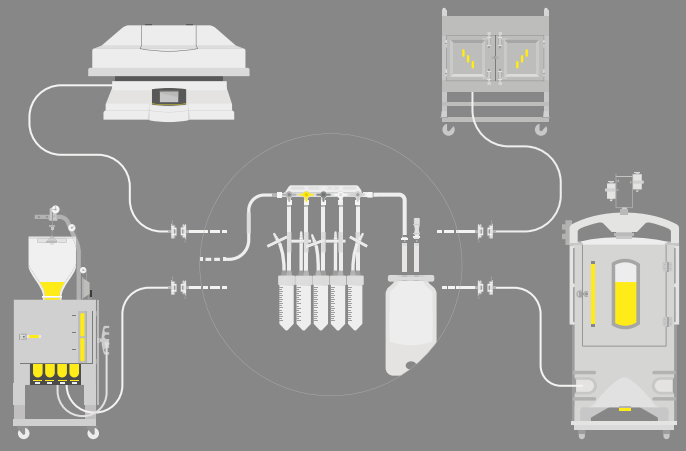
SARTORIUS

Product Datasheet

TakeOne® Flex

Simplified Sampling Solutions



Product Information

TakeOne® Flex is a family of solutions designed to provide a modular approach to sampling that helps meet the complex needs of process monitoring and regulatory compliance.

The portfolio is scalable from R&D to full-scale manufacturing and includes a wide array of collection container types in a range of volumes and materials that include: Flexsafe®, Flexboy® & Celsius® bags; bottles; and centrifuge tubes that feature Mycap®, a robust aseptic closure. This family of standard products also includes solutions to increase and expand your sample-taking capacity while maintaining a low hold-up volume to minimize product loss.

Benefits

TakeOne® Flex provides the highest degree of flexibility and adaptability by allowing configuration right at the moment the sample is taken. The point-of-use installation simplifies the handling of complex equipment and allows the same inventory of sampling assemblies to be used for any number of applications within a single process or across multiple sites.

- React on-demand
- Easily reduce costs and expand capabilities
- Ready for immediate use
- Scales up, down, and across applications

A Modular Approach to Sampling

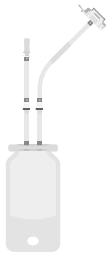
Fluids collected with TakeOne® Flex are used to measure critical quality attributes, such as bioburden and endotoxin levels, as well as essential process parameters, such as metabolites, nutrients, osmolality, and pH, that confirm your process is well controlled while protecting the process fluid from adventitious agents (table 1).

Table 1: *Types of Assays Commonly Performed According to Process Step*

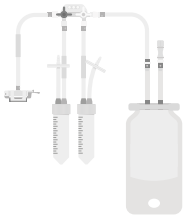
	pH | Cond | Osmol	Cells	Metabolites	Protein Analysis	Bioburden and Archiving	Endotoxin	Other
Media | Buffer Prep	■				■	■	■
Cell Culture | Downstream Intermediates	■	■	■	■	■	■	■
Drug Substance	■			■	■	■	■
Drug Product Formulation	■			■	■	■	■
	Correct balance | Concentration	Cell Count | Viability	Nutrient | Gas	Concentration | Purity	Contamination | Sterility	Regulatory limits check	Virus | By-products

Sartorius recognizes that sampling can be complex and process-specific. TakeOne® Flex was created to meet these widely varied process demands and take the complexity out of sample planning by offering a modular range of container formats, volumes, and fluid contact materials (table 2). Plan and adapt to any process situation by maintaining just a few SKUs, and create tens or hundreds of different sampling solutions while still optimizing for the most accurate and repeatable results using the precise volume the sample requires.

