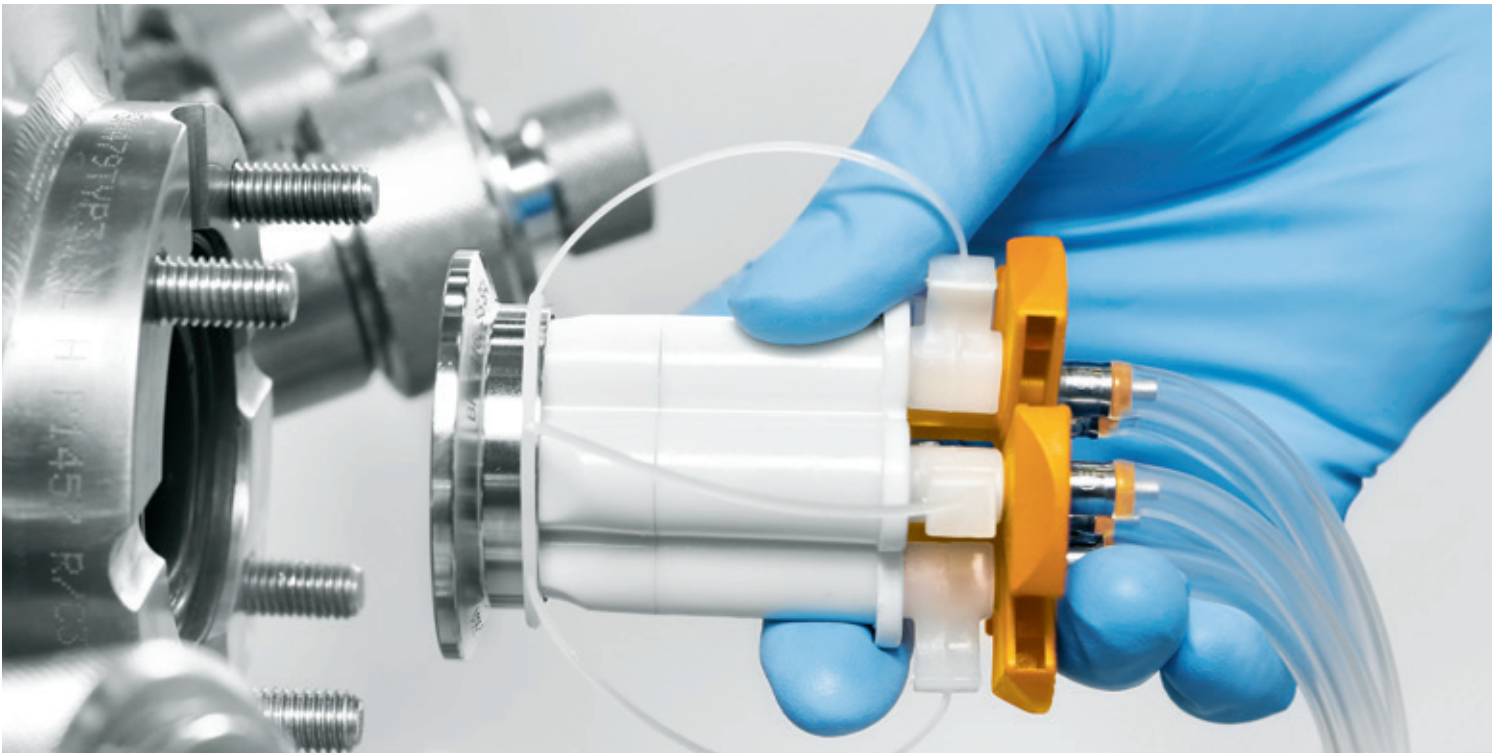




sartorius stedim
biotech

TakeOne[®] Aseptic Sampling Solutions The Heart of Your Microbial Control Program



