Sterisart®

Redefining Industry Standards

Simplifying Progress

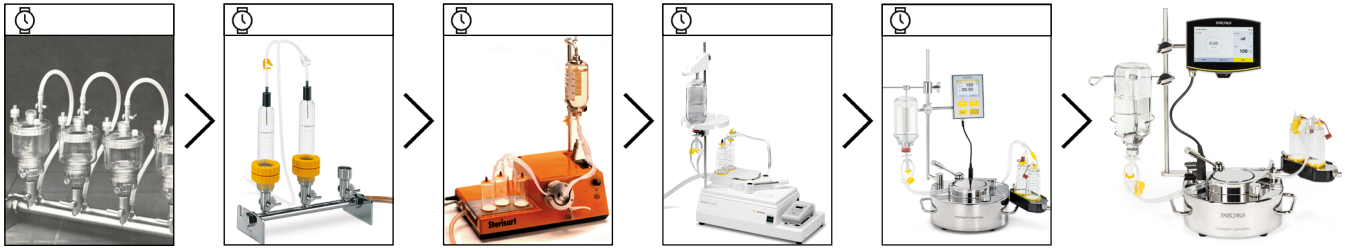
SARTORIUS

Our History- Sterility Testing

Sartorius, established in 1870, has a rich and diverse history. Founded as a company developing precision measuring instruments for academic research laboratories, it has transformed into a global enterprise supporting the biopharmaceutical industry through innovative technologies. These technologies enable our customers to develop therapies more efficiently, more economically, and ensures that these therapies remain safe for patient use.

In 1927, Sartorius co-founded a company manufacturing membrane filters which for the first time made the sterilisation of heat-sensitive solutions possible. These membranes have been continually enhanced for a range of applications and remain at the core of our current offering.

In the late 1960's, identifying a major need to ensure that pharmaceuticals are free of microbial contamination, Sartorius partnered with leading scientific institutes and the German pharmaceutical industry to develop the appropriate methods and tools. Besides sterilising grade membranes, Sartorius developed membrane filters for use in the predecessor of the modern single-use sterility test system. The 'Schiller system', as it was known in Germany, was part of the Sartorius portfolio and was the first closed, reusable sterility test which was in widespread use in Europe in the early 70's. Its successor, the Sterisart® family, through small but judicious innovations, has been at the vanguard and continues to redefine the standards of sterility testing today.



Innovation Timeline

Two Decades of Innovation

1999	2003	2006	2007	2008	2010	2015	2016	2024
								
First Gamma Sterilized units with raised venting filters	First Fully Metal Dual Needle	First Double Packaging Design	Non-Coring Needle	Sterisart® Universal Pump	First Integrated Septum Port	First Tethered Filter Caps	First Easy Access Canister Plugs	Sterisart® Universal Pump | Gen 4 (Built for 21 CFR Part11andAnnex11)

We believe in continuous improvement and are committed to serving the needs of our customers. Through regular discussions with our customers we have continually adapted and bettered our range of sterility testing solutions. In doing so we have redefined industry standards.

Sterility Testing Canisters

Sterisart® NF System

For more information please click on the +

State-of-the-art closed filtration system for lot-release sterility testing of sterile pharmaceuticals.

The Sterisart® NF system is easy to use and ensures the maximum reliability of your sterility test results.

The portfolio includes a number of devices adapted to cater to your specific sterility testing needs and is fully compliant with all pharmacopeial and regulatory requirements.

See Brochure

See Flyer

See Datasheet

See Second Supplier Validation Guide

Key Features and Benefits:

- Covers all standard sterility testing applications
- Compact, closed, ergonomic design
- Specially constructed needles for safe and easy piercing
- Guaranteed sterile barrier for aseptic septum sampling
- Gas-impermeable, color- and bar-coded packaging
- Adapters for use of the Sterisart® NF system in all pumps
- Meticulously controlled quality testing
- Fully compliant with USP <71>, Ph. Eur. <2.6.1> and JP <4.06>

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For more inform

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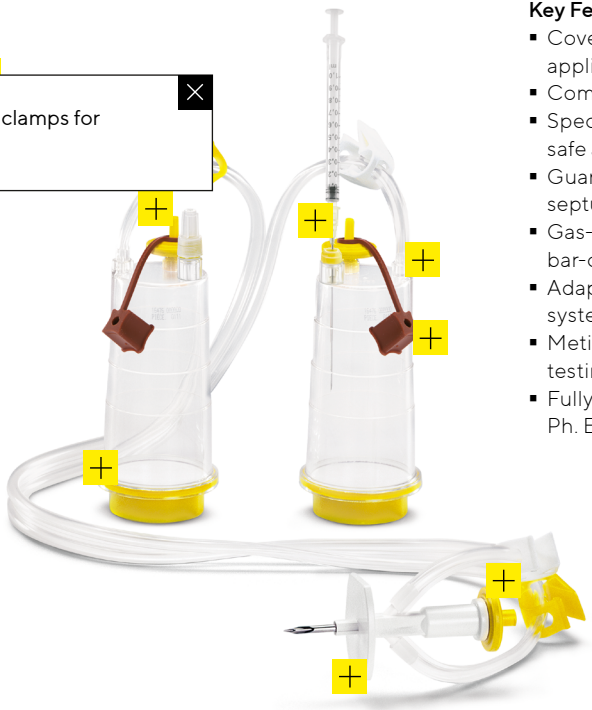
Pre-installed, color coded clamps for intuitive handling.



