



# Biosafe® RAFT System

Biosafe® Rapid Aseptic Fluid Transfer (RAFT) System

Aseptic Transfer Systems



## Features and Benefits

Aseptic and contained single-use technology	Enhanced sterility assurance
Segregated preparation and manufacturing areas	Substantial reduction of higher classification areas
Various bag sizes pre-assembled on Biosafe® RAFT system	High flexibility in process
Multiple manufacturing sites	High security of supply

### Introduction

The Biosafe® Rapid Aseptic Fluid Transfer (RAFT) system provides easy-to-use and reliable through-the-wall aseptic transfer of liquid between clean rooms of different environmental classification while ensuring a total confinement. When pre-assembled and pre-sterilized with Flexel® 3D or Flexboy® bags with flexibility in volumes, from a few liters up-to 3000L, the Biosafe® RAFT System opens up opportunities for modularity within the facility.

For use with the Biosafe® RAFT System, the Biosafe® aseptic transfer Ports are available in a variety of design to meet specific needs and applications.

### Applications

- Solutions supplied through the wall from unclassified area into process suites:
  - Transfer of cell culture media and other solution to bioreactor
  - Transfer of buffers to centrifugation, clarification and chromatography
  - Transfer of buffers to recovery operations and purification
- Sterile solutions transfer between segregated process areas - for example between live viral and inactivated viral suites.
- Outsourced ready-to-use buffers and media can be docked and fed directly to the process without having to enter the main facility.

### Risk reduction

As a single-use system, the Biosafe® RAFT System improves process safety as it reduces the risk of cross contamination from batch-to-batch and product-to-product.

### Optimized facility design and cost reduction

The Biosafe® RAFT System allows the user to segregate the preparation and supply of support solutions from the process areas. This results not only in substantial reduction of higher classification clean rooms but also in optimization of material and operators flows. As a single-use system, cost and time consuming CIP and SIP are minimized with a direct impact on capacity utilization.

### Aseptic Transfer lines of products

Besides the Biosafe® RAFT System for transfer of liquid, a complete range of Biosafe® Bags is available for aseptic transfer of components (stoppers, pumps, tools, QC test devices) and powders into critical areas - clean rooms, isolators, RABS or vessels.

### Technology Integration Support

Sartorius Stedim Biotech supports users at the preliminary design phase of a new production facility with the most comprehensive program to ensure successful design, implementation and validation of Single-Use Manufacturing.

### Security of Supply

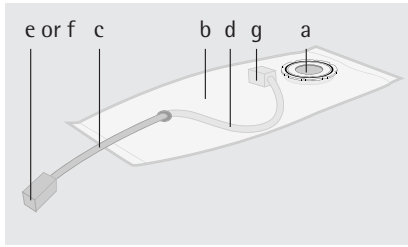
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

### Quality Assurance

Biosafe® RAFT System is designed, developed and manufactured in accordance with ISO 9001 and ISO 13485 Quality Management. Manufacture and Sterilization processes are conducted under conditions that mimic Biopharmaceutical operations and meet cGMP requirements.

Biosafe® RAFT System fluid paths are tested for compliance to:

- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Containers-Physicochemical tests - Plastics
- USP<85>and EP 2.1.14: Bacterial endotoxins test
- USP <788>Particulate matter in injections- Large-volume injections and E.P. 2.9.19: Particulate contamination-sub-visible particles
- ISO 11737: Microbiological methods- Determination of a population of micro-organisms on products
- ISO 11137: Sterilization of Health care products-Radiation



## Standard Specifications

### Biosafe® Connector

Material	ABS <sup>1</sup> port, HDPE <sup>2</sup> ring	a
Opening diameter	110 mm / 4 in.	a

### Film

Dimensions (L x W)	400 x 800 mm   15,7 x 31,5 in.	b
Material	PE/PA/PE <sup>3</sup> 100 µm	b

### Fittings

	Inlet Outside of the Biosafe® Bag		Outlet In the Biosafe® Bag	
<b>Tubing</b>				
Internal Diameter	3/8" or 1/2"	c	3/8" or 1/2"	d
Length	No restriction	c	Max. length = 2 m / 78 in	d
Material	Silicone Pt or Clear C-Flex ADCF	c	Silicone Pt or Clear C-Flex ADCF	d
<b>Bag   Filter</b>	Flexel® 3D Bag (100 L to 3000 L) or Flexboy® Bag (5 L to 50 L) Sartopore® 2 Gamma Capsule	e	N/A	
<b>Connection</b>	Female MPC or MPX, Tri clamp, Steam-thru connector, Kleenpak® connector	f	Male MPC or MPX, Tri clamp, Steam-thru connector, Kleenpak® connector, Open end tube	g

Sterilization by Gamma irradiation

<sup>1</sup> ABS: Acrylonitrile Butadiene Styrene

<sup>2</sup> HDPE: High Density Polyethylene

<sup>3</sup> PE/PA/PE: Polyethylene/Polyamide/ Polyethylene

### Ordering Information

Single-use systems configured with Biosafe® RAFT System are customized upon request following the above-mentioned standard specifications. Please consult your sales representative for ordering details.

### Library

Further documentation is available upon request:

- Biosafe® range of Aseptic Transfer Ports
- Biosafe® Aseptic Transfer Bags
- SART System™

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