

Takeone[®] Aseptic Sampling Solutions

For Stainless Steel
Processes

Simplifying Progress

SARTORIUS



Security in Simplicity Knock Out Bioburden at the Source

The Problem

4 out of 10 observations in Form FDA 483s are due to a lack of microbiological controls.

Our Solution

Not all samples are equal – and we don't treat them that way. Whether it is sterility, bioburden, endotoxin testing or routine process monitoring, the Takeone® device has been designed for your process demands.

With Takeone® reduce the risk of contamination that could delay production times and reduce complexity in your processes.

Enjoy Simplicity. Unpack, Clamp & Go!



Takeone® Benefits

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.

Sample Securely

Only a factory assembled aseptic sampling device can make this claim. Not only do you never need to touch a needle – it gives you assurance that your Takeone® is built right and can be relied upon.

Every sampling line of every Takeone® device is leak tested after assembly for reliable performance batch-to-batch.

Save up to 3 Months' Time

Takeone® was conceived to embrace the benefits of single-use technology.



3 min Unpack & Connect



**3 min × 1,500 Devices / Year
= 2 Man Weeks Used**

Hybrid Single | Multi-Use Systems



3 min Unpack & Connect + **6 min Parts Washing** + **4 min Equipment Prep** + **3 min Assembly** + **3 min Disassembly**



**19 min × 1,500 Devices / Year
= 12 Man Weeks Used**

Reduce Costs

You no longer need to over sample. Samples collected from a process are valuable product that cannot be replaced. Sartorius offers a wide variety of sample containers and procedures that can save valuable product.

Protect Sample & Product

The patented and intuitive Quickseal® aseptic disconnect is designed to easily remove the collection vessel. Thanks to its specially molded aluminum collar, quickly and securely cut apart the components.

A Solution for All Your Sampling Needs

Samples collected with Takeone® are used to measure critical purity attributes such as bioburden, sterility and endotoxin levels and important process parameters like metabolites, nutrients, osmolality, pH and more.

From Our Standard Range of Products:

Takeone® PDS (Pre-Designed Solution)

Select & Go
Choose from our 100 designs based on manufacturing step.



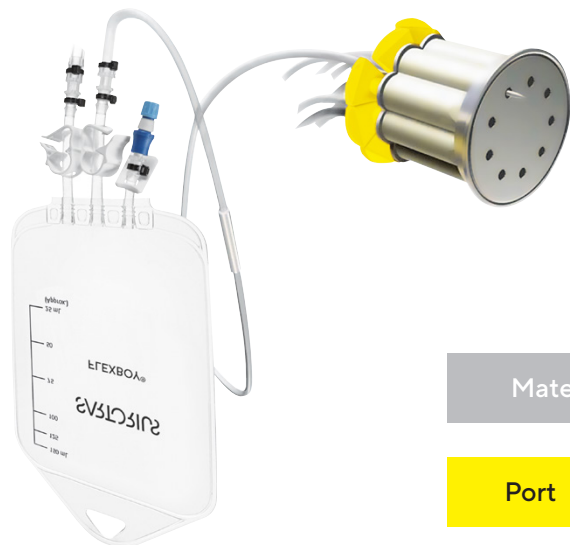
Takeone® Flex

Plan & Adapt
With just a few SKUs, easily expand your configuration options - at the moment of sampling.



Fully Customizable Products

Takeone® Design Services



Configure-To-Order
Need a little extra fine-tuning: standard features adjusted to your needs.

Engineer-To-Order
Engineered designs to match your exact requirements, right down to your allocated unique part number.

