

# Takeone<sup>®</sup> PDS

Pre-Designed Solutions for Aseptic Sampling

Simplifying Progress

**SARTORIUS**

## Takeone® Pre-Designed Solutions

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## Takeone® pre-designed solutions for

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## Digital Selection Map

Select your process step with the desired connection-type

Media | Buffer  
Preparation25 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  
Intermediates25 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  
Purification25 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  
Formulation25 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)

**Takeone® Pre-Designed Solutions**

# 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.

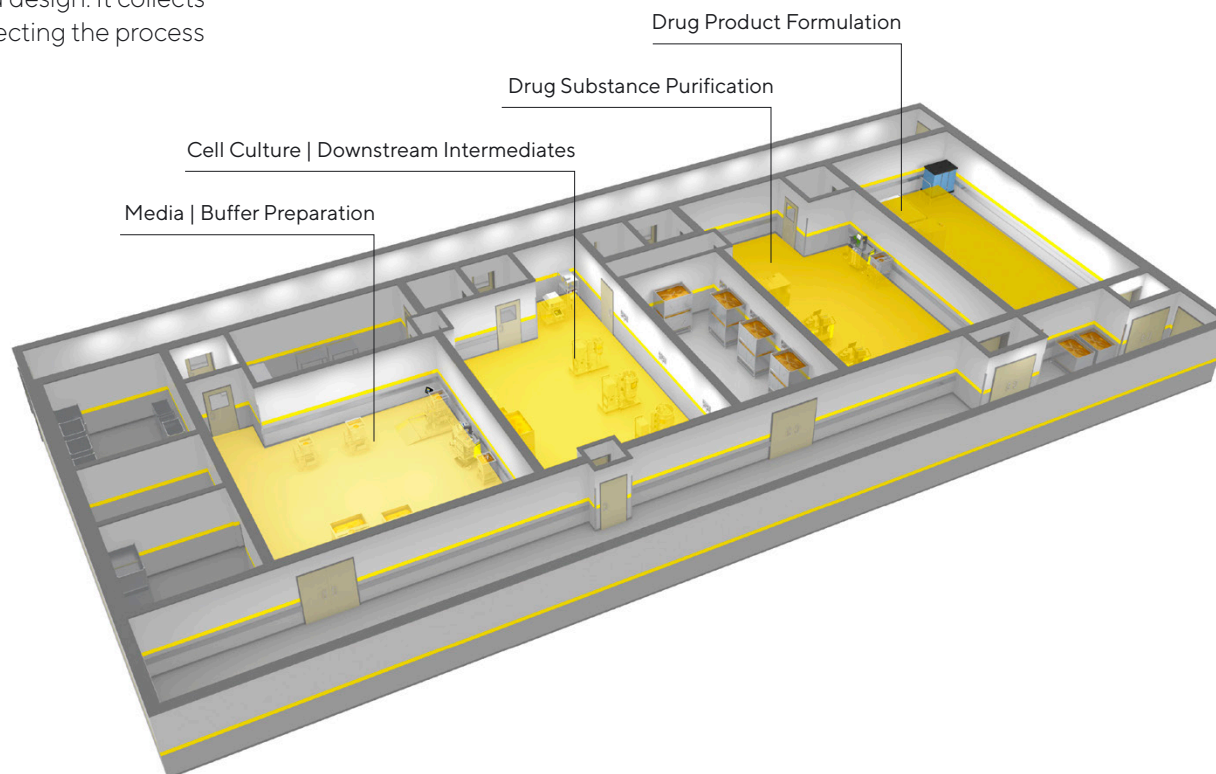
**Microbiological Assays**

Bioburden monitoring is required at every process step to demonstrate process control. Loss of sterility, detection of nonhost 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.



## Takeone® Pre-Designed Solutions

## Select &amp; Go

Simply Select, and Go - Takeone® is easy to use:



1. Install Takeone® aseptic sampling device



2. Sample



3. Disconnect



4. Remove & dispose

### 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.

## Efficient Sampling with Takeone®

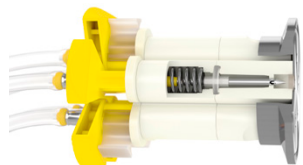
### Ready-To-Use

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.

