

TakeOne® PDS Pre-Designed Solutions for Aseptic Sampling

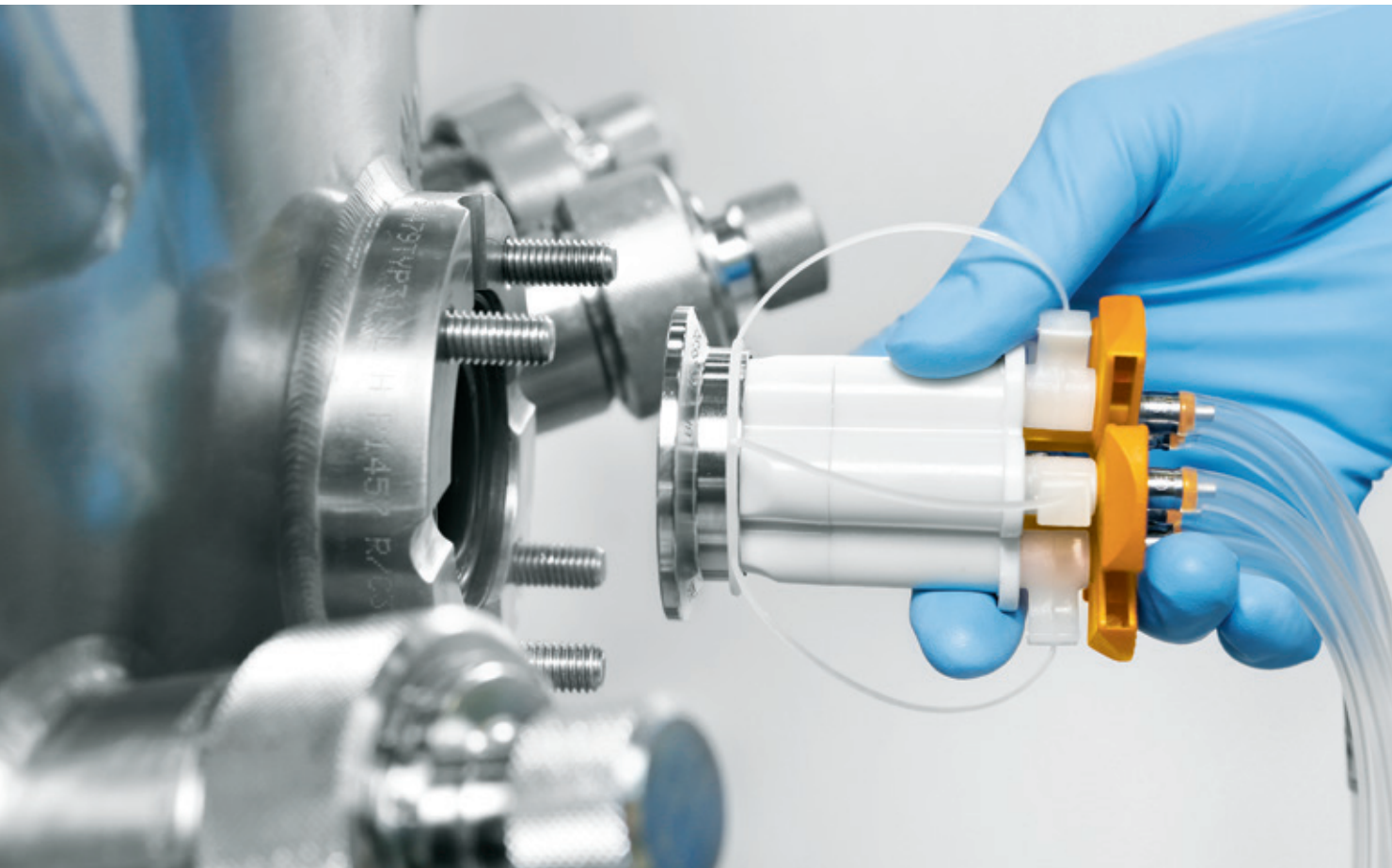


Table of Contents

Click on a headline to go to the selected page

Product Information	3
Select & Go	4
Containers for All Sampling Applications	5
Product Selection	6

TakeOne® Pre-designed Solutions for

Media Buffer Preparation	7
Cell Culture Downstream Intermediates	11
Drug Substance Purification	15
Drug Product Formulation	19

Reliable Performance Backed by Precise Manufacturing Controls	23
Technical Data	24
Ordering Information	25

Media | Buffer
Preparation

Cell Culture | Downstream
Intermediates

Drug Substance
Purification

Drug Product
Formulation

Back to Table
of Contents

Digital Selection Map

Select your process step with the desired connection-type

Media | Buffer Preparation

25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)

Cell Culture | Downstream Intermediates

25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)

Drug Substance Purification

25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)

Drug Product Formulation

25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)

Product Information

Not all samples are equal – categorization of a sampling plan by assay type reduces costs, improves sampling results and optimizes capacity of the sampling solution.

This guide will help you select the optimal TakeOne® configuration for your process and applications.

TakeOne® PDS has been engineered to take perfectly representative samples giving exact results with no risk of false-positives for each process step, thanks to its pre-assembled, sterile and closed design. It collects process fluids for analysis while protecting the process fluid from adventitious agents.

