Classical Food, Alternative Proteins and Cultivated Meat

A Full Product Range

Simplifying Progress

SARTORIUS

Introduction to Sartorius

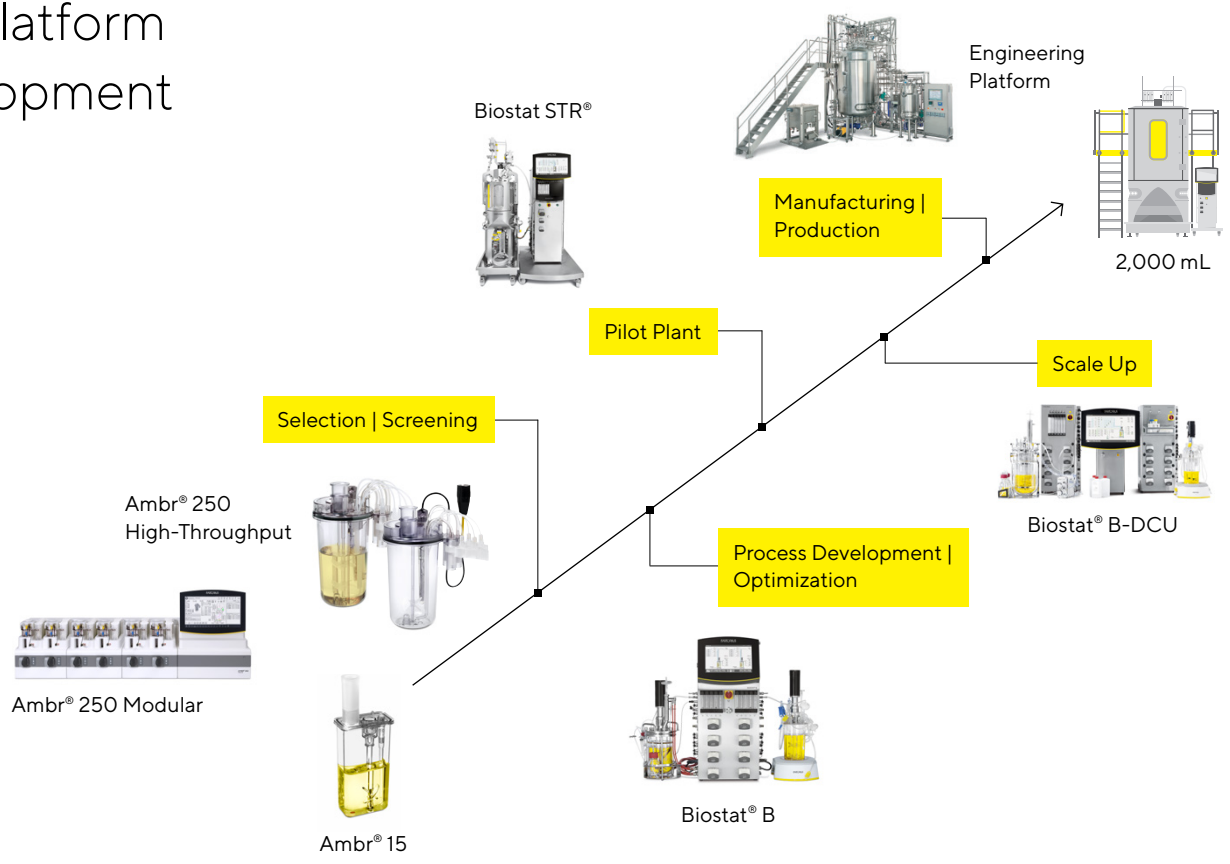
- Our outstanding track record in the pharma | biotech sector puts us in a prime position to fully support the food biotech industry.
- Our product range is 100% applicable to food products where there is a focus on proteins, colorants, additives and aromas and, indeed, where microorganisms and mammalian cells are key—for instance, cultivated meat.
- The solutions required, including data analytics software, are pretty much equivalent to those needed for drugs and vaccines.
- We are the only supplier that can truly call ourselves a 'one-stop shop' for this rapidly developing highly competitive market.
- We are a leader in protein purification for the food market.
- Time to market and optimization are both vital. Sartorius will get you there not only faster but also more cost-effectively.
- Only Sartorius can supply a full range of equipment, consumables and analytical software:
  - Expertise in the cultivation and purification technology required for microorganisms and mammalian cell cultures
  - Data analytics software to ensure optimum processes and actionable insights
  - A complete range of single-use containers and consumables

Watch video
The Future of Food and Beverage Starts Here

Complete Scalable Bioreactor Platform From Cell and Strain Line Development to Commercial Manufacturing

Sartorius offers bioreactors from 10 mL up to 2,000 L working volume:

- Multi-parallel bioreactors with the Ambr® product line
- Benchtop bioreactors with the Biostat® B, Biostat® B-DCU, Univessel® single-use or glass stirred tank bioreactors
- BioPAT® sensors
- Single-use bioreactors with the Biostat® RM and Biostat STR®



Ambr® 15 CC

Automated, High Throughput Microscale Bioreactor System That Replicates Laboratory Scale Bioreactor Performance (Liquid Handler)

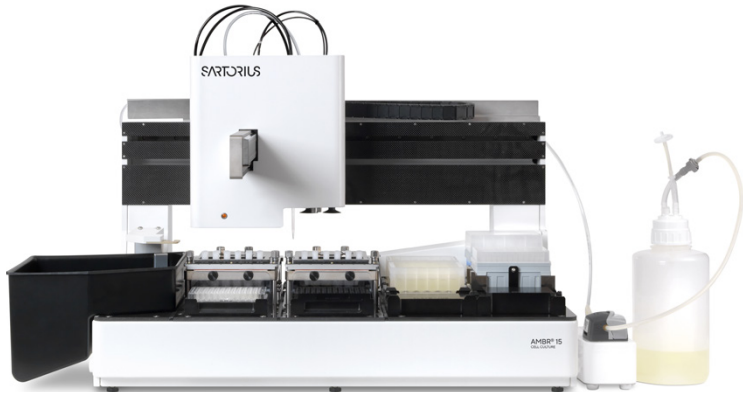
- 10 – 15 mL working volume
- For cell culture only
- Sits in a BioSafety™ cabinet (**not** included with the purchase)

Applications

- Clone selection
- Media and feed optimization
- Process intensification
- Development of advanced cell therapies
- Early-stage process optimization
- Screening under perfusion mimic conditions

- Can be configured either as a 24 vessel or 48 vessel system
- Single-use consumable bioreactor the size of a tic tac box (pre-sterilized and pre-calibrated)
- Comes with a comprehensive suite of software applications that allow the user to build and execute recipes, gather and review data in real-time and export raw data for further analysis
- Comes with added 1 year license for MODDE® DOE application and clone selection software (Umetrics®)

- Mimics a standard stir-tank environment making for optimum scalability (process insights software for scaling)
- Optional integrated analyzers (i.e cell counts, metabolites, etc.)

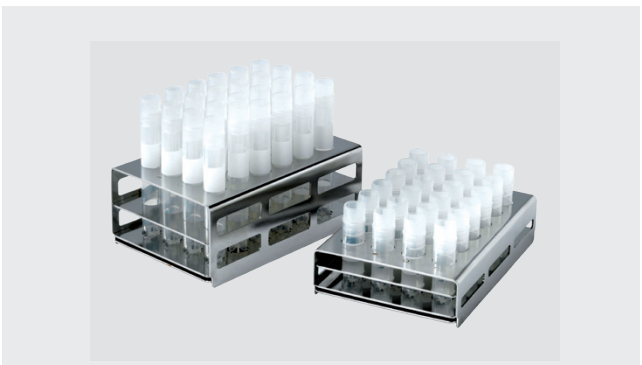


Fill-It : Production of High-Quality Cell Banks

Automated Cryovial Filling System for Cell Banking and Strain Banking Applications

Fill-It offers improved consistency and shortens process times compared to manual processing, giving the potential to increase batch sizes for cell banking and dramatically reduce QC costs.

It also reduces the dependence on operators to perform repetitive tasks, limiting health concerns such as RSI.

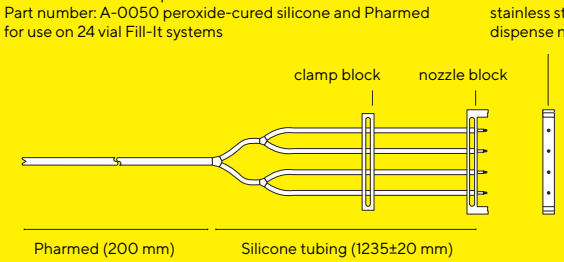


Available in three versions:

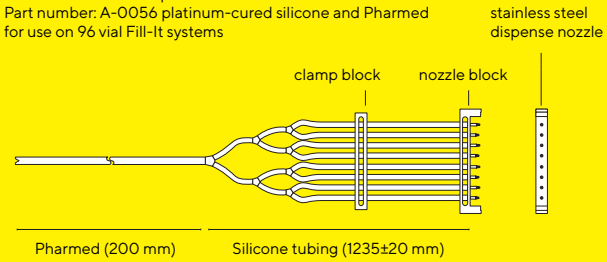
- 4-way tube sets compatible with conventional cryovials held in Sartorius supplied 24 vial racks
- V8-way tube sets compatible with cryovials supplied in pre-assembled 48 vial racks
- 8-way tube sets compatible with cryovials supplied in pre-assembled 96 vial racks

System combines proven decap | recap modules with aseptic liquid handling suitable for use within a GMP environment.

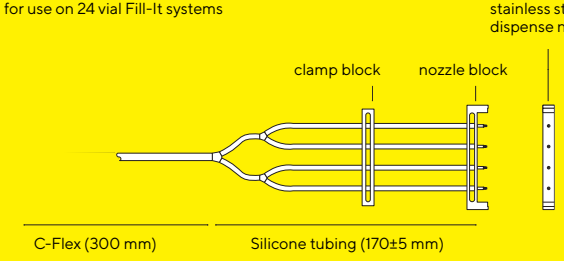
4-way tube set
Part number: A-0029 peroxide-cured silicone and Pharmed
Part number: A-0050 peroxide-cured silicone and Pharmed
for use on 24 vial Fill-It systems



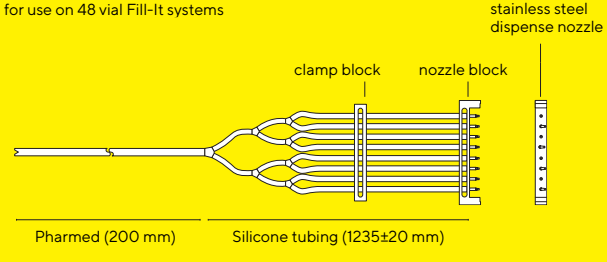
8-way tube set
Part number: A-0028 peroxide-cured silicone and Pharmed
Part number: A-0056 platinum-cured silicone and Pharmed
for use on 96 vial Fill-It systems



4-way tube set
Part number: A-0055 peroxide-cured silicone and C-Flex
for use on 24 vial Fill-It systems



V8-way tube set
Part number: A-0037 peroxide-cured silicone and Pharmed
for use on 48 vial Fill-It systems



Ambr® 250 High Throughput

Single-Use Multi-Parallel Bioreactor, Fully Automated for Accelerated Process Development

- For microbial and cell culture systems
- 100 – 250 mL single-use bioreactors (pre-sterilized and pre-calibrated)
- Fully automated liquid handling platform as well as liquid pumps
- Integrated into a BioSafety™ cabinet (included with the purchase)

Applications

- Clone selection
- Media and feed optimization
- Process intensification
- Process development and characterization
- Suitable for true perfusion processing

- Can be configured either as a 12 vessel or 24 vessel system
- Comes with a comprehensive suite of software applications that allow the user to build and execute recipes, gather and review data in real-time and export raw data for further analysis
- Comes with added 1 year license for MODDE® DOE application
- Geometrically similar to larger bioreactors making for optimum scalability (process insights software for scaling)

- Four positive displacement liquid pumps per bioreactor for high precision at low flow rates
- Individual bioreactor temperature control with heating or cooling
- Individual impeller speed control per bioreactor
- Optional integrated analyzers (i.e cell counts, metabolites, etc.)
- Integrated CIP | SIP for pumps and liquid lines

Ambr® 250 Modular

Innovative, Easy-To-Use, Expandable Benchtop System That Incorporates From 2 to 8 Fully Integrated Single-Use 100 – 250 mL Mini Bioreactors

- For microbial and cell culture systems
- Intended for benchtop installation
- 100 – 250 mL single-use bioreactors (pre-sterilized and pre-calibrated)
- Automated pumps for liquid handling

Applications

- Process characterization
- Process robustness experimentation in support of QbD studies
- Process scale-down model
- Process Optimization

- Can be used as a 2-way, 4-way, 6-way or 8-way depending on how many modules are needed and purchased (more modules can be integrated after purchase)
- Each bioreactor is fully integrated with 5 liquid reservoirs and proprietary single-use syringe pumps. The integration simplifies experimental set-up, eliminates any need for vessel sterilization, and significantly reduces any error due to manual handling

- Comes with a comprehensive suite of software applications that allow the user to build and execute recipes, gather and review data in real-time and export raw data for further analysis
- Geometrically similar to larger bioreactors making for optimum scalability (process insights software for scaling)
- The Ambr® 250 Modular system controller is operated via an intuitive touchscreen interface, ensuring user interactions are ergonomic and efficient

- Five positive displacement liquid pumps per bioreactor for high precision at low flow rates
- Individual bioreactor temperature control with heating and cooling
- Individual impeller speed control per bioreactor
- Optional off-gas analysis for CO_2 and O_2, also uses OUR and CER measurements
- Optional on-line biomass analyzer (for microbial only)

Biostat® B

Universal Benchtop Controller for Stirred and Rocking Motion Systems

Compatible With:

- Univessel® Glass (1 L, 2 L, 5 L or 10 L)
- Univessel® SU (0.6 L – 2 L working volume)

- Single or twin vessel control
- Semi-flexible configurations (i.e. size of MFC, gravimetric feed option, level control)
- Optional, high-precision MFCs (standard is 50:1 but can come at 200:1 with an ETO)
- Expandable with additional pumps, scales, sensors, etc. (up to 4 internal pumps with option for external pumps)

Note: The break-even point between multiple Biostat® Bs and one Biostat® B-DCU is 4 vessels. If you are interested in having 4 or more bioreactors, it is suggested to go with the Biostat® B-DCU from a cost perspective (especially with gravimetric feed and variable speed pump options).