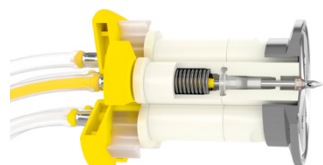
### Rest Assured with Reliable Performance Batch-to-batch

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.

### Cross-Section Before, During and After Actuation



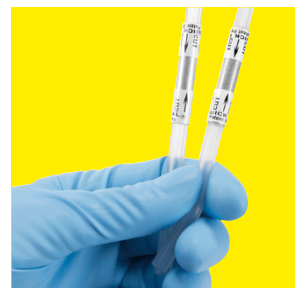
Before and After Actuation



During Actuation

fluid enters  
sampling pathway

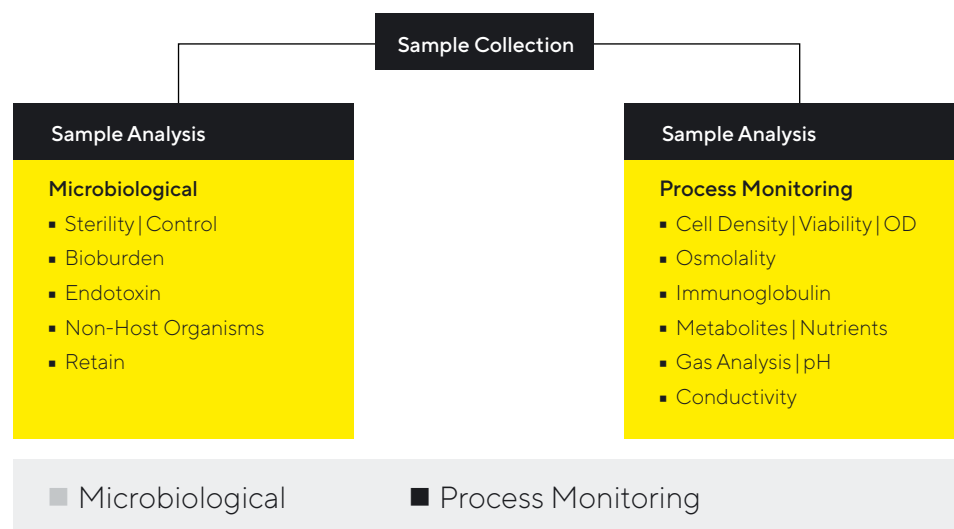
The robust design of Takeone® supports multiple actuation for high-frequency process monitoring samples.



For More Information, Visit  
<https://www.sartorius.com/en/products/fluid-management/transferring-sampling/takeone>

## Takeone® Pre-Designed Solutions

## 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® Bags &amp; Celsius®-Pak Bags

Flexboy® bags 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 &amp; 15 mL Centrifuge 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 Centrifuge 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.





## Takeone® Pre-Designed Solutions

# 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



- Microbiological Assay control for bioburden, endotoxin and sterility
- Process Monitoring for correct balance & concentrations

### Cell Culture | Downstream Intermediates



- Microbiological Assay for non-host organisms to ensure axenic culture
- Process Monitoring for cell count, viability, density, nutrient, gas

### Drug Substance Purification



- Microbiological Assay for bioburden, endotoxins and sterility test
- Especially prior to and at conclusion of filtration, chromatography & UF|DF process steps

### Drug Product Formulation



- Microbiological Assay for bioburden and endotoxin prior to filtration to ensure levels are within regulatory limits

Takeone® Pre-Designed Solutions

# Media | Buffer Preparation

## 2. Identify fitting size for the sampling site

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)

25 mm Ingold® Tank Mount

1.5" Sanitary Tank Mount

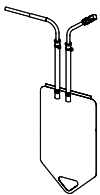
2" Sanitary Tank Mount

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

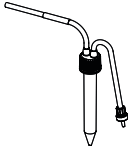
50 mL | 150 mL | 250 mL  
Luer-Activated Access on Outlet  
Tubing with Quickseal®



**Benchmark®**

- Process Monitoring Sampling

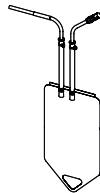
Luer-Activated Access  
Tubing with Quickseal®  
Up to 20 process monitoring samples



