

Food and Ingredients: An A-Z Product Portfolio

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, cultured 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

Ambr® 15 CC

Ambr® 250
High ThroughputAmbr® 250
Modular

Biostat® B

Biostat® RM

Biostat® B-DCU

Univessel®
SUUnivessel®
GlassBioPAT®
Sensors

Biostat® Cplus

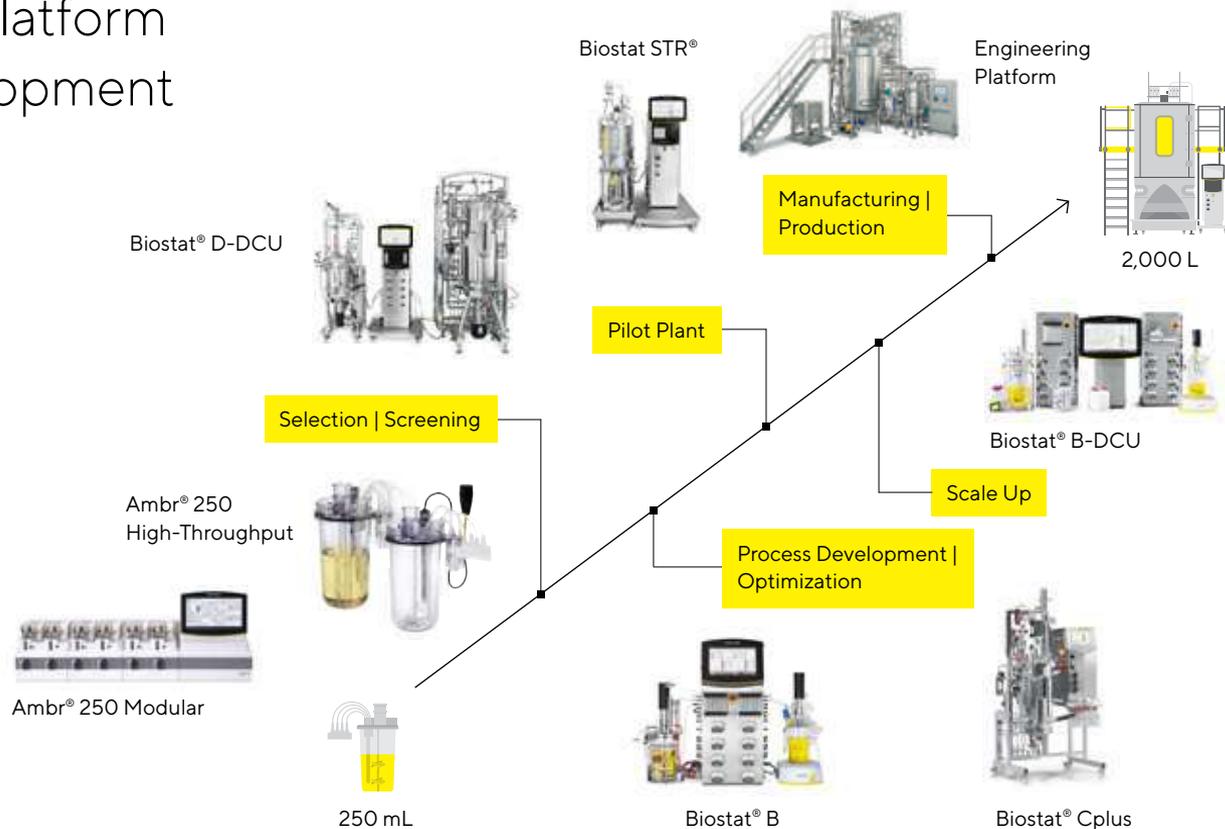
Biostat®
D-DCU

Biostat STR®

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
- Stainless steel bioreactors with the Biostat® Cplus and D-DCU
- Single-use bioreactors with the Biostat® RM and Biostat STR®



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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.)



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)



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- 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



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Biostat®
D-DCU

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- 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 CO₂ and O₂, also uses OUR and CER measurements
- Optional on-line biomass analyzer (for microbial only)



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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)
- Biostat® RM (100 mL to 100 L)

- 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).



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Biostat® B: Universal Controller for Your Lab

- **Largest** installation base worldwide with reference applications for many processes
- **Connection** to glass and single-use vessels and rocker
- Available in single and **twin** configurations
- **Various** gassing and feeding strategies available
- 12" touch screen with flush housing integration for liquid **protection**
- WM 114 **Easy** load pumps
- Controller, software and culture vessels **made in-house**
- Available with RM rocker option up to 200 L



Univessel® SU

Univessel® Glass

Biostat® B control tower

Biostat® RM

Biostat® B with RM 200
for working volumes up to 100 L

Biostat® RM and Flexsafe® RM Bag

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 With Biostat® B Control Tower

- 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



Biostat® RM 200



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Biostat® RM Product Family



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Ambr® 250 Modular

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Univessel® SU

Univessel® Glass

BioPAT® Sensors

Biostat® Cplus

Biostat® D-DCU

Biostat STR®

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 | CO₂ 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



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Features of the Biostat® B-DCU

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.