Table 2: *TakeOne® Flex Is Suitable for a Wide Range of Types, Materials, and Volumes*








Flexsafe®, Flexboy® Celsius® bags*	Mycap® centrifuge tubes	Mycap® bottles	Benchmark™ needleless access site	Stopcock manifolds, incl. purge bag	2-way splitter
20 | 30 | 50 | 100 | 150 | 250 | 500 | 1,000 mL	15 | 50 mL	30 | 60 | 125 | 250 | 500 | 1,000 mL	With | without check valve	2 | 5 collection vessels	Aseptic connections
PE | EVA	PS | PP	PETG* Other materials available upon request	SIL | PP | SAN	Per your selection	TPE | SIL

*Per your bag brand selection

Selecting the Right Sample Container

The optimal sample container selection is based on a variety of factors, such as process step, analysis type, assay sensitivities, material compatibility, fluid value, handling preferences, and volume. A properly chosen sample container can improve the accuracy of test results while decreasing the cost per sample and lost product.

Microbiological samples must be collected into an aseptically closed container in order to protect against false positive results or adventitious agents.

Microbiological

Sample Analysis

- Sterility | Control
- Bioburden
- Endotoxin
- Non-Host Organisms
- Retain

Sample Collection

Sample Analysis

- Cell Density | Viability | OD
- Osmolality
- Immunoglobulin
- Metabolites | Nutrients
- Gas Analysis | pH
- Conductivity

Process Monitoring

Easy Handling	Free-standing	High Accuracy	High Capacity
			
Flexsafe® Flexboy® Celsius®-Pak bags 20 – 1,000 mL	Mycap® bottles 30 – 1,000 mL	Mycap® centrifuge tubes 15 & 50 mL	Benchmark™ with and without check valve

Process Monitoring samples are analyzed in an open, non-aseptic environment. They can be, but do not need to be, collected into an aseptically closed container.

Collection Containers Impact Process and Results

While there are many ways to sample, Sartorius can guide you to the optimal solution for your sampling plans. We understand that container selection can significantly impact your process, from cost per sample, handling, and storage preferences to the reliability of assay results, which can be impacted by the sample's interaction with the collection container.

pH and Gas Analysis

Time from sample to analysis is critical
- O_2-consuming cells will release CO_2, initiating a chemical reaction resulting in a pH shift

The chemistry of pH
1. When carbon dioxide dissolves into water it exists in equilibrium to form carbonic acid: $CO_2 + H_2O \leftrightarrow H_2CO_3$
2. Carbonic acid disassociates to generate a free hydrogen ion which can change a solution's pH: A sample in a syringe can be taken directly to the analyzer, reducing container waste and sample alteration

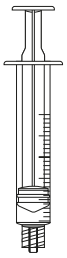
Surface area to volume ratio is important
- Fluid interface with both air and container enables gas exchange in the sample

Stable Surface Area to Volume Ratio
There is more opportunity for gas exchange where the solution is in contact with a surface. Consequently, gas exchange is less variable in syringes compared to bags, as syringes have a stable surface area to volume ratio (Table 3).

Environment
Saturation of O_2 and CO_2 in cell culture can be different from saturation levels in air. Gases in air bind to the plastic surface of the sample collection container prior to use. The bound gases transfer from high to low concentration, artificially changing dissolved gas in the sample. Syringes are not immune to the effect but the more stable surface area-to-volume ratio reduces its impact.

Material of construction plays a part
- All plastics are permeable
- Thicker/ridged plastics limit rate of exchange

Table 3: *Surface Area to Volume Ratios in Syringes vs Bags*



	10 mL Syringe		50 mL Bag	
Sample Volume Collected	Surface Area [cm²]	Surface Area to Volume	Surface Area [cm²]	Surface Area to Volume
2 mL	8.82	4.41	424	212.00
5 mL	17.10	3.42	424	84.80
10 mL	30.89	3.09	424	42.40

Benchmark™ multi-access valve is qualified for use with up to 40 needleless syringes

Table 4: *Container Comparison for pH and Gas Analysis*

	Bags	Bottles and Tubes	Syringes
Cost	■■	■■■	■
Volume accuracy	■	■■	■■■
SA/Vol ratio	■■■	■■	■
Time to analysis and waste reduction	■■■	■■■	■

