

Catalog Number: 4626

Product Description: Corning® ASEPTIC TRANSFER CAP, MICROCARRIERS, 100G, LUER, S, 1/1

Component Materials:

Cap	-	Virgin polypropylene, meets USP Class VI requirements for plastic containers and closures, Heavy metal free (meets CONEG req.) color concentrate.
Filter	-	0.2µ/polyester non-woven membrane, meets USP Class VI requirements for plastic containers and closures.
Diptube	-	Polypropylene, meets USP Class VI requirements for plastic containers and closures.
Tubing	-	C-Flex, Thermoplastic Elastomer, meets USP Class VI requirements for plastic containers and closures.
Y-connector	-	Polypropylene, meets USP Class VI requirements for plastic containers and closures.
Gasket	-	Polyolefin based thermoplastic elastomer, meets USP Class VI requirements.

Product Dimensions:

Cap Height - 0.99 in. +/- 0.01 in. Cap Major Diameter - 45.34mm +/- 0.5mm

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.

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". The acceptance level for product is ≤ 0.25 EU/mL or ≤ 10 EU/device.

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

Integrity 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