**15 mL Polystyrene Centrifuge Tube**

- Microbiological Sampling
- Process Monitoring Sampling

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



**Celsius®-Pak**

- Microbiological Sampling
- Process Monitoring Sampling

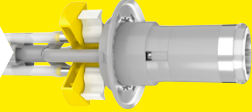
30 mL  
Luer-fitting on Outlet  
C-Flex® Tubing with Quickseal®  
Freeze Applications

Takeone® Pre-Designed Solutions

# Media | Buffer Preparation

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

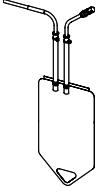
Media | Buffer Preparation

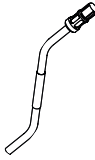


25 mm Ingold® Port  
(up to 3 independent sampling lines)

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

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

50 mL Flexboy®  


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	50 mL Flexboy® Bag	Benchmark®
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	22	2	INGP03PPDS0090	INGP03CPDS0089	3	2	1

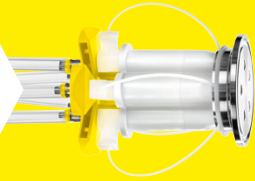


Takeone® Pre-Designed Solutions

# Media | Buffer Preparation

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

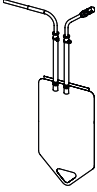
Media | Buffer Preparation

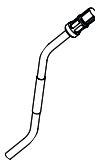


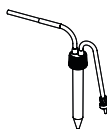
25 mm Ingold® Port  
(up to 3 independent sampling lines)

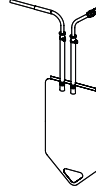
1.5" Sanitary Tank Mount  
(up to 5 independent sampling lines)

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

50 | 150 mL Flexboy®  


Benchmark®  


15 mL Tube  


30 mL Celsius®-Pak  


Ordering Information

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

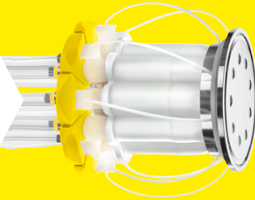
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	30 mL Celsius®-Pak	50 mL Flexboy® Bag	150 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	5	5	24TC05PPDS0029	24TC05CPDS0015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

Takeone® Pre-Designed Solutions

# Media | Buffer Preparation

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

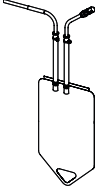
Media | Buffer Preparation

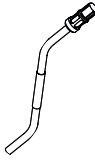


25 mm Ingold® Port  
(up to 3 independent sampling lines)

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

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

50 | 150 | 250 mL  
Flexboy®  


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	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	Benchmark®
1/8" ID x 1/4" OD Length – 6" Quickseal® at 3"	5	5	32TC05PPDS0043	32TC05CPDS0039	5	5	-	-	-
	7	7	32TC07PPDS0088	-	7	-	7	-	-
	28	8	32TC09PPDS0058	32TC09CPDS0048	9	-	-	8	1

## Takeone® Pre-Designed Solutions

## Cell Culture | Downstream Intermediates

## 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

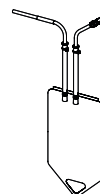


Faceplate: 316L Stainless Steel, Electropolished, Needle: 316L Stainless Steel, Electropolished, Septa: Platinum-Cured Silicone

## 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

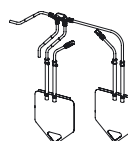
## Sampling Line Options



## Flexboy®

- Microbiological Sampling
- Process Monitoring Sampling

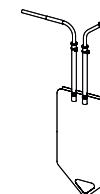
50 mL | 150 mL | 250 mL  
Luer-Activated Access on Outlet  
Tubing with Quickseal®



## 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®



## Celsius®-Pak

- Microbiological Sampling
- Process Monitoring Sampling

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



## 15 mL Polystyrene Centrifuge Tube

- Microbiological Sampling
- Process Monitoring Sampling

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



## Benchmark®

- Process Monitoring Sampling

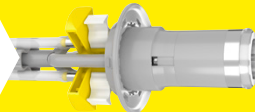
Luer-Activated Access  
Tubing with Quickseal®  
Up to 20 process monitoring samples