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

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



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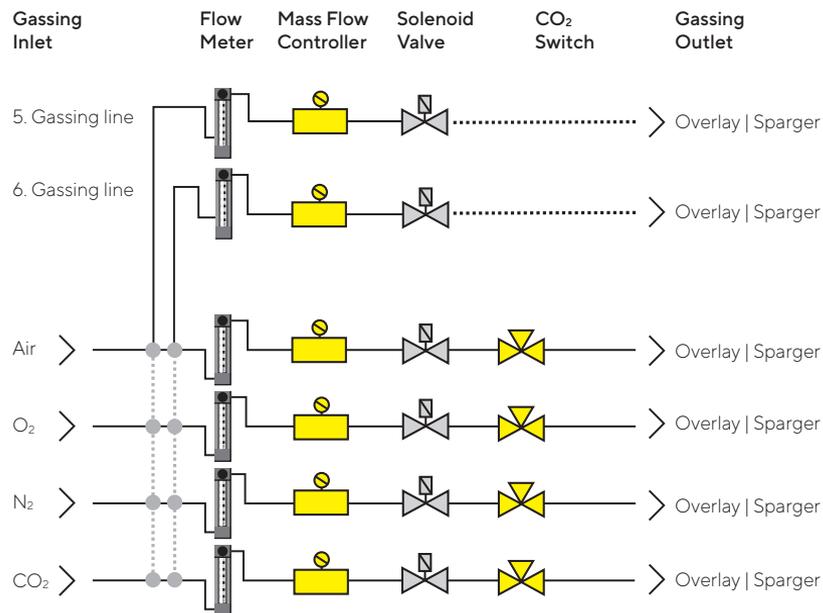
Biostat® Cplus

