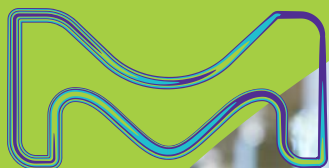


integrated Bioprocess solutions



The life science business of Merck operates
as MilliporeSigma in the U.S. and Canada.

MERCK

Spanning every step of your process

Consistent, reliable performance is the key to drug development and bio manufacturing. With trusted products, deep bioprocessing expertise and unrivalled regulatory support, we can help you improve your product's consistency and process efficiency.

From bench scale to full-scale production, we offer a full range of tools and technologies to help you meet your production goals, including filtration products, chromatography resins, systems, and integrated disposable technologies. Coupled with our in-house application experts who have decades of experience, we will work with you to tackle any processing challenge.

Leveraging a broad portfolio of single and multi-use systems, our team of bioprocess and regulatory experts will work with you to accelerate your life-enhancing therapeutics to market, or optimize an existing process to meet your efficiency goals. In addition to a full offering of standard systems, our experienced engineering team can design and manufacture customized systems to match your exact processing requirements.

Cell Culture Development

Bioreactor

Clarification

Affinity Chromatography

Virus Inactivation

Purification Chromatography

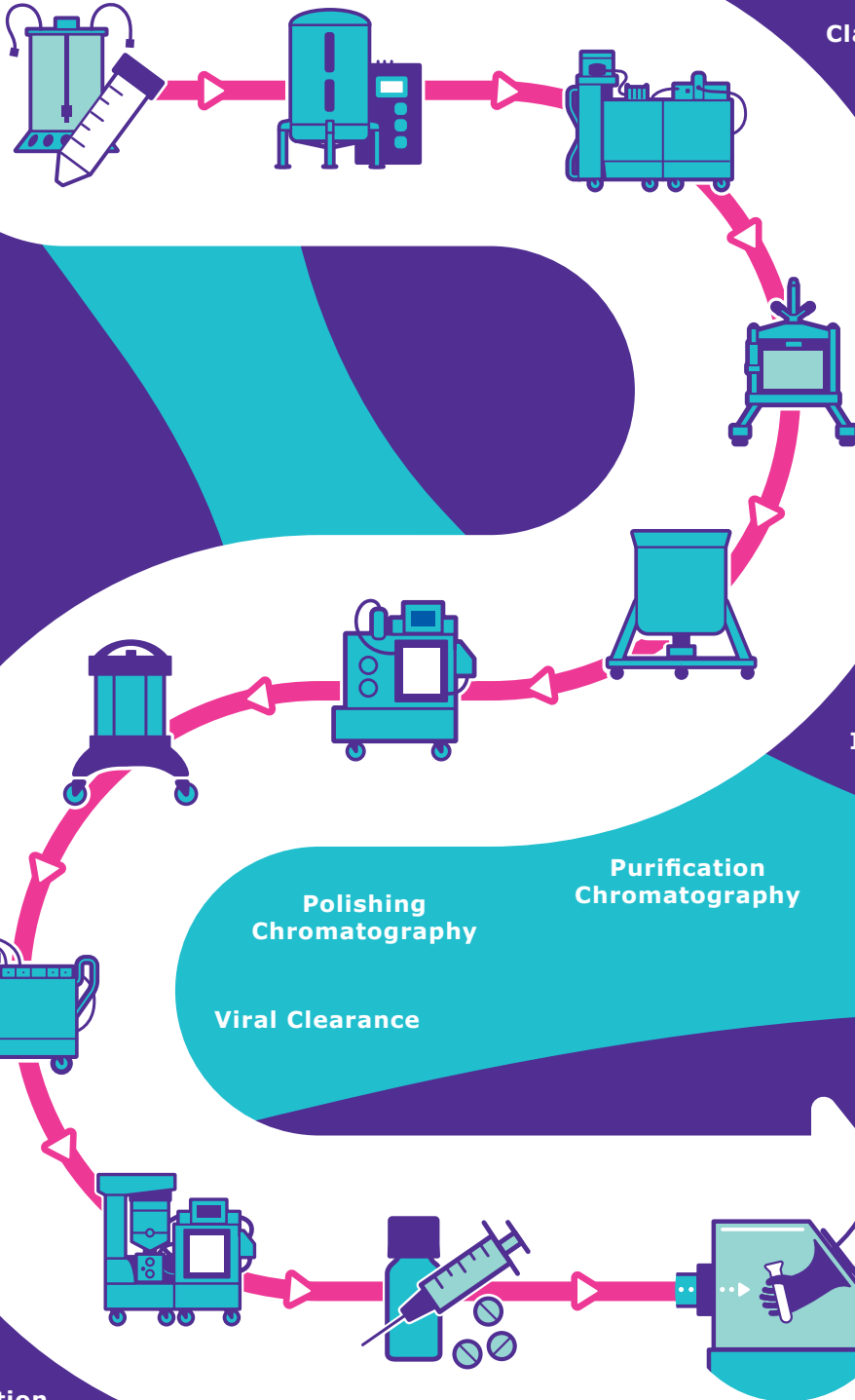
Polishing Chromatography

Viral Clearance

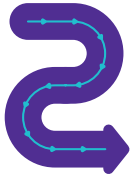
Concentration and Diafiltration

Formulation

Final Filtration and Filling



Comprehensive Services



We offer a full range of services to help you transition from R&D to commercial scale cGMP manufacturing. In addition to comprehensive product and in-process material testing, our process development experts can work with you to address your specific application needs, from optimizing individual operations to designing and executing a full process at your facility or at ours.



Code Key

+ Custom designs are available

If your process requirements are not met through our standard options, our expert engineering team can support your specific customization requests.

▲ Configured design options are available