turning science **into solutions**

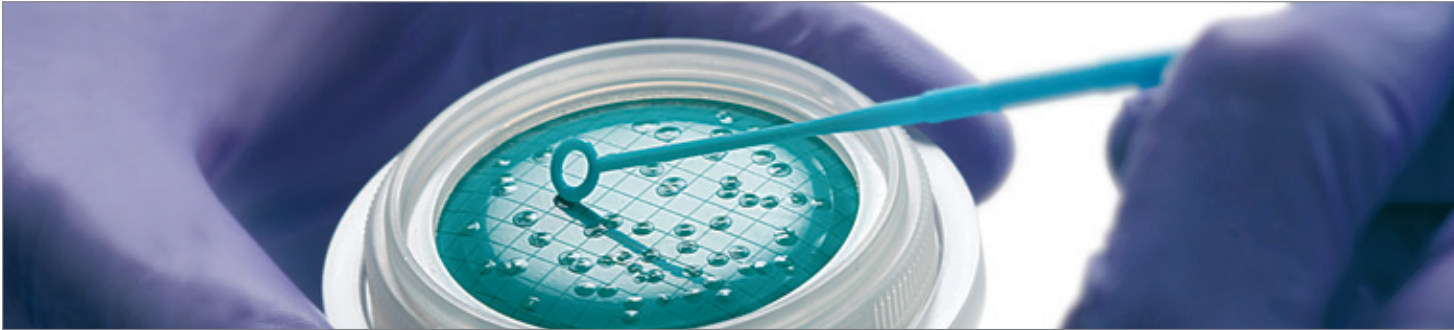


Enjoy Simplicity. Unpack, Clamp & Go!



Security in Simplicity

Knock out Bioburden at the Source



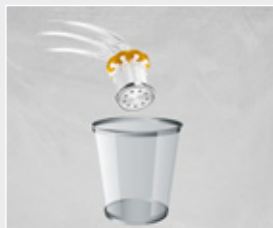
The Problem

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, reduce complexity in your processes and keep your operators as safe as possible.



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 Safely

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.

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.

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 + 6 min + 4 min + 3 min + 3 min

Unpack | Parts Equipment Assembly Disassembly
Connect Washing Prep



19 min × 1,500 Devices/Year

= 12 Man Weeks Used



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.

Alternatively, Discover Our:

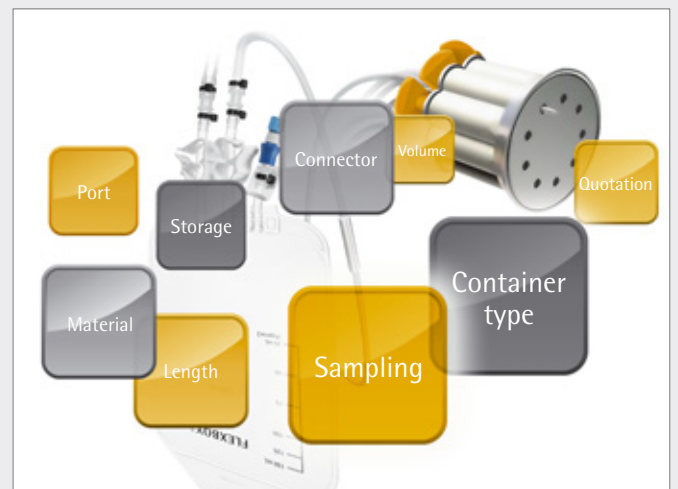
TakeOne® Design Services

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.



TakeOne[®] Solutions

Device

Spring-Loaded Actuator

- Never touch a needle
- Enhances operator safety
- Better sample volume accuracy

