

Surgical Drapes

Orthopedic

| | CODE | DESCRIPTION | CASE QTY | CASE DIMENSIONS |
|--|------------|--|----------|------------------------|
| | 80-09901 | Anterior Approach Hip Drape, 91x157" (230x400cm) | 5 | 18x13x16" (45x33x41cm) |
| | 80-09901-S | Anterior Approach Hip Drape, 91x157" (230x400cm) | 4 | 18x13x16" (45x33x41cm) |

Materials

- ONEZONE® Bi-Laminate Nonwoven Material (PP/PE)
- HydraGuard® Absorbent Reinforcement

Product Attributes

- Two adhesive fenestrations
- Absorbent reinforcement material for fluid management
- Absorbent top layer with impermeable film bottom layer

Sterilization

Sterile: Sterilized by EO (ethylene oxide). Product is sterile unless the package has been damaged or opened.
Non-Sterile: If a product is delivered non-sterile and is ultimately for use in sterile environments, it is intended to be sterilized by the re-packager. This includes further packaging and sterilization according to the validated processes of the re-packager. These products are to be sterilized by ethylene oxide (EO). Other methods of sterilization have not been validated by Alleset.

Shelf Life

Sterile: 5 years
Non-Sterile: Established at 5 years based upon sterile packaged product aging studies and normal warehouse storage conditions. After 5 years, the product should be performance tested to ensure compliance to specifications.

Product Certifications/Standards

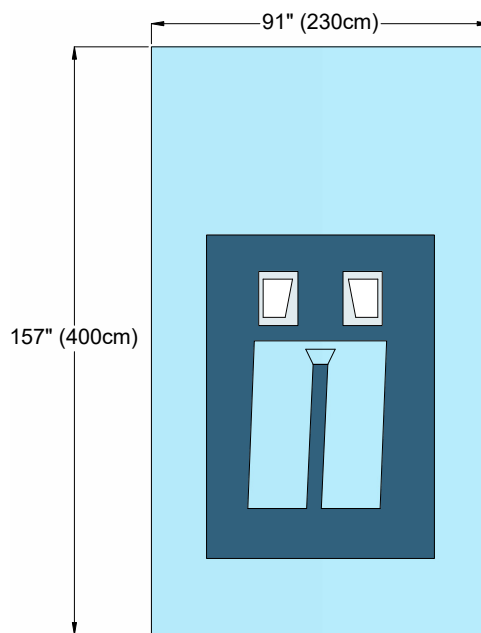
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- Class I Flammability per 16 CFR 1610.4 Standard
- L1 Laser Resistance per ISO 11810-1:2005

Manufacturing Certifications/Registrations

- EN ISO 13485:2016
- Medical Device Single Audit Process Certified

Storage

- General warehouse conditions



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 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.

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