Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: **7160**

Product Description: **Corning ® CellSTACK® 10 Chamber with one piece universal cap and vented overcap**

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.

Accessories:

One Piece Universal Cap	-	Virgin High Density Polyethylene, meets *USP Class VI* requirements for plastic containers and closures. Heavy metal free (meets CONEG requirements) color concentrate.
Vented Overcap	-	Dow LDPE 993I Natural.
Solid Overcap	-	Dow LDPE 993I Natural
Air Foil	-	Selig 1-19/S70A. .2µm Gore-Tex® PTFE Membrane, meets *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 of One Piece Universal Cap with Overcap	-	8.771 in.(222.78mm)	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 - 6360 cm^2

Recommended Working Volume - 1300-2000 mL

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.

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Baterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

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

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.

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 – Forward pressurization of the product to 1.5 PSI - 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

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