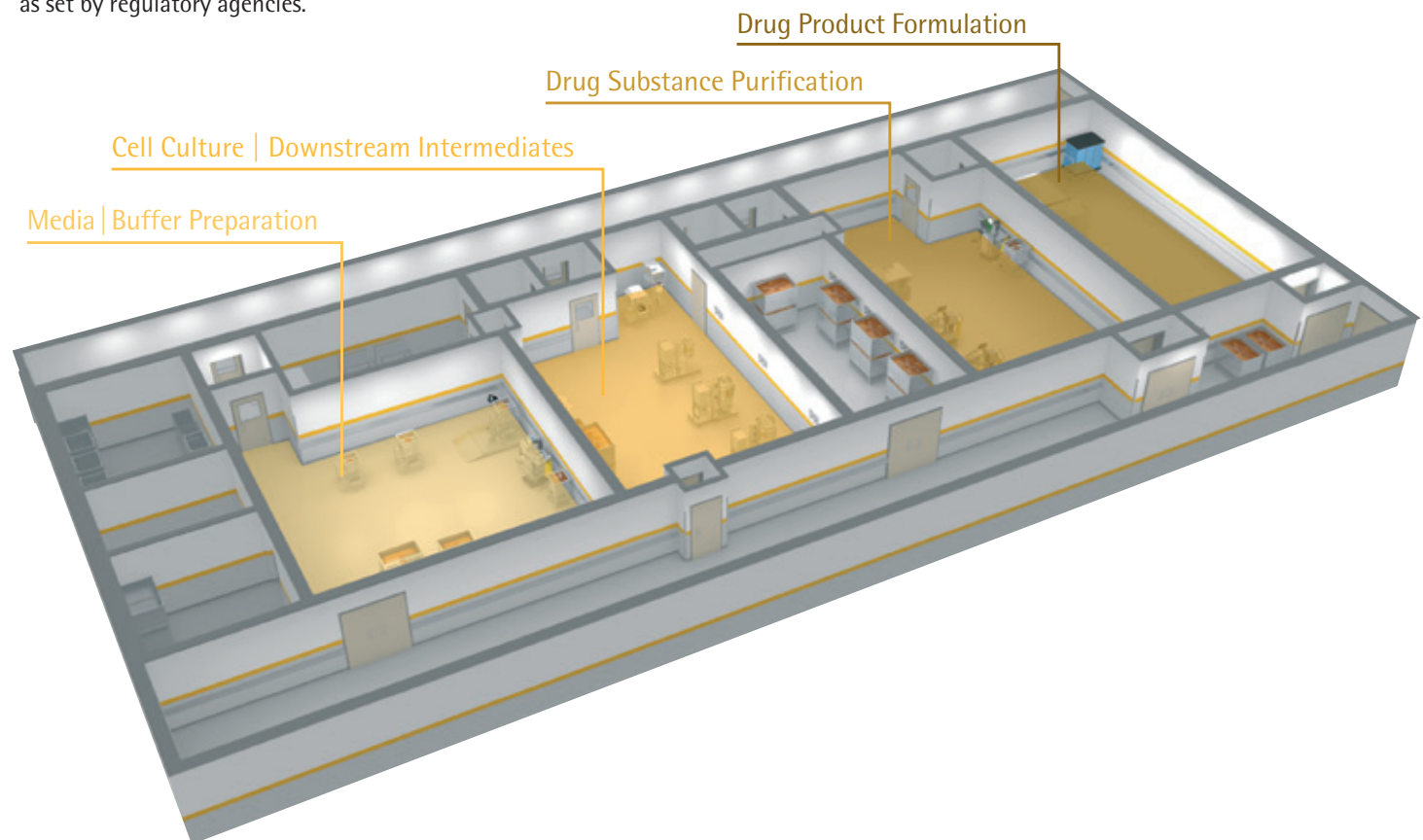
Microbiological Assays

Bioburden monitoring is required at every process step to demonstrate process control. Loss of sterility, detection of non-host organisms or high level of bioburden are causes for batch rejection.

Monitoring for endotoxin drug substance purification and drug product formulation process steps ensures compliance to endotoxin limits for final drug product as set by regulatory agencies.

Process Monitoring Assays

Successful drug production requires that critical parameters are met. Attributes include; Cell viability | density, osmolality, immunoglobulin, nutrients, conductivity, pH, gas analysis.



Select & Go

Simply Select, and Go

TakeOne® is easy to use:



1. Install TakeOne® aseptic sampling device

2. Sample

3. Disconnect

4. Remove & dispose

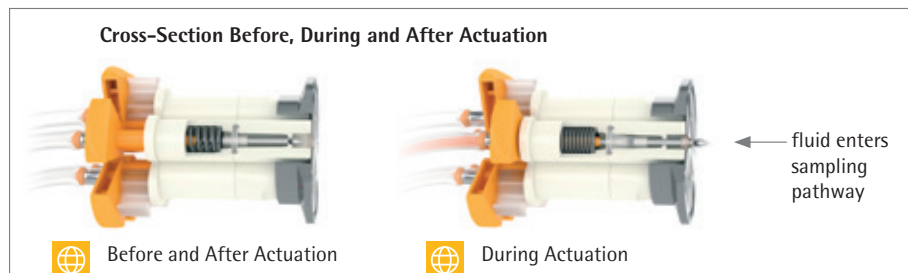
Efficient Sampling with TakeOne®

Ready-To-Use

Bypass parts washing, equipment prep and assembly with TakeOne® and break the bottlenecks of your processes. The device is delivered fully assembled, in individual packs, gamma sterilized and ready for immediate use.

Rest Assured with Reliable Performance Batch-to-batch

Sample and product integrity is preserved. The unique design of TakeOne® integrates a silicone diaphragm bonded to each individual cannula, and molded septa to the face plate. This provides an aseptic chamber to ensure a closed fluid pathway with no risks of leakage. In addition, all individual sampling lines have been 100% leak tested.



The robust design of TakeOne® supports multiple actuation for high-frequency process monitoring samples.

Sample Safely

All TakeOne® faceplates are made of 316L stainless steel to guarantee full compatibility with your tank mount. The device has been validated to pass 10 SIP cycles.

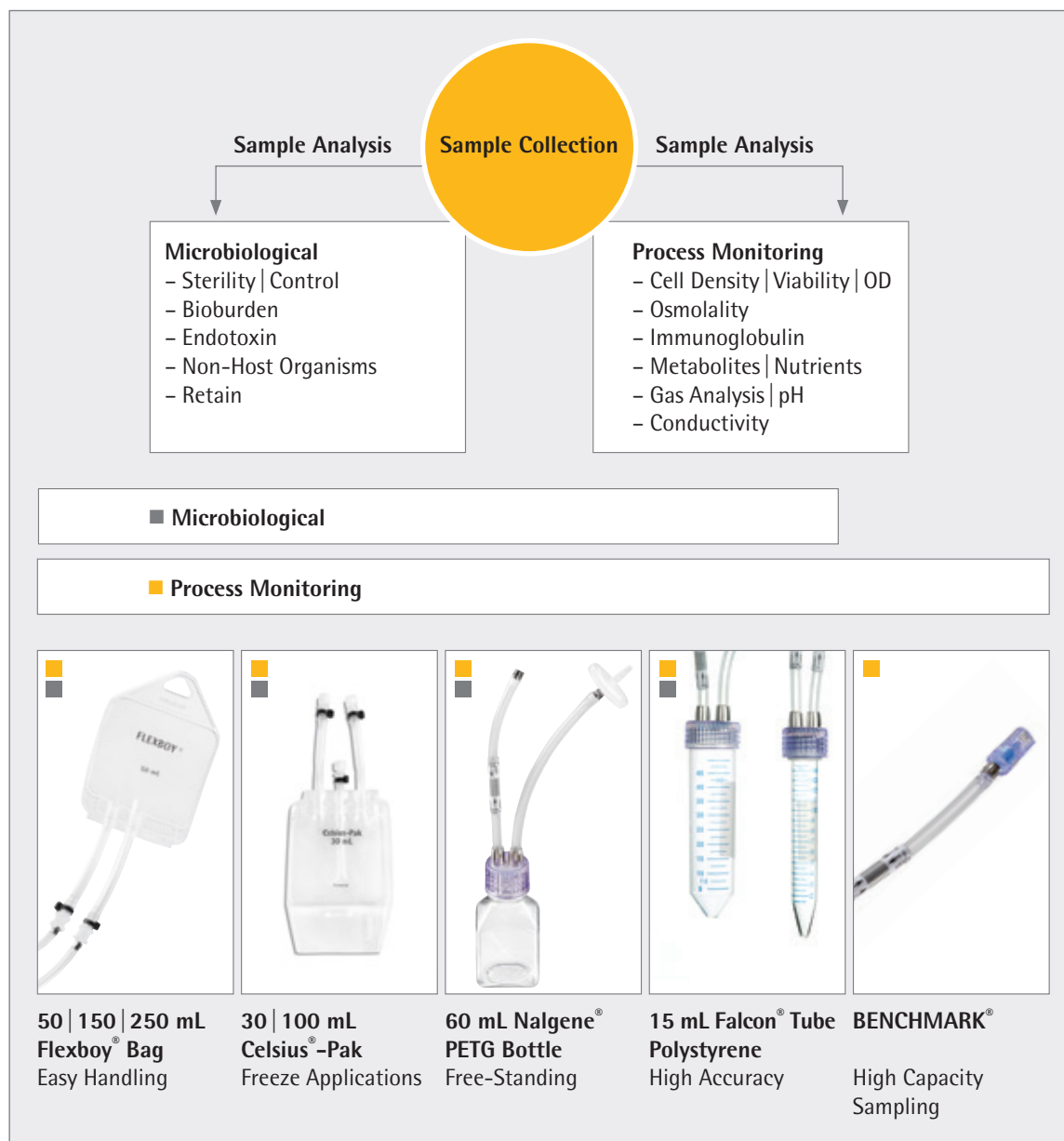
Quick, and Easy Disconnect

Each TakeOne® sampling line assembly includes a QUICKSEAL® aseptic disconnect.

Once the sample has been collected, operators easily cut the aluminum collar with a light and portable hand-held cutting tool. This aseptically seals the tubing while disconnecting the sampling container. QUICKSEAL® patented technology protects the sample and process vessel from contamination. A QUICKSEAL® silicone protective cap then shields the cut collar.



Containers for All Sampling Applications



TakeOne® Meets all Process Steps and Sampling Application Requirements

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

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

Flexboy® & Celsius® -Pak Bags

Flexboy® and Celsius® -Pak bags have a luer-activated access site on the outlet for easy fluid transfer. Samples collected are suitable for microbiological or process monitoring samples.

