Corning Incorporated
Life Sciences

Product Description

Catalog Number: **20036**

Product Description: **Corning® HYPERStack® Vessel, HYPERStack-36, multi-level cell growth vessel, CellBIND® treated w/fill and vent accessories**

Component Materials:

Vessel Body	-	Virgin Polystyrene, meets *USP Class VI* requirements for plastic containers and closures.
Vessel Bottom Plate	-	Virgin Polystyrene, meets *USP Class VI* requirements for plastic containers and closures.
Vessel Film Layers	-	Polystyrene, meets *USP Class VI* requirements for plastic containers and closures.
Tubing	-	Chemically resistant, heat sealable, thermoplastic elastomer, meets *USP Class VI* requirements for plastic containers and closures.
Filling Wye	-	Polycarbonate, meets *USP Class VI* requirements for plastic containers and closures.
Filter	-	50mm / 0.2 μm pore size Polytetrafluoroethylene (PTFE) membrane, meets *USP Class VI* requirements for plastic containers and closures.
MPC Connector/Plug	-	Polycarbonate, meets *USP Class VI* requirements for plastic containers and closures.
Intermodule connector	-	Silicone, meets *USP Class VI* requirements for plastic containers and closures

Product Dimensions:

Length	-	342 mm (13.42 in)
Width	-	207 mm (8.15 in)
Vessel Height with cover	-	278 mm (10.97 in)

Cell Growth Area per layer: 500 cm^2
Cell Growth Area per Vessel: 18,000 cm^2
Recommended Total Working Volume: 3,920 mL

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

Operational Settings: Refer to usage instructions for operating procedures for safe use to avoid compromising the integrity of the vessel.

Sterilization - The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of health care products- Requirements for validation and routine control-Radiation sterilization*.
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, “Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing” and USP 85, “Bacterial Endotoxins Test”. The acceptance level for product is ≤ 0.25 EU/mL or ≤ 10 EU/device.

Surface Characterization - Surface is characterized to be hydrophilic and negatively charged, composed of >20% oxygen atoms. This composition has been optimized for cell attachment and growth.

Tissue Culture – Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of four population doublings and a confluent surface is required for acceptance.

BSE/TSE - Product complies with the latest revision of EMA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

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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.

Or

7 Digit Lot Number: First digit – Last number of year of manufacture, Next 3 digits – Julian date, start of manufacturing, Last 3 digits – Batch identification

Serial Number Designation:
Location lot number as described plus 4 digit Incremental Identifier.

Rev 2