Glass Reinforced Polyester Body

Hermetically sealed cannula diaphragm

2 mm Cannula

Electropolished 316L stainless steel

Silicone Septa

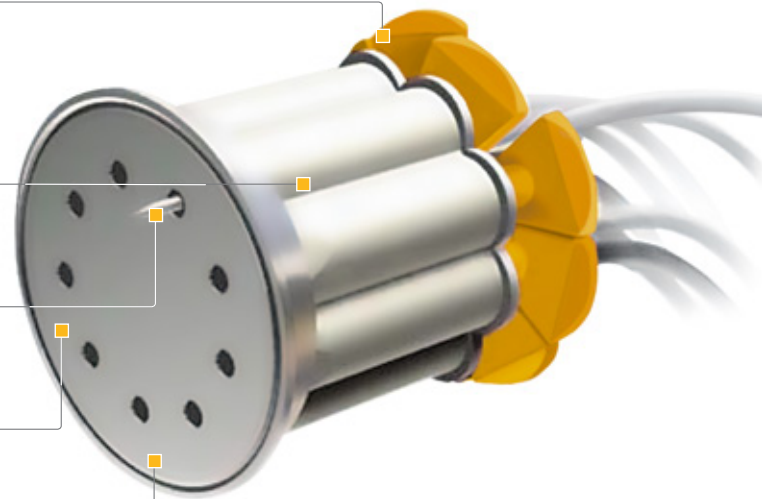
- Platinum-cured
- Self-sealing

Mount

Electropolished 316L stainless steel

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





QUICKSEAL®

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

Sample Containers

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



Flexboy® Bags

- Easy handling
- 50 | 150 | 250 | 500 | 1000 mL



Celsius®-Pak Bags

- Freeze applications
- 30 | 100 mL



PETG Bottles

- Free standing
- 30 | 60 | 125 | 250 | 500 | 1000 mL



Centrifuge Tubes

- High accuracy
- 15 | 50 mL



BENCHMARK®

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

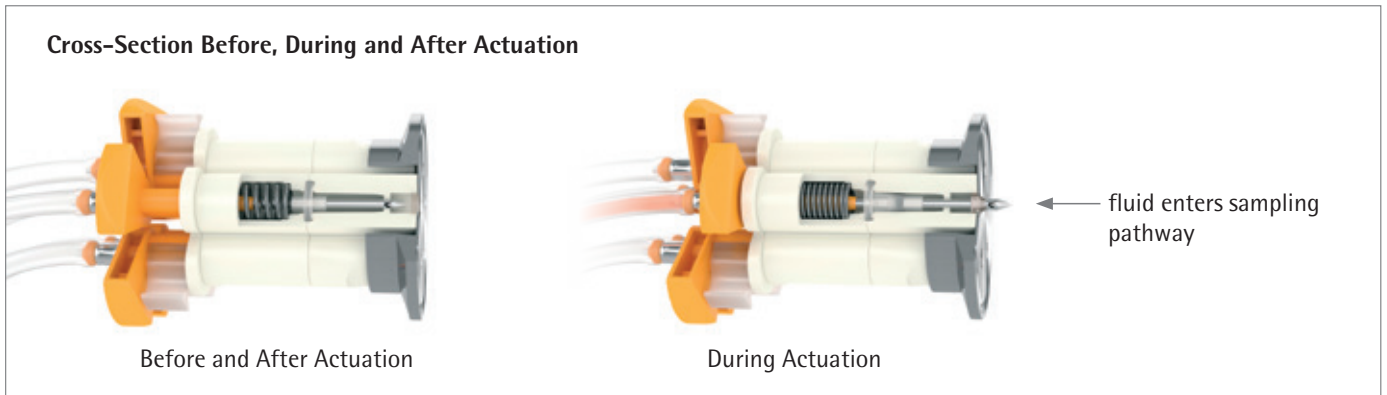


Manifolds with purge bag

- Increase capacity

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.



- 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 and 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.

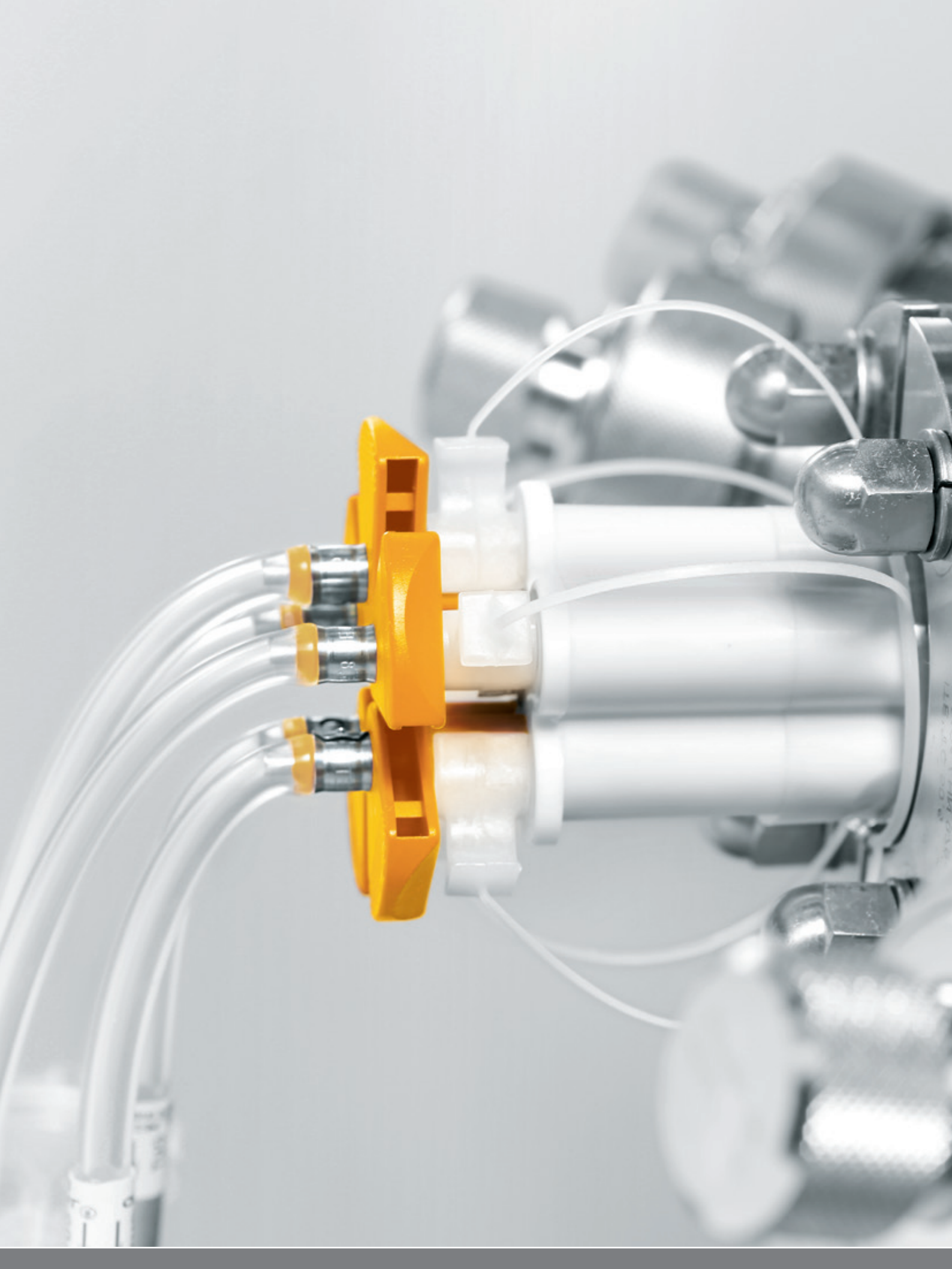
Our customers' problems are the objectives we set to overcome and help pioneer the way, setting standards for single-use products in a reliable and economical way.