Biostat®
D-DCU

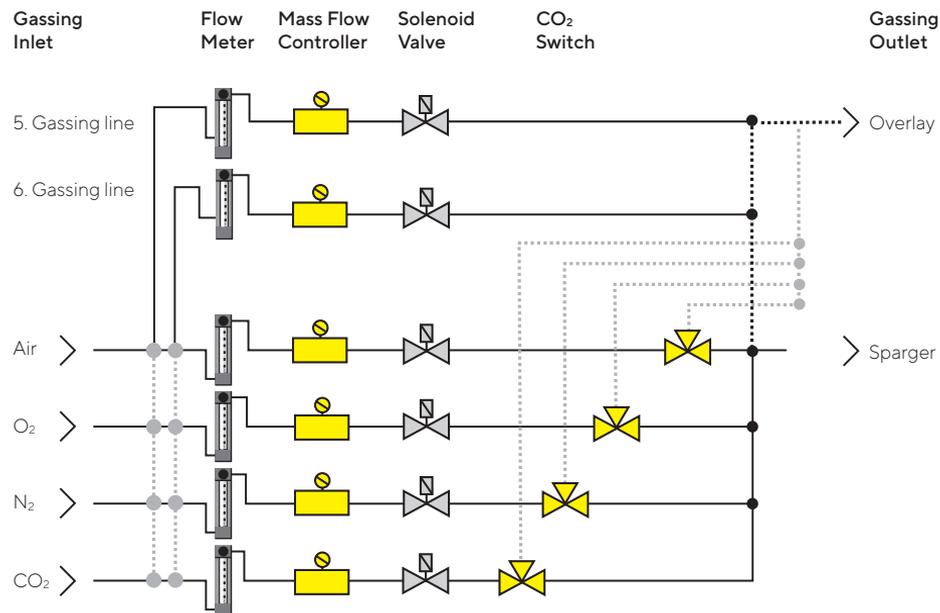
Biostat STR®

Cell Culture Aeration Modules for the Biostat® B-DCU

Advanced Additive Flow – Single Gas Outlets



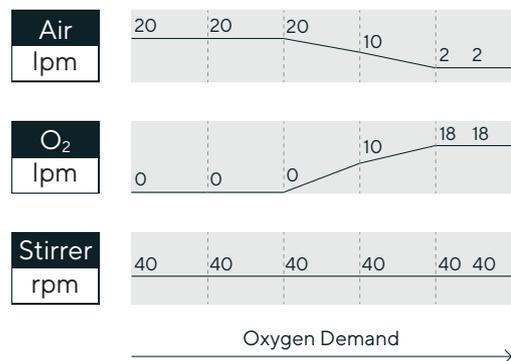
Advanced Additive Flow – 2 Gas Outlets



Cell Culture Aeration Modules for the Biostat® B-DCU

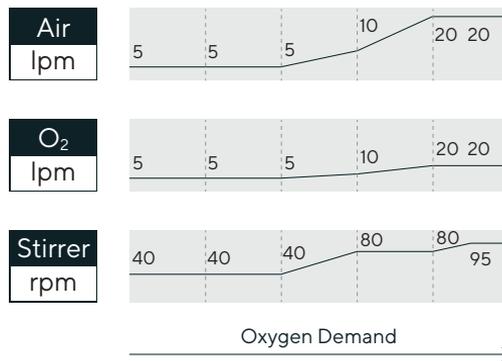
Advanced DO Control

Constant Gas Flow



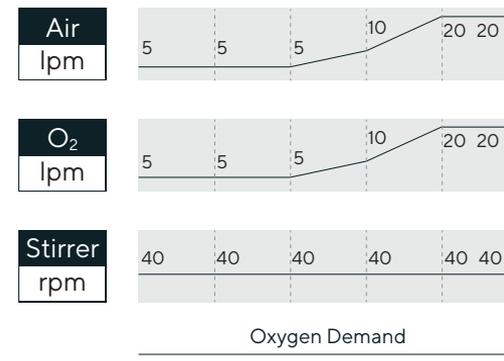
Constant gas flow decreases the flow of air and simultaneously increases oxygen gas

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	<ul style="list-style-type: none"> ▪ Foam, level ▪ Redox ▪ Turbidity (NIR) ▪ Off-gas ▪ Glucose and lactate ▪ Viability (capacitance) 	<ul style="list-style-type: none"> ▪ 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)



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Biostat STR®

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



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Ambr® 250 High Throughput

Ambr® 250 Modular

Biostat® B

Biostat® RM

Biostat® B-DCU

Univessel® SU

Univessel® Glass

BioPAT® Sensors

Biostat® Cplus

Biostat® D-DCU

Biostat STR®

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



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Univessel® Glass

Lighter

Carving out every unnecessary weight, makes the Univessel® Glass lighter than ever without losing 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 O₂ | CO₂ 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® Cplus: The Stainless-Steel Fermenter | Bioreactor for Your Laboratory

- Culture vessels with operating volumes of 5 L, 10 L, 15 L, 20 L and 30 L
- Sterilizable-in-place (SIP) fermenter
- The culture vessel can be sterilized with electro or steam heating (steam preferred).
- Bioreactor developed for the cultivation of microorganisms and cell cultures.
- It can easily be moved to another location using casters under the supply unit.
- DCU control unit with simple, intuitive touch screen operation
- Attractive additional functions such as gravimetric feed control, advanced DO controller, and integrated off-gas analyzer
- Maintenance-free agitator motor and automatic sequences for sterilization and pressure hold test ensure excellent safety
- Flexible gassing options allow for high cell density fermentation with high oxygen requirements through to cell culture with demanding gas mixing of up to four gases.
- Optional pressure control



Biostat® D-DCU: Your Fast Lane to Production

- Single or twin configurations
- Available in incremental sizes: 10 L, 20 L, 30 L, 50 L, 100 L and 200 L
- Powerful industrial rated DCU control system with 19" TFT color touch screen
- Automatic sterilization in place (SIP) is included
- Designed to interface single-use bags and sampling systems including the Takeone® Aseptic Sampling System
- Measurement and control opportunities of pH, DO, temperature, foam, level, vessel pressure, vessel weight, substrate addition, gas mixing, agitation, gravimetric feed and harvest control, constant total gas flow control, redox and turbidity, weight of storage vessels etc.
- Up to six integrated peristaltic pumps per vessel with options for fixed or variable speed control
- Choice of polarographic or optical DO sensors (optical preferred)
- Superior gas mixing with up to six flow meters and mass flow controllers
- Extended documentation package available, including logbook and 3-level password protection
- Minimal floor contact points for ease of cleaning
- Global spare part and service availability



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SU

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Glass

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Biostat STR®

Biostat STR®: Engineered for Ultimate Upstream Performance



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- 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



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

- Basal medium | 2 to 8 °C
- 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



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



MODDE®

SIMCA®

SIMCA® Online

Active Dashboard

MFCS

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.

