Surgical Drapes

Angiography



CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N 80-01186	Femoral Angiography Pacemaker Drape, 87x135" (221x343cm)	16	20x13x16" (52x32x40cm)
S 80-01186-S	Femoral Angiography Pacemaker Drape, 87x135" (221x343cm)	16	21x14x18" (54x35x46cm)
N 80-01186-HB	Femoral Angiography Pacemaker Drape, Handi-Bin , 87x135" (221x343cm)	160	48x40x24" (122x101x61cm)

Materials

- Clear Polyethylene (PE) Film
- Hydra™ Absorbent Reinforcement
- Spunbond Polypropylene (PP)

Product Attributes

- · Absorbent reinforcement material for fluid management
- Dual viewing windows
- · Two circular adhesive fenestrations
- Two rectangular adhesive fenestrations

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

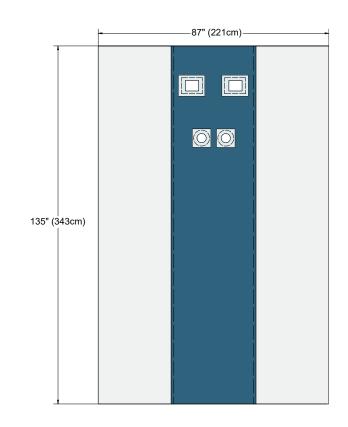
- Sterile: CE certified as Class I, according to MDD93/42/EEC Annex IX,
- · Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/Registrations

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

Storage

General warehouse conditions













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SM-TDS-003 2023

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



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EC REP

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