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Raised sterile venting, with a safety clearance, to prevent accidental clogging and minimise secondary contamination.

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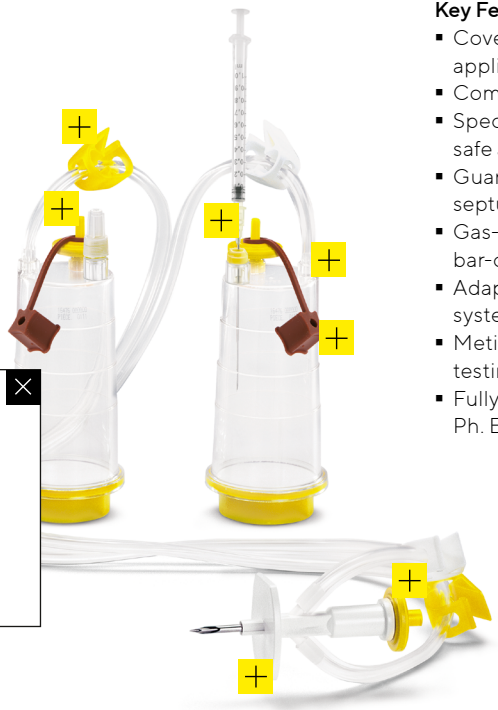
require

Carefully chosen Sartochem® regenerated cellulose and cellulose acetate membranes to cover all sterility testing applications.

Robust membranes to meet low adsorption, chemical compatibility, flow rate and microbial retention requirements.



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Large protective plate for safe and easy piercing of stoppers and containers.

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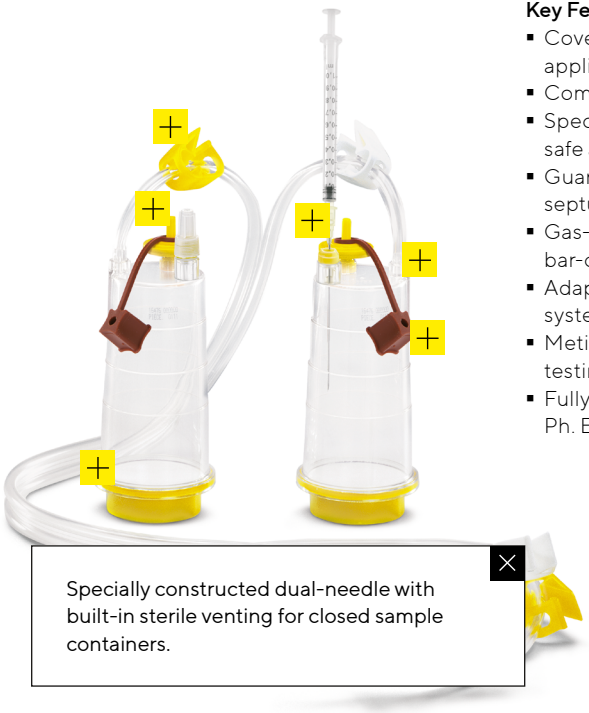

Specially constructed dual-needle with built-in sterile venting for closed sample containers.

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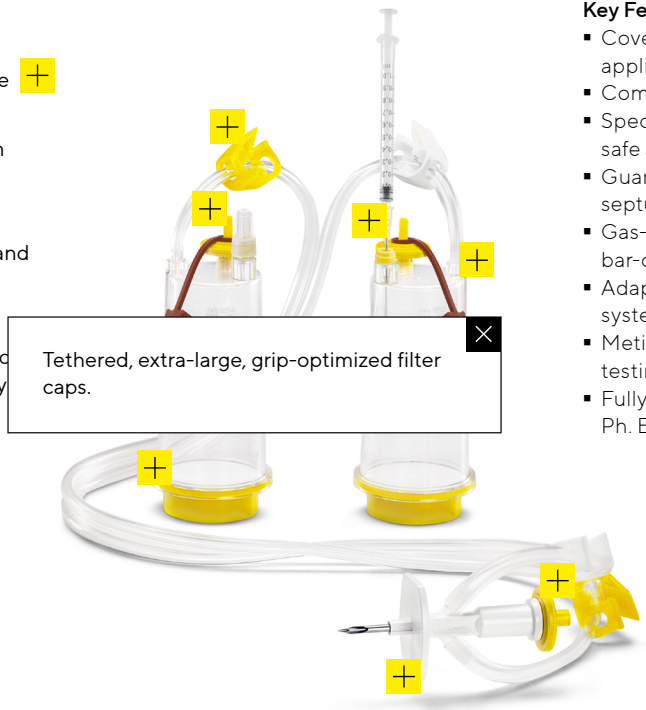

Tethered, extra-large, grip-optimized filter caps.