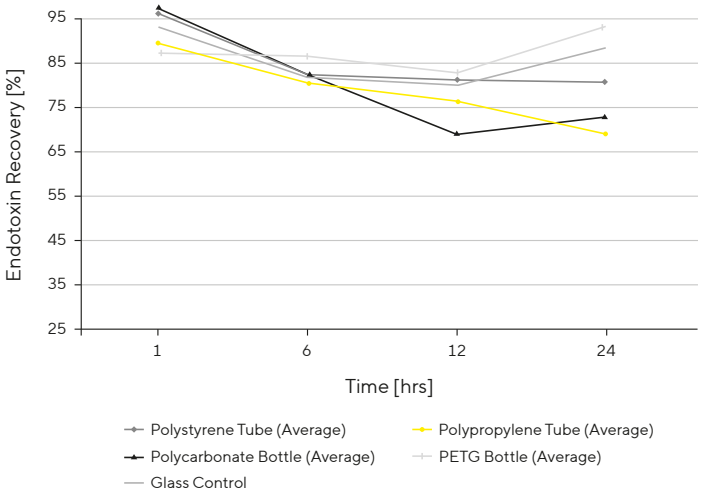
pH & Gas analysis is impacted by:
- Surface area to volume ratio
- Headspace gas exchange
- Permeability of container
- Time to analysis

Table 4 shows syringes provide:
- Lowest impact to sample quality
- Lowest cost and waste per sample
- High volume accuracy

Endotoxin Assay

Endotoxins adsorb onto surfaces of sample collection containers, impacting recovery efficiency (figure 1).

Figure 1: *Endotoxin Recovery Over Time*



Detection and accuracy of results can be affected by
- Fluid contact material
- Time from sample to assay

Table 5: *Material Comparison for Endotoxin Assay*

		Hours					
Type		1	6	12	24	Total	Score
Polystyrene	SD avg. pooled	■■■	■■	■■	■■	9	20
Polystyrene	SD between	■■	■■■	■■■	■■■	11	
PC	SD avg. pooled	■■■	■■	■	■	7	17
PC	SD between	■■■	■■	■■	■■■	10	
PETG	SD avg. pooled	■■	■■	■■	■■■	9	14
PETG	SD between	■	■	■	■■	5	

Polycarbonate or polystyrene collection containers are recommended for the most accurate endotoxin assay results when the assay is conducted within 6 hours of the sampling event.

PETG or polystyrene collection containers are suggested for the most consistent endotoxin assay results when the assay is conducted at variable times up to 24 hours of the sampling event (table 5).

Polystyrene is the preferred sample collection container for endotoxin assay for recovery and stability over time

Standard Design Portfolio at Your Fingertips

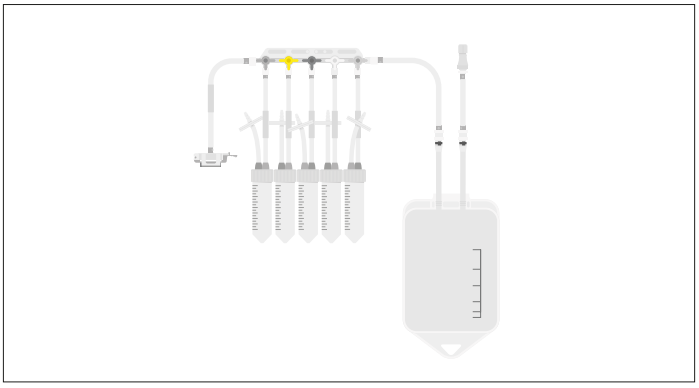
Simply Select, Connect and Use

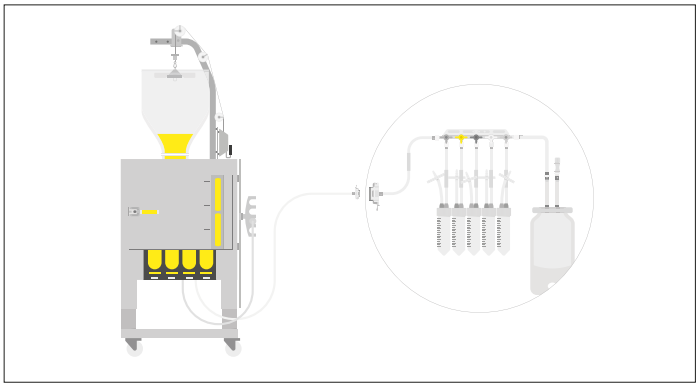
All designs include:
- Inlets with AseptiQuik® S size or a secure tube plug (only available for TPE)
- Silicone | TPE in ⅛"ID×¼"OD
- Quickseal® fast disconnection