Material	Storage	Connector	Container type	
Port	Length	Sampling	Volume	Quotation

Takeone® Solutions

Device

Spring-Loaded Actuator

- Never touch a needle
- Better sample volume accuracy

Glass Reinforced Polyester Body

Hermetically sealed cannula diaphragm

2 mm Cannula

Electropolished 316 L stainless steel

Silicone Septa

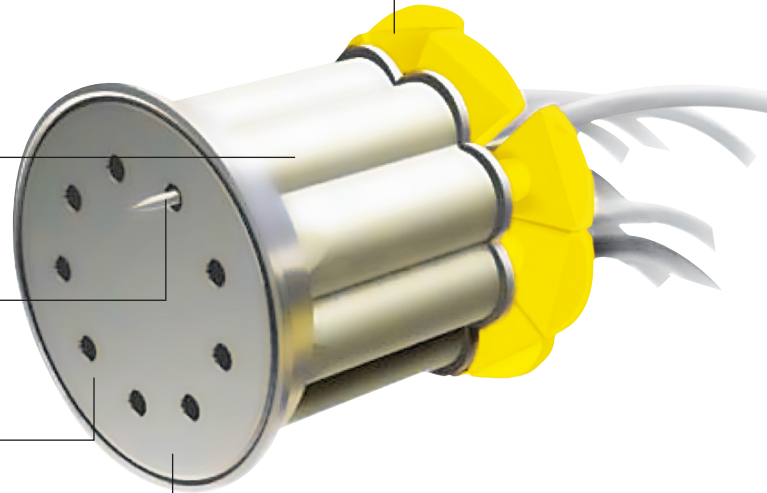
- Platinum-cured
- Self-sealing

Mount

Electropolished 316 L stainless steel

Quickseal®

Aseptic tube separation Platinum-cured Silicone, TPE & other tubing



Ingold® is a registered trademark of Mettler-Toledo.





Available sizes:

- 25 mm with up to 3 sampling lines (for Ingold® ports)
- 1.5" with up to 5 sampling lines
- 2" with up to 9 sampling lines

Sample Containers

Tailored to your needs, choose from: Bags, bottles, syringe access sites and tubes.



Flexboy® Bags

- Easy handling
- 50 | 150 | 250 | 500 | 1,000 mL



Flexsafe® Bags

- 20 | 50 | 150 | 250 | 500 | 1,000 mL



Celsius®-Pak Bags

- Freeze applications
- 30 | 100 mL



PETG Bottles

- Free standing
- 30 | 60 | 125 | 250 | 500 | 1,000 mL



Centrifuge Tubes

- High accuracy
- 15 | 50 mL



Manifolds with purge bag

- Increase capacity



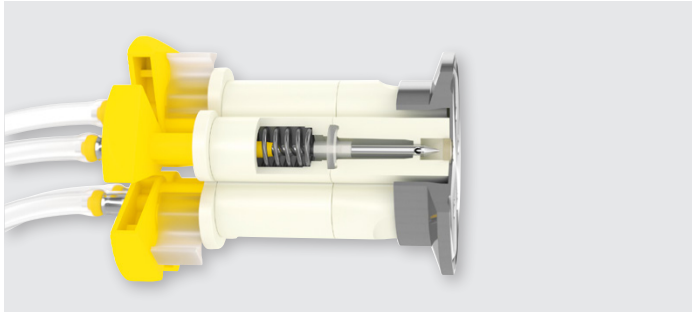
BENCHMARK®

- High capacity sampling
- Optional check valve (for needle-free syringes)

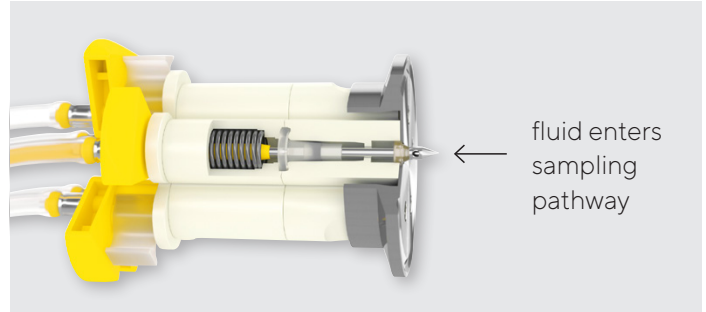
Protect Your Process Integrity

There are 6 sources of bioburden: people, raw materials, facilities, equipment, process & utilities. Takeone® knocks out each of the sources of bioburden by being pre-assembled and ready-to-use.