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



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 sensing
- Real-time supervisory control



Active Dashboard

What if you could compare performance across all of your production sites? Active Dashboard let's 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



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



Flexsafe® Pro Mixer

Flexsafe® SU Bags

Celsius® Bags

Biosealer® TC

Biowelder® TC

Clipster®
Aseptic Disconnecter

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 of 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

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® Pro Mixer

Flexsafe® SU Bags

Celsius® Bags

Biosealer® TC

Biowelder® TC

Clipster®
Aseptic Disconnect

Flexsafe® 2D Bags

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



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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



Flexsafe® Pro Mixer

Flexsafe® SU Bags

Celsius® Bags

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Aseptic Disconnect

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

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



1. Filling Operation

Celsius® Filling Station FS16-S2



2. Controlled Freezing Operation

Celsius® FT33 | 66 | 100



Celsius® FFT

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



Freezing and Storage in Conventional Freezer

Celsius® FT Shippers



3. Storage and Logistics

Celsius® Shippable Storage
Module (SSM)

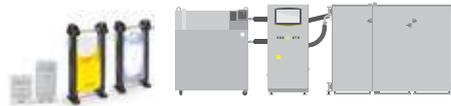


Celsius® SSM Shipper



4. Controlled Thawing Operation

Celsius® FT33 | 66 | 100



Flexsafe® Pro Mixer

Flexsafe® SU Bags

Celsius® Bags

Biosealer® TC

Biowelder® TC

Clipster®
Aseptic Disconnecter

Biosealer® TC

Sterile Disconnection of TPE Tubing

- Compatible tubing sizes:
 - $\frac{1}{8}$ " \times $\frac{1}{4}$ "
 - $\frac{1}{4}$ " \times $\frac{3}{8}$ "
 - $\frac{1}{4}$ " \times $\frac{7}{16}$ "
 - $\frac{3}{8}$ " \times $\frac{5}{8}$ "
 - $\frac{1}{2}$ " \times $\frac{3}{4}$ "
 - $\frac{3}{4}$ " \times 1"
- The Biosealer® TC provides to the user 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



Flexsafe® Pro Mixer

Flexsafe® SU Bags

Celsius® Bags

Biosealer® TC

Biowelder® TC

Clipster®
Aseptic Disconnect

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" x 1/4"	1/4" x 3/8"	1/4" x 7/16"	3/8" x 5/8"	1/2" x 3/4"	3/4" x 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	A or G	■	■	■	■	■	—
Pharmed® BPT	Pharmed	A or G	■	■	■	■	■	■

■ Available — Not available

*These parameter sets have been validated at room temperature.



Flexsafe® Pro Mixer

Flexsafe® SU Bags

Celsius® Bags

Biosealer® TC

Biowelder® TC

Clipster®
Aseptic Disconnect

Biowelder® 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 1/8" ID + 1/4" OD and 3/4" 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 Disconnecter

Description:

- The Clipster® Aseptic Disconnecter 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 Disconnecter may be sold as a stand-alone product or preassembled on our Fluid Management bag assemblies.
- The Clipster® Aseptic Disconnecter is safe, quick and easy to use. The disconnection is performed with a hand-held tool which ensures easy execution in various space requirements.

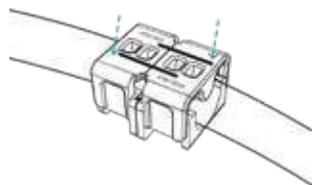
Application:

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

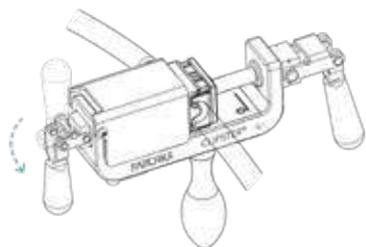


Clipster® Aseptic Disconnecter

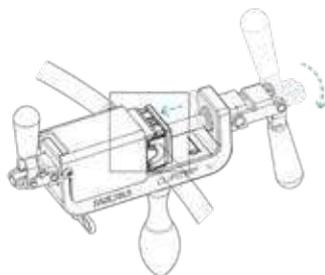
Operating Sequences



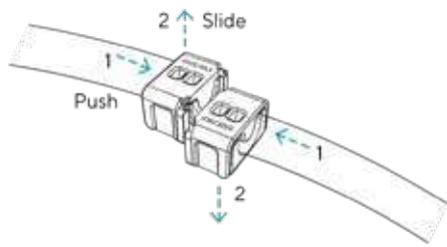
1. Assemble the Clipster® Aseptic Disconnecter on the tubing.



3. Cut the tubing.



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



4. Disconnect the Clipster® Aseptic Disconnecter.

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



Process Filtration

Leading Expertise and Unique Technologies

Sartorius' extensive filtration and purification portfolio help 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 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.