Flexboy® sampling lines feature one, two or five bags per sampling line. An easy to use stopcock valve directs fluid flow on manifold sampling lines.

60 mL PETG Bottles & 15 mL Falcon® Tubes

60 mL bottles and 15 mL tubes include the secure MYCAP® bottle closure. Samples collected are suitable for microbiological or process monitoring samples.

Bottles and tubes have graduations for accurate volume control. The 15 mL Falcon® tubes are marked at every 0.5 mL for best precision. A MiniSart® air vent filter allows fluid flow into the container.

BENCHMARK® for Needle-free Syringes

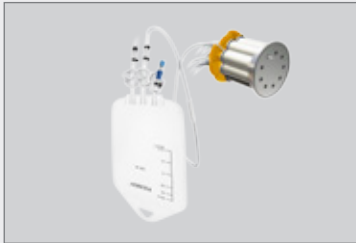



BENCHMARK® features a luer-activated access site. Samples collected are suitable for process monitoring samples.

This solution is ideal for high capacity sampling. A single BENCHMARK® line may be used to collect 20 samples, including 1 purge for each sample.

Product Selection

Choose from our standard designs, evaluated for our customers based on their needs.

In 3 simple steps, identify your ideal pre-designed solution for aseptic sampling:

1. Start by selecting your process step		
Media Buffer Preparation		<ul style="list-style-type: none"> – Microbiological Assay control for bioburden, endotoxin and sterility – Process Monitoring for correct balance & concentrations
Cell Culture Downstream Intermediates		<ul style="list-style-type: none"> – Microbiological Assay for non-host organisms to ensure axenic culture – Process Monitoring for cell count, viability, density, nutrient, gas
Drug Substance Purification		<ul style="list-style-type: none"> – Microbiological Assay for bioburden, endotoxins and sterility test. – Especially prior to and at conclusion of filtration, chromatography & UF DF process steps.
Drug Product Formulation		<ul style="list-style-type: none"> – Microbiological Assay for bioburden and endotoxin prior to filtration to ensure levels are within regulatory limits

Media | Buffer Preparation

2. Identify fitting size for the sampling site

Media and Buffer Preparation

25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)

25 mm Ingold® Tank Mount



1.5" Sanitary Tank Mount



2" Sanitary Tank Mount

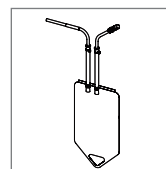


Faceplate: 316L Stainless Steel, Electropolished, **Needle:** 316L Stainless Steel, Electropolished, **Septa:** Platinum-Cured Silicone

Media | Buffer Preparation Sampling Guidelines

Media Preparation	Microbiological	Sterility Check, especially prior to and after additions transfers Endotoxin test prior to and after additions transfer, as necessary
	Process Monitoring	pH, Concentration, critical process parameters
Buffer Preparation	Microbiological	Sterility Check, especially prior to and after additions transfers Endotoxin test prior to and after additions transfer, as necessary
	Process Monitoring	Concentrations, Titration, pH, conductivity, critical process parameters

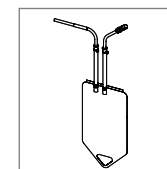
Sampling Line Options



Flexboy®

- Microbiological Sampling
- Process Monitoring Sampling

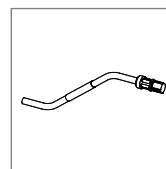
50 mL | 150 mL | 250 mL
Luer-Activated Access on Outlet
Tubing with QUICKSEAL®



Celsius®-Pak

- Microbiological Sampling
- Process Monitoring Sampling

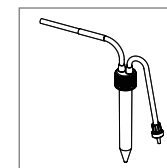
30 mL | 100 mL
Luer-fitting on Outlet
C-Flex® Tubing with QUICKSEAL®
Freeze applications



BENCHMARK®

- Process Monitoring Sampling

Luer-Activated Access
Tubing with QUICKSEAL®
Up to 20 process monitoring samples



Falcon® 15 mL Polystyrene Tube

- Microbiological Sampling
- Process Monitoring Sampling

MYCAP® Bottle Closure
25 mm Minisart® Vent Filter
Tubing with QUICKSEAL®
Ideal for Endotoxin or
Accurate Volume Sampling

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

Falcon® is a registered trademark of Corning Incorporated.

Ingold® is a registered trademark of Mettler-Toledo.

3. Determine the maximum number of microbiological & process monitoring samples

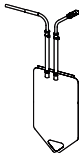
Media and Buffer Preparation



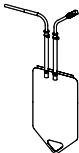
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)



50 | 150 | 250 mL
Flexboy®



30 mL | 100 mL
Celsius®-Pak



BENCHMARK®

Ordering Information

All TakeOne® PDS devices are individually packed and gamma sterilized for your convenience. A minimum order quantity of 5 applies.

Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius®-Pak	100 mL Celsius®-Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	BENCHMARK®
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	3	3	-	INGP03CPDS0109	3	3					
	22	2	INGP03PPDS0090	INGP03CPDS0089	3			2			1
	22	2	INGP03PPDS0100	INGP03CPDS0099	3				2		1
	22	2	INGP03PPDS0102	INGP03CPDS0101	3					2	1
	22	2	-	INGP03CPDS0110	3	1			1		1

9 TakeOne® Pre-designed Solutions for
Media | Buffer Preparation

Media | Buffer
Preparation

Cell Culture | Downstream
Intermediates

Drug Substance
Purification

Drug Product
Formulation

Back to Table
of Contents

3. Determine the maximum number of microbiological & process monitoring samples

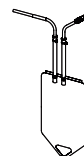
Media and
Buffer
Preparation



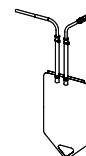
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

2" Sanitary Tank Mount
(up to 9 independent sampling lines)



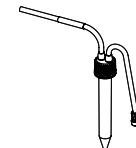
50 | 150 mL Flexboy®



30 mL | 100 mL
Celsius®-Pak



BENCHMARK®



15 mL Tube

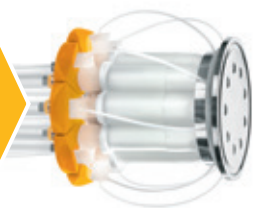
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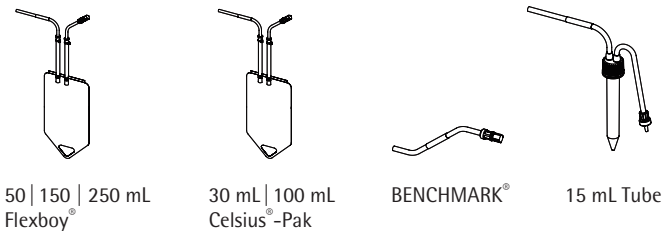
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® -Pak	100 mL Celsius® -Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	BENCHMARK®	15 mL Centrifuge Tube
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	24TC05PPDS0029	24TC05CPDS0015	5	-	-	5	-	-	-
	5	5	24TC05PPDS0086	24TC05CPDS0085	5	-	-	-	5	-	-
	5	5	-	24TC05CPDS0105	5	-	5	-	-	-	-
	22	2	24TC03PPDS0002	24TC03CPDS0001	3	-	-	2	-	1	-
	23	3	-	24TC05CPDS0106	5	1	-	-	2	1	1

3. Determine the maximum number of microbiological & process monitoring samples

Media and Buffer Preparation



- 25 mm Ingold® Port
(up to 3 independent sampling lines)
- 1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)
- 2" Sanitary Tank Mount
(up to 9 independent sampling lines)