Cross-Section Before, During and After Actuation



Before and After Actuation



During Actuation

- Every Takeone® solution maintains a 316L stainless steel face plate. This ensures compatibility with all your stainless steel equipment and does not introduce any new product contact materials.
- Every Takeone® solution sits at the interface of the vessel taking a true representative sample. Takeone® devices have been engineered to always reach the product container interface and avoid sampling the dead-leg space of the port.
- The unique design of Takeone® integrates an aseptic chamber to ensure a closed fluid pathway preventing any risk of microbial ingress.
- Be confident in the performance of your device. Takeone® has repeatedly demonstrated that its septum & aseptic chamber can undergo multiple actuations or SIP cycles without failure.
- Have complete control of sample volumes and improve sampling accuracy. A spring located inside the body of the device causes the needle to return to its starting position when released, protecting unsupervised sample collection containers from overfilling.

Sustainability

Did you know? With sustainability being one of our key drivers, we investigated the waste management cycle of Takeone®. As the device is in direct contact with biologically active components, whatever its composition, it is usually treated as medical-grade waste. In partnership with a medical waste company, the life cycle of Takeone® was investigated and it was confirmed that, after use, with its stainless steel parts: face plate and cannulas, Takeone® can be incinerated to produce new energy – it's called energy cogeneration! Talk to your facility managers about it. Diligent waste management requires collaborative efforts.

We've Got You Covered

Meeting cGMP Guidelines

Takeone® is assembled in an ISO 7 certified cleanroom in accordance with applicable cGMP guidelines. Each device undergoes a variety of in-process quality inspections including visual inspection and sampling line integrity testing.

Takeone® device meets or exceeds requirements as described in the table:

To assist you in following industry requirements, a detailed validation guide is available upon request.

Claim	Conformity
Sterility	ISO 11137-2 gamma irradiation > 25 kGy
Sterility - 10 SIP max	60 mins at 30 psig 2 bar 134.5°C
Assembly Manufacturing Space	ISO 7 per ISO 14644-1 (Class 10,000)
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)
Particulates	USP <788> (≤ 3 particles/mL >25 microns; ≤ 10 particles/mL >10 microns)

Confidence® Services for Takeone®

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

- Extractables | Leachables studies
- Physio-Chemical studies

Just Ask Our Application Support

Our expert Application Specialists provide global support for:

- Single-use process URS definitions and application development
- Process design with standard and custom solutions
- Sampling Plan Optimization
- SOP development, process validation and operator training
- Technology transfer and process optimization