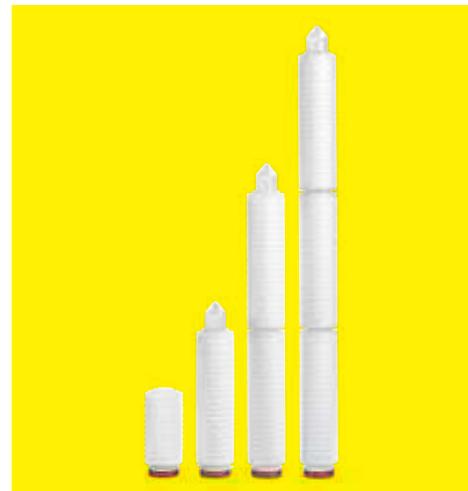
Membrane Filter Cartridges

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)
- Cellulose acetate (CA)
- Polytetrafluoroethylene (PTFE)

Integrity Testing

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



Filters

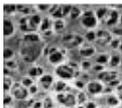
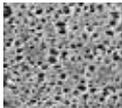
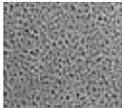
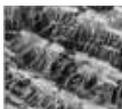
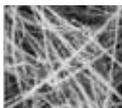
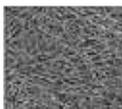
Hollow Fiber TFF Modules

Ksep® Systems

Ambr® Crossflow

Sartoflow® Smart System

Microcarriers

		Applications	Cartridge Construction (O-rings: silicone)	Available Heights*
	Sartobev PS The classic membrane filter cartridge for filtration of wine and sparkling wine	<ul style="list-style-type: none"> For the retention of microorganisms, particles and colloids in wine, sparkling wine and water 	<ul style="list-style-type: none"> Protective nonwoven polypropylene layer PES membrane Nonwoven polypropylene drainage layer Outer support, core and end caps: polypropylene 	10", 20", 30", 40"
	Aquasart® PS The high-performance membrane filter cartridge for water filtration	<ul style="list-style-type: none"> For the retention of microorganisms, particles and colloids in mineral water 	<ul style="list-style-type: none"> Protective nonwoven polypropylene layer PES membrane Nonwoven polypropylene drainage layer Outer support, core and end caps: polypropylene 	10", 20", 30", 40"
	Aquasart® Plus The innovative membrane filter cartridge for liquids to guarantee the lowest filtration costs	<ul style="list-style-type: none"> Best Retention of microorganisms, particles and colloids in mineral water as well as near-water beverages 	<ul style="list-style-type: none"> Protective nonwoven polypropylene layer Double layer PES Nonwoven polypropylene drainage layer Outer support, core and end caps: polypropylene 	10", 20", 30", 40"
	Aerosart The hydrophobic PTFE membrane filter cartridge	<ul style="list-style-type: none"> Sterile venting of tanks fermenters and bioreactors Sterile filtration of inlet and outlet air, gases, solvents and aggressive media 	<ul style="list-style-type: none"> Protective nonwoven polypropylene layer PTFE membrane Nonwoven polypropylene drainage layer Outer support, core and end caps: polypropylene Optional: EPDM, fluoroelastomer 	
	Sartopure® GA The special prefilter cartridge for tank venting	<ul style="list-style-type: none"> For venting tanks and containers in applications that do not necessarily require an integrity testable filter 	<ul style="list-style-type: none"> Protective nonwoven polypropylene layer Hydrophobic nonwoven glass fiber layers Nonwoven polypropylene Outer support, core and end caps: polypropylene 	10", 20", 30", 40"
	Sartosteel® Stainless steel filter cartridge for filtration of steam	<ul style="list-style-type: none"> For the removal of particles from steam and gases 	<ul style="list-style-type: none"> 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 	10", 20", 30"

* Standard versions are in bold-face type



Filters

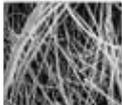
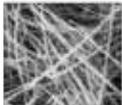
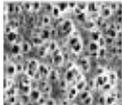
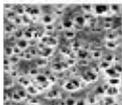
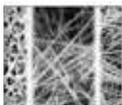
Hollow Fiber TFF Modules

Ksep® Systems

Ambr® Crossflow

Sartoflow® Smart System

Microcarriers

	Applications	Cartridge Construction	Available Heights**
 <p>Sartopure® IND The prefilter cartridge with particle-removing with polypropylen filter material</p>	<ul style="list-style-type: none"> Retention of particles; reduction of microorganisms by fractionized filter fleeces 	<ul style="list-style-type: none"> 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"
 <p>Sartopure® GF Plus The prefilter cartridge with particle-removing with polypropylen filter material</p>	<ul style="list-style-type: none"> Retention of particles and colloids, reduction of microorganisms by fractionized filter fleeces 	<ul style="list-style-type: none"> 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"
 <p>Sartocool® PS The prefilter cartridge with particle-removing with polypropylen filter material</p>	<ul style="list-style-type: none"> Retention of yeasts and beer-spoilage bacteria 	<ul style="list-style-type: none"> Protective nonwoven polypropylene layer PES membrane Nonwoven polypropylene drainage layer Outer support, core and end caps: polypropylene O-rings: silicone 	10", 20", 30", 40"
 <p>Vinosart® PS The prefilter cartridge with particle-removing with polypropylen filter material</p>	<ul style="list-style-type: none"> Specially developed for the retention of microorganisms, particles and colloids in all types of wine and sparkling wine 	<ul style="list-style-type: none"> 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"
 <p>Jumbo Star The prefilter cartridge with particle-removing with polypropylen filter material</p>	<ul style="list-style-type: none"> Retention of particles; reduction of colloids and bioburden in water, wine and beer and in alcohol production; also for venting large tanks 	<ul style="list-style-type: none"> Pleated construction with filter areas of up to 28 m²; pleats made of polypropylene or glass fiber material* 	10", 20", 30", 40"

* Polypropylene 559xxx Glass fiber 555xxx

** Standard versions are in bold-face type



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.