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Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius®-Pak	100 mL Celsius®-Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	BENCHMARK®	15 mL Centrifuge Tube
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	32TC05PPDS0043	32TC05CPDS0039	5	-	-	5	-	-	-	-
	9	9	32TC07PPDS0088	32TC07CPDS0087	9	-	-	-	9	-	-	-
	9	9	-	32TC09CPDS0107	9	-	9	-	-	-	-	-
	22	2	32TC03PPDS0034	32TC03CPDS0033	3	-	-	2	-	-	1	-
	28	8	32TC09PPDS0058	32TC09CPDS0048	9	-	-	-	-	8	1	-
	28	8	-	32TC09CPDS0108	9	2	-	-	4	-	1	2

2. Identify fitting size for the sampling site

Cell Culture | Downstream Intermediates

- 25 mm Ingold® Port
(up to 3 independent sampling lines)
- 1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)
- 2" Sanitary Tank Mount
(up to 9 independent sampling lines)

25 mm Ingold® Tank Mount



1.5" Sanitary Tank Mount



2" Sanitary Tank Mount

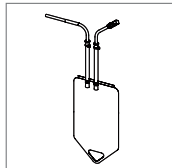


Faceplate: 316L Stainless Steel, Electropolished, Needle: 316L Stainless Steel, Electropolished, Septa: Platinum-Cured Silicone

Cell Culture | Cell Harvest Sampling Guidelines

Cell Culture	Microbiological	Sterility Non-Host Organism Check Pre Post Inoculation & Additions Batch Conclusion Endotoxin as necessary
	Process Monitoring	Cell Count Viability Density, critical process parameters
Cell Harvest	Microbiological	Sterility Non-Host Organism Check after Recovery & Hold Steps Endotoxin as necessary
	Process Monitoring	Cell Count Viability Density, critical process parameters

Sampling Line Options

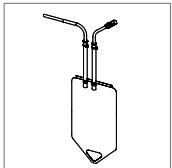


Flexboy®

Microbiological Sampling

Process Monitoring Sampling

50 mL | 150 mL | 250mL
Luer-Activated Access on Outlet
Tubing with QUICKSEAL®

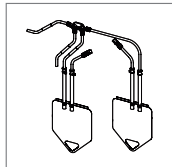


Celsius®-Pak

Microbiological Sampling

Process Monitoring Sampling

30 mL | 100 mL
Luer-fitting on Outlet
C-Flex® Tubing with QUICKSEAL®
Freeze applications

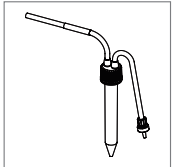


2 × 50 mL Flexboy®

Microbiological Sampling

Process Monitoring Sampling

Two 50 mL with 500 mL Purge Bag
Luer-Activated Access on Outlet
Polycarbonate, HDPE Stopcock Valve
Tubing with QUICKSEAL®

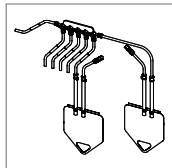


Falcon® 15 mL Polystyrene Tube

Microbiological Sampling

Process Monitoring Sampling

MYCAP® Bottle Closure
25 mm Minisart® Vent Filter
Tubing with QUICKSEAL®
Ideal for Endotoxin or Accurate Volume Sampling

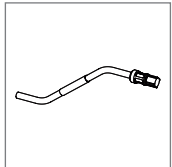


5 × 50 mL | 250 mL Flexboy®

Microbiological Sampling

Process Monitoring Sampling

Five 50 mL | 250 mL with 500 mL Purge Bag
Luer-Activated Access on Outlet
Polycarbonate, HDPE Stopcock Valve
Tube with QUICKSEAL®



BENCHMARK®

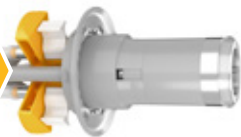
Process Monitoring Sampling

Luer-Activated Access
Tubing with QUICKSEAL®
Up to 20 process monitoring samples

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
Falcon® is a registered trademark of Corning Incorporated.
Ingold® is a registered trademark of Mettler-Toledo.

3. Determine the maximum number of microbiological & process monitoring samples

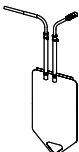
Cell Culture | Downstream Intermediates



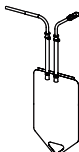
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

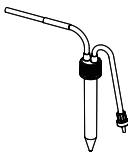
2" Sanitary Tank Mount
(up to 9 independent sampling lines)



50 | 150 mL | 250 mL
Flexboy®



30 mL | 100 mL
Celsius®-Pak



15 mL Tube



BENCHMARK®

Ordering Information

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Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius®-Pak	100 mL Celsius®-Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	BENCH-MARK®	15 mL Centrifuge Tube
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	3	3	INGP03PPDS0104	INGP03CPDS0103	3					3		
	3	3	INGP03PPDS0094	INGP03CPDS0093	3				3			
	3	3	-	INGP03CPDS0109	3		3					
	22	2	INGP03PPDS0092	INGP03CPDS0091	3			1			1	1
	22	2	-	INGP03CPDS0110	3	1			1		1	

13 TakeOne® Pre-designed Solutions for

Cell Culture | Downstream Intermediates

3. Determine the maximum number of microbiological & process monitoring samples

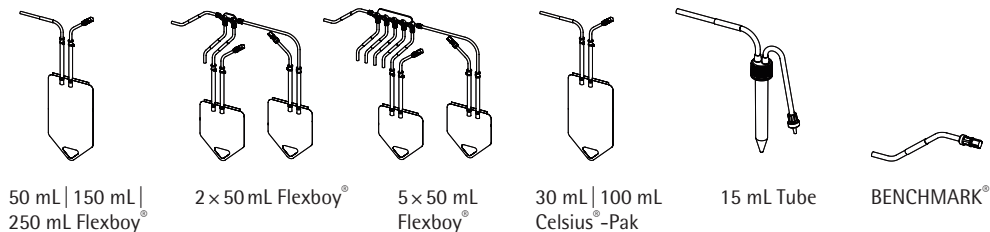
Cell Culture | Downstream Intermediates



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2" Sanitary Tank Mount
(up to 9 independent sampling lines)



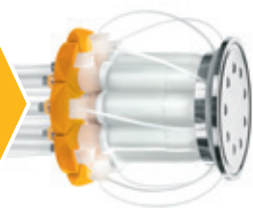
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Tubing Features	Total Sampling Capacity	(of which) Micro-biological ONLY Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® -Pak	100 mL Celsius® -Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	2 x 50 mL Flexboy® bag	5 x 50 mL Flexboy® bag	5 x 250 mL Flexboy® bag	BENCH-MARK®	15 mL Centrifuge Tube
1/8" ID x 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	24TC05PPDS0021	24TC05CPDS0007	5	-	-	-	-	4	-	-	-	-	1
	5	5	24TC05PPDS0023	24TC05CPDS0009	5	-	-	4	-	-	-	-	-	-	1
	5	5	24TC05PPDS0028	24TC05CPDS0014	5	-	-	-	-	5	-	-	-	-	-
	5	5	24TC05PPDS0029	24TC05CPDS0015	5	-	-	5	-	-	-	-	-	-	-
	5	5	24TC05PPDS0086	24TC05CPDS0085	5	-	-	-	5	-	-	-	-	-	-
	5	5	-	24TC05CPDS0105	5	-	5	-	-	-	-	-	-	-	-
	10	10	24TC05PPDS0074	24TC05CPDS0076	5	-	-	-	-	-	5	-	-	-	-
	19	19	24TC05PPDS0079	24TC05CPDS0080	5	-	-	-	-	-	2	3	-	-	-
	23	3	24TC04PPDS0004	24TC04CPDS0003	4	-	-	2	-	-	-	-	-	1	1
	23	3	-	24TC05CPDS0106	5	1	-	-	2	-	-	-	-	1	1
	24	4	24TC05PPDS0022	24TC05CPDS0008	5	-	-	-	-	4	-	-	-	1	-
	24	4	24TC05PPDS0024	24TC05CPDS0010	5	-	-	4	-	-	-	-	-	1	-
	25	25	24TC05PPDS0030	24TC05CPDS0016	5	-	-	-	-	-	-	-	5	-	-
	25	25	24TC05PPDS0031	24TC05CPDS0017	5	-	-	-	-	-	-	5	-	-	-
	28	8	24TC05PPDS0077	24TC05CPDS0078	5	-	-	-	-	-	4	-	-	1	-
	34	14	24TC05PPDS0081	24TC05CPDS0082	5	-	-	-	-	-	2	2	-	1	-
	40	20	24TC05PPDS0025	24TC05CPDS0011	5	-	-	-	-	-	-	-	4	1	-
	40	20	24TC05PPDS0026	24TC05CPDS0012	5	-	-	-	-	-	-	4	-	1	-