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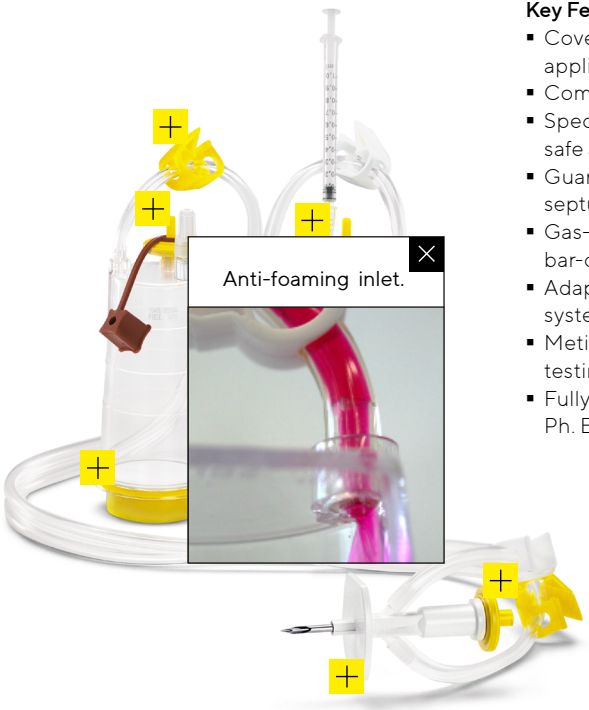

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Septum versions guarantee a sterile barrier for aseptic sampling.

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Canister Types

Yellow Base

Regenerated Cellulose

White Base

Cellulose Acetate

Material of construction

- Housing: Styrene acrylonitrile (SAN)
- Tubing: PVC (double lumen) & silicone
- Standard sampling needle: Polycarbonate & stainless steel
- Dual needle: Acrylonitrile butadiene styrene (ABS) & stainless steel
- Wing nuts: Polyethylene (PE)
- Filter plugs: Silicone
- Septum: Polyisoprene and acrylonitrile butadiene styrene (ABS)

Maximum operating pressure:
3 bar at 20 °C

Maximum operating temperature:
50 °C

Burst pressure of the housing:
> 5 bar

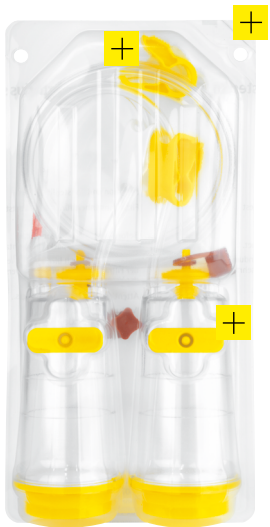
Capacity:
120 ml (graduations at 50 ml, 75 ml and 100 ml)

Venting filter

- Hydrophobic polytetrafluoroethylene (PTFE) membrane
- Penetration pressure > 3 bar

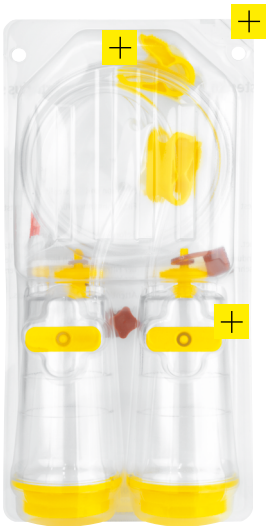
Sterilization:
Gamma irradiation

Packaging



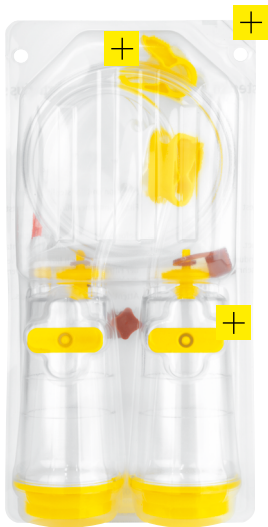
Packaging

Color- and bar-coded packaging for easy identification and traceability.



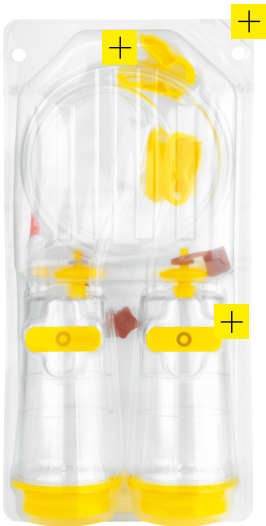
Packaging

Double packed for easy and secure transfer into a clean-room, laminar flow hood or isolator.