Biostat® RM and Flexsafe® RM Bag – Working Volume from 1 L to 100 L

Biostat® RM Bioreactor Powered by the Biobrain® Automation Platform – Versatile Rocking Motion Bioreactor From Basic to Intensified Operations

Biostat® RM 20 | 50 Basic
- Cell culture without need for sophisticated control
- Cost effective and fast seed production
- Alternative to roller bottle, spinner flask or shake flask

Biostat® RM 20 | 50 | 200 powered by Biobrain®
- Fully automated and controlled batch, fed-batch or high cell density perfusion cultures
- Use of Flexsafe® RM bags with single-use pH, DO and biomass sensors
- Highest cell densities | product yields with ease of use

Cells
- Mammalian cell culture
- Insect cell culture
- Low to medium density microbial cultures
- Shear sensitive cells such as stem cells

Biostat® RM and Flexsafe® RM Bag

Biostat® RM Bioreactor Powered by Biobrain®

Biostat® RM 200

Biostat® RM Product Family

Total Volume | Max. Working Volume ↑

200 L | 100 L
100 L | 50 L

Biostat® RM 200 Rocker

50 L | 25 L
20 L | 10 L
10 L | 5 L

Biostat® RM 20 | 50 Rocker

2 L | 1 L
1 L | 0.5 L

Biostat® RM 20 | 50 Basic

- A tailored bioreactor solution for shear-stress-sensitive cell lines based on Biobrain®, a GMP-ready automation platform
- Advantageous vaporized hydrogen peroxide (VHP) cleanability
- Certified IP 54 dust ingress for the Biostat® RM Control Tower, IP 23 for the Biostat® RM 20 | 50 Rocker and IP 21 for Biostat® RM 200 Rocker
- Offers flexibility in process set up with a variety of controllers and actuators
- An integral component of the intensified modular seed train
- Easier to operate when compared to stirred tank bioreactors for shear-stress-sensitive cell lines
- Simplified process transfer frombasic to intensified operation with a change of the Flexsafe® RM bag
- A bioreactor family that includes Biostat® RM 20 | 50 Rocker and Biostat® RM 200 Rocker as unique solution for commercial manufacturing (CM) market

Biostat® RM 20 | 50
Basic Features

Tube and cable organizer

Colour coded plugs and socket for easy operation

Standard Ethernet and Modbus RTU interface (optional ProfiBus DP interface) guaranteed to work with DeltaV

Lid design with space for filter heater

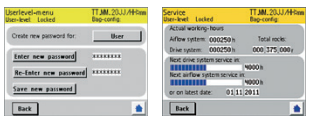
Load cells

Optional gassing module with integrated Air | CO_2 mixing

Individual control of 2 bags (T, gasfl)

Automatic sample function

Colour touch screen with trend and alarm display
- 3 different user levels
- Service interval display



Biostat® B-DCU

The Industry Standard Bioreactor for Advanced Process Optimization and Characterization

- Univessel® Glass (1 L, 2 L, 5 L or 10 L) or Univessel® SU (0.6 L – 2 L working volume)
- Independent control of up to 6 vessels
- Optional pressure control up to ½ barg or 7 PSI

Highly Flexible Configurations

- Expandable with additional pumps (up to 8)
- Optional high-precision MFCs (CTO)
- Extra gassing options (advanced gassing strategy comes standard with the B-DCU)
- Additional load cell options (up to 4 per supply tower)
- Optional additional sensors (i.e. gas, glucose, cell density, etc.)

Maximum Flexibility for Advanced Process Development

- Independent process control for up to six culture vessels
- Improved connectivity of utilities and probes
- Interchangeable operation with glass or single-use culture vessels
- Fully flexible gassing strategy to meet your cells gassing requirement
- Advanced feeds and control loops

Features of the Biostat® B-DCU

Comfortable operation with a 19" display that can also be operated with gloves

Intelligent mass flow controllers with a flow range of 1:200

Optional flow meters

Connect your Sartorius Cubis®, Quintix® or Secura® balance and other Sartorius standard balances.

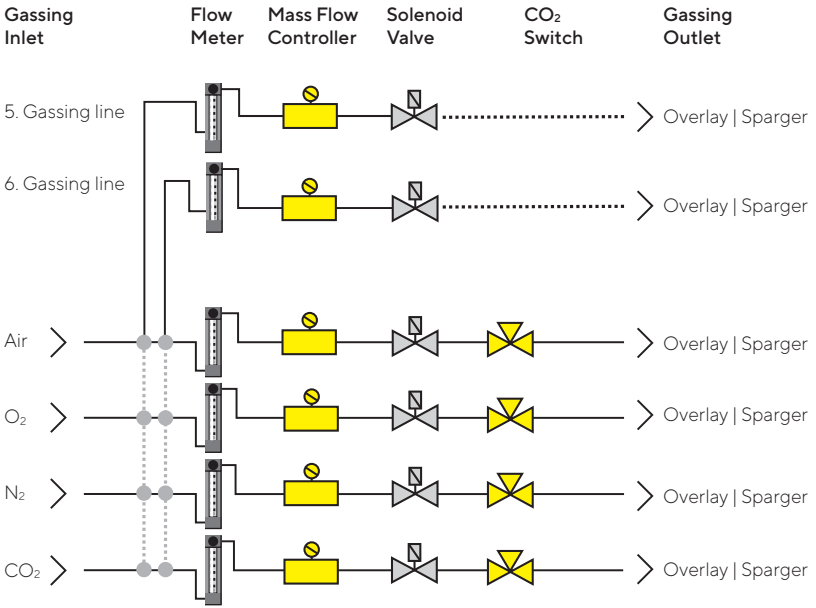
Fast load pump heads for fast and secure handling of tubing

Choose up to four variable speed pumps with a wide range of 0.15 – 150 rpm and up to four fixed speed pumps

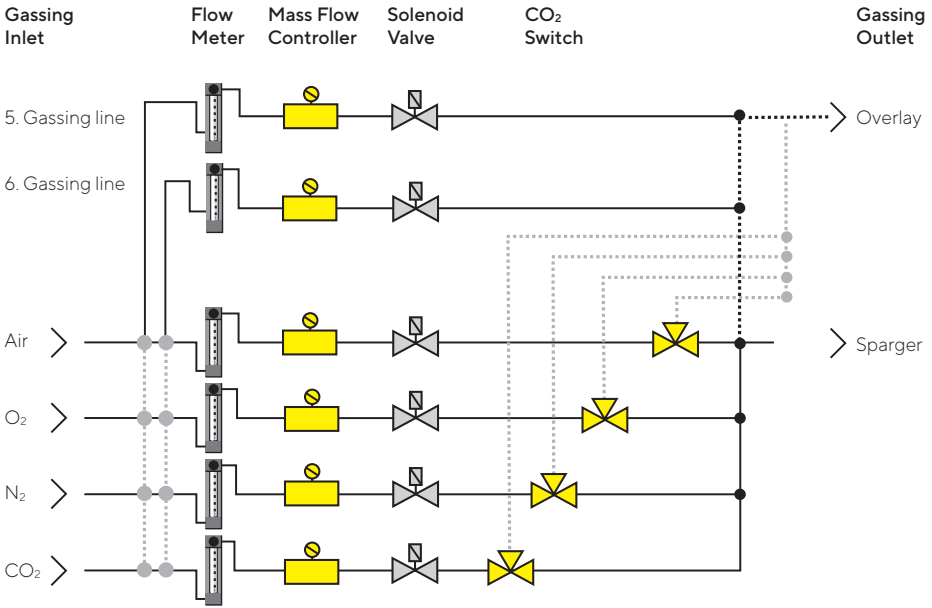
Manual operation buttons for tube loading | unloading

Cell Culture Aeration Modules for the Biostat® B-DCU

Advanced Additive Flow—Single Gas Outlets



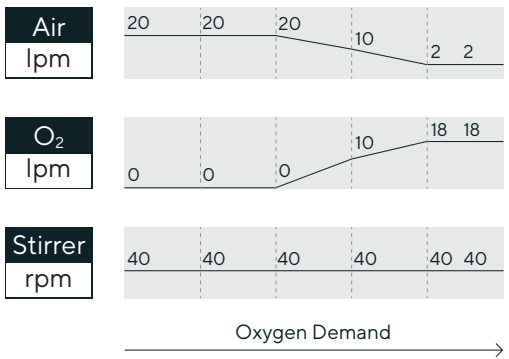
Advanced Additive Flow—2 Gas Outlets



Cell Culture Aeration Modules for the Biostat® B-DCU

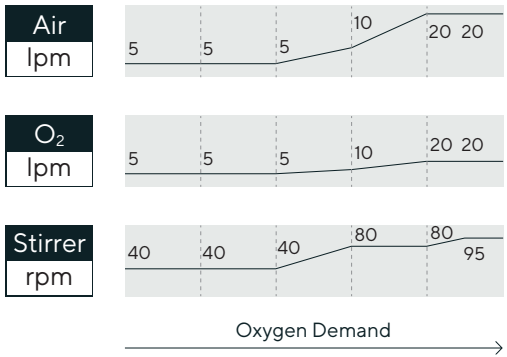
Advanced DO Control

Constant Gas Flow



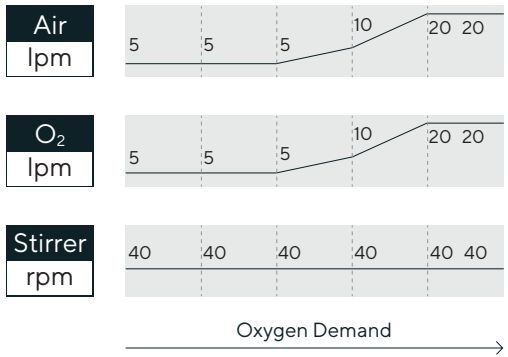
Constant gas flow decreases the flow of air and simultaneously increases oxygen gas

Bubble Size Optimization



Bubble size optimization enables fine tuning of the oxygen % and gas-liquid interface area

Constant Gas Ratio



Constant gas ratio, where both air and oxygen % are increased at the same rate

lpm litre per minute
rpm revolutions per minute

Biostat® B versus Biostat® B-DCU

	Biostat® B	Biostat® B-DCU
Operation | Display	12" touch screen	19" touch screen
Parallel Vessels	Single or twin	Single, up to 6-fold
Standard Measurements	Temperature, pH, DO, stirrer speed	
Optional Measurements and Control	▪ Foam, level ▪ Redox ▪ Turbidity (NIR) ▪ Off-gas ▪ Glucose and lactate ▪ Viability (capacitance)	▪ Foam, level ▪ Redox ▪ Turbidity (NIR) ▪ Off-gas ▪ Glucose and lactate ▪ Viability (capacitance)
Pressure Control	Not available	0.1 – 0.5 barg, 3 flow ranges
External Inputs (Optional)	4 per vessel (0 – 10 V | 4 – 20 mA)	4 per vessel (0 – 10 V | 4 – 20 mA)
Weight Measurement and Control	Vessel | substrate (max. 2)	Vessel | substrate (max. 4)
Gassing System	Exclusive flow or advanced additive flow (upgrade option)	
Gassing Lines (Max. Number)	5 gasses with 2 outlets	6 gasses with 2 or 6 outlets
	4 MFCs max. (optional)	6 DIGITAL MFCs max. (optional)
Pumps Internal | External (Var.-Speed)	4 | 2 (2)	8 | 2 (4)
Vessel Sizes	1 L | 2 L | 5 L | 10 L Univessel® or 2 L Univessel® SU or Biostat® RM	1 L | 2 L | 5 L | 10 L Univessel® or 2 L Univessel® SU
DO Control	Cascade (standard) or advanced (option)	Advanced DO controller (standard)

Univessel® SU

Stirred Tank Single-Use Bioreactor
The Efficient Toll for Process Development

- Mimics classical glass bioreactor design (2:1)
- Robust rigid polycarbonate vessel
- 0.6 L – 2 L working volume
- Designed for cell culture applications (only exception would be anaerobic microorganisms)
- Completely assembled and pre-sterilized
- Integrated single-use pH and DO sensors
- Up to 400 RPM

Fully Single-Use:

- No cleaning
- No autoclaving
- No set-up hassles
- No sensor or vessel maintenance

Univessel® SU

Motor adaptor SSB and third-party motors

Heating blanket

Water jacket

Exhaust filter heater

Conventional probes for pH, DO and temperature and integrated single-use sensors for pH and DO

Univessel® Glass

Lighter
Carving out every unnecessary weight, makes the Univessel® Glass lighter than ever without loosing stability or risking sterility.

No More Damaged Glass Vessel
New fixation for cleaning to secure glass vessel during cleaning. It takes only 5 seconds to protect your glass vessel.

Sparger Options
Now also a ring sparger with holes facing downwards is available.

Know Your Vessel Characteristics
Complete characterization data available for straightforward scale-up and scale-down

Ease of Cleaning
The dish-washer proof stirrer design enables cleaning in a dishwasher without removing the stirrer from the head plate.

Handling
The additional, integrated handles make the Univessel® Glass easier to carry.

Stability
The round shape of the stand provides a maximum of sturdiness.

BioPAT® Process Insights Software – Predictive Bioreactor Scale-Up | Down

- Maximum in process understanding
- Effective automation of your cell cultivation or fermentation process

BioPAT® ViaMass
- Determine the viable biomass volume inline continuously
- Based on the proven principle of capacitance measurement
- Reduce operator-to-operator variability
- Reduce manual sampling and lower risk of contamination

BioPAT® Trace
- Ideal for simultaneous online monitoring of glucose, lactate and alcohol during cultures of micro-organisms or animal cells
- Fully disposable sensor and fluidics set for easy setup and immediate use
- Fast concentration determination without any loss of volume

BioPAT® Xgas
- Precisely track O_2 | CO_2 concentration changes in respiratory gas emission
- Highest accuracy by automatic moisture and pressure compensation
- Compact design and parallel measurement in a single analyzer saves space in your lab

BioPAT® Fundalux
- Absorption-based probe using near infrared light for total biomass determination
- Range of optical path lengths (1, 5 and 10 mm) yields optimal total biomass coverage for your specific process
- Robust LED light source with up to 10-year lamp lifetime

Biostat STR®: Engineered for Ultimate Upstream Performance

- Available in incremental sizes: 50 L, 200 L, 500 L, 1,000 L and 2,000 L
- Improved hardware design
- Utilizes SU Flexsafe STR® bags for excellent cell growth and robustness
- Single-use, non-invasive biomass monitoring
- Easily connect your Biostat STR® to our BioPAT® MFCS or third-party supervisory software like DeltaV™.
- Benefit from our flexible stirrer and sparger options.
- Successfully grow your shear sensitive cells on microcarriers and ensure excellent cell growth and viability.

Cell Culture Media and Buffers in Food and Beverage

Development of powerful cell culture media and feed strategies have dramatically changed the way culture meat and milk are produced. 50 years of culture media experience backed by 150 years of pharma industry innovations have led Sartorius to long-term relationships with dual sourced raw material suppliers which guarantees supply, quality and excellent regulatory support for all of your projects.

We support our customers with the manufacture of their proprietary media formulations, either in liquid or powder format. We will follow the clients' requested parameters and project scope.

We offer customized packaging, media and buffer formats, and release assays.

Off-the-shelf cell culture media and buffers as well as proprietary formulation manufacturing:

- Classical media formulations incl. RPMI, MEM, DMEM
- Chemically defined media for CHO, MDCK, Vero, BHK-21, Insect, HEK293 cell lines for batch and fed-batch applications
- From WFI-Quality water to regular DSP buffers to strong acids, bases, alcohols and detergents

NutriFreez™ D10 Cryopreservation Medium
A chemically defined, animal component-free, protein-free, serum free, cryopreservation solution which is composed of Methylcellulose and 10% Dimethyl Sulfoxide (DMSO)

The product is designed to maintain all mammalian and human cell types, including a multitude of cell types, including hMSC from various sources, hPSC, neurons, PBMCs, as well as primary cells and extremely sensitive cell lines in ultralow temperatures (–196 °C)

Storage and Stability
- Store at 2 – 8 °C
- Up to 18 months stability

NutriStem® hPSC XF Medium | 05 – 100-1A (500 mL) Ready-To-Use
Ready-to-use medium for the culture and expansion of human pluripotent stem cells: human embryonic stem cells (hESCs) and human induced pluripotent stem cells (hiPSCs)

Storage
- Store at –20 °C
- Up to 2 freeze | thaw cycles
- After thaw stable for 2 weeks at 2 – 8 °C

MSC NutriStem® XF basal medium
A Defined, Xeno-Free (XF), Serum-Free (SF) Medium, Designed to Support the Growth of hMSC

Storage
- 2 – 8 °C

MSC NutriStem® XF supplement
Medium for the isolation and expansion of human mesenchymal stem cells from various sources such as: bone marrow, adipose tissue, umbilical cord, placenta, Wharton jelly, and dental pulp

Storage
- Supplement | –20 °C (up to 2 freeze | thaw cycles)
- The complete MSC NutriStem® XF Medium is stable at 2 to 8 °C for up to 30 days

Spent Media Analytics

Unlock New Process Insights
Spent media analytics is the examination of the used media from production steps throughout process development. The information gathered facilitates the selection of an optimal cell culture medium and feed combination, as well as the development of suitable feeding strategies.