Many of our systems and components are optimized around standard process templates and are highly configurable (e.g., materials of construction, sizing, sensing technologies, and automation) to meet your unique needs.



■ **Services available**

We offer a comprehensive portfolio of services to evaluate the safety of your raw materials, optimize your process and minimize your risk. Backed by an industry leading team of engineers and applications specialists, your process will get the personalized, expert attention it deserves.

● **Cell culture media and critical raw material services**

We offer standard and custom liquid and powder formulations, comprehensive raw material testing, spent media analysis, and custom bulk packaging options. Our team of cell culture scientists are available for process optimization.

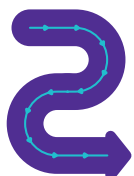
◆ **System automation**

Programmable systems incorporate intelligent, accurate, and reliable automation features that are typical to each unit operation. Features like user-configurable alarm set points and automated data acquisition can help enhance your productivity.

★ **CCP® Ready for GMP manufacturing**

From bioreactors to clarification, chromatography, tangential flow filtration and virus filtration, our CCP® software offers you a familiar interface to simplify and automate your software management and operations. Our CCP® process control and monitoring system includes data acquisition and batch reporting options.

Speed your drug to market, safely and reliably



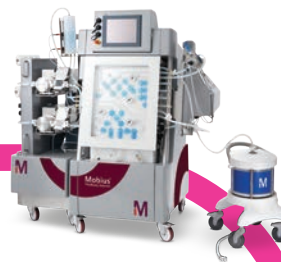
Mobius® FlexReady Solutions offer you the flexibility to build an entire single-use process train or integrate an individual unit operation.



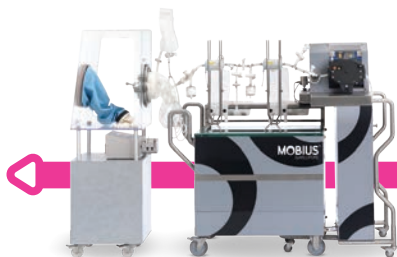
Mobius® Single-use Bioreactors



Mobius® FlexReady System for Large-scale Clarification



Mobius® FlexReady System with smart Flexware® Assemblies for Chromatography



Mobius® FlexReady System for Final Filling



Mobius® FlexReady System with smart Flexware® Assemblies for Tangential Flow Filtration



Mobius® FlexReady System for Large-scale Virus Filtration

- Pre-sterilized and tested, ready-to-use, single-use Flexware® assemblies.
- Ergonomically designed single-use systems are installed quickly and easily, for fast start-up with reduced operator error.
- Plug-and-play systems enable rapid scale up from process development to commercial manufacturing.