Material ▶		Particle Reduction		Prefilters Bioburden Reduction			Sterile Filters		Sterile Filters			Mycoplasma Retentive Filters	Prefilters	Sterile Filters	Sterile Filters	Sterile Filters		
		PP3	GF Plus	PES	GF	NF	Platinum 0.2 µm	Platinum HB	HF	0.2 µm	XLG	XLI	Sartopore® 2 XLM	Sartoclean® GF	CA	Sartobran® P 0.2 µm	Sartolon	Sartofluor® LG
		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	Application																	
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	Intermediate Process Filtration (Protection of Columns, Crossflow)			■				■									■	
Globulines	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

Application	Midisart®		Sartopore® Air	Sartopore®	Sartofluor®	
	Sartopore® Air	2000			GA	HR
Material ▶	PES	PTFE	PES	GF	PTFE	PTFE
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			■		■	



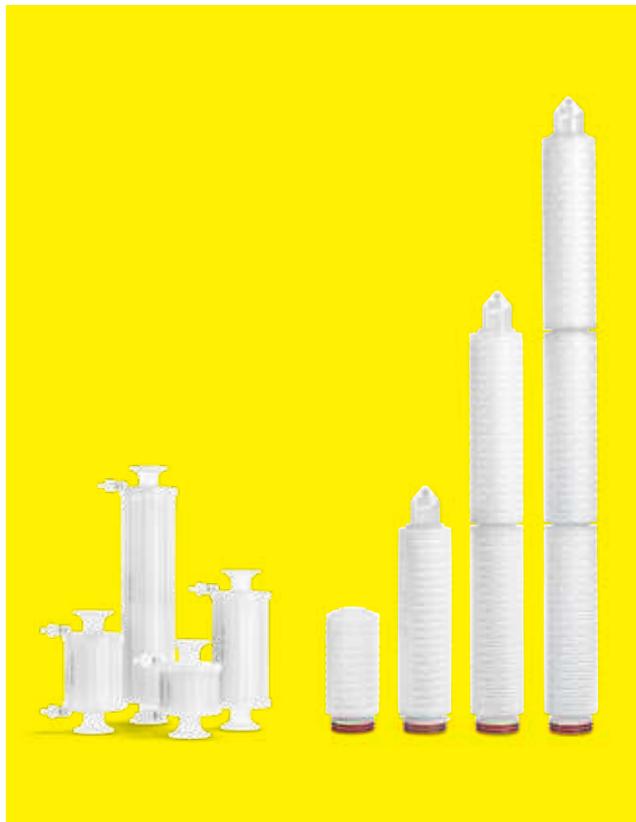
Most Common Filters for Food Companies

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 ophthalmic 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 Polyether-sulfone 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 enables 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. coli* 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 offers 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 ft² (0.0052 m²) up to 26.9 ft² (2.5 m²).

Relevant Applications

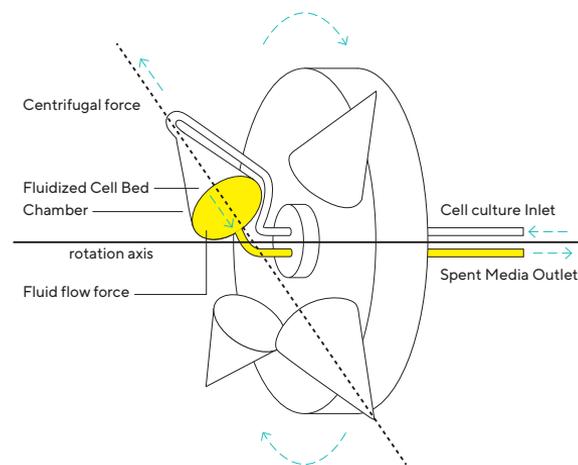
- Cell perfusion with a conventional pump operated crossflow perfusion system. Bioreactor and steamer hollow fiber assembly can be autoclaved simultaneously.
- Concentration and diafiltration of gene therapy products as well as monoclonal antibodies, enzymes, blood components and other proteins.