Takeone® Pre-Designed Solutions

# Cell Culture | Downstream Intermediates

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  
Flexboy®

15 mL Tube

Benchmark®

Ordering Information

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

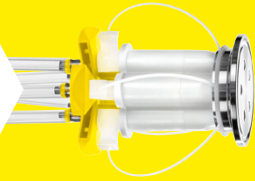
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	50 mL Flexboy® Bag	150 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube
1/8" ID x 1/4" OD	3	3	-	INGP03CPDS0093	3	-	3	-	-
Length - 6"									
Quickseal® at 3"	22	2	INGP03PPDS0092	INGP03CPDS0091	3	1	-	1	1

Takeone® Pre-Designed Solutions

# Cell Culture | Downstream Intermediates

## 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)

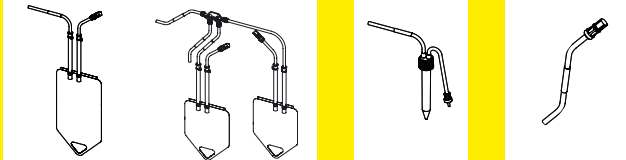
2" Sanitary Tank Mount  
(up to 9 independent sampling lines)

50 | 150 | 250 mL  
Flexboy®

2 × 50 mL  
Flexboy®

15 mL Tube

Benchmark®



### Ordering Information (1/2)

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

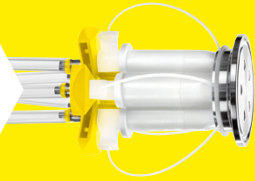
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	2 × 50 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube
1/8" ID × 1/4" OD Length – 6" Quickseal® at 3"	5	5	-	24TC05CPDS0007	5	-	-	4	-	-	1
	5	5	24TC05PPDS0023	-	5	4	-	-	-	-	1
	5	5	24TC05PPDS0028	24TC05CPDS0014	5	-	-	5	-	-	-
	5	5	24TC05PPDS0029	24TC05CPDS0015	5	5	5	-	-	-	-
	5	5	24TC05PPDS0086	-	5	-	5	-	-	-	-
	10	10	24TC05PPDS0074	24TC05CPDS0076	5	-	-	-	5	-	-
	23	3	24TC04PPDS0004	-	4	2	-	-	-	1	1

Takeone® Pre-Designed Solutions

# Cell Culture | Downstream Intermediates

### 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)

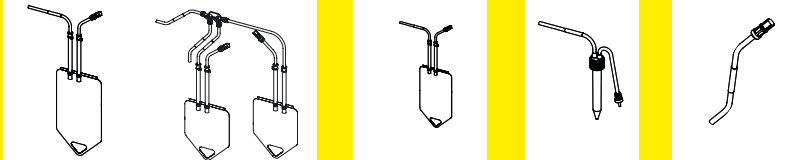
50 | 150 | 250 mL  
Flexboy®

2 x 50 mL  
Flexboy®

30 mL  
Celsius®-Pak

15 mL Tube

Benchmark®



### Ordering Information (2/2)

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	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	2 x 50 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	23	3	-	24TC05CPDS0106	5	1	-	2	-	-	1	1
	24	4	24TC05PPDS0022	24TC05CPDS0008	5	-	-	-	4	-	1	-
	24	4	24TC05PPDS0024	24TC05CPDS0010	5	-	4	-	-	-	1	-
	28	8	-	24TC05CPDS0078	5	-	-	-	-	4	1	-

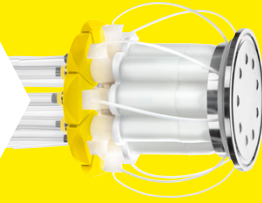


Takeone® Pre-Designed Solutions

# Cell Culture | Downstream Intermediates

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

Cell Culture | Downstream Intermediates



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

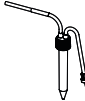
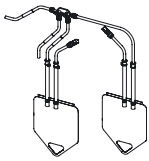
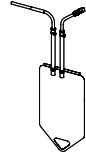
1.5" Sanitary Tank Mount  
(up to 5 independent sampling lines)

