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Description: ESA Vessel Product Specification				

1.0 Purpose

1.1 To define specifications for acceptability of Falcon Cell Culture Multi-Flask.

2.0 Description

Family Name:

Falcon Cell Culture Multi-Flask

Catalog Name

353143 Falcon Cell Culture Multi-Flask-3 TC, 3-layer, 525 cm²

353144 Falcon Cell Culture Multi-Flask-5 TC, 5-layer, 875 cm²

This product is an expanded surface area, disposable T-flask for culturing attachment dependent cell types. It comes in a 3-layer, 525 cm², or 5-layer, 875 cm², surface area. The culture surface is tissue culture (TC) treated and the cap is vented.


3.0 Product Usage

3.1 This product is design for use in manual culture of a broad range of adherent mammalian cells.

4.0 Product Requirements

Customer Requirements	Design Requirement	Product Specification
Support growth of homogenous cell population.	Even media distribution -Shall maintain even distribution of media volume across working volume of 5-50ml, in the horizontal orientation for 72 hours	-At reagent volume of 50ml per layer, maximum difference between any 2 layers shall be 6ml (12%) -At reagent volume of 5 ml per layer, minimum per layer shall be 3 ml -Shall be able to hold 50ml per layer of media for 72 hours at 37°C; maximum difference between any 2 layers shall be 6ml (12%)
	Even cell distribution -Shall allow even distribution of cells in media within layer) -Shall allow distribution of cells in media between layers when inoculate within the vessel (mixing)	1mm maximum concave or convex on growth surface Infra-flask cell seeding distribution between layers shall be ≤ 15 % CV
	Even TC treatment on growth surfaces	Intra layer cell confluency shall be 15% CV (cell type BHK-21)
Shall support growth of adherent cells in comparable surfaces.	Shall provide sufficient gas exchange to support cell growth	1.Shall use T175 vented cap Part no. 135451PLY 2.Aeration port foot print: minimum of 1.26 in ² 3.Aeration gap cross section area: .375 in ²
	Shall not leak in typical cell culture environment (i.e. 20C to 37C @80-90%RH for 72 hrs)	No leak allowed at time 0 when pressurized to 2.5psi for 25 seconds
	Shall allow addition of reagents using up to 100	Minimum neck opening shall be 0.375"


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	ml pipette	
	Shall allow removal of reagents using 10ml pipette	Minimum distance between top cover and top growth surface shall be 0.395
	Material must not interfere with cell growth	Growth surface shall be made of virgin polystyrene
	Sterile to meet current Corning standard for cell culture vessel	SAL 10 ⁻⁶
	Shall be made of non-cytotoxic materials	Non-cytotoxic per USP
	Shall be non-pyrogenic	<0.1 EU/ml
	Material shall be USP class VI	Polystyrene resin shall be USP class VI
	Particulate level must not hinder cell growth	Must meet FI3015001 Visual defect limits
Cell yield per unit area shall be equivalent to current process.	Cell yield per unit area shall be equivalent or better than Falcon T175 Cell Culture vessel.	1. Surface area: 525.5 cm ² (3 layer) & 868.7 cm ² (5 layer) +/-2% 2. Cell yield: At a minimum, statistically equivalent to T175 per cm ² basics
Fit in current process (e.g. fit under microscope, incubator, hoods, and stable during transportation, supports visualization of cells, chemical resistance, writing patch).	Shall have writing patch	1.4" x .4" per strip, on all intermediate layers, and the top layer, on both sides of the neck
	Shall have vertical and horizontal stability	Ratio of Length to Height shall not exceed 4:1
	Optimize foot print that will fit into existing equipment (e.g. incubator)	Shall meet drawing specs of 7.742+/- .005, 4.997+/- .005"
	Optimize shelf height that will fit into existing equipment (e.g. microscope)	(Target 5-layer: 3.135" +/- .030"(Total Height) (79.6mm) Target 3-layer: 2.165" +/- .020"(Total Height) (54.9mm)
	Shall have volumetric graduation	Label volume per layer, 0-50ml. 10 ml resolution. Location: bottom layer. Include "mL/Layer" wording. Total tolerance is 10%.
	Shall be stackable to minimum of 5 high during transportation	Stacking rib shall be minimum 0.04"
	Resistant to 70% ethanol	Polystyrene, vessel shall not crack, craze.
	Compatible with use of cell fixing reagents (i.e. 4% paraformaldehyde, 1% DMSO)	Polystyrene, vessel shall not crack, craze
	Shall have optical clarity on appropriate viewing surfaces to meet current Corning Standards	1. Cell growth surface: spec per FI5530001 2. Non cell growth surfaces: spec per FI3015001
	Shall have a flat surface to enable applying a barcode label	Shall have a flat surface at least 60mm x 10mm
Vessel shall provide traceability, and have a shelf life.	Product shall have an expiration date -Minimum 1 year shelf life	1 year accelerated for US launch, 2 years accelerated for international launch, 5 year real time to start concurrently
	Product shall be supplied with Batch/lot number	Batch/lot number traceability shall be printed on the vessel <ul style="list-style-type: none"> Printed information = ISO lot number symbol, followed by seven numeric's. Color = Black Numeric height = ~5mm ISO symbol height = ~5mm Font type = any clearly legible i.e. Arial Position = opposite end to the cap, 8mm from the top edge and centrally justified. Resistant 70% ethanol Resistant to gamma irradiation Shall withstand 37C @ 80-90% RH Shall remain legible for a minimum of 2 years