Packaging

Gamma-sterilized to prevent secondary contamination and mitigate the risk of false positives.



Packaging

Gas-impermeable packaging to eliminate the risk of false-negatives, following VHP-decontamination in isolators.

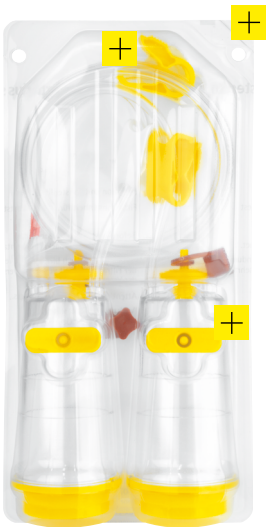
Packaging

Corner reinforcement for easy- peeling and hanger holes.

Packaging

Recess housing directly-accessible, large canister plugs.

Packaging



Sterisart® Septum

During growth incubation, sampling of the culture medium may be required for any one of the following reasons:

- The growth media is rendered turbid by microbial growth, following incubation, and necessitates the identification of the micro-organism as part of a root cause analysis.
- The product renders the growth medium turbid, prior to incubation, and requires sub-culturing | dilution.
- Samples are supplemented with agents to counteract anti-microbial components of the tested product.
- Samples are drawn to test for microbial contamination by rapid detection methods

Sampling via the tubing can compromise the integrity of the sterility test and preclude re-incubation of the sterility testing canisters. The aseptic sampling port not only eliminates the risk of introducing false positives through external contamination but also ensures operator safety and prevents accidental spillage during sampling.

Given the interest in rapid sterility testing solutions, Sartorius has partnered with Charles River to pair our Sterisart® Septum canisters with the Celsis® detection platform.

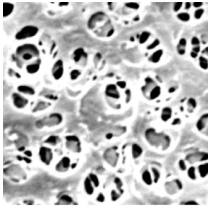
See Application Note
Click here for a study on how the Sterisart® Septum facilitates the recurrent sterile extraction of samples

Learn More
Learn more about our partnership with Charles River here:

Membranes

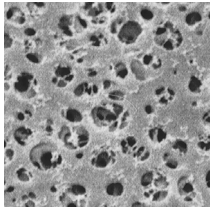
Regenerated Cellulose

Material	Regenerated cellulose, reinforced with non-woven cellulose
Properties	▪ Combines excellent chemical resistance and thermal stability with very low adsorption characteristics ▪ Hydrophilic
Chemical Compatibility	Aqueous solutions (pH 3-12) and organic solvents
Pore size	0.45 µm
Flow Rate for Water per cm^2 (DIN 58355:)	30 ml/min at Dp =1 bar | ~15 psi
Thickness (DIN 53105)	150 – 170 µm
Wetting time	< 1 second, with deionised water



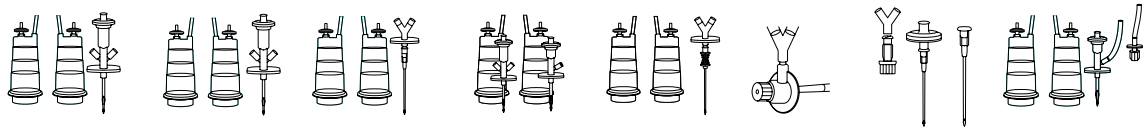
Cellulose Acetate

Material	Cellulose acetate
Properties	▪ Combines high-flow rates and thermal stability with very low adsorption characteristics, making it ideal for difficult-to-filter, viscous substances ▪ Hydrophilic
Chemical Compatibility	Aqueous solutions (pH 4-8), oils, alcohols and several organic solvents
Pore size	0.45 µm
Flow Rate for Water per cm^2 (DIN 58355:)	65 ml/min at Dp =1 bar | ~15 psi
Thickness (DIN 53105)	115 – 145 µm
Wetting time	< 1 second, with deionised water



Ordering Information

For more information, please select each column's +



Regenerated Celluose								
Standard	16466--------GBD	16476--------GBD	16467--------GBD	16475--------GBD	16477--------GBD	16469--------GBD	16468--------GBD	16478--------GBD
Septum	16466--------GSD	16476--------GSD	16467--------GSD	16475--------GSD		16469--------GSD		
Cellulose Acetate								
	16466-----CA-GSD		16467-----CA-GSD					
Sample Type								
Product Container	Closed	Closed	Open	Closed	Closed with bow-fill seals	Syringes	Male luer locks or female slip	Male luer locks

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Next: Sterility Testing Solutions for Liquid Transfer and Dilution