Features and Benefits
- Ready-to-use validated analytical methods
- Available as bundles to simplify your analytics process
- Industry-leading expertise
- Fast turnaround times to speed up your media selection and process optimization

Relevant Applications
Spent media analytics is a valuable tool that enables the tracking of changes in medium composition. The information gathered reveals insights into the metabolic processes of the cell population and how the media influences process and product characteristics. These services can help users:
- Assess media performance in mAbs and biosimilars, recombinant proteins, viral vaccines, and gene therapy applications
- Monitor nutrient consumption to quickly identify any adverse outcomes
- Optimize feeding strategies to maximize cell viability and productivity
- Speed up upstream process development timelines
- Troubleshoot commercial production processes and find opportunities for improvement

Relevant Process Steps:

Product Development
- Media benchmarking studies
- Understanding growth conditions for clones, ensuring critical quality attributes are maintained

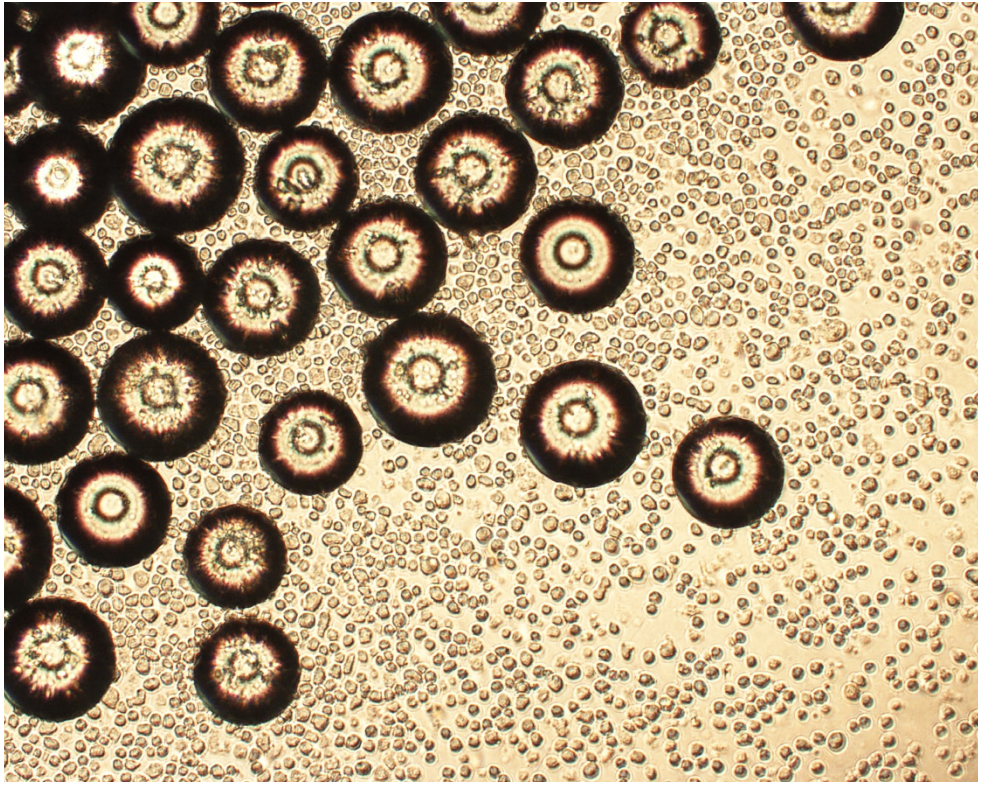
Process Development
- Process optimization minimize to the content of components | metabolites
- Identification of critical specific components in media and determination of their influence on cell growth/productivity and product quality
- Analyzing culture conditions and feed strategies to see how they affect process performance

Commercial Lot Release
- Process troubleshooting and maximizing productivity

Microcarriers

(by SoloHill®)

- Microcarriers are tiny spheres that normally range from 90 to 300 microns in diameter. The relative density of microcarriers is close to water, which facilitates easy suspension in a cell culture medium.
- Their core material, surface chemistry, and coating promote attachment and growth of anchorage-dependent cells and influence the production of biologics in cell culture processes.
- A fundamental benefit of microcarriers is that they provide a large effective surface area with a relatively small footprint, allowing large-scale manufacturing of biologics for lower capital investment.
- Proven track record: used by the animal and human health industry for over 30 years.
- Streamlined solution: simply sterilize and use: hydration and pre-swelling steps are not required.
- Ready-to-use: sterile format with sterility assurance level (SAL) 10^{-6} eliminates sterilization validation and shortens manufacturing process.



Umetrics® Suite of Data Analytics Software

The applications of the Umetrics® Suite provide you with full control over your data in food & beverage development and production. Streamline your processes and accelerate your time to market with new products with this powerful software suite.

- MFCS
- MODDE®: Design of Experiment Solutions
- SIMCA®: Turn Data into Growth
- SIMCA®-online: Ensuring Manufacturing Success
- Active Dashboard: Interactive Performance Insight

MFCS

BioPAT® MFCS enables you to incorporate a new standard in bioprocess data management and automation.
Its reliable data acquisition, efficient trend monitoring, and advanced recipe control make it an ideal tool for all upstream and downstream processes, no matter if you prefer single-use or reusable systems.

The new BioPAT® MFCS is your solution for robust and reproducible processes – all backed by our expertise since 1986.

Features

- Intuitive graphically guided configuration
- Drag & drop operations and phases
- Sequential, parallel and repeated execution of phases
- State and time-dependent transitions
- Pre-defined phase types for setpoints, feeding profiles or timers

Benefits

- Improved batch-to-batch consistency
- Decreased risk of errors
- Minimized number of rejected lots
- Automated processing to free up operator time
- ANSI-88 compliant standardized automation

MODDE®

MODDE® is a lot more than just DOE software.
It also provides a quality analysis on your decisions and looks at the risks—warning you about critical settings and guiding you towards more robust conclusions.

Offers:
- Reduce the number of required experiments
- Guide you through the set-up of your experiment
- Provide confidence in your data handling
- Help you make better decisions
- Integrate with your systems
- Meet your quality goals

At a Glance:
- Automated analysis wizard
- Robust optimum identification
- Interactive setpoint analysis with risk estimate
- Design Space visualization
- Generalized subset designs
- Stability testing design setup

Why Use SIMCA®?

Wherever you create data you can use SIMCA®. That's why companies in many different industries have worked with us to help their business grow.

- A major bio-process company improved process yield by 75%, reduced cycle time by 40% and trebled plant output
- An international food processing company resolved a logistics issue and saved USD 1 million per year in shipping costs
- A wastewater treatment company used SIMCA® to improve their processes for a cleaner, safer environment

At a Glance:

- Integrated spectroscopy features through context-based ribbons
- Interactive graphical interface
- Flexibility to handle complex data in many forms
- An easy way to script your workflow
- Seamless model update integration with SIMCA®-online

How Does SIMCA®-Online Work?

Instead of monitoring each variable, you can concentrate them into one view that is key to your whole process. Easy-to-understand graphics make interpretation simple.

- Monitor in real time and swiftly detect deviations: With SIMCA® you can model your ideal process from your collected data. Transferred into SIMCA®-online, the model acts as a valuable reference for your current production
- Predict with confidence: You can predict final quality from the properties of the raw material and the process parameters as well as forecast the final quality
- Control at a glance: SIMCA®-online uses an 'ideal process' model to anticipate the effect of changes and recommend immediate adjustments. This will ensure product performance according to specifications and optimize throughput

At a Glance:

- Remote predictive monitoring
- Root-cause-analysis
- Predicting final quality attributes
- Soft sensoring
- Real-time supervisory control

Active Dashboard

What if you could compare performance across all of your production sites? Active Dashboard lets you do just that. It takes the data from your SIMCA®-online solutions and visualizes it in a series of easy-to-understand interactive charts. Or you can connect Active Dashboard to other data sources like OSIsoft's PI System™ via the Asset Framework infrastructure.

Active Dashboard gives you options for innovative role-based data visualization. For example, easy, self-service visual analytics with cross-filtering make the involvement of data analysis experts less important.

You can view information about your final products and the relationship between processes and product performance. You can also view information about the processes themselves and about your raw materials.

You will be able to see which sites are performing well and which sites are performing less well and then investigate further to find out why—and do something about it.

The bottom line for your business is maximized yield, optimized quality, and lower costs across your production. Active Dashboard gives you the improved transparency you need to make the right decisions.

If you need further analysis, it will also export seamlessly into SIMCA®.

At a Glance:

- Production transparency
- Interactive charts and maps
- Product quality assurance
- Performance insight
- A summarized real-time view of all your sites and products

The Pioneer in Single-Use

With over 20 years of experience in manufacturing single-use solutions, we are your best partner for running your future manufacturing facilities.
We partner with you and we provide the most reliable, economical and safest solutions for all your process steps and applications. You can fully benefit from our experience and the advantages of our single-use solutions to accelerate your time to market, improve your manufacturing flexibility and reduce your costs.

Flexsafe® Pro Mixer

The Fast, Flexible and Intelligent Single-Use Mixer for All Mixing Steps

By combining speed and efficiency to deliver high-performance mixing during powder dissolution with a levitating impeller to preserve the drug during low shear blending applications, the Flexsafe® Pro Mixer can accommodate a wide range of mixing operations.

- Scales from 50 L to 3,000 L
- Consists of three main components:
  - Flexsafe® Pro Mixer Bag
  - Palletank® for Mixing
  - Pro Mixer drive unit
- Its strong vertical vortex combined with a baffle effect and cubical tank design enables instant downward movement and the efficient dissolution of floating powders such as media
- Single-use sensors for in line measurement:
  - pH sensor with 2 calibration points
  - Pre-calibrated conductivity sensor
  - Thermowell for temperature measurement

Flexsafe® 2D Bags

Simpler, Safer, Faster and Cheaper Supply Chains for Single-Use System (SUS)

The adoption of SUS in all process steps & applications of commercial production drives the need for reducing complexity, enhancing quality, improving assurance of supply and reducing leadtimes.

20 mL, 50 mL, 150 mL, 250 mL, 500 mL, 1 L, 3 L, 5 L, 10 L, 20 L, 50 L

Media Formulation

Pre-designed solutions for media storage and feeding of bioreactors

Drug Substance

Pre-designed solutions for storage of drug substance

Buffer Formulation

Pre-designed solutions for storage of buffers used for purification or final formulation

Sampling

Pre-designed solutions for easy and safe sampling whatever the process step

Cell Harvest & Downstream Intermediates

Pre-designed solutions for harvesting cell cultures and for handling all the process intermediates

Flexsafe® 3D Bags

Flexsafe® 3D Bags for Palletank®:
100 L, 200 L, 500 L

Flexsafe® 3D Bags for Drum:
50 L, 100 L, 200 L

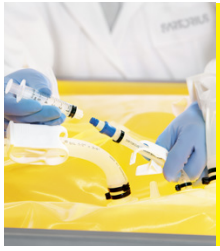
Flexsafe® 3D Bags for Palletank®:
1,000 L, 1,500 L, 2,000 L, 2,500 L, 3,000 L

Media

Pre-designed solutions for media storage, shipping and feeding of bioreactors

Drug Substance

Pre-designed solutions for storage and shipping of drug substance post virus filtration after the last cross-flow step



Buffer

Pre-designed solutions for storage and shipping of buffers used for purification or final formulation

Sampling

Pre-designed solutions for easy and safe sampling whatever the process step

Cell Harvest & Downstream Intermediates

Pre-designed solutions for harvesting cell cultures and for handling all the process intermediates before the last cross-flow step

Drug Product

Pre-designed solutions for sterile filtration, hold and transfer of drug products

Celsius® Product Lines

Robust, Complete and Scalable Solutions for Frozen Storage and Shipment

Celsius® Controlled Freeze & Thaw (CFT)
The Celsius® CFT systems use a proprietary heat transfer technology to freeze and thaw biopharmaceutical solutions, scalable from process development to commercial scale production products.

Celsius® Flexible Freeze & Thaw (FFT)
The Celsius® FFT single-use assemblies are designed to provide the freezing container used in conventional freezer. The associated logistics for frozen storage and shipping of biopharmaceuticals is also available.

Celsius -Pak

1. Filling Operation

Volumes: 1 L, 2 L, 8.3 L and 16.6 L

Celsius® Filling Station FS16-S2

2. Controlled Freezing Operation

Celsius® FT33 | 66 | 100

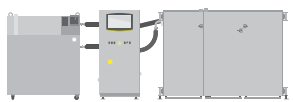
3. Storage and Logistics

Celsius® Shippable Storage Module (SSM)

Celsius® SSM Shipper

4. Controlled Thawing Operation

Celsius® FT33 | 66 | 100



Celsius FFT

Freezing and Storage in Conventional Freezer

Volumes: 2 L, 4 L, 6 L and 12 L

Celsius® FT Shippers

Biosealer® TC Aseptic Tube Sealing Device

Automated Aseptic Thermoplastic Tubing Disconnection

Sterile Disconnection of TPE Tubing

- Compatible tubing sizes:
  - ⅛" × ¼"
  - ¼" × ⅜"
  - ¼" × 7/16"
  - ⅜" × ⅝"
  - ½" × ¾"
  - ¾" × 1"

- The Biosealer® TC provides the user with a wider sealing of 20 mm for a more robust disconnection operation
- A cutting guideline embedded into the seal ensures a proper and clean cut with scissors by the operator
- Fully automated device for sealing thermoplastic tubing
- An LCD touch screen guides the user through the operator menu. Each process step can easily be followed and monitored by the information provided on the display.
- The Biosealer® TC is equipped with an SD Card slot to allow loading and printing of the sealing cycle data via a computer

Device Features and Benefits

Extended Wide Range of Sealing Possibilities in a Single Device

Standard sealing parameters for up to 6 sizes for:

- TuFlux® TPE
- C-Flex® 374
- AdvantaFlex®
- SaniPure™ BDF™
- Pharmed® BPT

Full flexibility of tubing materials and sizes from R&D to commercial manufacturing with 1 device. Reduced capital investment.

Summary Table of Validated Tubing Materials and Sizes Which Can Be Sealed on Biosealer® TC

TPE Tubing Material	Sealing Parameter Name Installed on Biosealer® TC	Sterilization Methods of Tubing Covered by the Parameters	Tubing Sizes Qualified per Sealing Parameter					
			1/8" × 1/4"	1/4" × 3/8"	1/4" × 7/16"	3/8" × 5/8"	1/2" × 3/4"	3/4" × 1"
Tuflux® TPE	Tuflux® TPE	A or G	■ (yellow)	■ (orange)	■ (red)	■ (white)	–	–
C-Flex® 374	C-Flex® 374	A or G	■	■	■	■	■	■
AdvantaFlex®	AdvantaFlex®	A or G	■	■	■	■	■	■
SaniPure™ BDF™	SaniPure™ BDF™	A or G	■	■	■	■	■	–
Pharmed® BPT	Pharmed® BPT	A or G	■	■	■	■	■	■

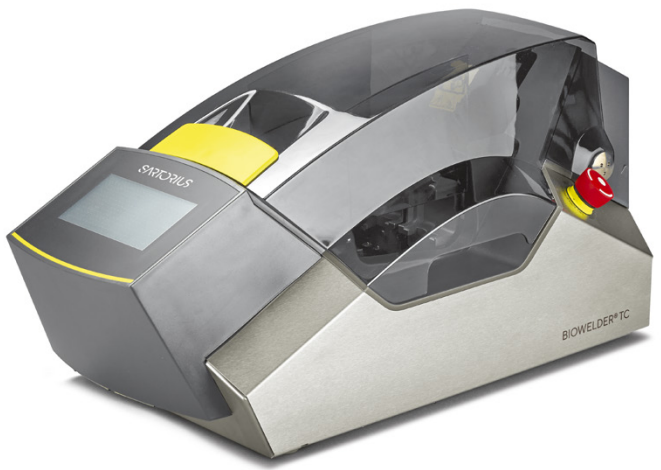
■ Available – Not available

*These parameter sets have been validated at room temperature.