TakeOne® Flex products are delivered fully assembled, individually bagged, gamma sterilized, and ready for immediate use allowing you to bypass parts washing, equipment prep, and assembly.

Quick and Easy Disconnect

Each TakeOne® Flex sampling line assembly includes a Quickseal® aseptic disconnect. Once the sample has been collected, operators easily cut the aluminum collar using a light, portable hand-held cutting tool. Quickseal® patented technology protects the sample and process vessel from contamination. A Quickseal® silicone protective cap then shields the cut collar.





Integrating TakeOne® Flex Into Your Process

Rapidly adapt your sampling plan using our broad standard product portfolio of collection containers.

Accessories (stopcock manifolds and 2-Way splitters) are available to easily expand sample-taking capacity, providing a modular approach that may avoid requiring custom solutions. However, customized solutions can be offered if you have specific process needs.

Design Services

Sartorius offers a range of pre-configured yet modular TakeOne® products. If the standard-to-order designs do not meet the process requirements, our application-based design experts can tailor solutions to meet them.

Specific documentation is available upon request to support your regulatory needs:

- Technical drawing
- Instructions for use
- Product and sterilization certificates

Source all your needs for process optimization, customized validation, and regulatory support with Confidence® Services for TakeOne® Solutions. Confidence® provides the closest interpretation of current regulatory requirements and industry standards by working with you to define relevant test conditions for all your process components. Services include, but are not limited to:

- Extractables assessment | Leachable studies
- Toxicological assessment | Safety evaluation
- Physio-chemical studies

Technical Specifications

All TakeOne® Flex single-use assemblies are assembled in ISO 7-certified cleanrooms. Each system undergoes a variety of in-process quality inspections, including but not limited to:

- Product conformity against technical drawing
- Visual inspection (particles or contamination, correctness assembly, etc.)
- Pressure decay test (batch release) performed when the system includes a Mycap® with container
- Product packaging controls
- Product labeling controls

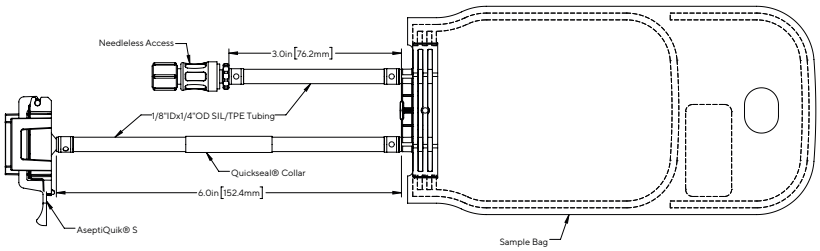
Aseptic Disconnection	Quickseal® ⅛"×¼"
Inlet Tube Diameter (ID×OD)	⅛"×¼"
Inlet Tube Length	6" (152 mm)
Inlet Tube Material	Silicone or TPE*
Manufacturing Environment	ISO 7
Sterilization Method	Gamma Irradiation (25 kGy-45 kGy)
Shelf Life	2 years
Biocompatibility	USP <88> Class VI
Bacterial Endotoxin	USP <85>
Particulate Matter	USP <788>
Biological Reactivity Test In-Vitro	USP <87> and ISO10993-5
TSE/BSE	EMA/410/01, rev 3 and E.P 5.2.8