Ordering Information

For more information, please select each column's +

Sterility Testing Solutions for Liquid Transfer and Dilution			
			
	(for sample prep and dilution)	(for liquid transfer)	(for liquid transfer)
	16470--------GBD	16471--------GBD	16472--------GBD
Sample Type			
Transfer To	Closed container	Open Container	Open/Vented Container
	+	+	+

Back: Sterility Testing Canisters

Ordering Information

Regenerated Cellulose		Cellulose Acetate
Standard Canisters	Septum Canisters	Septum Canisters
16466--------GBD	**16466--------GSD**	**16466-----CA-GSD**
		
Connector: Long (41 mm) dual-needle with built-in venting filter		
Designed for: Liquids in closed, large volume containers		

Ordering Information

Regenerated Cellulose

Standard Canisters	Septum Canisters
16476--------GBD	**16476--------GSD**
	

Connector: Short (21 mm) dual-needle with built-in venting filter

Designed for: Liquids in closed, small volume containers

Ordering Information

Regenerated Cellulose		Cellulose Acetate
Standard Canisters	Septum Canisters	Septum Canisters
16467--------GBD	**16467--------GSD**	**16467-----CA-GSD**
		

Connector: Standard sampling needle (52 mm) Separate needle for sterile venting (40 mm)

Designed for: Liquids in open containers

Ordering Information

Regenerated Cellulose

Standard Canisters	Septum Canisters
16475--------GBD	**16475--------GSD**
	

Connector: Standard (35 mm) dual-needle with built-in venting filter & sampling dual-needle (23 mm)

Designed for: Soluble lyophilisates in closed containers

Ordering Information

Regenerated Cellulose

Standard Canisters

16477--------GBD

Non-coring needle

Connector: Non-coring needle (56 mm)
Separate needle for sterile venting (40 mm)

Designed for: Liquids in plastic containers with blow-fill seals

Ordering Information

Regenerated Cellulose

Standard Canisters	Septum Canisters
16469--------GBD	**16469--------GSD**
	

Connector: Standard (35 mm) dual-needle with built-in venting filter & syringe adaptor

Designed for: Liquids in pre-filled syringes

Ordering Information

Regenerated Cellulose

Standard Canisters

16468--------GBD (One-Connector System)

Connector: Standard sampling needle (60 mm) & detachable two-way female Luer adaptor. Separate needle for sterile venting (40 mm)

Designed for: Liquids in containers with a Luer connector

Ordering Information

Regenerated Cellulose

Standard Canisters

16478--------GBD (Two-Connector System)

Connector: Standard (35 mm) dual-needle with built-in venting filter & female Luer adaptor.

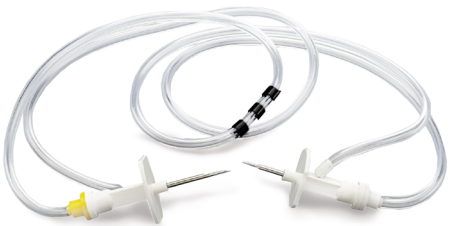
Designed for: Liquids in containers with a male Luer connector

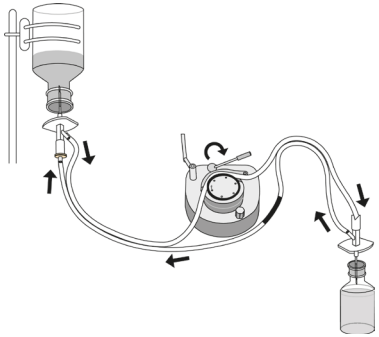
Ordering Information

Sterility Testing Solutions for Liquid Transfer and Dilution

Sample Preparation

16470--------GBD





Connector: 37 mm and 23 mm dual-needle for sampling

Designed for: Sample preparation of poorly soluble lyophilized products

Ordering Information

Sterility Testing Solutions for Liquid Transfer and Dilution

Sample Preparation

16471----------GBD

Connector:	29 mm dual-needle for sampling
Designed for:	Direct inoculation: Transfer of liquids that are difficult to filter Sample pooling of small volumes prior to membrane filtration

Ordering Information

Sterility Testing Solutions for Liquid Transfer and Dilution

Sample Preparation

16472--------GSD

Connector:	17 mm dual-needle and 80 mm standard needle for sampling
Designed for:	Direct inoculation: Transfer of liquids that are difficult to filter Sample pooling of small volumes prior to membrane filtration

Quality Assurance

Routine testing of every lot includes:

- Incoming Materials Testing
  Qualification of the membrane filters, plastic and tubing
- Rigorous In-Process Controls
  Physical integrity test of the housing container, tubing and venting filter
- Stringent Final Release Testing
  Includes a physical integrity test, bacterial challenge test and growth promotion test.

A quality assurance certificate is delivered with every unit for your records.

A comprehensive validation/qualification guide is available on request.