Biowelder® TC Sterile Tube Welding Device

Automated Sterile Tube Welding for Total Containment

- The Biowelder® TC is used to connect thermoplastic tubing such as TuFlux® TPE, C-Flex® 374, AdvantaFlex ®, SaniPure™ BDF™ and PharMed® BPT used on disposable bags or bag assemblies within all biopharmaceutical manufacturing processes
- Biowelder® TC can weld either dry or liquid-filled tubing in non classified and classified environment while maintaining product sterility
- The interchangeable and color-coded tube holders are available in a variety of sizes between ⅛" ID + ¼" OD and ¾" ID + 1" OD, which allow a quick and easy adaptation to the process needs
- The Biowelder® TC identifies each holder size when installed, which minimizes operator error
- An LCD touch screen guides the user through the operator menu. Each process step can easily be followed and monitored by the information provided on the display
- The Biowelder® TC is equipped with an SD Card slot to allow loading and printing of the welding cycle data via a computer
- The average welding cycle times are between 1 min 30 and 2 min 30 which provides time savings along the process chain



Clipster® Aseptic Point-of-Use Disconnector

Description:

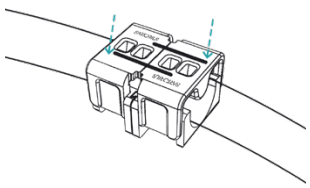
- The Clipster® Aseptic Disconnector is a single-use device developed by Sartorius Stedim Biotech that completes our range of products by performing aseptic disconnections of tubing
- The Clipster® Aseptic Disconnector may be sold as a stand-alone product or preassembled on our Fluid Management bag assemblies
- The Clipster® Aseptic Disconnector is safe, quick and easy to use. The disconnection is performed with a hand-held tool which ensures easy execution in various space requirements

Application:

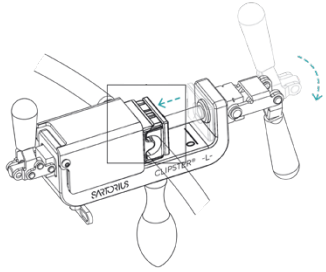
- The Clipster® Aseptic Disconnector is used after a fluid transfer to disconnect single-use transfer lines and bag assemblies used in biopharmaceutical applications
- The Clipster® Aseptic Disconnector allows aseptic disconnection in non classified and classified environments while maintaining product sterility
- It can be applied to multiple types and sizes of tubing

Clipster® Aseptic Disconnector

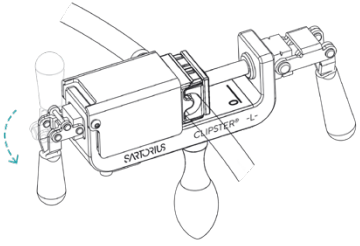
Operating Sequences



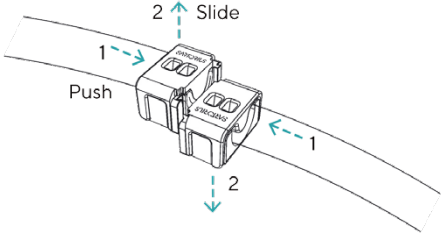
1. Assemble the Clipster® Aseptic Disconnector on the tubing.



2. Position the Clipster® Aseptic Disconnector in the hand-held tool and clamp it.



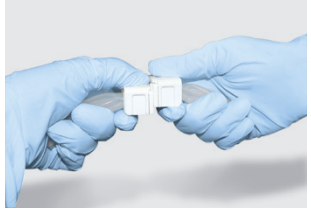
3. Cut the tubing.



4. Disconnect the Clipster® Aseptic Disconnector.

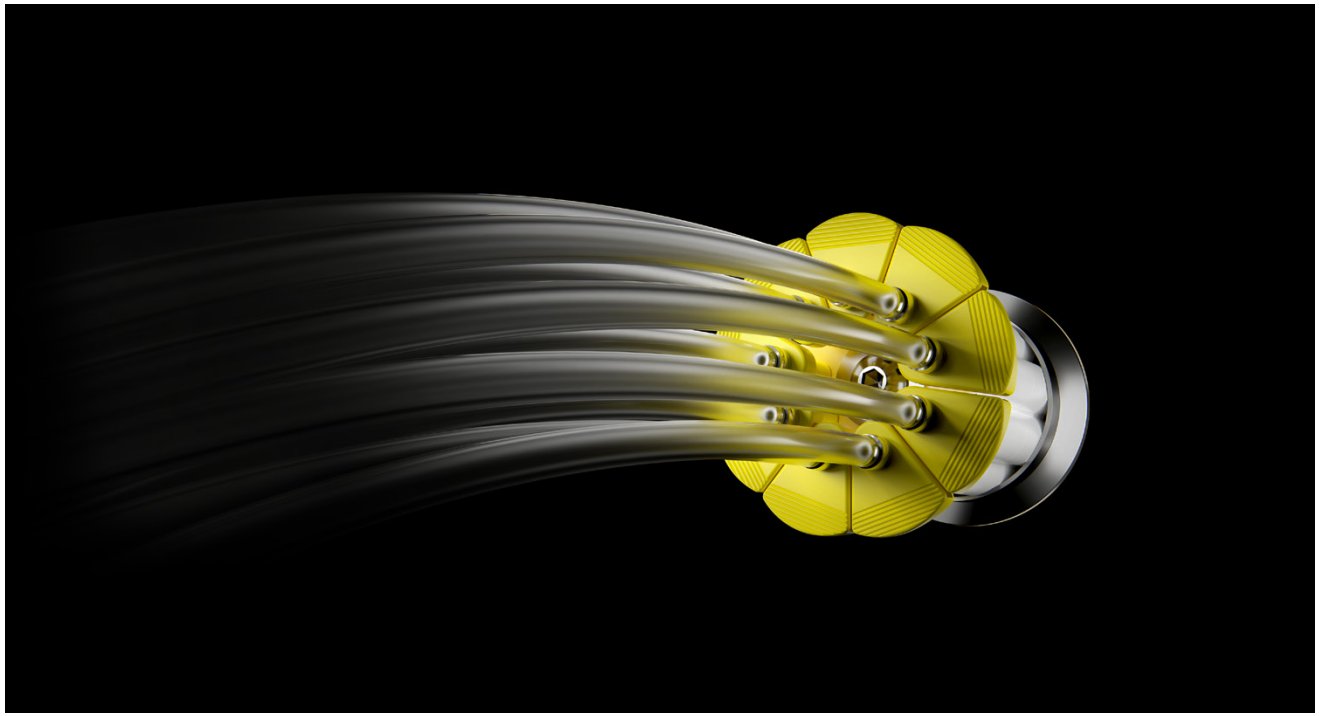
Features and Benefits

Mechanical disconnection	Could be performed on platinum cured silicone and TPE tubings
Error proof design	Prevents mistakes
4-step operation	Easy, quick, robust and repeatable
Intensively qualified	Safe and robust
Available as stand alone product or preassembled	Flexible
Hand-held tool	Easy to use
3 Clipster® sizes	Compatible with 5 tubing dimensions



Preassembled, Presterilized, Single-Use: For Simplified Sampling

Aseptic sampling is a principal component of an effective microbial control program. Samples collected with Takeone® are used to measure critical purity attributes, such as bioburden and endotoxin levels, as well as important process parameters, such as metabolites, nutrients, osmolality, pH and more. Takeone® aseptic sampling solutions have been designed to integrate seamlessly with stainless steel or single-use processes.



Quickseal® Disconnectors

Reliable Aseptic Disconnection

Quickseal® aseptic disconnectors simplify critical fluid management by making aseptic disconnection fast and secure. Quickseal® collars are available for an array of tubing materials covering the range of tube internal diameters from ⅛" (3.2 mm) to ¾" (19.0 mm). Extensively tested, Quickseal® is ideally suited for most applications in biopharmaceutical, vaccine and cell and gene therapy production.

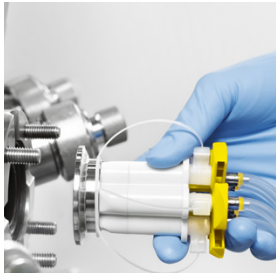
Takeone® Aseptic Sampling Solutions and Quickseal® Disconnectors

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

1. Install Takeone® aseptic sampling device

2. Sample

3. Disconnect



4. Remove & dispose

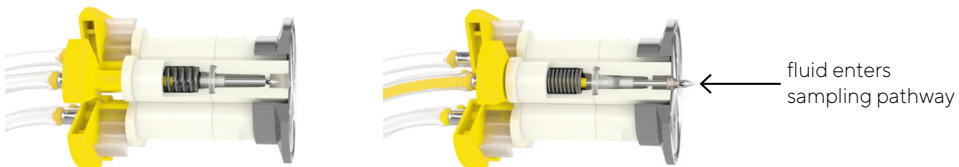
Efficient Sampling with Takeone®

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

Rest Asssured 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.

Takeone® Aseptic Sampling Solutions and Quickseal® Disconnectors

Cross-Section Before, During and After Actuation



Before and After Actuation

During Actuation

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

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

Quick, and Easy Disconnect: Each Takeone® sampling line assembly includes a Quickseal® aseptic disconnect. Once the sample has been collected, operators easily cut the aluminum collar with a light and portable hand-held cutting tool. This aseptically seals the tubing while disconnecting the sampling container. Quickseal® patented technology protects the sample and process vessel from contamination. A Quickseal® silicone protective cap then shields the cut collar.

Process Filtration

Leading Expertise and Unique Technologies

Sartorius' extensive filtration and purification portfolio helps you to overcome your major challenges. We partner closely with you and make sure you get the most reliable and economical as well as the safest solution for your application.

Benefit from our long-standing expertise and innovative power, which has made us one of the industry's market leaders in process filtration.

Prefilter Cartridges

The broad variety of different prefilter materials combine unmatched total throughput performance with a level of clarification as never seen before. Increase the total throughput of your final filtration run and protect your processes from premature blockage with the right choice of prefilter.

Jumbo Star Cartridges

Unique Jumbo filter cartridges for high-volume flow rates and maximum throughput and featuring the smallest footprint.

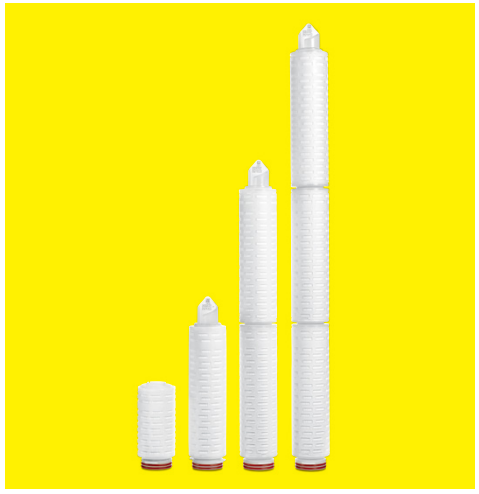
Membrane Filter Cartridges

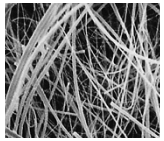
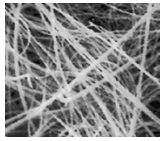
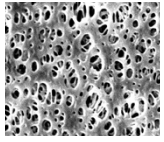
These membrane filters are generally used in the final filtration stage and installed directly upstream of the filling unit. Sartorius supplies the following membrane types for filtration of liquids and gases:

- Polyethersulfone (PES)
- Polytetrafluoroethylene (PTFE)

Integrity Testing

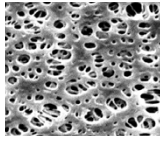
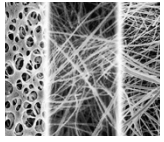
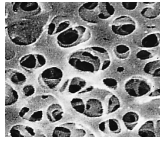
Ensure 100% reliable filling by testing all final membrane filters with our testing system Sartocheck®.



		Applications	Cartridge Construction	Available Heights	Adapter Types (**)
	**Sartopure® IND** The prefilter cartridge with particle-removing with polypropylen filter material	Retention of particles; reduction of microorganisms by fractionized filter fleeces	▪ Protective nonwoven polypropylene layer ▪ Nonwoven polypropylene filter layers ▪ Nonwoven polypropylene drainage layer (heat-sealed, non-fiber-releasing) ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone ▪ Delivered in packages of 25 cartridges	10", 20", 30", 40"	21, 25, 27, 28
	**Sartopure® GF Plus** The fleece based filter cartridge with adsorptive nonwoven glass fiber materials for maximum protection	Retention of particles and colloids, reduction of microorganisms by fractionized filter fleeces	▪ Protective nonwoven polypropylene layer ▪ Nonwoven glass fiber layers ▪ Nonwoven polypropylene drainage layer (heat-sealed, non-fiber-releasing) ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone	10", 20", 30", 40"	21, 25, 27, 28
	**Sartocool® PS** The high-performance membrane cartridge for cold sterilization of beer	Retention of yeasts and beer-spoilage bacteria	▪ Protective nonwoven polypropylene layer ▪ PES membrane ▪ Nonwoven polypropylene drainage layer ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone	10", 20", 30", 40"	25, 27, 28

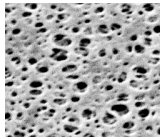
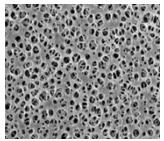
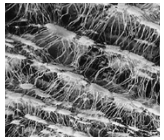
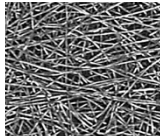
* Polypropylene 559xxx | Glass fiber 555xxx

The pictures shown are for reference only, the actual product may differ.

		Applications	Cartridge Construction	Available Heights	Adapter Types (**)
	**Vinosart® PS** The high-performance membrane filter cartridge for wine and sparkling wine filtration	Specially developed for the retention of microorganisms, particles and colloids in all types of wine and sparkling wine	▪ Protective nonwoven polypropylene layer ▪ Single-layer PES membrane ▪ Nonwoven polypropylene drainage layer ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone	10", 20", 30", 40"	25, 27, 28
	**Jumbo Star** The large-area filter cartridge for easy handling and high flow rates	Retention of particles; reduction of colloids and bioburden in water, wine and beer and in alcohol production; also for venting large tanks	Pleated construction with filter areas of up to 28 m^2; pleats made of polypropylene or glass fiber material*	10", 20", 30", 40"	40
	**Sartobev® PS** The classic membrane filter cartridge for filtration of wine and sparkling wine	For the retention of microorganisms, particles and colloids in wine, sparkling wine and water	▪ Protective nonwoven polypropylene layer ▪ PES membrane ▪ Nonwoven polypropylene drainage layer ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone	20", 30", 40"	25, 28

* Polypropylene 559xxx | Glass fiber 555xxx

The pictures shown are for reference only, the actual product may differ.

