard Health Inc.*
©2015 Halyard Belgium BVBA. All rights reserved.
Created 17-dec-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.