Sterility Testing Pump

For more information please click on the +

The Sterisart® Universal Pump, can be used in isolators, laminar flow hoods, biosafety cabinets and cleanroom benches. Since space is often at a premium, the pump features a compact architecture with a space-saving footprint.

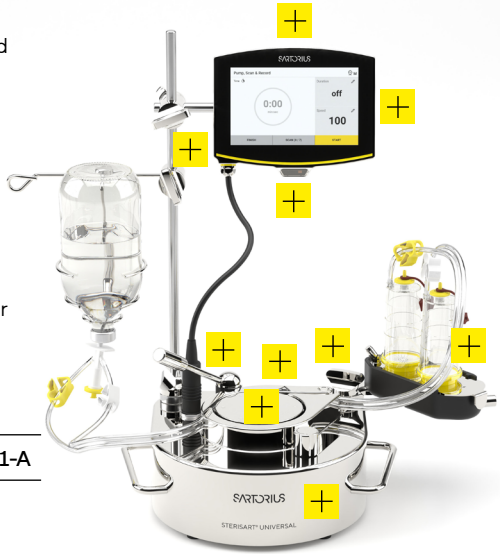
We have designed our pump focusing on your convenience. Combined with our Sterisart® sterility testing canisters, we offer you complete confidence in your sterility test results.

Model numbers	16421-B;16421-E;16421-A

See Brochure

See Flyer

See Datasheet



Key Features and Benefits:

- Compact, low-profile for comfortable use
- Effortlessly detachable components to facilitate easy-access for cleaning
- Robust & durable: Rugged stainless-steel body that is compatible with all commonly used chemical sterilants and fully VHP-resistant
- Easy tube-placement with convenient, malfunction-proof, locking mechanism
- Open-design: compatible with other filtration devices on the market
- 7" high resolution touch-screen display optimised for use with isolator gloves
- Integrated barcode scanner supporting 28 formats
- Advanced software built for 21 CFR Part 11
- Customisable and comprehensive electronic reports
- Visual guidance of workflows
- Remote configuration and operability

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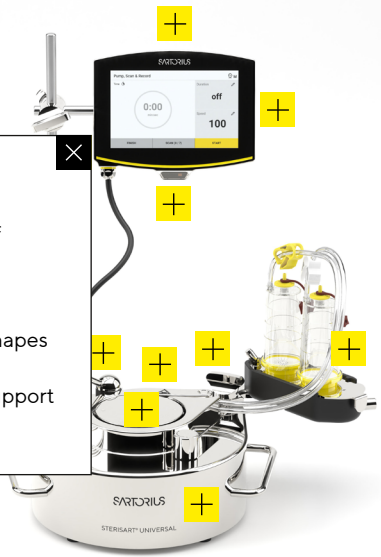
Tailored for Every User
- Adjustable height
- Swivel angles and orientations of essential elements

Multi-functional Bottle Holder
- Accommodates various bottle shapes and sizes
- Features an extended hook to support infusion bags | medical devices



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test results.

Seamless Tube Placement

- Easy access for tube insertion
- Tube Threading guide with ridges and clamps

Fail-Safe Locking Mechanism

- Error-free operation: Reliable malfunction-proof locking mechanism
- Effortless bow, lever, and rotor disassembly for an easy and thorough cleaning

Key Features and Benefits:

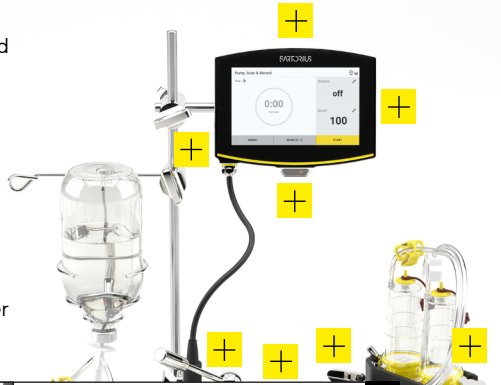
- Compact, low-profile for comfortable use
- Effortlessly detachable components to facilitate easy-access for cleaning
- Robust & durable: Rugged stainless-steel body that is compatible with all commonly used chemical sterilants and fully VHP-resistant
- Easy tube-placement with convenient, malfunction-proof, locking mechanism
- Open-design: compatible with other filtration devices on the market
- 7" high resolution touch-screen display optimised for use with isolator gloves
- Integrated barcode scanner supporting 28 formats
- Advanced software built for 21 CFR Part 11
- Customisable and comprehensive electronic reports
- Visual guidance of workflows
- Remote configuration and operability

Sterility Testing Pump

For more information please click on the +

The Sterisart® Universal Pump, can be used in isolators, laminar flow hoods, biosafety cabinets and cleanroom benches. Since space is often at a premium, the pump features a compact architecture with a space-saving footprint.