		Applications	Cartridge Construction	Available Heights	Adapter Types (**)
	**Aquasart® PS** The high-performance membrane filter cartridge for water filtration	For the retention of microorganisms, particles and colloids in mineral water	▪ Protective nonwoven polypropylene layer ▪ PES membrane ▪ Nonwoven polypropylene drainage layer ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone	10", 20", 30", 40"	25, 27, 28
	**Aquasart® Plus** The innovative membrane filter cartridge for liquids to guarantee the lowest filtration costs	Best retention of microorganisms, particles and colloids in mineral water as well as near-water beverages	▪ Protective nonwoven polypropylene layer ▪ Double layer PES ▪ Nonwoven polypropylene drainage layer ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone	20", 30", 40"	25, 28
	**Aerosart** The hydrophobic PTFE membrane filter cartridge	Sterile venting of tanks fermenters and bioreactors. Sterile filtration of inlet and outlet air, gases, solvents and aggressive media	▪ Protective nonwoven polypropylene layer ▪ PTFE membrane ▪ Nonwoven polypropylene drainage layer ▪ Outer support, core and end caps: polypropylene ▪ O-rings: silicone ▪ Optional: EPDM, fluoroelastomer		25, 27, 28
	**Sartosteel®** Stainless steel filter cartridge for filtration of steam	For the removal of particles from steam and gases	▪ Sintered nonwoven stainless steel mesh: AISI 316L ▪ Reinforced on both sides with sintered-on mesh filter support: AISI 316L ▪ Core and outer support: AISI 316L ▪ O-rings: silicone	10", 20", 30"	21, 25, 27, 28

* Polypropylene 559xxx | Glass fiber 555xxx

The pictures shown are for reference only, the actual product may differ.

Application | Filter Matrix

■ recommended
■ alternatively recommended

Operating Sequences

This matrix provides a guideline for selection of the right filter in a given application backed up by decades of experience in the biopharmaceutical industry. However, it is recommended carrying out small scale filtration trials to identify the optimal filter combination based on the actual product and process conditions.

		Particle Reduction		Prefilters | Bioburden Reduction			Sterile Filters		Sterile Filters				Mycoplasma Retentive Filters	Prefilters		Sterile Filters	Sterile Filters	Sterile Filters
		Sartopure®		Sartoguard			Sartopore® Platinum		Sartopore® 2				Sartopore® 2	Sartoclean®		Sartobran® P	Sartolon	Sartofluor®
		PP3	GF Plus	PES	GF	NF	Platinum 0.2 µm	Platinum HB	HF	0.2 µm	XLG	XLI	XLM	GF	CA	0.2 µm		LG
Material ▸		PP	GF	PES	PES + GF	PES + NF	mod.PES	mod. PES	PES	PES	PES	PES	PES	CA + GF	CA	CA	Polyamide	PTFE
Biotech	**Application**																	
mAb, rec. Proteins, Vaccines	Media Preparation			■	■	■				■	■	■	■					
	pH adjustment in Cell Culture | Fermentation	■								■								
	Cell Removal | Clarification		■		■	■				■	■							
	Buffer Preparation			■					■	■		■						
	Downstream Intermediates (Protection of Columns, Crossflow)			■			■				■							
	ADC Solvent Filtration																■	
	Form & Fill						■	■								■		
Viral Vaccines Cell Culture	Media Preparation			■	■					■	■		■					
	pH adjustment in Cell Culture | Fermentation	■								■								
	Cell Removal | Clarification		■		■					■	■			■	■	■		
	Buffer Preparation			■					■	■								
	Downstream Intermediates (Protection of Columns, Crossflow)			■			■				■				■	■		
	Filtration after Virus Inactivation			■							■			■		■		
	Form & Fill						■	■			■					■		
Pharma	**Application**																	
Ophthalmics	Form & Fill	■		■			■	■		■		■				■		
SVP | LVP	Form & Fill	■						■		■	■	■						
API – Antibiotics	Form & Fill	■						■									■	■
API – Water based	Form & Fill							■		■	■							
Blood & Plasma	**Application**																	
Albumin Globulines	Intermediate Process Filtration (Protection of Columns, Crossflow)			■			■				■				■	■		
	Filtration after Virus Inactivation				■						■			■		■		
	Form & Fill						■	■		■						■		
Clotting Factors	Intermediate Process Filtration (Protection of Columns, Crossflow)			■							■				■	■		
	Form & Fill						■	■								■		
Other	**Application**																	
	Water	■								■	■							
	Oily formulations	■					■										■	
	Solvents	■								■							■	■

Application | Filter Matrix

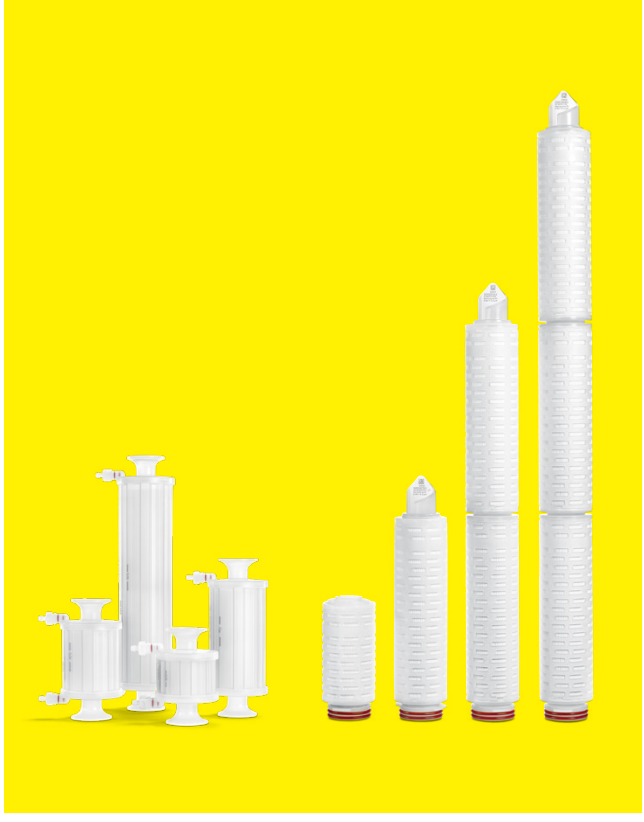
■ recommended
■ alternatively recommended

	Midisart® Sartopore® Air	Midisart® 2000	Sartopore® Air	Sartopure® GA	Sartofluor® GA	Sartofluor® HR
Material ▸	PES	PTFE	PES	GF	PTFE	PTFE
Application						
Compressed gases					■	
Venting of tanks						
Pressure resistant					■	
Non pressure resistant				■		
Glas & plastic bottles		■				
Venting, inflating & leak testing of single-use bags | assemblies	■		■			
Venting of WFI loops (high temperature)						■
Venting of production machinery		■			■	
Bioreactors | Fermentors						
Single-use	■		■			
Stainless steel		■			■	
Protection of integrity test devices			■		■	

Most Common Filters for Food Companies

Sartofluor®
Suited to demanding venting applications with high volume gas streams, extreme humidity, and stringent Steam In Place regimes. The hydrophobic PTFE membranes used in Sartofluor® filters offer reliability, process security, and a long service life.

Applications
- Bioreactors (Inlet | Outlet)
- Storage Tank Venting
- Filling Equipment Venting
- Freeze Dryer
- Autoclave Venting



Most Common Filters for Food Companies

Sartopure® GF Plus
Adsorptive depth filters are designed for removal of contaminants like colloids, lipids, protein aggregates (Host Cell Protein) and particles from biopharmaceutical fluids. They are used for protection of membrane filters, chromatography columns and ultrafiltration systems in pharmaceutical and biotechnological production processes.

Applications
- Cell Culture fluids after cell harvest
- Fermentation broths
- Serum free or serum containing cell culture media
- Serum
- Highly viscous opthalmic and LVP solutions
- All media containing lipids and colloids as contaminants

Most Common Filters for Food Companies

Sartopore® 2 (0.2 µm)
Sartopore® 2 filter elements feature a unique hydrophilic heterogeneous double layer design of a 0.45 µm pre-filter and 0.2 µm final filter membrane with an exceptionally high throughput and flow-rate. In addition to its outstanding performance, the Polyethersulfone membrane gives Sartopore® 2 0.2 µm broad chemical compatibility, including a pH-range from pH 1 to pH 14, and a high thermal resistance.

Applications
- Biological fluids
- Media
- Antibiotics
- WFI
- Buffers
- Chemicals
- Cleaning and sanitizing agents

Most Common Filters for Food Companies

Sartopure® IND
A polypropylene fleece-based prefilter offering both highest total throughput and protective abilities. Its outstanding filtration ability results in a significant reduction of the required filtration area, essentially reducing filter consumption and the overall cost of prefiltration. Sartopure® IND is the ideal choice for particle retention and protection of downstream equipment for all product contact applications.

Robust Processes
Sartopure® IND provides exceptional robustness to prefiltration applications based on the unique retention performance of its fleece material. The fleece retains particles with high efficiency even under varying process conditions, ensuring secure and reliable operation.

High Product Yield
The all-polypropylene design of Sartopure® IND provides low unspecific binding for highest product yield during your filtration processes.

High Flexibility
Sartopure® IND filter elements are available with a broad variety of retention ratings from 0.45 µm up to 50 µm making them ideally suited for numerous prefiltration applications.

Broad Compatibility and Low Extractables
Sartopure® IND filter elements consist entirely of polypropylene, which leads to broad chemical compatibility with a large number of solvents, acids and bases. Moreover, the all-polypropylene design guarantees a small extractable profile.

Cost-Saving
The outstanding throughput performance and retention capability of Sartopure® IND enable downsizing of the required filtration area for pre- and final sterilizing grade filtration steps, resulting in significant cost savings.

Hollow Fiber TFF Modules

Green Line

- Green Line single-use hollow fiber modules offer you the perfect solution to save money and time, preserve space, and increase flexibility through scalable design.
- Green Line modules provide a linear and predictive scale-up process from laboratory to pilot-scale to manufacturing scale by using matching materials, fluid-path length, and performance characteristics.
- Green Line modules are fully scalable from batch volumes from 10 mL up to 1,500 L with corresponding membrane surface areas from 0.056 ft² (0.0052 m²) up to 166.0 ft² (15.42 m²).
- Green Line modules are offered in molecular weight cut-offs (MWCO) that range from 3kD to 750kD and in pore sizes from 0.1 µm to 0.65 µm, with lumen ID's of 0.5 mm, 1.0 mm and 2.0 mm.

Relevant Applications

- Concentration and purification of vaccines
- Concentration and diafiltration of gene therapy products cell-harvest (e.g. excellent results have been achieved with both *E. Coli* whole cells and *E. oli* lysates, as well as other microbial process streams.)
- Clarification of mammalian | CHO cell cultures and maximizing protein recovery concentration
- Diafiltration of monoclonal antibodies, recombinant proteins, biological macromolecules and peptides.

Hollow Fiber TFF Modules

Reuse Line

- Reuse Line hollow fiber modules offer a modified polyethersulfone (m-PES) membrane which is gentle on your cells, biomolecules and viruses
- Generate high yields and low hold-up volumes
- Reuse Line modules provide a linear and predictive scale-up process from laboratory and pilot-scale to manufacturing scale by using matching materials, fluid-path length, and performance characteristics
- Reuse Line modules are fully scalable with batch volumes from 10 mL up to 1,500 L with corresponding membrane surface areas from 0.056 ft² (0.0052 m²) up to 166.0 ft² (15.42 m²)
- Due to the inhouse production of the membrane the Reuse Line can offer you a high batch-to-batch consistency. Reuse Line hollow fiber modules can be sanitized and cleaned in 0.5 – 1.0 N NaOH, and stored in 0.1 N NaOH between uses

Relevant Applications

- Clarification of mammalian | CHO cell cultures and maximizing protein recovery concentration
- Diafiltration of monoclonal antibodies, recombinant proteins, biological macromolecules and peptides.
- Concentration and purification of vaccines
- Concentration and diafiltration of gene therapy products
- Cell-harvest (e.g. excellent results have been achieved with both *E. Coli* whole cells and *E. Coli* lysates, as well as other microbial process streams.)

Hollow Fiber TFF Modules

Steamer Line

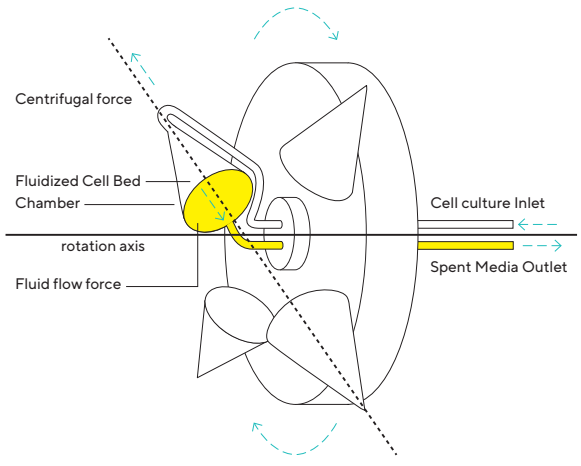
- Steamer Line hollow fiber membrane products incorporate our latest glycerin free low extractables, heat resistant modified polyethersulfone (m-PES) membrane technology
- All Steamer Line modules are gamma irradiated and ready to use without any tedious pre-rinse
- The extractables level for the Steamer Line modules is approximately 80× less than a glycerin conditioned membrane
- After a quick buffer conditioning the module is ready to be used or autoclaved
- Steamer Line modules are fully scalable from batch volumes from 10 mL up to 250 L with corresponding membrane surface areas from 0.056 ft^2 (0.0052 m^2) up to 26.9 ft^2 (2.5 m^2)

Relevant Applications

- Cell perfusion with a conventional pump operated crossflow perfusion system. Bioreactor and steamer hollow fiber assembly can be autoclaved simultaneously
- Concentration and diafiltration of gene therapy products as well as monoclonal antibodies, enzymes, blood components and other proteins
- Rapid clarification of volumes from 10 mL to 250 L of cell culture, fermentation solutions and virus | vaccine suspensions
- Production scale aseptic operations or any other sterile application requiring autoclaving

Ksep® Systems (Advanced, Scalable, Single-Use Automated Centrifugation Systems)

- The only current technology that provides significant advantages for users that want to either harvest cells as product or discard cells as by-product during manufacturing
- Solve the problems of traditional centrifugation and filtration-based technologies by handling very high cell densities while providing high recoveries and product quality
- Through the balance of centrifugal and fluid flow forces, the Ksep® retains particles such as cells or microcarriers, as a concentrated fluidized bed under a continuous flow of media or buffer
- These are the only bowl centrifuges that do not stop rotating while discharging
- The system can be operated under sterile conditions and all consumables are delivered pre-sterilized

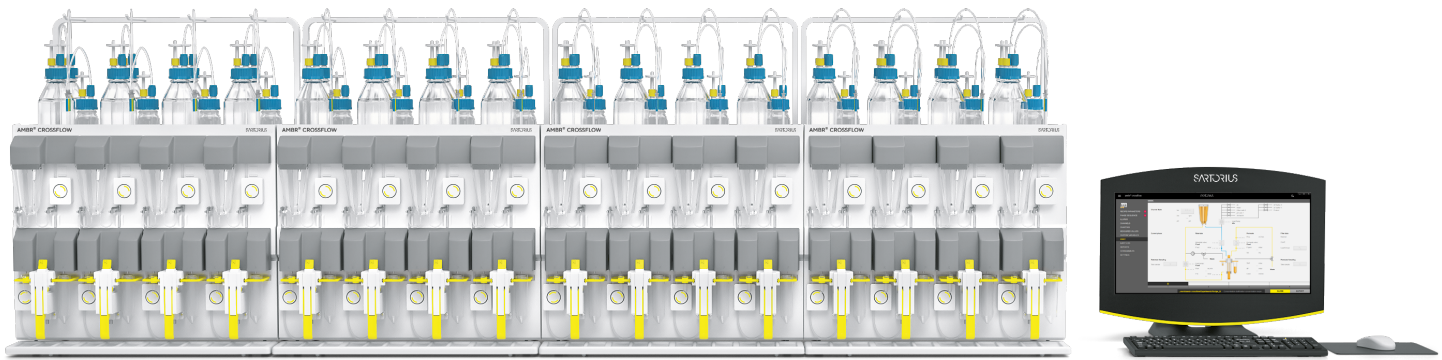


Ambr® Crossflow: The High Throughput Solution for Parallel Screening

- Study factors for manufacturability
- Up to 16 automated, parallel trials
- Lowest process volumes – 5 mL recirculation volume

Flexibility for Automated Processing

- Expand your Ambr® crossflow system and tailor it to your actual demand with 4, 8, 12 or 16 channels
- Each Ambr® crossflow module consists of four independent crossflow channels

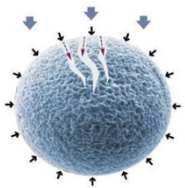


Sartoflow® Smart System

- Excellent flexibility
- Ideal for membrane surface areas from 50 cm² to as much as 0.14 m²
- Intuitive and user-friendly
- One operating design and predefined sequences for all Sartoflow® systems
- The highest product yields
- Low shear 4-piston membrane pump

The Right Technology for the Task

Resins



Average pore size 15 – 40 nm (diffusive)

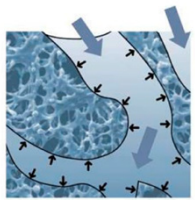
- Capture and intermediate steps of molecules below 200 kDa – Bind & Elute
- Multi-use
- Packing required
- Key Applications: proteins (mAbs, recombinant proteins, etc.)

