Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: **3569**

Product Description: **DISPOSABLE SPINNER FLASK,1L,W/ASEPTIC ACCESSORY,S,IND,1/6**

Component Materials:

Vessel	-	Virgin Polystyrene, meets *USP, Class VI requirements for plastic containers and closures*, "complies with International Organization for Standardization (ISO) 10993-18, Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials (2005)".
Impeller	-	Polypropylene, meets *USP, Class VI requirements for plastic containers and closures*, "complies with International Organization for Standardization (ISO) 10993-18, Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials (2005)".
Caps	-	High Density Polyethylene, meets *USP, Class VI requirements for plastic containers and closures*.
Tubing	-	C-Flex thermoplastic elastomer, meets *USP, Class VI requirements for plastic containers and closures.*
Filter	-	0.2µm polyester non-woven membrane, meets *USP, Class VI requirements for plastic containers and closures*

Accessories:

Magnet	-	Polytetrafluoroethylene encapsulated ALNICO magnet, 12800 Gauss induction.

Product Dimensions:

Height of Vessel	-	9.64 in. (24.48cm)	Diameter of Vessel	-	8.0 in. (20.32cm)
Sidearm Opening of Vessel	-	1.53 in. (3.88cm)	Sidearm Cap of Vessel	-	45mm GL 45
Cap Diameter	-	1.77 in. (4.49cm)	Cap Height	-	1.0 in. (2.54cm)
Tolerances	-	+/-0.05 in.	Maximum Volume	-	1L
			Recommended Volume	-	.5L

Sterilization: - The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of health care products- Requirements for validation and routine control-Radiation sterilization*.
Sterility Assurance Level (SAL) of 10^{-6}.

Sterility - Products labeled Sterile Fluid Path have been designed to ensure sterility of the portion of the product intended for contact with fluids.

BSE/TSE – This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

Non-Pyrogenic - Vessel tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing". The acceptance level for product is ≤ 0.10 EU/mL or ≤ 4 EU/device.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass
Packaging Inspection – Pass

Lot Number Designation:
8 Digit Lot Number: First 3 digits – Julian date, start of manufacturing; Next 2 digits – Year of manufacture; Last 3 digits – Batch identification.

Rev 9

Plant of Responsibility: 2 Alfred Rd. Kennebunk, ME 04043 Tel: 1-800-492-1110