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

50 | 150 | 250 mL  
Flexboy®

2 x 50 mL  
Flexboy®

15 mL Tube



### Ordering Information (1/2)

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

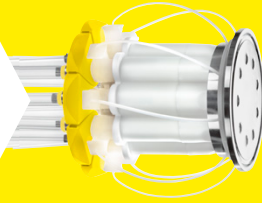
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	2 x 50 mL Flexboy® Bag	15 mL Centrifuge Tube
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	9	9	32TC09PPDS0057	32TC09CPDS0047	9	-	-	8	-	1
	9	9	32TC09PPDS0063	32TC09CPDS0053	9	-	-	9	-	-
	9	9	32TC09PPDS0065	32TC09CPDS0055	9	9	-	-	-	-
	18	18	32TC09PPDS0064	32TC09CPDS0054	9	-	-	-	9	-

Takeone® Pre-Designed Solutions

# Cell Culture | Downstream Intermediates

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

Cell Culture | Downstream Intermediates



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

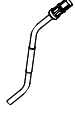
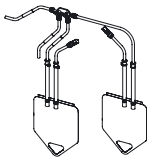
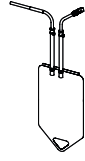
1.5" Sanitary Tank Mount  
(up to 5 independent sampling lines)

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

50 | 250 mL  
Flexboy®

2 x 50 mL  
Flexboy®

Benchmark®



### Ordering Information (2/2)

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	50 mL Flexboy® Bag	250 mL Flexboy® Bag	2 x 50 mL Flexboy® Bag	Benchmark®
1/8" ID x 1/4" OD Length – 6" Quickseal® at 3"	28	8	32TC09PPDS0058	32TC09CPDS0048	9	-	8	-	1
	28	8	32TC09PPDS0061	32TC09CPDS0051	9	8	-	-	1
	36	16	32TC09PPDS0059	32TC09CPDS0049	9	-	-	8	1

Takeone® Pre-Designed Solutions

# Drug Substance Purification

## 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

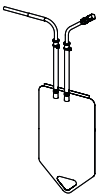
2" Sanitary Tank Mount

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

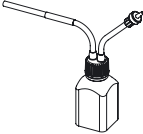
## Sampling Line Options



**Flexboy®**

- Microbiological Sampling
- Process Monitoring Sampling

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



**Nalgene® 60 mL PETG Bottle**

- Microbiological Sampling
- Process Monitoring Sampling

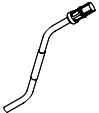
Mycap® Bottle Closure  
25 mm Minisart® Vent Filter  
Tubing with Quickseal®



**15 mL Polystyrene Centrifuge Tube**

- Microbiological Sampling
- Process Monitoring Sampling

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



**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.  
Ingold® is a registered trademark of Mettler-Toledo.

Takeone® Pre-Designed Solutions

# Drug Substance Purification

### 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)

60 mL PETG Bottle



### Ordering Information

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

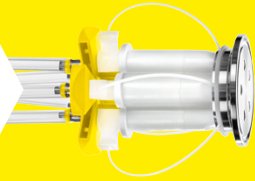
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	60 mL PETG bottle
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	3	3	INGP03PPDS0098	INGP03CPDS0097	3	3

Takeone® Pre-Designed Solutions

Drug Substance Purification

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

Drug Substance Purification

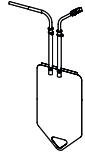


25 mm Ingold® Port  
(up to 3 independent sampling lines)

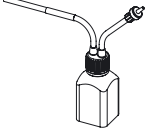
1.5" Sanitary Tank Mount  
(up to 5 independent sampling lines)

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


50 mL  
Flexboy®



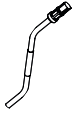
60 mL PETG  
Bottle



15 mL Tube



Benchmark®



Ordering Information

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

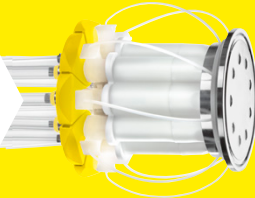
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	50 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID x 1/4" OD Length – 6" Quickseal® at 3"	5	5	-	24TC05CPDS0006	5	3	-	2	-
	5	5	24TC05PPDS0027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