Monoliths

Channel size 1.3 to 6 µm (convective)

- Capture and polishing of large biomolecules – Bind & Elute
- Single-use or multi-use
- Ready to use (no packing)
- Key applications: viruses (AAV, lenti, adeno, flu), nucleic acids (mRNA, pDNA), exosomes

Membranes



Average pore size 3 – 5 µm (convective)

- Polishing in flow-through mode
- Ready to use (no packing)
- Key Applications: DNA, HCP, endotoxin removal, virus clearance

Matrix and Modality	Affinity	Ion Exchange	Hydrophobic Interaction	Mixed-Mode	Immobilization
Membrane	Sartobind® Rapid A	Sartobind® Q Sartobind® S Sartobind® STIC PA	Sartobind® Phenyl		
Monoliths	CIMmultus® Oligo dT18	CIMmultus® QA CIMmultus® DEAE CIMmultus® SO3 CIMmultus® EV CIMmultus® EDA	CIMmultus® C4-HLD CIMmultus® OH	CIMmultus® H-Bond CIMmultus® PrimaS	Epoxy Carboxydiimine Hydrazide Ethylenediamine Aldehyde
Resin	Heparin Hyper D Lysine Hyper D Blue Trisacryl M	Q Ceramic Hyper D DEAE Ceramic Hyper D CM Ceramic Hyper D* Hypercel Star AX	SDR Hyper D	CMM HyperCel MEP HyperCel HEA HyperCel PPA HyperCel HA Ultrogel	

* SPEC 70 SLS Cation Exchanger for F&B.

Broad Resin Portfolio for Large Scale Purification of MAbs, Recombinant Proteins, Vaccines, Nucleic Acids, and Plasma Fractionation

- Features and Benefits:
  - Average pore size 15-40 nm (diffusive)
- Capture and intermediate steps of molecules below 200 kDa–Bind & Elute
- Multi-use
- Packing required
- Key Applications: proteins (mAbs, recombinant proteins, etc.)

Chromatography Modes
- **Ion Exchange** | Q, DEAE, CM, STAR AX
- **Mixed Mode** | CMM, MEP, HEA, PPA, HA
- **Affinity** | Heparin, Lysine, Blue Dye, SDR

Base Matrices
- **HyperCel** | rigid cellulose
- **Ultrogel** | hydroxyapatite agarose composite
- **Ceramic HyperD** | hydrogel in rigid ceramic bead
- **Trisacryl** | synthetic polymer

Capability	Benefit
Range of base matrices	Select best base for target application of resin – cellulose, synthetic polymer, mineral composite
IEX, mixed-mode and AF modes	Cover most biopharma applications and provide unique selectivities for difficult separations and new molecular entities
Format options	RoboColumns and small repacked columns for screening and PD; bulk resins in assorted pack sizes up to 10 L
Technical support	Column packing expertise and support for process development and optimization
Suited to commercial manufacturing	Produced in volumes and quality to meet cGMP manufacturing demands, with RSF to support customer regulatory submissions

Ion Exchange Resins, Mixed Mode Resins and Specialty Resins

Features

- High dynamic capacity
- Variety of selectivity´s
- Salt tolerant chemistries available
- Chemical and mechanical stability

Benefits

- Excellent productivity
- Separation of wide variety of products and contaminants
- Efficient and cost effective by easy interfacing process steps
- Scalable packing and long resin lifetime

Development

- Small 1 mL pre-packed columns

- Loose resins to pack columns
- Small 1 and 5 mL pre-packed columns

- RoboColumns for high throughput (200 and 600 µL)[1]
- Loose resin to pack 96-well plates

Pilot

- Loose resins to pack columns
- Small 1 and 5 mL pre-packed columns
- Resolute FM columns for Pilot scale

Production

- Loose resins in 1, 5, 10, 20 L drums to pack columns
- Resolute columns for production scale column chromatography

Resin Selection Guide

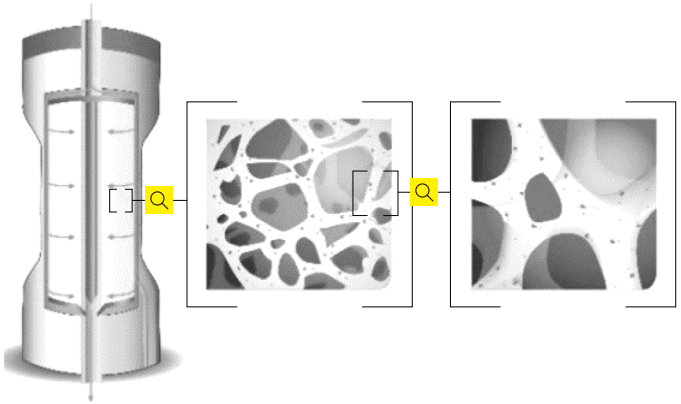
Resin	mAb	Rec. Protein	Vaccine, VLP	Blood Fract.	Nucleic Acids
Ion Exchange					
Ceramic HyperD F CM	■	■	■	■	
Ceramic HyperD F DEAE	■	■	■	■	■
Ceramic HyperD F Q	■	■	■	■	■
HyperCel STAR AX	■	■		■	
Mixed Mode					
CMM HyperCel	■	■			
MEP HyperCel	■	■			
HEA HyperCel	■	■			
PPA HyperCel	■	■			
HA Ultrogel		■	■		

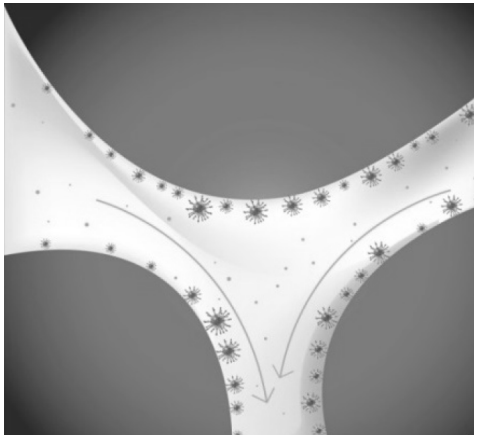
Resin	mAb	Rec. Protein	Vaccine, VLP	Blood Fract.	Nucleic Acids
Affinity | Specific					
Heparin HyperD M		■	■	■	
Lysine HyperD		■			
Blue Trisacryl M		■	■		
Hydrophobic Interaction					
SDR HyperD	Removal of detergent and | or solvent				

Monoliths

Key Monolith Attributes

- Very fast processes by convective mass transport — flow independent resolution and capacity
- High-capacity large molecules by fully accessible void volume in the channels
- High yields by laminar flow — no shear stress
- High resolution - separates full capsids from empty capsids (For AAV)
- Ready-to-use, single-piece, continuous polymethacrylate monolith with channels ranging from 1.3 to 6 µm in diameter
- Capture and polishing of large biomolecules — Bind & Elute
- Single-use or multi-use
- Ready to use (no packing)
- Key applications: viruses (AAV, lenti, adeno, flu), nucleic acids (mRNA, pDNA), exosomes, etc.





CIM Monoliths

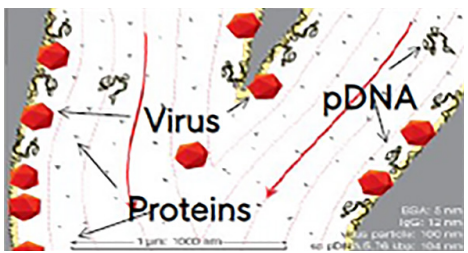
CIM monoliths contain highly cross-linked, porous poly-methacrylate material with well-defined channel-size distribution

CIMac

- Ready-to-use analytical columns designed for large biomolecules
  - Rapid – a matter of minutes
  - High throughput
  - High resolution
  - Accurate and reproducible
  - Available with different chemistries (AEX, CEX, HIC, affinity)
  - Specialised CIMac for pDNA, AAV, Adeno, Trypsin
- Perfect tool for analysis and control of manufacturing processes
- Compatible with most HPLC, UPLC, FPLC systems

Summary of Advantages of Monoliths

High surface accessibility	High dynamic binding capacities for large molecules
Convective mass transport	Flow independent performance, easy scale up
Convective mass transport	Excellent resolution, small peak broadening
High porosity and large channels	Low pressure drop, high flow rates
Laminar flow	Low shear forces



Ideal for the separation and purification of large biomolecules; pDNA, viruses, mRNA, large proteins and extracellular vesicles

CIMmultus®

3 Channel Sizes

- 1.3 µm for small proteins | molecules
- 2 µm "Standard channel"
- 6 µm for virus | large molecules

Available Sizes for Scale-up

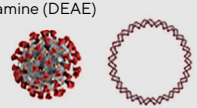
- 1 mL, 4 mL, 8 mL, 40 mL, 80 mL, 400 mL, 800 mL, 4 L and 8 L

CIMmultus® — Ligands and Applications

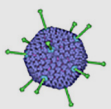
Ion Exchange

Quaternary amine:
QA, EV and AAV F/E

Diethylamine (DEAE)

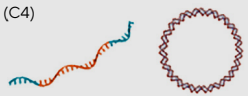


Sulfonyl (SO3)

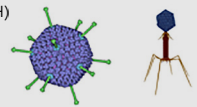


HIC

Butyl (C4)

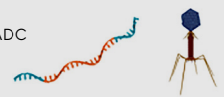


Hydroxyl (OH)



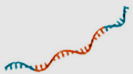
Multimodal

PrimaS®
H-Bond ADC



Affinity

Oligo dT



Protein A
Protein G
Protein L

Metal chelate (IDA)

Custom ligands

Activated (immobilizations)

Epoxy Carboxydiimine (CDI)

Hydrazide (HDZ)

Ethylenediamine (EDA)

Aldehyde (ALD)

AAV F/E: Separation of Empty | Full capsids of Adena-Associated-Viruses
pDNA SC/OC: Separation of super-coiled from open circular plasmid DNA

Sartobind® Membrane Absorbers

- Scalable device portfolio from screening to production
- Average pore size 3–5 µm (convective)
- Polishing in flow-through mode
- Ready to use (no packing)
- Key Applications: DNA, HCP, endotoxin removal, virus clearance, etc.
- Made from regenerated cellulose
- Supports high flow rates (5–20 MV/min)
- Variety of chemistries (Q, S, Phenyl, STIC)
- New Sartobind® Mini available

Bed height	96 well plate	Pico	Nano	Mini	5"	10"	20"	30"	Jumbo	Cassette
4 mm	0.019 mL	0.08 mL	1 mL	10 mL	75 mL	200 mL	400 mL	600 mL	2,500 mL	800 mL
8 mm			3mL	20 mL	150 mL	400 mL	800 mL	1,200 mL	5,000 mL	1,600 mL

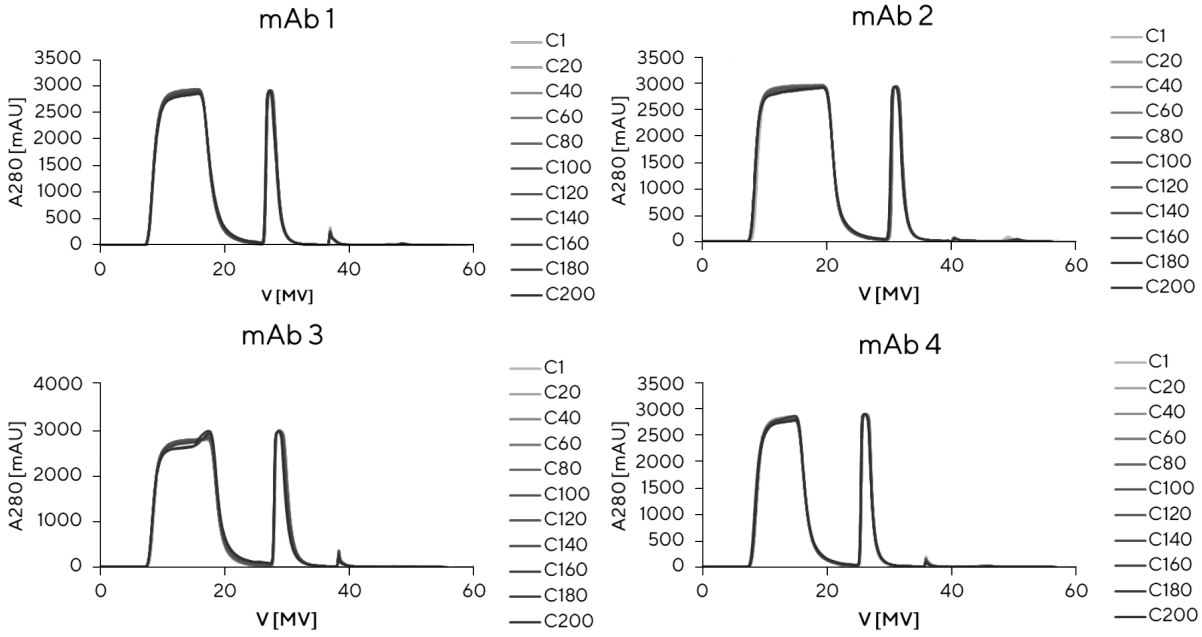
Screening Device →

Process — Bench Scale →

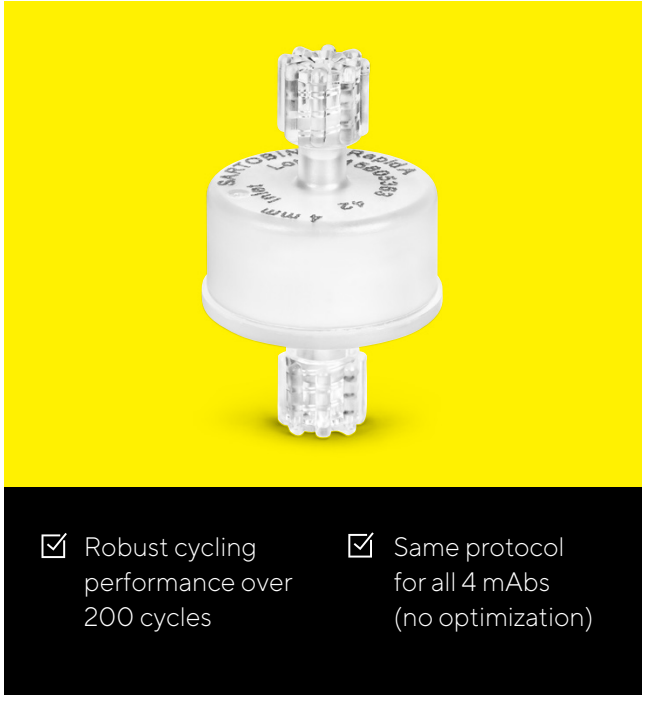
Pilot — Pre-Industrial Scale →

Manufacturing — Commercial Scale →

Sartobind® Rapid A Provides Robust Performance



Grünberg et al., Membranes 2022



- ☑ Robust cycling performance over 200 cycles
- ☑ Same protocol for all 4 mAbs (no optimization)

