# **Surgical Drapes**

# Ophthalmic



|   | CODE       | DESCRIPTION  | CASE QTY | CASE DIMENSIONS        |
|---|------------|--|----------|------------------------|
| N | 80-08120   | Ophthalmic Drape w/ Full Incise and Fluid Collection Pouch, 55x71" (140x180cm) | 50       | 23x14x17" (58x36x43cm) |
| S | 80-08120-S | Ophthalmic Drape w/ Full Incise and Fluid Collection Pouch, 55x71" (140x180cm) | 17       | 16x11x17" (40x27x42cm) |

#### Materials

- Multilayered SMS Material with Antistatic Properties and Alcohol Repellency
- Clear Polyethylene (PE) Film

#### **Product Attributes**

- · Adhesive incise area, non fenestrated
- · Malleable breather bar
- · Fluid collection pouches

#### 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 repackager. 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**

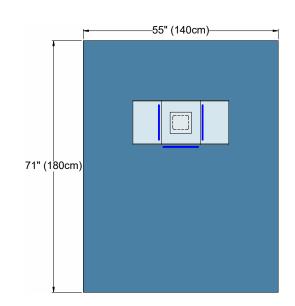
• CE certified as Class I, according to MDR 2017/745, Annex VIII, Rule 1

# **Manufacturing Certifications/Registrations**

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

# Storage

· General warehouse conditions















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