5.0 Packaging & Labeling Requirements

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Customer Requirements	Design Requirement	Product Specification
Shall provide product identification	Shall comply with current Corning Identity guidelines.	Must meet Corning identity standard
	Shall be labeled as sterile	"Sterile" shall be applied on the bag and box
	Shall be labeled as non-pyrogenic.	"Non-pyrogenic" shall be applied on the bag and box
	Shall be labeled with manufacturing location	"Manufacturing location" shall be applied on the bag, label and box
	Shall be labeled as single use	"Single use" shall be applied on the bag and box
	Shall be labeled with cm ² growth surface (as appropriate for flask).	Growth surface area shall be applied on the bag and box
	Shall be labeled with appropriate surface treatment.	Surface treatment shall be applied on the bag and label
	Package labeling shall contain case quantity (# of flasks per case)	Case quantity to be applied on label
	Packaging shall be supplied with Batch/lot number	Batch/lot number traceability shall be printed on the vessel, and label
	Labeling shall contain expiration date.	Expiration date shall be applied on the label
	Product packaging performance shall be equivalent or better than T175. Product packaging shall be designed to fit into existing sterilization and distribution processes. Box must fit within carrier dimension 3165mm x 90mm x 240mm	3 layer: 2 per single bag, 12 vessels per case 5 layer: 1 per single bag, 8 vessels per case Box size shall be 472cm L x 411cm W x 209cm H
	Labeling shall contain expiration date.	Expiration date shall be applied on the label
Product shall maintain sterility when shipped via air, sea, and/or ground freight and shall be compatible with typical temperature and pressure extremes.	Product packaging performance shall be equivalent or better than T175.	3 layer: 2 per single bag, 12 vessels per case 5 layer: 1 per single bag, 8 vessels per case Box size shall be 472cm L x 411cm W x 209cm H
	Product packaging shall be designed to fit into existing sterilization and distribution processes.	
	Box must fit within carrier dimension 3165mm x 90mm x 240mm	

6.0 Regulatory Requirements

6.1 Product is a class I medical device with intended use as tissue culture vessel and is exempt from 510k submission.

6.2 Products are to be manufactured in accordance with current Quality System requirements, which include but are not limited to verification and validation of design, performance and production requirements, certification of compliance to specification, sterilization testing where applicable, etc.

6.3 Compliance with worldwide import, export, and product registration regulations for Europe, Japan and domestic regulations.

6.4 Compliance with the WW translation regulations will be determined and the number of translations required will be identified.

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Revision History				
Rev.	Revision Date	Description of Change	ECO No.	Revised By
Draft	5/26/2010	First draft (Note: ECO release not planned at this time, this version is to capture the design requirements for definition phase. Complete product specifications will be completed in development phase.)	N/A	A.Cai
1.0	03/18/2011	Initial Release	ECO131258	A. Cai
2.0	10/28/13	Revised to change all applicable references to BD or Becton Dickinson to appropriate Corning references; deleted "competition" section; content moved to new EtQ system template.	CCF#1543 CCF#1617	M. Marisic

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