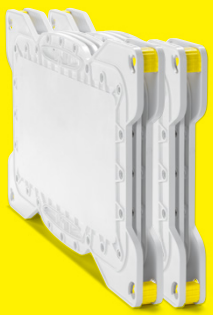
Sartobind® Membrane Absorbers

Cassettes

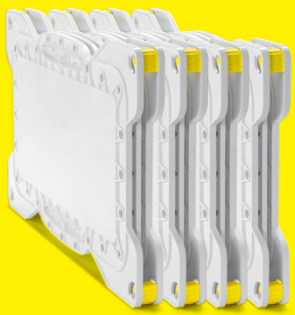
- Allow a simplified direct modular scale up
- Installation of up to 13 cassettes ~21 L in the Pilot filter holder, larger holders can take up to 100 L.
- Available gamma irradiated for safer purification
- Enables fully SU membrane-based DSP process

USP

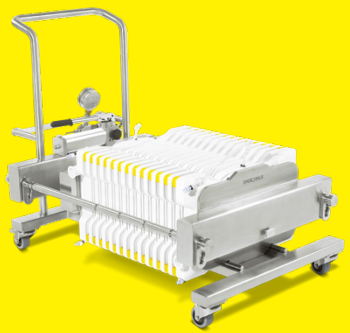
2,000 L
10 kg



4,000 L
20 kg



12,000 L
60 kg

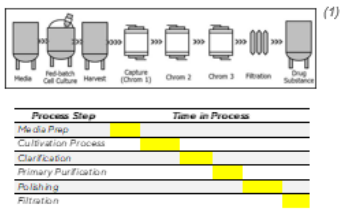


Multi-Use Batch Chromatography Systems

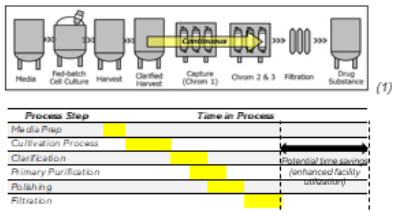
- Most large molecule customers today are using a batch process, where each step is disconnected with no overlap
- Ultimately the industry wants to get to continuous manufacturing, since there is significant cost and time savings
- While we haven't reached continuous manufacturing yet, some companies have taken a hybrid approach to start reaping the rewards of continuous manufacturing
- A hybrid process will connect some of the steps in a continuous fashion, while the other steps will still be performed in batch mode
- Another term for this is "intensified processing", which is where many customers are interested today

Intensified Processing

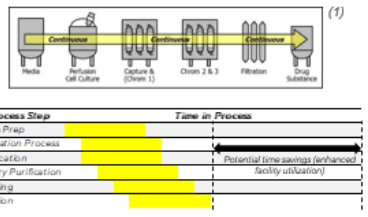
Batch



Hybrid



Continuous



Linking continuous Unit Operations:

- Significant cost savings on purification consumables and equipment
- Eliminating or minimizing interstage product hold containers
- Significant time savings due to parallel operation

Resolute® BioSC

Features

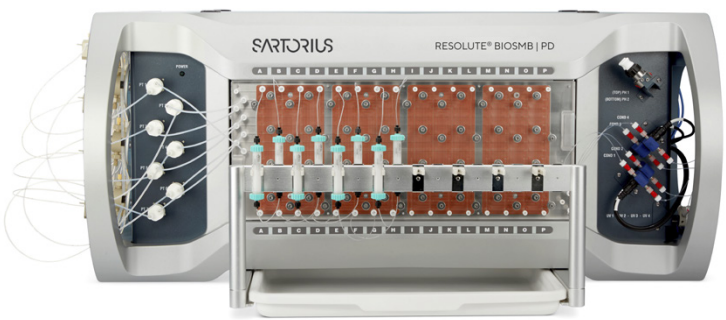
- Adaptability: BioSC Pilot operates from 1 up to 6 columns in batch, parallel batch, continuous chromatography or continuous process
- Easy switch from batch to continuous, optimizing process parameters with BioSC Predict software
- Reduction of media and buffer consumption by up to 75%
- Increased productivity by 2 to 6-fold
- Wide range of process scenario screening: Possibility to work from 1 to 6 columns or membrane to adapt all customer objectives (productivity, media and buffer savings...)
- Whatever your process strategy (with or without elution gradient), BioSC allows you to develop or process in accordance with equipment specifications
- In addition to the standard chromatography sensors (pH, UV, conductivity), BioSC also features extra sensors (flowmeter, pressure, temperature) for PAT approach
- BioSC Predict is the unique simulation and optimization software for the development of continuous chromatography processes dedicated for the purification of biopharmaceuticals

Process Intensification With Resolute® BioSMB – Merck and Co.

- A total of 2.3 kg mAb was purified in 11 hours
- 80% reduction in chromatography costs
- 3.5 fold increase in productivity
- 5 columns was the optimal configuration
- All work done within 3 weeks
- The process was successfully scaled up >150-fold
- Product quality attributes were maintained

	Batch Process	BioSMB Process
Number of cycles	3	13
Column diameter	40 cm	14 cm
Column height	16 cm	5 cm
Number of columns	1	5
Volume of Protein A sorbent	**20 L**	**3.85 L**

	Batch Benchmark	PD System	Process System
Eluted mAb concentration	9.54 g/L	13.84 g/L	13.85 g/L
mAb yield	98%	97%	97%
Aggregate	< 1%	< 1%	< 1%
LRV* DNA	n.a.	4.16	5.02
LRV HCP	2.4	2.6	2.5
Specific productivity	**16 g/L/h****	**56 g/L/h**	**56 g/L/h**



See Application Note USD 3181, "Scale-Up of Multi-Column Chromatography Using BioSMB Process System"

With acknowledgement of Mark Brower, Nuno Pinto, Doug Richardson, Bhumit Patel, Jun Heo, SenXu, Mike Cuzzola and Ed Glowacki of Merck & Co., Inc.

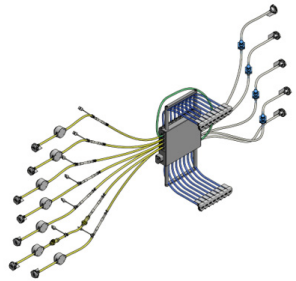
Resolute® BioSMB Process

Direct Scale-up From PD to mfg
- 0 – 100 mL/min (PD), 5 – 350 L/h (Process)
- Transferable recipes
- Identical flow path architecture
- Identical phase editor

Transferred Realized Benefits
- High productivity
- Lower buffer consumption
- Lower media consumption

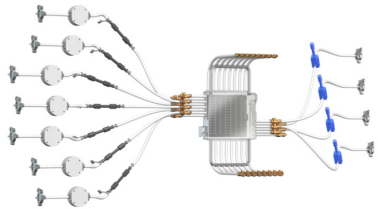
Resolute® BioSMB Process 80 Manifold*

7 inlets (Quattroflow pumps, Ultrasonic flowmeter, In-line pressure transducers)	5 outlets (4 with UV | Vis, pH and Cd. sensors, 1 waste/drain)	8 chromatography column positions Maximum operating pressure of 4 barg	Exclusive feature: ▪ Manifold supplied in complete unit ▪ Aseptic connectors for buffers, outlets and columns



Resolute® BioSMB Process 350 Manifold*

Colder HFC connectors between manifolds	Gamma irradiated SU flow path can be replaced within 30 minutes	Pre-calibrated sensors	Exclusive feature: ▪ Manifold supplied in four sections ▪ Tri-Clamp connectors for buffers, outlets and columns



Resolute® Flowdrive SU Chromatography System

Resolute® Flowdrive Single Use

- Capable of processing batch sizes between 200 L and 2,000 L
- Offers a combination of hardware, automation and single-use assemblies designed to work together seamlessly
- Up to 900 L/hr
- Isocratic operation or dual pump gradient option
- Ready to use gamma irradiated flow kits
- No calibration of single-use sensors
- Flow kits installed on front side of the system
- Utilizes new valve block technology
- Designed for optimized purification performance and process robustness
- SU systems designed for pilot-scale and commercial production
- Open architecture allows the use of resins and membrane adsorbers with Resolute or columns from 3rd parties
- State of the Art Flow Kit
- Prepacked | conventional columns up to 60 cm at 300 cm/hr
- Quattroflow pumps
- Pre and Post-column conductivity, pH, UV and flow cell options

Process Flexibility in One System

Manifolds are available in gradient or isocratic configuration.

Each configuration is available in ⅜" or ½" ID tubing for different flowrate capabilities.

⅜" ID Manifold
- 10 to 500 L/hr
- 0.5 L hold-up volume
- 75 to 800 mL Sartobind®
- 100 to 400 mm column

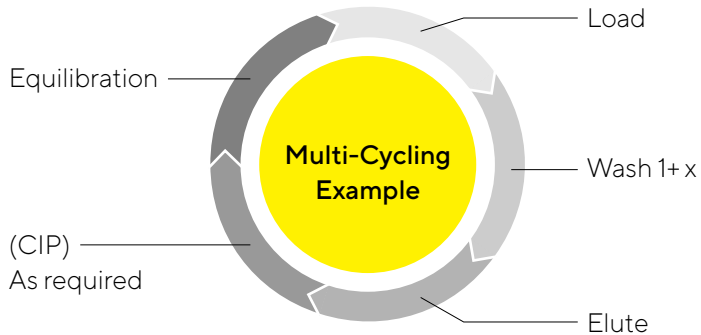
½" ID Manifold
- 20 to 900 L/hr
- 1.0 L hold-up volume
- 75 to 800 mL Sartobind®
- 200 to 600 mm column

Varying configurations with two different tubing sizes allows for expanded processing capabilities with a single system, decreasing CAPEX

Multi Use RCC

- RCC is a fully scalable, intensified technology
- Sartobind® membrane scalability
- RCC offers up to a 15-fold increase in productivity
- Ability to process one batch on one membrane economically.
- RCC offers the opportunity to move to true single-use manufacturing with chromatography consumables.
- Flow rate up to 150 L/h
- Fits 5" and 10" Sartobind® capsules
- Scalability PD to commercial manufacturing

	RCC	Trad. Chromatogr.
Cycle no.	~30 – 150 min	4 – 6 hr
Cycle time	~5 – 8 min	> 2 hr
Time of each phase in a cycle	~1 min	Several min to hr



Resolute® Flowdrive ATEX

The Resolute® Flowdrive Atex product family provides a solution for customers requiring systems for use in an explosive environment. Rated to ATEX Zone or Class 1 Div 2 these systems are fully configurable and come in a range of sizes to suit a wide range of clinical and commercial applications.

* PKP and PK available upon request

Hipersep® Flowdrive: Preparative HPLC Chromatography Systems

Batch, Tides and Small API

Hipersep® Flowdrive is an automated high-performance liquid chromatography system built from process development to large scale pharmaceutical manufacturing.

The proven design meets process demands for intermediate purification and polishing of peptides, oligonucleotides, mRNA and other small molecules.

Benefits

- Unmatched performance levels: pressure capacity of up to 100-bars
- Meet the challenges of new applications: high temperature purification processes: up to 85 °C operation
- Flexibility: extended flow rate range and easy-to-clean system
- Save manufacturing space: compact and ergonomic equipment

Hipersep® Flowdrive Pilot

Hipersep® Flowdrive Process M

Hipersep® Flowdrive XXL

Flow Rates Range

Hipersep® Flowdrive Pilot	6 – 90 L/hr
Hipersep® Flowdrive Process M	60 – 500 L/hr (20 – 200 L/hr, low flow version)
Hipersep® Flowdrive L	300 – 1,000 L/hr
Hipersep® Flowdrive XL	500 – 1,600 L/hr
Hipersep® Flowdrive XXL	1,000 – 2,500 L/hr

* Hipersep Varicol available upon request for very large industrial needs

PATfix® HPLC Platform

Analytical Needs Covered by HPLC Analytics:

Raw material control
- pDNA content/purity
- NTP purity
- Capping reagent purity
- Enzyme purity

DS Stability
- Stability indicating methods
- Content

DS analytics
- Content
- Purity

DSP IPC analytics
- Content
- Purity

IVT reaction monitoring
- mRNA content
- NTP content
- Capping reagent content
- pDNA content
- Capping efficiency

Benefits – PATfix Analytics & CIMac Columns:

- Analyses of various biomolecules; pDNA, mRNA, AAV, Ad5...
- Used for process monitoring or release of product and control
- Rapid chromatographic analytical methods (~15 min)
- HPLC analytics does not require expensive reagents
- Broad diversity of column chemistries; SO3, QA, PrimaS, pDNA, SDVB...
- Various analytical techniques; pH, gradients, RP, SEC, HIC

PATfix is your main source of analytical insight.

A One Stop Shop for:
- Process Development
- Production Tracking
- Quality Control

- **Lowers initial knowledge | skill barrier**
  - Ease of adoption
- **Easy analytics scale-up**
  - Software can pool data from multiple machines
- **New staff requires only basic analytical chromatography knowledge**
- **From sample to the result in 20 minutes or less**
  - Speeds up process development

Included

Buffer Tray

Pump
Ceramic, 10 mL/min, CIP compatible

UV Detector
4 simultaneous, 190 – 700 nm,
100 Hz sampling

Autosampler
108 slots, 4 – 40 °C, auto needle wash

Cond./pH
Contactless, 0.1 – 999 mS/cm,
pH 2 – 12

Optional

Column Oven
Multicolumn, 5 – 85 °C, Temp. gradients

Fluorescence Detector
2 simultaneous, 200 – 650 nm

Fraction Collector

All-In-One Computer
108 slots, 4 – 40 °C, auto needle wash

Hybrid Expansion
Combines analytics with prep scale chromatography

Hipersep® Prochrom Columns: Preparative HPLC Chromatography Columns

Hipersep® Prochrom columns meet high standards of design ensuring efficiency and scalability.