*based on PN

Ordering Information

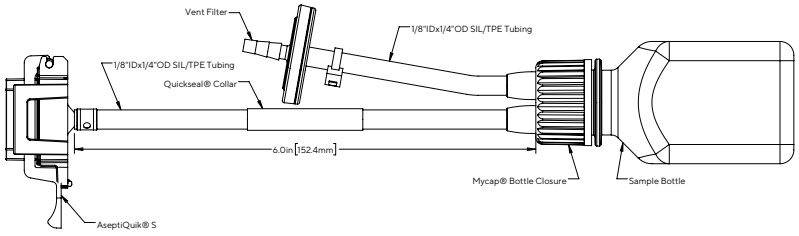
Takeone® Flex | Sample Containers

Single Collection Container



Bags

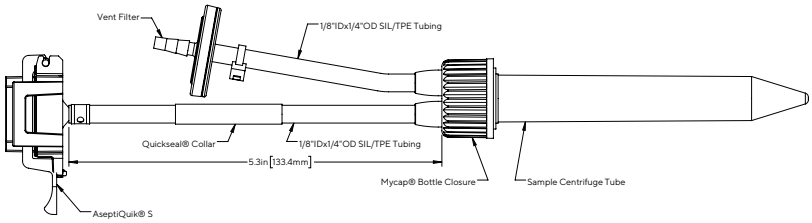
Container Type	Volume	Catalog Number TPE Tube	Catalog Number Silicone (Pt) Tube	Container Inlet	Container Outlet	Container Material	Other Fluid Contact Materials*
Flexsafe® bag	20 mL	FLS0021CASQLT	FLS0021PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Benchmark® (for needle-free syringes)	Polyethylene (S80)	Polycarbonate, polypropylene (PP), silicone (Pt)
	50 mL	FLS0051CASQLT	FLS0051PASQLT				
	150 mL	FLS0151CASQLT	FLS0151PASQLT				
	250 mL	FLS0251CASQLT	FLS0251PASQLT				
	500 mL	FLS0501CASQLT	FLS0501PASQLT				
	1000 mL	FLS1001CASQLT	FLS1001PASQLT				
Flexboy® bag	50 mL	FBY0051CASQLT	FBY0051PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Benchmark® (for needle-free syringes)	Ethylene-vinyl acetate (EVA S71)	Polycarbonate, polypropylene (PP), silicone (Pt)
	150 mL	FBY0151CASQLT	FBY0151PASQLT				
	250 mL	FBY0251CASQLT	FBY0251PASQLT				
	500 mL	FBY0501CASQLT	FBY0501PASQLT				
	1000 mL	FBY1001CASQLT	FBY1001PASQLT				
Celsius® Pak bag	30 mL	CSP0031CASQLT	-	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Luer fitting	Ethylene-vinyl acetate (EVA S71-360 µm)	Polycarbonate, polypropylene (PP), silicone (Pt)
	100 mL	CSP0101CASQLT	-				



Bottles

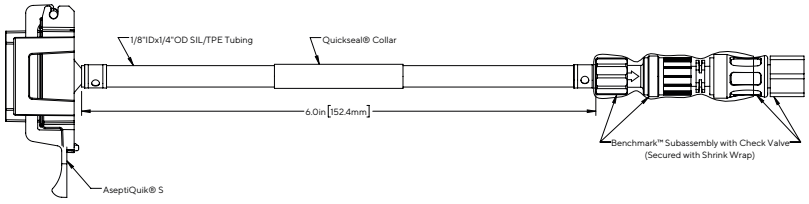
Container Type	Volume	Catalog Number TPE Tube	Catalog Number Silicone (Pt) Tube	Container Inlet	Container Outlet	Container Material	Other Fluid Contact Materials*
Square bottle	30 mL	PTG0031CASQLT	PTG0031PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polyethylene terephthalate glycol-modified (PETG)**	Polycarbonate, silicone (Pt)
	60 mL	PTG0061CASQLT	PTG0061PASQLT				
	125 mL	PTG0121CASQLT	PTG0121PASQLT				
	250 mL	PTG0251CASQLT	PTG0251PASQLT				
	500 mL	PTG0501CASQLT	PTG0501PASQLT				
	1000 mL	PTG1001CASQLT	PTG1001PASQLT				