We have designed our pump focusing on your convenience. Combined with our Sterisart® sterility testing canisters, we offer you complete confidence in your sterility test results.



State-Of-The-Art Rotor Head

- Accurate and reliable volume splitting of sampled liquids
- Easy disassembly for complete cleaning

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Flexible Modular Design
Upgrade as your needs evolve.
- Sterisart® Basic: Pump without display
- Sterisart® Essential: Pump with display
- Sterisart® Advanced: Pump with display and advanced software

Universal Pump
- One Pump, Multiple Environments
- Effortless integration into different workspaces
  - Benchtop use in a Laminar Air Flow | Biosafety Cabinet | RABS
  - Integration in a Sterility Testing Isolator
- Reliable and Robust: crafted from 316L grade Stainless Steel

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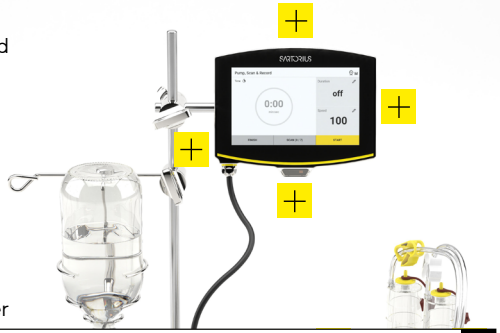

Flexible Drain Orientation
- Two orientations of the drain tray

Open Design
- Designed with an open approach – compatible with other filtration devices in the market

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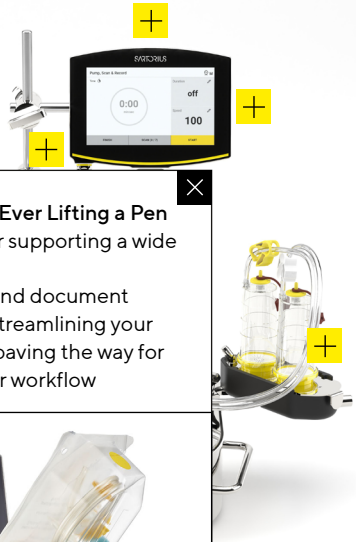

Documentation Without Ever Lifting a Pen

- Built in barcode scanner supporting a wide range of formats
- Automatically capture and document every user interaction, streamlining your method validation and paving the way for semi-automation in your workflow

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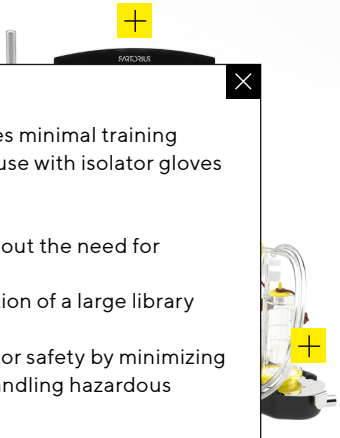

Intuitive Interface
- Instinctive navigation that requires minimal training
- Large touch panels designed for use with isolator gloves

Remote Management
- Browser-based connectivity, without the need for additional software
- Remote configuration and operation of a large library of customized SOPs
- Remote operation: Ensure operator safety by minimizing the duration of exposure when handling hazardous substances

Advanced Software
- End-to-end data integrity
- Customizable GxP-Compliant Reports
- Built for 21CFR Part 11: User Access Control, Tamper-proof Audit Trail, Data Backup
- LDAP Server Configuration

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test results.

Enhanced Display

- 7" high resolution display
- Touch-screen optimized for use with isolator gloves
- Brilliant colors and crip visuals

Intuitive Control

- Complete control of the interface through the touch-screen or the grip-optimised control knob, with haptic feedback

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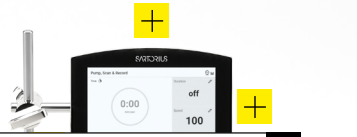

Advanced Pressure-Sensing

- Real-time pressure detection in the sterility testing canisters
- Minimise stress on microorganisms and enhances process security by reducing downtime
- Two modes: visual prompt for operator intervention when pressure exceeds the desired threshold, and automatic pressure stabilization

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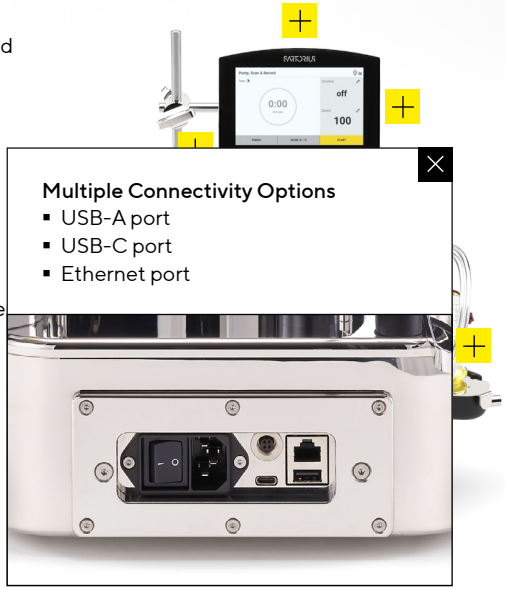