3. Determine the maximum number of microbiological & process monitoring samples

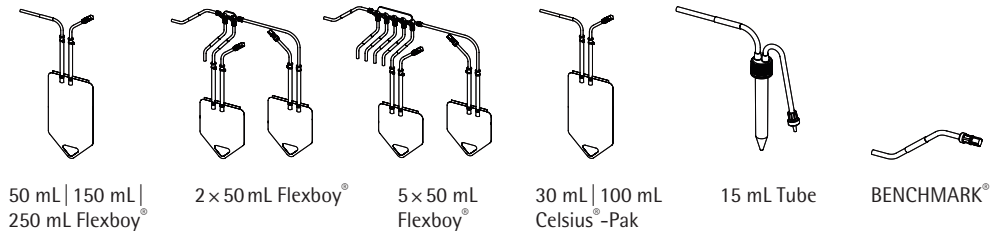
Cell Culture | Downstream Intermediates



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1.5" Sanitary Tank Mount
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Ordering Information

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Tubing Features	Total Sampling Capacity	(of which) Micro-biological ONLY Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius®-Pak	100 mL Celsius®-Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	2 x 50 mL Flexboy® bag	5 x 50 mL Flexboy® bag	BENCHMARK®	15 mL Centrifuge Tube
1/8" ID x 1/4" OD Length – 6" QUICKSEAL® at 3"	9	9	32TC09PPDS0088	32TC09CPDS0087	9	-	-	-	9	-	-	-	-	-
	9	9	32TC09PPDS0057	32TC09CPDS0047	9	-	-	-	-	8	-	-	-	1
	9	9	32TC09PPDS0060	32TC09CPDS0050	9	-	-	8	-	-	-	-	-	1
	9	9	32TC09PPDS0063	32TC09CPDS0053	9	-	-	-	-	9	-	-	-	-
	9	9	32TC09PPDS0065	32TC09CPDS0055	9	-	-	9	-	-	-	-	-	-
	9	9	-	32TC09CPDS0107	9	-	9	-	-	-	-	-	-	-
	18	18	32TC09PPDS0064	32TC09CPDS0054	9	-	-	-	-	-	9	-	-	-
	23	3	32TC04PPDS0036	32TC04CPDS0035	4	-	-	2	-	-	-	-	1	1
	25	25	32TC05PPDS0044	32TC05CPDS0040	5	-	-	-	-	-	-	5	-	-
	28	8	32TC09PPDS0058	32TC09CPDS0048	9	-	-	-	-	8	-	-	1	-
	28	8	32TC09PPDS0061	32TC09CPDS0051	9	-	-	8	-	-	-	-	1	-
	28	8	-	32TC09CPDS0108	9	2	-	-	4	-	-	-	1	2
	30	30	32TC06PPDS0071	32TC06CPDS0072	6	-	-	-	-	-	-	6	-	-
	33	33	32TC09PPDS0069	32TC09CPDS0070	9	-	-	3	-	-	-	6	-	-
	36	16	32TC09PPDS0059	32TC09CPDS0049	9	-	-	-	-	-	8	-	1	-
	45	25	32TC06PPDS0046	32TC06CPDS0045	6	-	-	-	-	-	-	5	1	-
	50	30	32TC07PPDS0073	32TC07CPDS0075	7	-	-	-	-	-	-	6	1	-
	52	32	32TC09PPDS0067	32TC09CPDS0068	9	-	-	2	-	-	-	6	1	-

Drug Substance Purification

Media | Buffer
PreparationCell Culture | Downstream
IntermediatesDrug Substance
PurificationDrug Product
FormulationBack to Table
of Contents

2. Identify fitting size for the sampling site

Drug Substance Purification

25 mm Ingold® Port
(up to 3 independent sampling lines)1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)2" Sanitary Tank Mount
(up to 9 independent sampling lines)

25 mm Ingold® Tank Mount



1.5" Sanitary Tank Mount



2" Sanitary Tank Mount

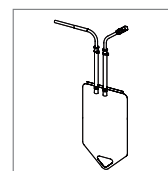


Faceplate: 316L Stainless Steel, Electropolished, **Needle:** 316L Stainless Steel, Electropolished, **Septa:** Platinum-Cured Silicone

Downstream Aseptic Sampling Guidelines

Chromatography, Ultrafiltration Diafiltration	Microbiological	Bioburden and Endotoxin during equipment calibration end of process
	Process Monitoring	Osmolality, Virus Protein Concentration, critical process parameters
Chemical & Buffer Addition	Microbiological	Bioburden and Endotoxin after any addition
Sterile Filtration	Microbiological	Bioburden prior to any 0.2 µm Filtration
Virus Inactivation Filtration	Microbiological	Bioburden and Endotoxin at end of process, as necessary
	Process Monitoring	pH, Viral Concentration, critical process parameters

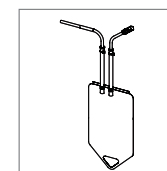
Sampling Line Options



Flexboy®

- Microbiological Sampling
- Process Monitoring Sampling

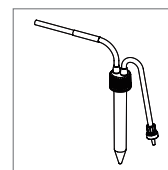
50 mL
Luer-Activated Access on Outlet
Tubing with QUICKSEAL®



Celsius® -Pak

- Microbiological Sampling
- Process Monitoring Sampling

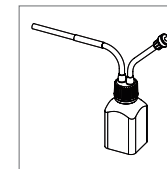
30 mL
Luer-fitting on Outlet
C-Flex® Tubing with QUICKSEAL®
Freeze applications



Falcon® 15 mL Polystyrene Tube

- Microbiological Sampling
- Process Monitoring Sampling

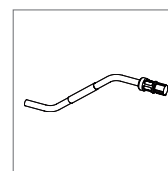
MYCAP® Bottle Closure
25 mm Minisart® Vent Filter
Tubing with QUICKSEAL®
Ideal for Endotoxin or
Accurate Volume Sampling



Nalgene® 60 mL PETG Bottle

- Microbiological Sampling
- Process Monitoring Sampling

MYCAP® Bottle Closure
25 mm Minisart® Vent Filter
Tubing with QUICKSEAL®



BENCHMARK®

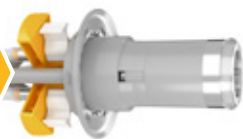
- Process Monitoring Sampling

Luer-Activated Access
Tubing with QUICKSEAL®
Up to 20 process monitoring samples

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
Nalgene® is a registered trademark of Nalge Nunc.
Falcon® is a registered trademark of Corning Incorporated.
Ingold® is a registered trademark of Mettler-Toledo.

3. Determine the maximum number of microbiological & process monitoring samples

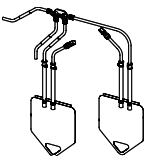
Drug Substance Purification



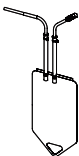
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

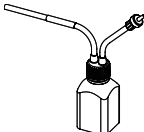
2" Sanitary Tank Mount
(up to 9 independent sampling lines)



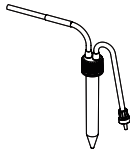
2 x 50 mL
Flexboy®



30 mL
Celsius®-Pak



60 mL PETG Bottle



15 mL Tube

Ordering Information

All TakeOne® PDS devices are individually packed and gamma sterilized for your convenience. A minimum order quantity of 5 applies.

Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® - Pak	2 x 50 mL Flexboy® Bag	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID x 1/4" OD Length – 6" QUICKSEAL® at 3"	3	3	INGP03PPDS0098	INGP03CPDS0097	3				3
	3	3	-	INGP03CPDS0111	3	1		2	
	4	4	INGP03PPDS0096	INGP03CPDS0095	3		1	2	

3. Determine the maximum number of microbiological & process monitoring samples

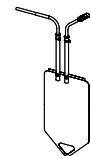
Drug
Substance
Purification



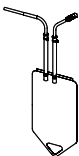
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

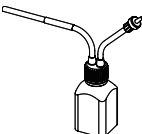
2" Sanitary Tank Mount
(up to 9 independent sampling lines)



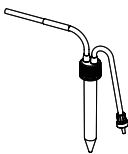
50 mL Flexboy®



30 mL Celsius®-Pak



60 mL PETG Bottle



15 mL Tube



BENCHMARK®

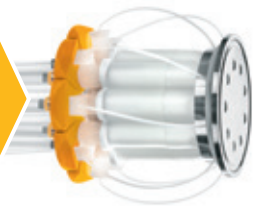
Ordering Information

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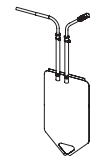
Tubing Features	Total Sampling Capacity	(of which) Micro-biological ONLY Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® -Pak	50 mL Flexboy® Bag	BENCHMARK®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	24TC05PPDS0020	24TC05CPDS0006	5	-	3	-	2	-
	5	5	24TC05PPDS0027	24TC05CPDS0013	5	-	-	-	5	-
	5	5	24TC05PPDS0029	24TC05CPDS0015	5	-	5	-	-	-
	5	5	24TC05PPDS0032	24TC05CPDS0018	5	-	-	-	-	5
	5	5	-	24TC05CPDS0112	5	2	-	-	3	-
	24	4	24TC05PPDS0019	24TC05CPDS0005	5	-	3	1	1	-

3. Determine the maximum number of microbiological & process monitoring samples

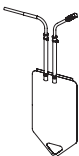
Drug Substance Purification



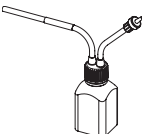
- 25 mm Ingold® Port
(up to 3 independent sampling lines)
- 1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)
- 2" Sanitary Tank Mount
(up to 9 independent sampling lines)



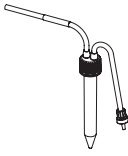
50 mL Flexboy®



30 mL Celsius® -Pak



60 mL PETG Bottle



15 mL Tube



BENCHMARK®

Ordering Information

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Tubing Features	Total Sampling Capacity	(of which) Micro-biological ONLY Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® -Pak	50 mL Flexboy® Bag	BENCHMARK®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	32TC05PPDS0042	32TC05CPDS0038	5	-	3	-	2	-
	9	9	32TC09PPDS0062	32TC09CPDS0052	9	-	-	-	9	-
	9	9	32TC09PPDS0065	32TC09CPDS0055	9	-	9	-	-	-
	9	9	32TC09PPDS0066	32TC09CPDS0056	9	-	-	-	-	9
	9	9	-	32TC09CPDS0113	9	4	-	-	5	-
	24	4	32TC05PPDS0041	32TC05CPDS0037	5	-	3	1	1	-

2. Identify fitting size for the sampling site

Drug Product
Formulation

- 25 mm Ingold® Port
(up to 3 independent sampling lines)
- 1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)
- 2" Sanitary Tank Mount
(up to 9 independent sampling lines)

25 mm Ingold® Tank Mount



1.5" Sanitary Tank Mount



2" Sanitary Tank Mount

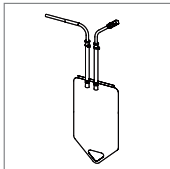


Faceplate: 316L Stainless Steel, Electropolished, Needle: 316L Stainless Steel, Electropolished, Septa: Platinum-Cured Silicone

Formulation, Fill | Finish Aseptic Sampling Guidelines

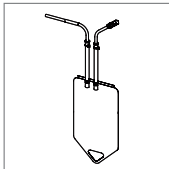
Formulation	Microbiological	Bioburden and Endotoxin at end of process
	Process Monitoring	Osmolality, Concentrations pH, Conductivity, Critical process parameters
Fill Finish	Microbiological	Bioburden and Endotoxin prior to Fill Finish
Sterile Filtration	Microbiological	Bioburden prior to any 0.2 µm Filtration
Hold Storage Vessels	Microbiological	Bioburden and Endotoxin after filing & end of hold time

Sampling Line Options



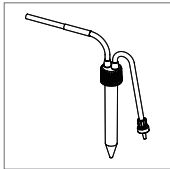
Flexboy®
■ Microbiological Sampling
■ Process Monitoring Sampling

50 mL
Luer-Activated Access on Outlet
Tubing with QUICKSEAL®



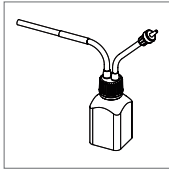
Celsius®-Pak
■ Microbiological Sampling
■ Process Monitoring Sampling

30 mL
Luer-fitting on Outlet
C-Flex® Tubing with QUICKSEAL®
Freeze applications



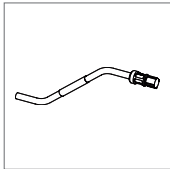
Falcon® 15 mL Polystyrene Tube
■ Microbiological Sampling
■ Process Monitoring Sampling

MYCAP® Bottle Closure
25 mm Minisart® Vent Filter
Tubing with QUICKSEAL®
Ideal for Endotoxin or
Accurate Volume Sampling



Nalgene® 60 mL PETG Bottle
■ Microbiological Sampling
■ Process Monitoring Sampling

MYCAP® Bottle Closure
25 mm Minisart® Vent Filter
Tubing with QUICKSEAL®



BENCHMARK®
■ Process Monitoring Sampling

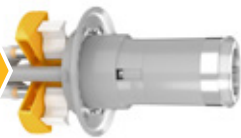
Luer-Activated Access
Tubing with QUICKSEAL®
Up to 20 process monitoring samples

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
Nalgene® is a registered trademark of Nalge Nunc.
Falcon® is a registered trademark of Corning Incorporated.
Ingold® is a registered trademark of Mettler-Toledo.

TakeOne® Pre-designed Solutions for
Drug Product Formulation

3. Determine the maximum number of microbiological & process monitoring samples

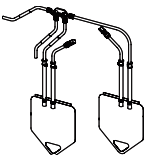
Drug Product
Formulation



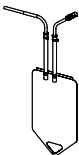
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

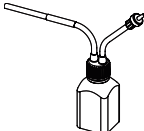
2" Sanitary Tank Mount
(up to 9 independent sampling lines)



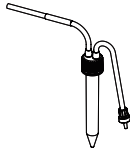
2 x 50 mL
Flexboy®



30 mL
Celsius®-Pak



60 mL PETG Bottle



15 mL Tube

Ordering Information

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Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® - Pak	2 x 50 mL Flexboy® Bag	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID x 1/4" OD Length – 6" QUICKSEAL® at 3"	3	3	INGP03PPDS0098	INGP03CPDS0097	3				3
	3	3	-	INGP03CPDS0111	3	1		2	
	4	4	INGP03PPDS0096	INGP03CPDS0095	3		1	2	

3. Determine the maximum number of microbiological & process monitoring samples

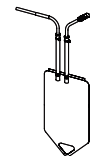
Drug Product
Formulation



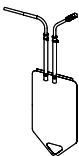
25 mm Ingold® Port
(up to 3 independent sampling lines)

1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)

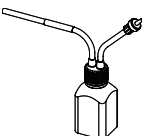
2" Sanitary Tank Mount
(up to 9 independent sampling lines)