- 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

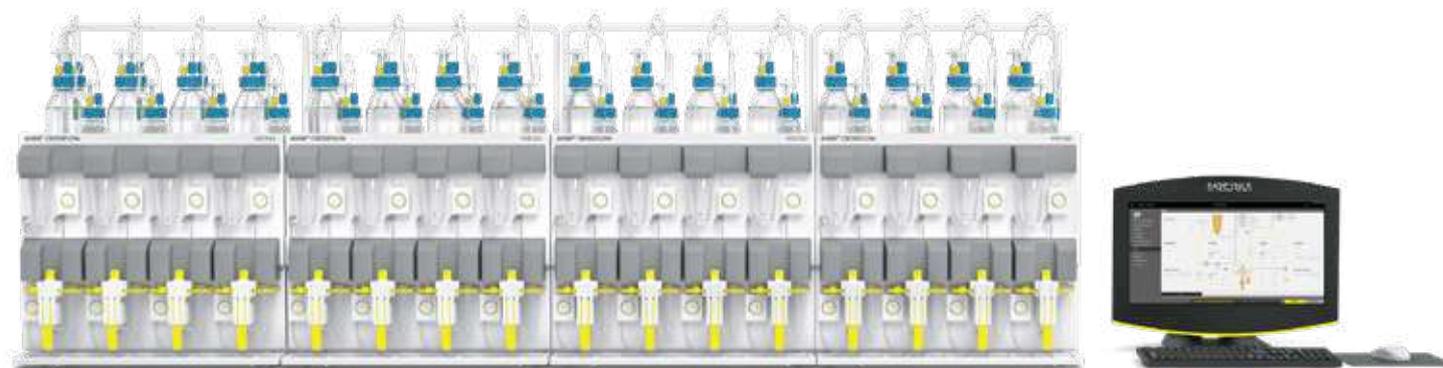


Ambr® Crossflow: The High Throughput Solution for Parallel Screening

- 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



Filters

Hollow Fiber
TFF Modules

Ksep® Systems

Ambr® Crossflow

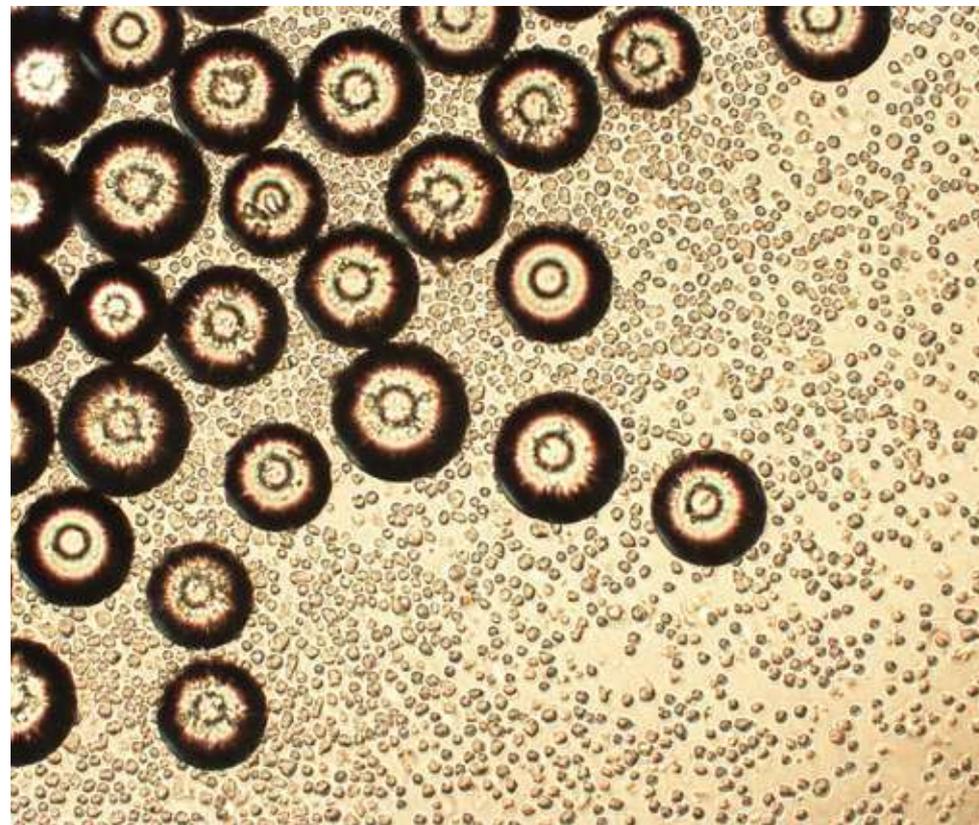
Sartoflow®
Smart System

Microcarriers

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 influences 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.



