Corning Incorporated
Life Sciences

Registered
ISO 9001

# Product Description

**Catalog Number:** **13009**

**Product Description:** **3L DISPOSABLE SPINNER FLASK,W/ASEPTIC CONNECTOR, and vent Cap, S**

**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)". |
| Vent Caps | - | High-density polyethylene (HDPE), with 0.2µm, modified, non-woven polytetrafluoroethylene (PTFE) vent filter material, both meeting USP, Class VI requirements for plastic containers and closures. |

**Accessories:**

| | | |
|---|---|---|
| Magnet | - | Polytetrafluoroethylene encapsulated ALNICO magnet, 12800 Gauss induction. |
| Tubing | - | C-Flex, Thermoplastic Elastomer, meets USP, Class VI requirements for plastic containers and closures. |
| Diptube | - | Polypropylene, meets USP Class VI requirements for plastic containers and closures. |
| Filter | - | 0.2µm Acrylic/Vesapor, meets USP, Class VI requirements for plastic containers and closures. |

**Product Dimensions:**

| | | | | | |
|---|---|---|---|---|---|
| Height of Vessel | - | 10.20 in. (25.91cm) | Diameter of Vessel | - | 10.08 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) |
| Working Volume | - | 3L maximum | Tolerances | - | +/-0.05 in. |

**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-** Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

**Non-Pyrogenic -** Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing". The acceptance level for product is ≤ 0.25 EU/ml or ≤ 10 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.