Takeone® Pre-Designed Solutions

Drug Substance Purification

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

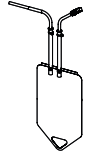
Drug Substance Purification

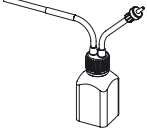



25 mm Ingold® Port  
(up to 3 independent sampling lines)

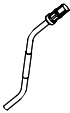
1.5" Sanitary Tank Mount  
(up to 5 independent sampling lines)

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

50 mL Flexboy®  


60 mL PETG Bottle  


15 mL Tube  


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	50 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID x 1/4" OD Length – 6" Quickseal® at 3"	5	5	32TC05PPDS0042	-	5	3	-	2	-
	9	9	32TC09PPDS0062	32TC09CPDS0052	9	-	-	9	-
	9	9	32TC09PPDS0065	32TC09CPDS0055	9	9	-	-	-
	9	9	32TC09PPDS0066	32TC09CPDS0056	9	-	-	-	9
	24	4	-	32TC05CPDS0037	5	3	1	1	-



## Takeone® Pre-Designed Solutions

## Drug Product Formulation

## 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



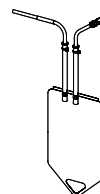
2" Sanitary Tank Mount

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

## Formulation, Fill | Finish Aseptic Sampling Guidelines

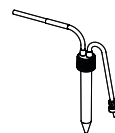
Formulation	Microbiological	Bioburden and Endotoxin at end of process
	Process Monitoring	Osmolality, Concentrations pH, Conductivity, Critical process parameters
Fill   Finish	Microbiological	Bioburden and Endotoxin prior to Fill   Finish
Sterile Filtration	Microbiological	Bioburden prior to any 0.2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

## Sampling Line Options

**Flexboy®**

- Microbiological Sampling
- Process Monitoring Sampling

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

**15 mL Polystyrene Centrifuge Tube**

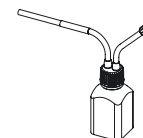
- Microbiological Sampling
- Process Monitoring Sampling

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

**Benchmark®**

- Process Monitoring Sampling

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

**Nalgene® 60 mL PETG Bottle**

- Microbiological Sampling
- Process Monitoring Sampling

Mycap® Bottle Closure  
25 mm Minisart® Vent Filter  
Tubing with Quickseal®

Takeone® Pre-Designed Solutions

# 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)

60 mL PETG Bottle



Ordering Information

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

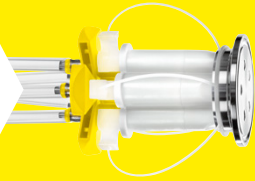
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	60 mL PETG bottle
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	3	3	INGP03PPDS0098	INGP03CPDS0097	3	3

Takeone® Pre-Designed Solutions

# Drug Product Formulation

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

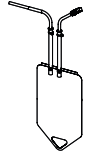
Drug Product Formulation

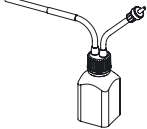



25 mm Ingold® Port  
(up to 3 independent sampling lines)


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

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

50 mL Flexboy®  


60 mL PETG Bottle  


15 mL Tube  


Benchmark®  


### Ordering Information

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

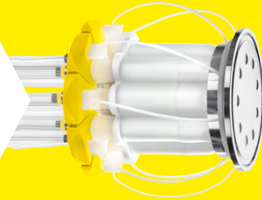
Tubing Features	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	50 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID x 1/4" OD Length – 6" Quickseal® at 3"	5	5	-	24TC05CPDS0006	5	3	-	2	-
	5	5	24TC05PPDS0027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

Takeone® Pre-Designed Solutions

# Drug Product Formulation

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

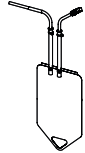
Drug Product Formulation

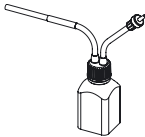



25 mm Ingold® Port  
(up to 3 independent sampling lines)

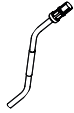
1.5" Sanitary Tank Mount  
(up to 5 independent sampling lines)