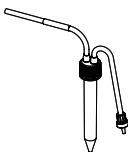
50 mL Flexboy®



30 mL
Celsius®-Pak



60 mL PETG Bottle



15 mL Tube



BENCHMARK®

Ordering Information

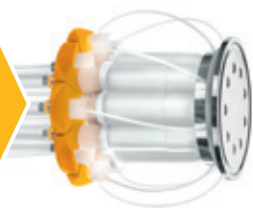
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Tubing Features	Total Sampling Capacity	(of which) Micro-biological ONLY Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® -Pak	50 mL Flexboy® Bag	BENCHMARK®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	24TC05PPDS0020	24TC05CPDS0006	5	-	3	-	2	-
	5	5	24TC05PPDS0027	24TC05CPDS0013	5	-	-	-	5	-
	5	5	24TC05PPDS0029	24TC05CPDS0015	5	-	5	-	-	-
	5	5	24TC05PPDS0032	24TC05CPDS0018	5	-	-	-	-	5
	5	5	-	24TC05CPDS0112	5	2	-	-	3	-
	24	4	24TC05PPDS0019	24TC05CPDS0005	5	-	3	1	1	-

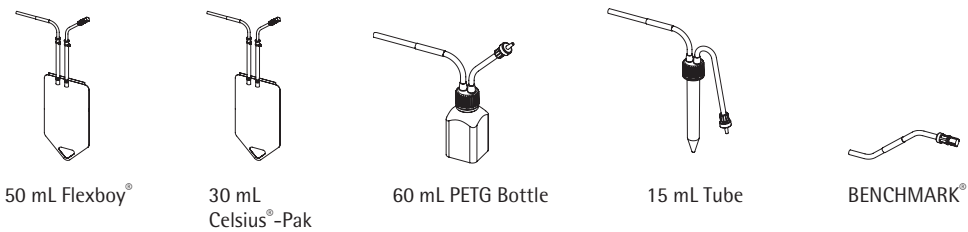
TakeOne® Pre-designed Solutions for
Drug Product Formulation

3. Determine the maximum number of microbiological & process monitoring samples

Drug Product
Formulation



- 25 mm Ingold® Port
(up to 3 independent sampling lines)
- 1.5" Sanitary Tank Mount
(up to 5 independent sampling lines)
- 2" Sanitary Tank Mount
(up to 9 independent sampling lines)



Ordering Information

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Tubing Features	Total Sampling Capacity	(of which) Micro-biological ONLY Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius® -Pak	50 mL Flexboy® Bag	BENCHMARK®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID × 1/4" OD Length – 6" QUICKSEAL® at 3"	5	5	32TC05PPDS0042	32TC05CPDS0038	5	-	3	-	2	-
	9	9	32TC09PPDS0062	32TC09CPDS0052	9	-	-	-	9	-
	9	9	32TC09PPDS0065	32TC09CPDS0055	9	-	9	-	-	-
	9	9	32TC09PPDS0066	32TC09CPDS0056	9	-	-	-	-	9
	9	9	-	32TC09CPDS0113	9	4	-	-	5	-
	24	4	32TC05PPDS0041	32TC05CPDS0037	5	-	3	1	1	-
	28	8	32TC09PPDS0083	32TC09CPDS0084	9	-	7	1	1	-

Reliable Performance Backed by Precise Manufacturing Controls

Facility Standards and Controls

The manufacturing and assembly operations adhere to the key principles of cGMP and follow strict SOPs to produce a consistent product suitable for use in the most critical production processes. Quality checks for accuracy, cleanliness and correctness

occur throughout the production process. Manufacturing technicians are expertly trained to produce high-quality parts and distinguish between acceptable and not acceptable components.

Raw Material Inventory Room	ISO 8 per ISO14644-1 (Class 100,000)		
Manufacturing Cleanroom	ISO 7 per ISO14644-1 (Class 10,000)		
Viable Organism Control	End of Batch Line Clearance Weekly Equipment and Surface Cleaning Routine LpH®, Vesphene®, Spor Klenz® Sanitization		
Viable Organism Monitoring	Quarterly per ISO14698	Air: less than 100 CFU Surface: less than 25 CFU Wall: less than 5 CFU	
Non-Viable Organism Monitoring	Weekly per ISO14644-1	Criteria	0.5µ/m³ 5.0µ/m³

LpH®, Vesphene® and Spor Klenz® are registered trademarks of Steris Corporation.

Diaphragm & Septa Polymer Selection

Specifications and Controls

- Selected for Intended Application
- Elongation
- Tear Strength
- Self-Sealing

Polymer Mixing & Part Molding

Design Space, Operating Ranges and Controls

- Batch-to-Batch material consistency
- 100% component visual inspection
- Lot control

Manufacture & Assembly

Leak Testing & Controls

- Strict SOPs for Assembly
- 100% Leak Testing

Benefits

- Batch to batch Consistent performance
- Cradle to grave traceability from raw material to device assembly and release

The lot to lot consistent performance of TakeOne® is assured by cradle to grave traceability of all raw materials, components, assemblers and assembly parameters. Every sampling line of every device is leak-tested confirming the device was assembled correctly and is ready for use in the most demanding aseptic applications.



Criteria for Selection & Device Certification

USP Class VI	Pass
USP <87> USP <88>	
TSE-BSE	ADCF
Endotoxin	Pass
USP <85>	< 0.125 EU/mL
Sub-Visible Particles	Pass
USP <788>	≤ 3 particles/mL ≥ 25 µm ≤ 10 particles/mL ≥ 10 µm
Gamma Irradiation	Pass
ISO11137-2	

Technical Data

TakeOne® Specifications

Equipment Interface | Mounting Mechanism

25 mm port Ingold® port	up to 3 sampling lines
1.5" Sanitary TC Close coupled	up to 5 sampling lines
2" Sanitary TC Close coupled	up to 9 sampling lines

Operating Parameters

Maximum Steam-in-Place Conditions	1 cycle @ 60 mins at 43 psi 3 bar 143.7 °C
SIP cycles after actuation	10 cycles @ 60 mins at 29 psi 2 bar 134 °C
Actuations per Line	40
Temperature Range	-55 °C to 300 °C
Operating Temperature Range	-20 °C to 50 °C (configuration dependent)
Device Burst Pressure	129 psi 8.9 bar before actuation 105 psi 7.3 bar after actuation
Recommended Maximum Operating Pressure	45 psi 3.1 bar at 25 °C (do not overfill or pressurize collection vessels)

Manufacturing

Manufacturing Environment	ISO® 7
Sterilization Method	Gamma Irradiation (25 kGy – 45 kGy)
Device Release Criteria	100% Leak-Tested (pressure decay)

Materials of Contact (Device Only)

Septum	Platinum-cured Silicone
Equipment Interface	316L Stainless Steel, electropolished (< 15 µin Ra)
2 mm Cannula	316L Stainless Steel, electropolished (< 15 µin Ra)
Tubing Material	Silicone(Pt) or C-Flex® (374)

Regulatory Compliance

Silicone Elastomer for Closures and Tubing	USP 381 EP 3.1.9 21CFR177.2600
Biocompatibility	USP <88> Class VI
Bacterial Endotoxin	USP <85> (<0.125 EU/mL)
Particulate Matter	USP <788> (≤ 3 particles/mL > 25 microns; ≤ 10 particles/mL > 10 microns)

Sartorius, Your Partner to Innovation

At Sartorius, we strive to provide you with innovative products and technologies, and help you successfully implement these in your complex and quality-critical biomanufacturing processes across the globe. Our customers' problems are the objectives we set to overcome and help pioneer the way, setting standards for single-use products in a reliable and economical way.

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
Ingold® is a registered trademark of Mettler-Toledo.