**Other materials available upon request



Centrifuge Tubes

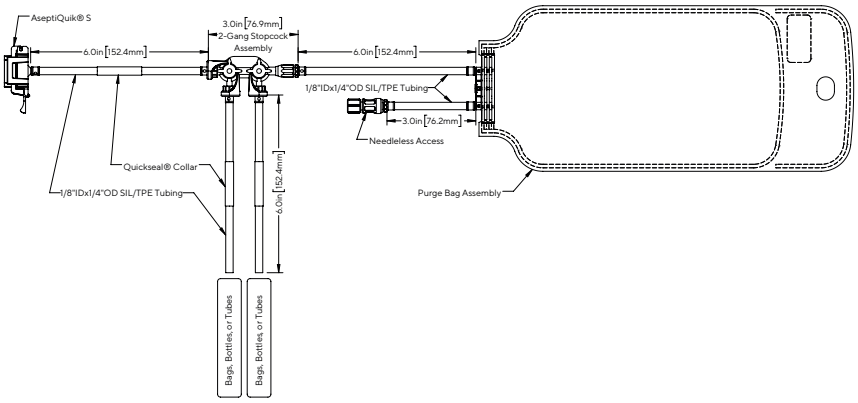
Container Type	Volume	Catalog Number TPE Tube	Catalog Number Silicone (Pt) Tube	Container Inlet	Container Outlet	Container Material	Other Fluid Contact Materials*
Centrifuge tube	15 mL	PSCT0151CASQLT	PSCT0151PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polystyrene	Polycarbonate, high-density polyethylene (HDPE), silicone (Pt)
	50 mL	PPCT0051CASQLT	PPCT0051PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polypropylene (PP)	Polycarbonate, silicone (Pt)



Benchmark® Needleless Access Site

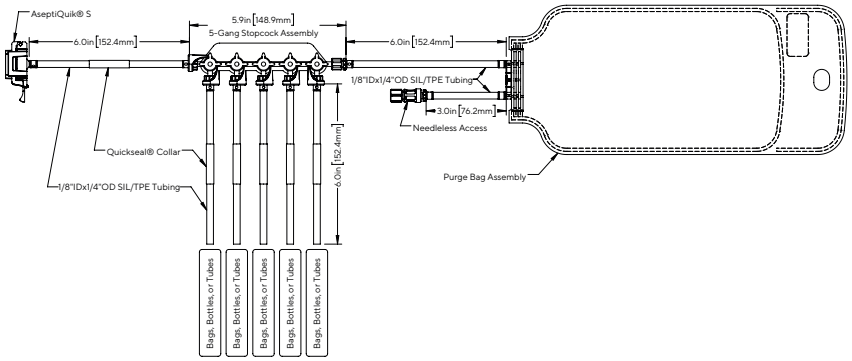
		Catalog Number TPE Tube	Catalog Number Silicone (Pt) Tube	Container Inlet	Container Outlet	Container Material	Other Fluid Contact Materials*
Benchmark®	with check valve	BNCHCV1CASQLT	BNCHCV1PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	-	As selected	Polycarbonate, polypropylene (PP), styrene acrylonitrile (SAN), silicone (Pt)
	w/out check valve	BNCH1CASQLT	BNCH1PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	-	As selected	Polycarbonate, silicone (Pt)
	with check valve	BNCHSSBH0004**		¼"×¼" TPE tube, 12" long with tube plug	-	As selected	Polycarbonate, polypropylene (PP), styrene acrylonitrile (SAN), silicone (Pt)

