Corning Incorporated
Life Sciences
Registered
ISO 9001

Product Description

Catalog Number: **3303**

Product Description: **Corning ® Ultra Low Attachment, 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.
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.
Adhesive	-	Proprietary Acrylate, meets ISO-10993, Biocompatibility requirements
Surface	-	Proprietary hydrogel, meets ISO-10993, Biocompatibility requirements

Product Dimensions:

Overall length	-	13.2 in. (335mm)	Overall Width	-	8.1 in. (206mm)
Overall Height with cap	-	2.0 in. (51mm)	Tolerance	-	+/- 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 cm^2

Recommended Working Volume:
130-200 ml

Animal Content – Product does not contain materials of animal origin.

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" 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.

Surface Characterization – Surface is characterized to be hydrophilic and neutrally charged, composed of a covalently bound hydrogel layer that is biologically inert and non-degradable. This surface composition has been optimized for cell attachment inhibition.

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

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
Flatness Test – Pass

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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.

Rev 9