

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 3268

Product Description: Corning® CellSTACK® - 1 Chamber

Component Materials:

- Top Plate - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Bottom Plate - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Cap - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* req.) color concentrate.
- Filter - .2µm/polyester non-woven membrane, meets *USP, Class VI* requirements for plastic containers and closures.
- Adhesive - Proprietary Acrylate, meets ISO-10993, Biocompatibility requirements and does not contain any animal products.

Product Dimensions:

- | | | | | | |
|-------------------------|---|------------------|-------------------------|---|---------------------|
| Overall Length | - | 13.2 in. (335mm) | Overall Width | - | 8.1 in. (206mm) |
| Overall Height with cap | - | 2.0 in. (51mm) | Tolerances | - | +/- 0.1 in. (2.5mm) |
| Neck ID | - | 1.0 in. (26mm) | Neck O.D. incl. Threads | - | 1.3 in. (32mm) |
| Distance between plates | - | 0.67 in. (17mm) | | | |

Total Cell Growth Area:

636 cm²

Recommended Working Volume:

130 - 200 ml

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*

Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

The CellStack 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)

Surface Characterization:

Surface is characterized to be hydrophilic and negatively charged. The negatively charged, carboxyl surface composition, has been optimized for cell attachment and growth.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth utilizing an attachment- dependent mammalian cell line in a serum supplemented media.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product does not contain materials of animal origin.

Performance Testing:

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

Integrity Testing:

Forward pressurization of the product to 1.5 psi.

Cell Culture Treatment:

Wettability test using water to insure the presence of a hydrophilic surface.

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.

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Serial Number Designation:

12 Digit Serial Number: First 8 digits - Lot number (see lot number designation above); Next 3 digits CellSTACK serial number; Last digit - Stack designation.

Rev No: 17

DOMINIQUE DUTSCHER SAS