Manifolded Collection Containers



2-Gang Manifold

Container Type	Volume	Catalog Number TPE Tube	Catalog Number Silicone (Pt) Tube	Container Inlet	Container Outlet	Fluid Contact Materials*
Flexsafe® bags on stopcock manifold	2×20 mL	FLS0022CASQLT	FLS0022PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Benchmark® (for needle-free syringes)	Polycarbonate, high-density polyethylene (HDPE), polyethylene (PE S80), polypropylene (PP), silicone (Pt)
	2×50 mL	FLS0052CASQLT	FLS0052PASQLT			
	2×150 mL	FLS0152CASQLT	FLS0152PASQLT			
	2×250 mL	FLS0252CASQLT	FLS0252PASQLT			
	2×500 mL	FLS0502CASQLT	FLS0502PASQLT			
	2×1,000 mL	FLS1002CASQLT	FLS1002PASQLT			
Flexboy® bags on stopcock manifold	2×50 mL	FBY0052CASQLT	FBY0052PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Benchmark® (for needle-free syringes)	Polycarbonate, high-density polyethylene (HDPE), ethylene-vinyl acetate (EVA S71), polypropylene (PP), silicone (Pt)
	2×250 mL	FBY0252CASQLT	FBY0252PASQLT			
	2×1,000 mL	FBY1002CASQLT	FBY1002PASQLT			
Centrifuge tube on stopcock manifold	2×15 mL	PSCT0152CASQLT	PSCT0152PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polycarbonate, polystyrene, high density polyethylene (HDPE), silicone (Pt)
	2×50 mL	PPCT0052CASQLT	PPCT0052PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polycarbonate, high density polyethylene (HDPE), polypropylene (PP), silicone (Pt)
Bottle on stopcock manifold	2×60 mL	PTG0062CASQLT	PTG0062PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polycarbonate, high density polyethylene (HDPE), polyethylene terephthalate glycol-modified (PETG), silicone (Pt)
2-way splitter		2WAY001CASQLT	2WAY001PASQLT	AseptiQuik® S ⅛"×¼" Length 6"	AseptiQuik® S (×2) ⅛"×¼" Length 6"	Polycarbonate, high density polyethylene (HDPE), silicone (Pt)



5-Gang Manifold with Purge Vessel

Container Type	Volume	Catalog Number TPE Tube	Catalog Number Silicone (Pt) Tube	Container Inlet	Container Outlet	Fluid Contact Materials*
Flexsafe® bags on stopcock manifold	5×20 mL	FLS0025CASQLT	FLS0025PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Benchmark® (for needle-free syringes)	Polycarbonate, high density polyethylene (HDPE), polyethylene (PE S80), polypropylene (PP), silicone (Pt)
	5×50 mL	FLS0055CASQLT	FLS0055PASQLT			
	5×150 mL	FLS0155CASQLT	FLS0155PASQLT			
	5×250 mL	FLS0255CASQLT	FLS0255PASQLT			
	5×500 mL	FLS0505CASQLT	FLS0505PASQLT			
	5×1,000 mL	FLS1005CASQLT	FLS1005PASQLT			
Flexboy® bags on stopcock manifold	5×50 mL	FBY0055CASQLT	FBY0055PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Benchmark® (for needle-free syringes)	Polycarbonate, high-density polyethylene (HDPE), ethylene-vinyl acetate (EVA S71), polypropylene (PP), silicone (Pt)
	5×250 mL	FBY0255CASQLT	FBY0255PASQLT			
	5×1,000 mL	FBY1005CASQLT	FBY1005PASQLT			
Centrifuge tube on stopcock manifold	5×15 mL	PSCT0155CASQLT	PSCT0155PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polycarbonate, polystyrene, high-density polyethylene (HDPE), silicone (Pt)
	5×60 mL	PTG0065CASQLT	PTG0065PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polycarbonate, high-density polyethylene (HDPE), polypropylene (PP), silicone (Pt)
Bottle on stopcock manifold	5×60 mL	PTG0065CASQLT	PTG0065PASQLT	AseptiQuik® S ⅛"×¼" Length 6" Quickseal® 3"	Minisart® Vent Filter	Polycarbonate, high-density polyethylene (HDPE), polyethylene terephthalate glycol-modified (PETG), silicone (Pt)
	5×125 mL	PTG0125CASQLT	PTG0125PASQLT			
	5×250 mL	PTG0255CASQLT	PTG0255PASQLT			

Accessories

	Catalog Number	Fluid Contact Materials*
Quickseal® cutter (small diameter)	QSCUTTERSD	-
Quickseal® silicone caps, ¼" OD (50/pack)	QS04CAPSILNT	-

*List does not include tubing type material

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