

**Corning Incorporated  
Life Sciences**

Registered  
ISO 9001:2008

**Product Description**

**Catalog Number:** 3321

**Product Description:** Corning® CellSTACK®- 40 Chamber with Corning® CellBIND® surface

**Component Materials:**

- Top Plate - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Middle 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.
- 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 fitting | - | 28.1 in. (714mm) | 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:**

25440 cm<sup>2</sup>

**Recommended Working Volume:**

5200 - 8000 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<sup>-6</sup>

**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, negatively charged, and composed of ≥20% oxygen atoms. The surface composition has been developed 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 is manufactured and packaged with animal free materials.

**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: 15

DOMINIQUE DUTSCHER SAS