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)



Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5-7
34302 Guxhagen
Phone +49.5665.407.0

France

Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques - CS 91051
13781 Aubagne Cedex
Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques - CS 71058
13781 Aubagne Cedex
Phone +33.442.845600

Austria

Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna
Phone +43.1.7965763.18

Belgium

Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles
Phone +32.2.756.06.80

Hungary

Sartorius Stedim Hungária Kft.
Kagyló u. 5
2092 Budakeszi
Phone +36.23.457.227

Italy

Sartorius Stedim Italy S.r.l.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)
Phone +39.055.63.40.41

Netherlands

Sartorius Stedim Netherlands B.V.
Phone +31.30.60.25.080
filtratie.nederland@sartorius-stedim.com

Poland

Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn
Phone +48.61.647.38.40

Russian Federation

LLC "Sartorius Stedim RUS"
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg
Phone +7.812.327.53.27

Spain

Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)
Phone +34.913.586.098

Switzerland

Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen
Phone +41.52.354.36.36

U.K.

Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QQ
Phone +44.1372.737159

Ukraine

LLC "Sartorius Stedim RUS"
Post Box 440 "B"
01001 Kiev, Ukraine
Phone +380.44.411.4918

Americas

USA

Sartorius Stedim North America Inc.
5 Orville Drive, Suite 200
Bohemia, NY 11716
Toll-Free +1.800.368.7178

Argentina

Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires
Phone +54.11.4721.0505

Brazil

Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil
Phone +55.11.4362.8900

Mexico

Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepotzotlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepotzotlan,
Estado de México,
C.P. 54605
Phone +52.55.5562.1102
leadsmex@sartorius.com

Asia | Pacific

Australia

Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175
Phone +61.3.8762.1800

China

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China
Phone +86.21.6878.2300

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Beijing Branch Office
No. 33 Yu'an Road
Airport Industrial Park Zone B
Shunyi District, Beijing 101300
Phone +86.10.8042.6501

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Guangzhou Branch Office
Room 1105
Xing Guang Ying Jing Building
No. 119, Shui Yin Road
Yue Xiu District, Guangzhou 510075
Phone +86.20.3836.4193

India

Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India
Phone +91.80.4350.5250

Japan

Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan
Phone +81.3.4331.4300

Malaysia

Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia
Phone +60.3.8996.0622

Singapore

Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684
Phone +65.6872.3966

South Korea

Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space B/D,
PanGyoYeok-Ro 220, Bundang-Gu
SeongNam-Si, GyeongGi-Do, 463-400
Phone +82.31.622.5700



▶ www.sartorius-stedim.com