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

50 mL Flexboy®  


60 mL PETG Bottle  


15 mL Tube  


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	50 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube	60 mL PETG bottle
1/8" ID x 1/4" OD Length - 6" Quickseal® at 3"	5	5	32TC05PPDS0042	-	5	3	-	2	-
	9	9	32TC09PPDS0062	32TC09CPDS0052	9	-	-	9	-
	9	9	32TC09PPDS0065	32TC09CPDS0055	9	9	-	-	-
	9	9	32TC09PPDS0066	32TC09CPDS0056	9	-	-	-	9
	24	4	-	32TC05CPDS0037	5	3	1	1	-
	28	8	32TC09PPDS0083	32TC09CPDS0084	9	7	1	1	-

## Takeone® Pre-Designed Solutions

# 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 USP <85>	Pass < 0.125 EU/mL
Sub-Visible Particles USP <788>	Pass < 3 particles/mL > 25 µm <10 particles/mL >10 µm
Gamma Irradiation ISO11137-2	Pass

Takeone® Pre-Designed Solutions

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.



Takeone® Pre-Designed Solutions

Ordering Information

Takeone® PDS | Accessories

Catalog Number	Description
QSCUTTERSD	Quickseal® Cutter (small diameter)
QS04CAPSILNT	Quickseal® Silicone caps, ¼" OD (50/pack)
TKOTCHD	Takeone® tab actuator lock (5/pack)
INGDEPTH01	Takeone® 25 mm depth accessory 1 (30 mm Ingold® port length)
INGDEPTH02	Takeone® 25 mm depth accessory 2 (46 mm Ingold® port length)
INGDEPTH03	Takeone® 25 mm depth accessory 3 (52 mm Ingold® port length)
INGDEPTH04	Takeone® 25 mm depth accessory 4 (40 mm Ingold® port length)

Ingold® is a registered trademark of Mettler-Toledo.

Tank Fitting: 25 mm Ingold® Port

Process Step	Total Sampling Capacity	(of which) Micro-biological Monitoring	Catalog Number Silicone	Catalog Number TPE	Qty Sample Lines	50 mL Flexboy® Bag	150 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube	60 mL PETG Bottle
CC & DI	3	3	-	INGP03CPDS0093	3		3			
DSP   DPF	3	3	INGP03PPDS0098	INGP03CPDS0097	3					3
M & B	22	2	INGP03PPDS0090	INGP03CPDS0089	3	2		1		
CC & DI	22	2	INGP03PPDS0092	INGP03CPDS0091	3	1		1	1	

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

## Takeone® Pre-Designed Solutions

## 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	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
M & B   CC	5	5	24TC05PPDS0086	-	5			5					
DSP   DPF	5	5	-	24TC05CPDS0006	5		3				2		
CC & DI	5	5	-	24TC05CPDS0007	5				4		1		
CC & DI	5	5	24TC05PPDS0023	-	5		4				1		
DSP   DPF	5	5	24TC05PPDS0027	-	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	
CC & DI	10	10	24TC05PPDS0074	24TC05CPDS0076	5								5
M & B	22	2	24TC03PPDS0002	24TC03CPDS0001	3		2			1			
CC & DI	23	3	24TC04PPDS0004	-	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	28	8	-	24TC05CPDS0078	5					1			4

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

Takeone® Pre-Designed Solutions

# 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	50 mL Flexboy® Bag	150 mL Flexboy® Bag	250 mL Flexboy® Bag	Benchmark®	15 mL Centrifuge Tube	60 mL PETG Bottle	Flexboy® Manifold 2 × 50 mL
DSP   DPF	5	5	32TC05PPDS0042	-	5	3				2		
M & B	5	5	32TC05PPDS0043	32TC05CPDS0039	5	5						
M & B	7	7	32TC07PPDS0088	-	7		7					
CC & DI	9	9	32TC09PPDS0057	32TC09CPDS0047	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	
CC & DI	18	18	32TC09PPDS0064	32TC09CPDS0054	9							9
DSP   DPF	24	4	-	32TC05CPDS0037	5	3			1	1		
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		
CC & DI	36	16	32TC09PPDS0059	32TC09CPDS0049	9				1			8

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

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