Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: **3032**

Product Description: **Corning ® CellBIND® CellCube® Culture Module, 100 Layer**

Fluid Path Component Materials:

Middle Plates	-	Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures.
End Plates	-	Polycarbonate, meets USP, Class VI requirements for plastic containers and closures.
Encapsulate & Clips	-	Polycarbonate and white concentrate blend, both meet USP, Class VI requirements for plastic containers and closures.
Hose Barb Adapter	-	Polycarbonate, meets USP, Class VI requirements for plastic containers and closures.
Conical End Plug	-	Polycarbonate, meets USP, Class VI requirements for plastic containers and closures.
Tubing	-	Silicone, meets USP, Class VI requirements for plastic containers and closures.

Product Dimensions:

Overall Length - 39 cm. (15.4 in.) Overall Width - 25cm. (9.8 in.)
Overall Height - 25 cm. (9.8 in.) Tolerances - +/- 1 cm. (+/- 0.4 in.)
Distance between plates - 1 mm (reference dimension)

Total CellCube Module: 85, 000 cm^2

Average Module Working Volume: 5.6 liters +/- 0.2

Operating Pressures: Not to exceed 5.0 psi

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.

Surface Characteristics - The surface is characterized to be hydrophilic and negatively charged. The negatively charged, carboxyl surface composition, has been optimized 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 serum supplemented media.

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.

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.

Rev 1

Plant of Responsibility: 2 Alfred Rd. Kennebunk, ME 04043 Tel: 1-800-492-1110