

Catalog Number: 431132

Product Description: Corning® easy grip vent cap, bulk pack

Component Materials:

Cap - Virgin High Density Polyethylene meets *USP, Class VI* requirements for plastic containers and closures. 0.2 µm microporous PTFE membrane. Heavy metal free (meets *CONEG* req.) color concentrate.

Product Dimensions:

Height of cap	-	1.00 in.	I.D. (without threads)	-	1.87 in.
Outer Diameter of cap	-	2.13 in.	Tolerances	-	+/- 0.05 in.

Sterilization:

The product has been irradiated and dosimetrically released based on the *Sterilization of healthcare products- Requirements for validation and routine control-Radiation sterilization*.

Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72: *Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing*. Results: less than 0.1EU/mL

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Performance Testing:

Integrity Testing:

Forward pressurization of the cap at molding stage to 39 inches of water column. Forward pressurization of the membrane seal to 10 inches of water column using an aqueous dye solution.

Visual Attributes:

Visual examination of the product.

Packaging:

Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Revision Date:

10-17-18

Rev No: 11