Sartorius, Your Partner to Innovation

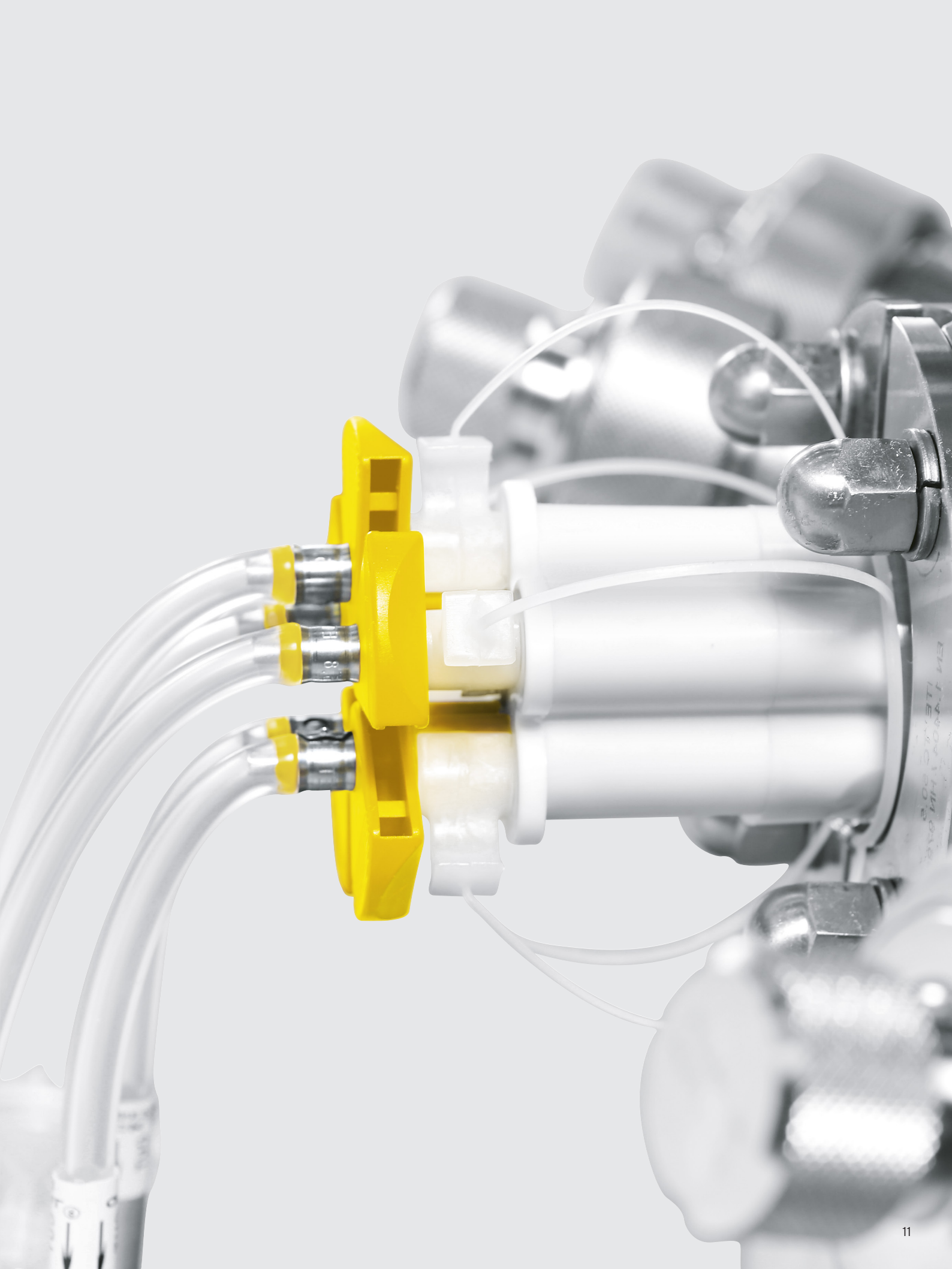
At Sartorius we strive to provide you with innovative products and technologies, and help you successfully implement these in your complex and quality-critical biomanufacturing processes across the globe. Our customers' problems are the objectives we set to overcome and help pioneer the way, setting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



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
Sampling Mechanism	2 mm cannula (needle) pierces self-sealing platinum-cured silicone septum
Sterilization Method	Gamma Irradiation (25 kGy – 45 kGy)
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)
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)
Manufacturing Environment	ISO 7
Device Release Criteria	100% Leak-Tested (pressure decay)
Silicone Elastomer For Closures and Tubing	USP 381 EP 3.1.9 21CFR177.2600
Materials of Construction – Mounting Mechanism	316L Stainless Steel, electropolished (<15 µin Ra)
Materials of Construction – 2mm Cannula	316L Stainless Steel, electropolished (<15 µin Ra)
Material of Construction – Takeone® Body	Polybutylene terephthalate (PBT), glass reinforced (non-product contact)
Aseptic Disconnect	Quickseal® Aseptic Disconnect. (non-product contact)




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Specifications subject to change without notice.

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