Ordering Information

TakeOne® PDS | Accessories

Catalog Number	Description
QSCUTTERSD	QUICKSEAL® Cutter (small diameter)
QS04CAPSILNT	QUICKSEAL® Silicone caps, 1/4" OD (50/pack)
TKOTCHD	TakeOne® tab actuator lock (5/pack)
INGDEPTH01	TakeOne® 25mm depth accessory 1 (30mm Ingold® port length)
INGDEPTH02	TakeOne® 25mm depth accessory 2 (46mm Ingold® port length)
INGDEPTH03	TakeOne® 25mm depth accessory 3 (52mm Ingold® port length)
INGDEPTH04	TakeOne® 25mm depth accessory 3 (40mm Ingold® port length)

Tank Fitting: 25mm Ingold® Port

Process Step	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog number Silicone	Catalog number TPE	Qty sample lines	30 mL Celsius-Pak®	100 mL Celsius-Pak®	50 mL Flexboy® bag	150 mL Flexboy® bag	250 mL Flexboy® bag	BENCH-MARK®	15 mL Centrifuge tube	60 mL PETG Bottle	Flexboy® Manifold 2 × 50 mL
CC & DI	3	3	INGP03PPDS0104	INGP03CPDS0103	3					3				
CC & DI	3	3	INGP03PPDS0094	INGP03CPDS0093	3				3					
DSP DPF	3	3	INGP03PPDS0098	INGP03CPDS0097	3								3	
M & B CC & DI	3	3	-	INGP03CPDS0109	3		3							
DSP DPF	3	3	-	INGP03CPDS0111	3	1						2		
DSP DPF	4	4	INGP03PPDS0096	INGP03CPDS0095	3							2		1
M & B	22	2	INGP03PPDS0090	INGP03CPDS0089	3			2			1			
CC & DI	22	2	INGP03PPDS0092	INGP03CPDS0091	3			1			1	1		
M & B	22	2	INGP03PPDS0100	INGP03CPDS0099	3				2		1			
M & B	22	2	INGP03PPDS0102	INGP03CPDS0101	3					2	1			
M & B CC & DI	22	2	-	INGP03CPDS0110	3	1			1		1			

M & B = Media | Buffer Preparation
CC & DI = Cell Culture | Downstream Intermediates
DSP = Drug Substance Purification
DPF = Drug Product Formulation

Ordering Information

Tank Fitting: 1.5" Sanitary TC

Process Step	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog number Silicone	Catalog number TPE	Qty sample lines	30 mL Celsius-Pak®	100 mL Celsius-Pak®	50 mL Flexboy® bag	150 mL Flexboy® bag	250 mL Flexboy® bag	BENCH-MARK®	15 mL Centrifuge tube	60 mL PETG Bottle	Flexboy® Manifold 2×50 mL	Flexboy® Manifold 5×50 mL	Flexboy® Manifold 5×250 mL
M&B CC	5	5	24TC05PPDS0086	24TC05CPDS0085	5				5							
DSP DPF	5	5	24TC05PPDS0020	24TC05CPDS0006	5			3				2				
CC&DI	5	5	24TC05PPDS0021	24TC05CPDS0007	5					4		1				
CC&DI	5	5	24TC05PPDS0023	24TC05CPDS0009	5			4				1				
DSP DPF	5	5	24TC05PPDS0027	24TC05CPDS0013	5							5				
CC&DI	5	5	24TC05PPDS0028	24TC05CPDS0014	5					5						
All	5	5	24TC05PPDS0029	24TC05CPDS0015	5			5								
DSP DPF	5	5	24TC05PPDS0032	24TC05CPDS0018	5								5			
M&B CC&DI	5	5	-	24TC05CPDS0105	5		5									
DSP DPF	5	5	-	24TC05CPDS0112	5	2						3				
CC&DI	10	10	24TC05PPDS0074	24TC05CPDS0076	5									5		
CC&DI	19	19	24TC05PPDS0079	24TC05CPDS0080	5									2	3	
M&B	22	2	24TC03PPDS0002	24TC03CPDS0001	3			2			1					
CC&DI	23	3	24TC04PPDS0004	24TC04CPDS0003	4			2			1	1				
M&B CC&DI	23	3	-	24TC05CPDS0106	5	1			2		1	1				
DSP DPF	24	4	24TC05PPDS0019	24TC05CPDS0005	5			3			1	1				
CC&DI	24	4	24TC05PPDS0022	24TC05CPDS0008	5					4	1					
CC&DI	24	4	24TC05PPDS0024	24TC05CPDS0010	5			4			1					
CC&DI	25	25	24TC05PPDS0030	24TC05CPDS0016	5											5
CC&DI	25	25	24TC05PPDS0031	24TC05CPDS0017	5										5	
CC&DI	28	8	24TC05PPDS0077	24TC05CPDS0078	5						1			4		
CC&DI	34	14	24TC05PPDS0081	24TC05CPDS0082	5						1			2	2	
CC&DI	40	20	24TC05PPDS0025	24TC05CPDS0011	5						1					4
CC&DI	40	20	24TC05PPDS0026	24TC05CPDS0012	5						1				4	

M&B = Media | Buffer Preparation

CC&DI = Cell Culture | Downstream Intermediates

DSP = Drug Substance Purification

DPF = Drug Product Formulation

Ordering Information

Tank Fitting: 2" Sanitary TC

Process Step	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog number Silicone	Catalog number TPE	Qty sample lines	30 mL Celsius-Pak®	100 mL Celsius-Pak®	50 mL Flexboy® bag	150 mL Flexboy® bag	250 mL Flexboy® bag	BENCH-MARK®	15 mL Centrifuge tube	60 mL PETG Bottle	Flexboy® Manifold 2 × 50 mL	Flexboy® Manifold 5 × 50 mL
DSP DPF	5	5	32TC05PPDS0042	32TC05CPDS0038	5			3				2			
M & B	5	5	32TC05PPDS0043	32TC05CPDS0039	5			5							
M & B CC & DI	9	9	32TC09PPDS0088	32TC09CPDS0087	9				9						
CC & DI	9	9	32TC09PPDS0057	32TC09CPDS0047	9					8		1			
CC & DI	9	9	32TC09PPDS0060	32TC09CPDS0050	9			8				1			
DSP DPF	9	9	32TC09PPDS0062	32TC09CPDS0052	9							9			
CC & DI	9	9	32TC09PPDS0063	32TC09CPDS0053	9					9					
CC & DI DSP DPF	9	9	32TC09PPDS0065	32TC09CPDS0055	9			9							
DSP DPF	9	9	32TC09PPDS0066	32TC09CPDS0056	9								9		
M & B CC & DI	9	9	-	32TC09CPDS0107	9		9								
DSP DPF	9	9	-	32TC09CPDS0113	9	4						5			
CC & DI	18	18	32TC09PPDS0064	32TC09CPDS0054	9									9	
M & B	22	2	32TC03PPDS0034	32TC03CPDS0033	3			2			1				
CC & DI	23	3	32TC04PPDS0036	32TC04CPDS0035	4			2			1	1			
DSP DPF	24	4	32TC05PPDS0041	32TC05CPDS0037	5			3			1	1			
CC & DI	25	25	32TC05PPDS0044	32TC05CPDS0040	5										5
M & B CC & DI	28	8	32TC09PPDS0058	32TC09CPDS0048	9					8	1				
CC & DI	28	8	32TC09PPDS0061	32TC09CPDS0051	9			8			1				
DPF	28	8	32TC09PPDS0083	32TC09CPDS0084	9			7			1	1			
M & B CC & DI	28	8	-	32TC09CPDS0108	9	2			4		1	2			
CC & DI	30	30	32TC06PPDS0071	32TC06CPDS0072	6										6
CC & DI	33	33	32TC09PPDS0069	32TC09CPDS0070	9			3							6
CC & DI	36	16	32TC09PPDS0059	32TC09CPDS0049	9						1			8	
CC & DI	45	25	32TC06PPDS0046	32TC06CPDS0045	6						1				5
CC & DI	50	30	32TC07PPDS0073	32TC07CPDS0075	7						1				6
CC & DI	52	32	32TC09PPDS0067	32TC09CPDS0068	9			2			1				6

M & B = Media | Buffer Preparation

CC & DI = Cell Culture | Downstream Intermediates

DSP = Drug Substance Purification

DPF = Drug Product Formulation

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