

Catalog Number: 3269

Product Description: Corning® CellSTACK® - 2 Chamber

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.
- Adhesive - Proprietary Acrylate, meets ISO-10993, Biocompatibility requirements and does not contain any animal products.
- Vent Cap - Virgin High-Density Polyethylene (HDPE), meets USP, Class VI requirements for plastic containers and closures, with heavy metal-free (meets CONEG requirements) color concentrate; 0.2 µm pore size, modified, non-woven polytetrafluoroethylene (PTFE) membrane meeting USP, Class VI requirements for plastic containers and closures.

Product Dimensions:

- | | | | | | |
|-------------------------|---|--------------------|-------------------------|---|-----------------|
| Overall Length | - | 13.2 in.(335mm) | Overall Width | - | 8.1 in. (206mm) |
| Overall Height with cap | - | 2.6 in. (66mm) | Neck ID | - | 1.0 in. (26mm) |
| Tolerances | - | +/-0.1 in. (2.5mm) | Neck O.D. incl. Threads | - | 1.3 in. (32mm) |
| Distance between plates | - | 0.67 in. (17mm) | | | |

Total Cell Growth Area - 1272 cm²

Recommended Working Volume – 260-400 mL

Regulatory Compliance - Product manufactured in a facility that is registered to the current version of ISO 9001 or ISO 13485.

Animal Content – Product does not contain materials of animal origin

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 alternative to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

Sterilization - Product has been sterilized and dosimetrically released per the requirements ANSI/AAMI/ISO 11137 "Sterilization of health care products- Radiation". Products meet a minimum 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.

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 95% confluency is required for acceptance.

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.

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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

Cell Attachment & Growth Treatment Verification – Pass

Leak Test – 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.

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