Chromatography Columns and Resins

SPEC 70 SLS, resin specifically designed for Lactoferrin extraction several years ago:

- Ion exchanger resin with spherical semi-rigid microbead
- Acrylic polymer
- Size between 260 and 600 μm
- Highly hydrophilic and resistant to micro-organisms
- Macro-porous polymer allowing large mass transfers
- Binding capacity > 20 mg/mL for LF
- Working pH: 4 to 13
- Cleaning pH: 1 to 14



Ultrafiltration Systems and Membranes

- Concentration of Lactoferrin with cassettes
- Hydrosart Membrane 30 KD
- Modular system fully scalable
- From 0.02 m² to hundreds m²
- Perfect flow stability
- High cleanability
- Low shear 4-piston membrane pump



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

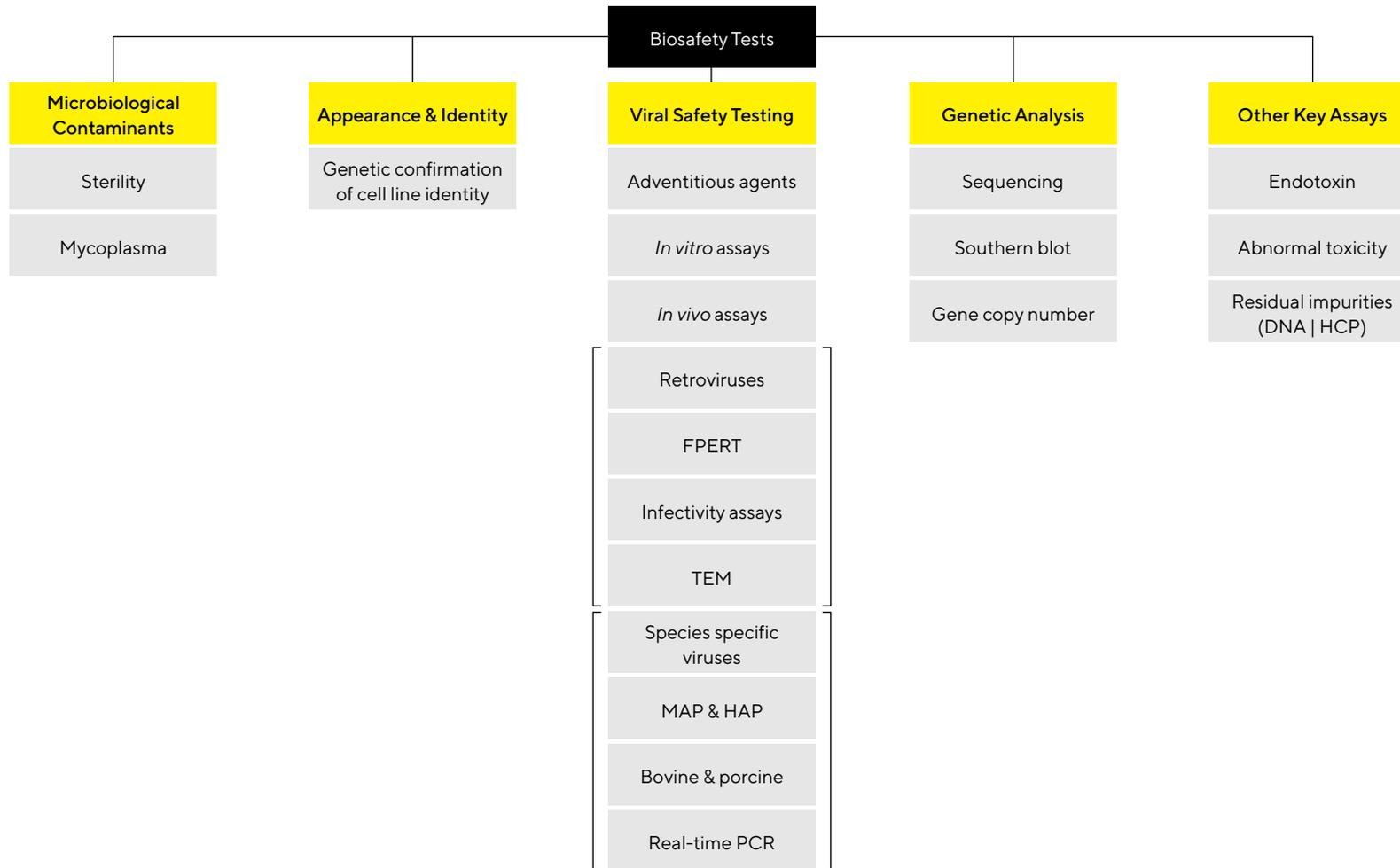
Clone Selection

Process Optimization

Product
Characterization

GMP Lot Release





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



Worldwide Services

Support

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

After-Sales Services

- Maintenance contracts
- Commissioning
- Calibration
- Repair
- Operators training



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