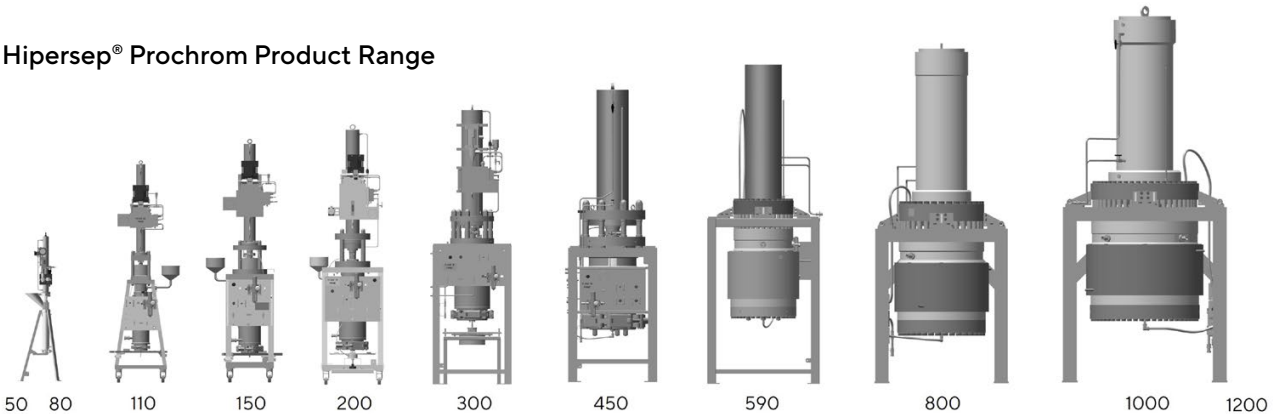
- Designed for process development and manufacturing. They are available from 50 to 1,200 mm internal diameter
- The design is similar throughout the range assuring true linear scale up of column performance. This simplifies the scale and does not require method redevelopment
- Dynamic Axial Compression (DAC) technology combined with packing methodology allows reproducibility and robustness over time
- Our packing technology has been developed to achieve a well-packed bed in a minimum amount of time
- Our columns are engineered for ease of cleaning and maintenance operations while maximizing operator safety

Hipersep® Prochrom Columns: Preparative HPLC Chromatography Columns

Features and Benefits

- Efficiency and scalability: A complete range from lab to industrial scale from 50 to 1,200 mm internal diameter
- Fast and safe packing and unpacking: Packing in 15 to 30 minutes maximum
- High standards of design meeting explosion-proof requirements
- 100 bars maximum operating pressure

Hipersep® Prochrom Product Range

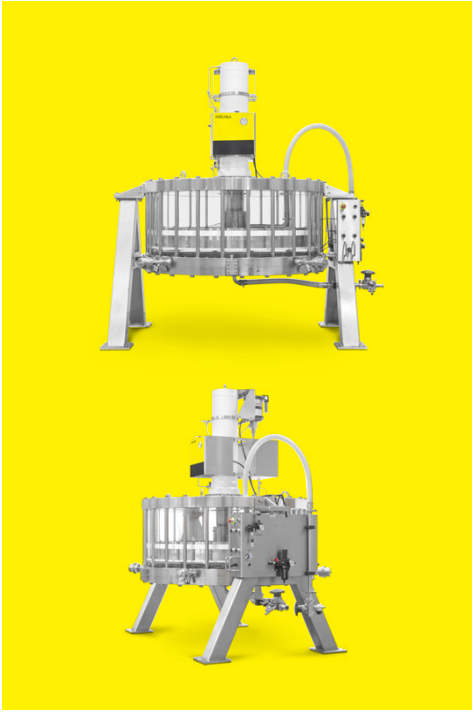


Resolute® Prochrom Column

Features
- High performance, high reproducibility
- Complete scalability from pilot to manufacturing scale and 5 bar pressure rating
- Regulatory Compliance: sanitary design, compliant with the cGMP guidelines
- Adaptable to any chromatography skid

Elemental Packing:
- One single packing method allows to save time
- No column opening, actuated piston. As a result, column can be packed easier and safer
- Number of operations are limited. Operator's skill/experience is not critical for success
- Elemental packing requires nothing more than the column, a buffer tank, a slurry tank
- Simplified with dedicated tools. Save time and footprint

Automated Packing:
- One single packing method allows to save time with simplified packing study
- Packing sequences are managed by the packing unit. Piston drop and packing valve closing are performed by the operator
- No extra media required for packing
- Dynamic Axial Packing
- No slurry concentration limitation
- Undiluted unpacking procedure
- Among the lightest and the smallest columns on the market
- Hoist-free, no need to move the column



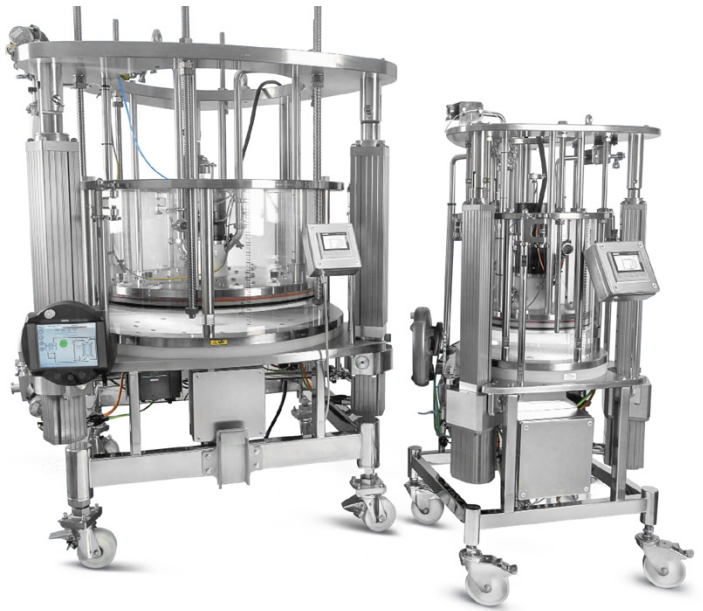
Resolute® Linear Columns: Automated Chromatography Columns for Pilot and Process Scale

- Resolute® Linear chromatography columns are designed for large scale pilot and production use.
- They are available from 350 mm to 2000 mm internal diameter (ID), in all common sizes
- AutoPak Software, Pack-in-Place Technology, Electronic Control Unit, etc.
- Typical flow rate ranges are from 30 to 800 cm/h

Benefits

The Resolute® Linear column range offers a unique combination of active multi-axis piston control, precision linear actuation and fully automated operation that delivers the following benefits to the end-user:

- Fully automated, reliable, efficient packing
- Reduced operator activity and human error
- Safe, clean, quiet operation
- Reduction of additional equipment and cleanroom size
- Configurable to suit a wide range of processes



Resolute® Linear Columns: Automated Chromatography Columns for Pilot and Process Scale

Resolute® AutoPak Software:
Let the Column Do the Packing

- The Resolute® AutoPak system was developed in direct response to an industry need for fully automated operations
- Often key column preparation operations, particularly packing, are regarded as high-risk clean room events

Resolute® Linear Columns: Automated Chromatography Columns for Pilot and Process Scale

Resolute® AutoPak System Features and Benefits

Feature	Benefit
Fully automated packing, unpacking, and CIP	Reproducible results. Reduced time for column packing. Less reliance on skilled operations.
Fully automated re-packing	No need to open the column or use slurry tank to re-pack. No recalculation of slurry concentration. Efficient use of buffers.
Greatly simplified operator interaction	Risk of operator error reduced. Fewer operators required.
Ability to use all the sorbent in the tank	Reduction in media costs. An empty slurry tank after packing enables fast slurry tank cleaning, storage, or re-use elsewhere.
Simplified pipework compared to pump pack methods	Quicker, error free set-up.
Multiple fully configurable packing methods	Easy to adjust to changing plant requirements. Ability to pack a wide range of sorbents.
Ability to save packing parameters as recipes	Easy to transfer recipes between columns on different sites. Faster, lower risk validation for new sites.
Column-mounted secondary valve and nozzle control	The system valves can be adjusted whilst the handheld remote control is being used on other columns.

Resolute® Linear Columns: Automated Chromatography Columns for Pilot and Process Scale

Resolute® AutoPak System Sequences

The fully automated system includes four main sequences as standard. Each sequence has configurable parameters so that it can be adapted to a variety of requirements.

Sequence	Description
Auto Pack	At the touch of a button, valves, nozzles, and piston movement are coordinated to draw slurry into the column and achieve a robust packed bed.
Auto Re-Pack	At the touch of a button, a packed bed is re-agitated using process air, buffer is added, and the bed is re-packed without the need for an external slurry tank. Buffer consumption is minimal.
Auto Unpack	At the touch of a button, the bed is re-agitated and slurry is expelled back to the slurry tank. Media is fully rinsed from the column with the option of an additional rinse.
Auto CIP (empty column)	In the first automated step, cleaning liquid is drawn into the column using piston movement and routed through all possible flow paths before being drained. The operator then connects the Resolute AutoPak system tank valve to a neutralizing tank. The second automated step rinses all of the wetted surface and neutralizes the column. An additional rinse is optional. Cleaning and neutralization can be accomplished in as little as 2 column volumes.

Resolute® Manual Chromatography Columns

Resolute® columns have proven performance with a wide range of chromatography resins and chromatographic modes including ion exchange, mixed-mode, affinity and hydroxyapatite.

Benefits

- High resolution flow path provides optimum efficiency, capacity, and peak symmetry
- Central nozzle valve provides all column functions required for packing, unpacking, and running the column within a closed system
- Scalable, reproducible packing methods reduce validation efforts as processes scale up
- Common design from 280 to 1,200 mm diameter (and up to 2,000 mm on request)
- Designed to minimize packing events and buffer usage to optimize process economics
- Options for manual or remote-controlled nozzle valves

Biosafety Testing (For Biologics and Viral Vaccines)

Biosafety Testing within the manufacturing process should be established in the early stages of drug development. Before clinical trials the following cell banks require complete testing as well as demonstrating that the process samples are free from contamination:

- Master Cell Bank
- Working Cell Bank
- End of Production Cell Bank (EPC)

BioOutsource also supports the testing of:

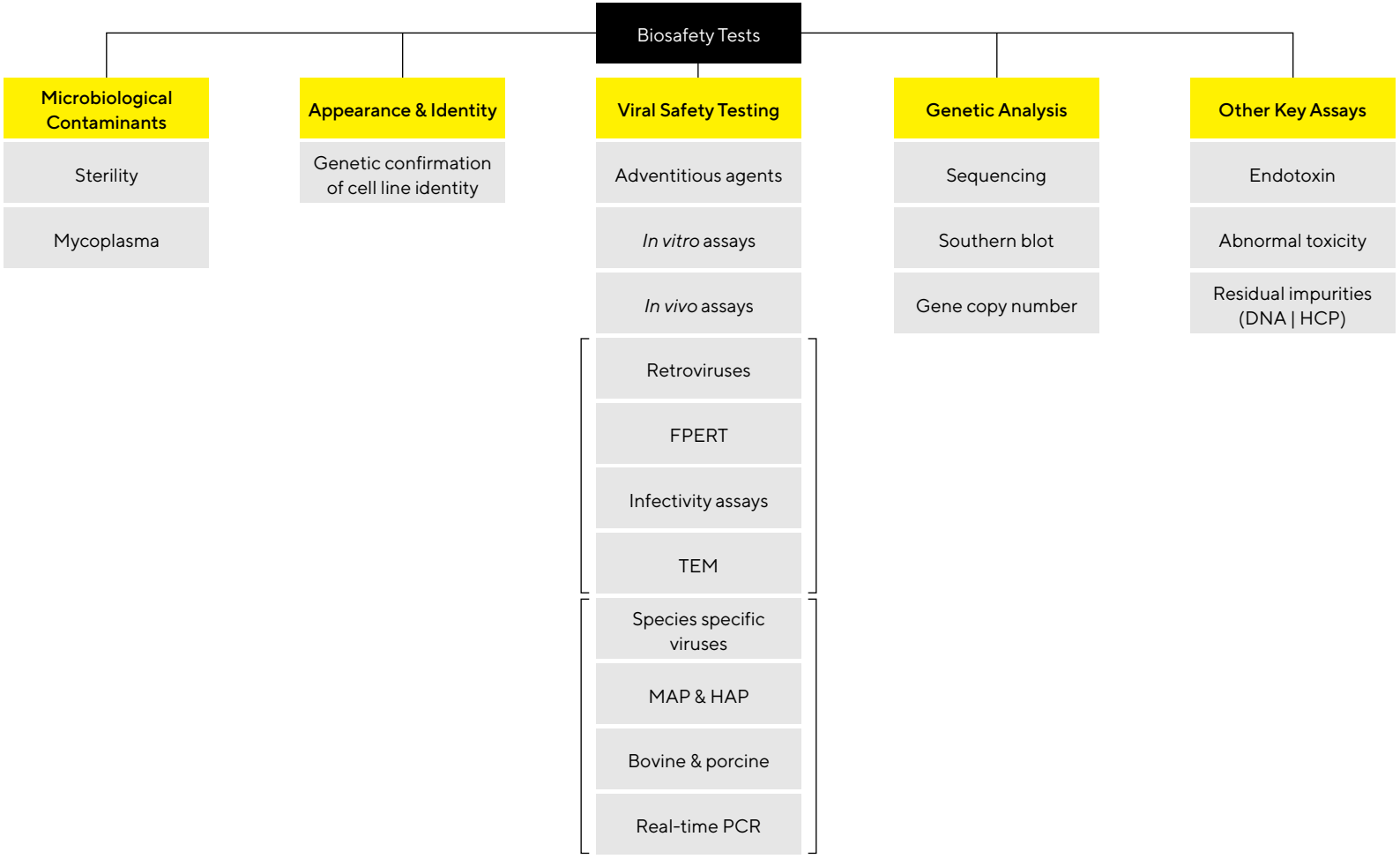
- Bulk harvest
- Genetic stability and identity of cell banks
- Final product lot release

We have developed and validated a range of assays to characterize cell banks originating from different species including murine, hamster, human and primate and have experience working with the following products:

- Biosimilar monoclonal antibodies
- Monoclonal antibodies
- Recombinant proteins
- Vaccines
- Gene therapy vectors
- Regenerative medicine

BioOutsource Partner With Clients From Early Stage Development Through to Commercialisation of the Product:

Cell Line Development → **Clone Selection** → **Process Optimization** → **Product Characterization** → **GMP Lot Release**


Biosafety Tests
Microbiological Contaminants
Sterility
Mycoplasma
Appearance & Identity
Genetic confirmation of cell line identity
Viral Safety Testing
Adventitious agents
In vitro assays
In vivo assays
Retroviruses
FPERT
Infectivity assays
TEM
Species specific viruses
MAP & HAP
Bovine & porcine
Real-time PCR
Genetic Analysis
Sequencing
Southern blot
Gene copy number
Other Key Assays
Endotoxin
Abnormal toxicity
Residual impurities (DNA | HCP)

Cell-Line Development and Testing Solutions

Cell line development and characterization package
- CHO DG44 cell line
- RCB, MCB, WCB manufacture and characterization
- Protein characterization during clone selection

Protein testing and assay development
- Biosafety testing for cell lines, NBEs and biosimilars
- Bioanalytical testing for NBEs and biosimilars
- Platform assay development

Platform Development Services – Food and Beverage

What do we do?

Process Development & Optimization | Scale Up

What does it cost?

$0 for the service

How will it help?

- Sartorius toolbelt
- Hands-on optimization
- Dedicated Sartorius experts

Cell Selection | Screening → Cell Culture Optimization → Bioreactor Production → Harvest → Clarification → Chromatography → Filtration → Final Formulation

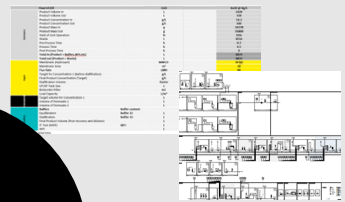
Sartorius Integrated Solutions (InSo)

Collaborating with our account managers and product specialists to evaluate customer process requirements to provide solutions inside-and-outside of our standard product portfolio.

Specialized Equipment

- Filtration
- Freeze thaw
- Chromatography
- Flexact Modular

Conceptual Design



- Room Layouts and Flow
- Process Flow Diagrams
- Mass Balance Report
- Operating Expense Model

Integrated Solutions

Engineered-to-Order (ETO)

- Stainless TFF Skids
- Drug Substance Bag Filling Station

End-to-End Process Solutions

R&D > PD > Pilot > GMP

Desing (CD | BD) > **Quotation** > **Equipment Production & Delivery** > **FAT | SAT** > **Operational Support**

Worldwide Services

Support
- Optimization trials
- On-site assistance
- Training seminars
- Filtration process analysis

After-Sales Services
- Maintenance contracts
- Commissioning
- Calibration
- Repair
- Operators training

These Products and Services Are Must-Haves in Any Laboratory

Lab Instruments
Balances, Moisture Analysers, Pipettes, Lab Water Systems, Microbiological Testing Equipment, Protein Detection (Octet® Systems)

Consumables
Syringe Filters, Microbiological Testing Consumables, Pipette Tips, Filtration Devices, Filter Paper

Services
Installation, Servicing | Repair, Qualification (IQ | OQ), Calibration, Training

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