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Accessories

Model No.	Description
1ZW---0002	Ampoule breaker
1ZA---0024	Syringe adaptor | support for pre-filled syringes
1ZE---0033	Foot switch
1EE---0015	Extension cable control unit | display (2.9 m)
1ZG---0024	Stainless steel drain cover | adaptor for Millipore sterility test units
1ZE---0057	Isolator installation kit
1ZGF--0020	Transport tray (10-canister holder)

Accessories

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1ZW---0002 - Ampoule Breaker

Accessories

Model
1ZW--
1ZA---
1ZE---
1EE---
1ZG---
1ZE---
1ZGF-

1ZA---0024- Syringe adaptor for pre-filled syringes

For liquids in pre-filled syringes

For use with 16469--------GBD or 16469--------GSD.

A foot-switch controls both the operation of the pump and the pinch-valve, which acts as a flow restrictor, through a communication hub. The valve regulates the flow of the rinsing fluid through the tubing and thereby eliminates the need to overturn the rinsing fluid bottle between sample injections. The Sterisart® syringe adaptor can also be attached to the main support rod of the pump to minimize the space used.

Accessories

Model No.
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1ZA---0024
1ZE---0033
1EE---0015
1ZG---0024
1ZE---0057
1ZGF--0020

1ZE---0033 - Foot switch

Accessories

Model No.
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1ZA---0024
1ZE---0033
1EE---0015
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1ZE---0057
1ZGF--0020

1EE---0015 - Extension cable control unit | display (2.9 m)

Accessories

Model
1ZW--
1ZA---
1ZE---
1EE---
1ZG---
1ZE---
1ZGF-

1ZG---0024 Stainless steel drain cover/ adaptor for Millipore™ sterility test units

Accessories

Model
1ZW--
1ZA---
1ZE---
1EE---
1ZG---
1ZE---
1ZGF-

1ZE---0057 - Isolator installation kit

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1ZGF--0020 - Transport tray (10-canister holder)

Sterisart® Universal | Gen 4 Highlights

Sterisart® Universal | Gen 4	Basic	Essential	Advanced
Ordering Code	16421-B	16421-E	16421-A
Hardware			
Sterility Testing Pump	●	●	●
Display & Integrated Barcode Scanner	○	●	●
Pressure Sensor	~ (Restricted functionality)	●	●
Connectivity –USB-A/C & Ethernet Port	~ (Connectors present but restricted functionality)	●	●
Software			
Workflow Configuration	○	○	●
Simple Report	○	●	●
Extended Report	○	○	●
Remote Operation	○	○	●
21 CFR Part 11 Conformity	○	○	●

Select the perfect fit for your needs and seamlessly upgrade to more advanced versions as your requirements evolve. This adaptability ensures your investment matures in line with your ambitions, reducing the need for costly equipment replacements.

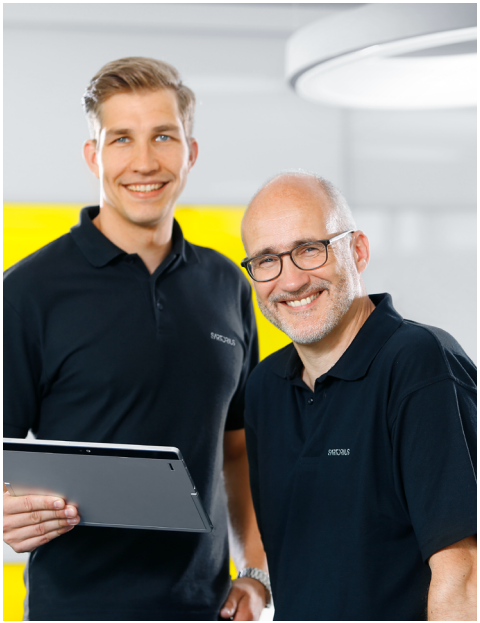
Service Support

Service life cycle management is a critical element when purchasing your equipment. This routinely involves:

- Proper installation of the equipment
- Basic user training
- Routine preventative maintenance visits (IQ/OQ)

These services will increase the longevity of the unit, while reducing the downtime.

We serve customers around the globe – with service contracts and a full range of services to suit every need. If you have questions about our service offerings or are in need of technical support, we are here for you. Just provide us with detailed information in our contact form, and we will promptly get in touch with you.



Order Codes

Sterisart® Universal Pump IQ/OQ	84QAM04
Sterisart® Annual maintenance/Preventive Maintenance	84MAM04
Sterisart® upgrade including requalification (IQ/OQ)	84UBM04

Click to Learn More

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www.sartorius.com

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