

**Corning Incorporated  
Life Sciences**

Registered  
ISO 9001:2008

**Product Description**

**Catalog Number:** 3561

**Product Description:** Corning® Spinner Flask, Disposable, 1L

**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.
- 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 | - 45 mm GL 45       |
| Working Volume            | - 1L maximum         | Tolerances            | - +/- 0.05          |

**Sterilization:**

The product is irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*.  
Sterility Assurance Level: SAL 10<sup>-6</sup>

**Pyrogens:**

This vessel has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*.  
Results: ≤ 0.1 EU/mL (≤ 4EU/device)

**Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:**

This product is manufactured and packaged with animal free materials.

**Performance Testing:**

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes:

Visual examination of the product.

Packaging:

Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

**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 No: 8