

Laparoscopic Accessories

Anti-Fog Solution

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N 37-001	Anti-Fog Solution, 6ml Bottle	1100	26x14x18" (66x36x45cm)
S 37-001-S	Anti-Fog Solution, 6ml Bottle	200	23x15x11" (59x37x27cm)
N 37-002	Sponge, Adhesive Pad for Anti-Fog Solution	2000	23x15x15" (59x37x39cm)
S 37-005-S	Anti-Fog Solution Kit, 6ml Bottle with Sponge	200	23x15x11" (59x37x27cm)

Materials

- Solution: Isopropyl Alcohol (< 10.00%); Surfactant (< 2.00%); Water (> 90.00%)
- Foam Pad: Polyurethane Foam, Blue

Product Attributes

- Sponge is a non-abrasive foam, safe for use on today's delicate scopes
- Sponge includes x-ray detectible element for added safety

Sterilization

Sterile: Sterilized by Gamma Irradiation (R)
Non-Sterile Bottle: The sealed bottle has been previously gamma irradiated so that the interior is sterile. The bottle is ultimately for use in sterile environments and is intended to be sterilized by the re-packager so that the outside of the bottle is sterile. This includes further packaging and sterilization according to the validated processes of the re-packager
Non-Sterile Pad: If product 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

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

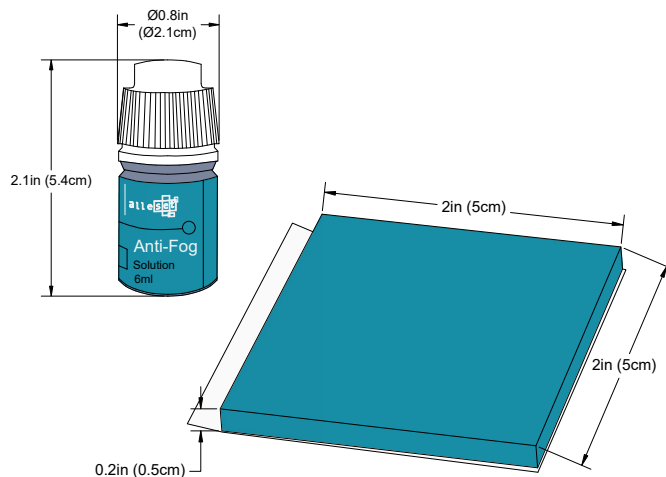
- Sterile: CE certified as class IIa, according to MDD 93/42/EEC Annex IX, Rule 7
- Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/Registrations

- EN ISO 13485:2016

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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