Mobius® single-use assembly manufacturing facility (Danvers, Massachusetts)

Film Technology

Safe, ergonomic and flexible solutions for your process, including your most critical applications

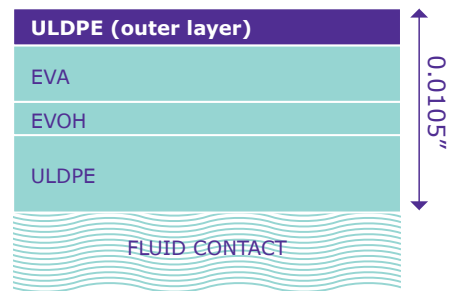
Robust Film Technology

PureFlex™ and PureFlex™ Plus films are used in Mobius® assemblies and NovaSeptum® sterile sampling products, and are safe, robust and chemically resistant.

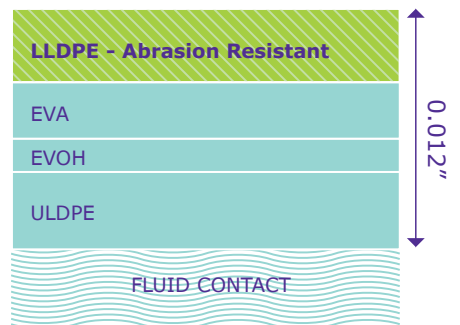
PureFlex™ and PureFlex™ Plus Film ■

- **Fluid contact material:**
Ultra low-density polyethylene (ULDPE)
- **Gas barrier:**
Polyethylene vinyl alcohol-copolymers (EVOH)
- **Outer layer:**
 - **PureFlex™ film:** Ethylene vinyl acetate (EVA) and ULDPE
 - **PureFlex™ Plus film:** EVA and linear low density polyethylene (LLDPE) which increases the film’s resistance to abrasion, puncture, stretching, and tearing

PureFlex™ Film



PureFlex™ Plus Film



Single-use Fluid Handling



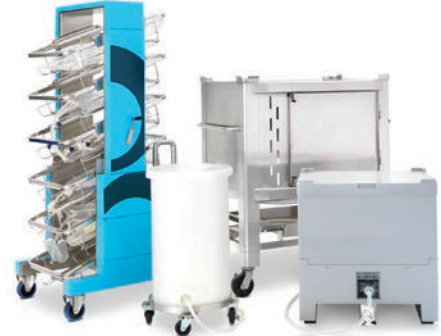
Our Mobius® single-use mixers, assemblies, sterilizing-grade filters, transport containers and Mobius® FlexReady systems can help you work faster and more efficiently.



merckmillipore.com/pureflexplus

Mobius® Assemblies +▲■

Designed to improve your processing flexibility, Mobius® 2D and 3D assemblies are key components in delivering efficient, ergonomic and scalable solutions to your production area. Our 3D bags include a patented folding feature that reduces operator intervention during bag installation and filling. With a full spectrum of carriers to choose from, you get greater flexibility, mobility and support for your single-use technologies.



A variety of PE drums, stainless steel bins, collapsible bins and container carts are available to support your fluid storage and transfer requirements.

Sterile Connectors

Reliable and easy to use, the unique design of Lynx® sterile connectors enables risk-free fluid transfer. Lynx® connectors are available in a wide range of sizes and configurations.



Lynx® S2S Connector

Lynx® S2S (Sterile to Sterile) Connector ■

- Designed to integrate single-use systems
- Robust sterility validation via surface soiling aerosolized bacterial challenge
- Gamma and autoclave-compatible

Lynx® ST (Steam-To) Connector ■

- Designed to integrate stainless steel and single-use systems via standard TC fittings
- Valve component allows sterile disconnection of your single-use system
- SIP, autoclave and gamma-compatible



Lynx® ST Connector

Lynx® CDR (Connect, Disconnect, Reconnect) Connector ■

- Industry's first disposable connector to enable multiple aseptic connections
- Validated for up to six connections and disconnections
- Enables disconnection with wet and pressurized flow paths



Lynx® CDR Connector

Mobius® Single-use Mixing Systems +■

Our scalable, ready-to-use mixers are available from 10 L to 1000 L and can be used throughout your process, from buffer and media preparation to final formulation. Choose from a variety of standard mixing assemblies, or customize with filters, connectors and tubing.

- Ergonomic design for quick and easy bag installation
- Interchangeable electronic drive unit, motor and control box for production flexibility
- Optional integrated load cells, temperature sensor and closed, sterile sampling system
- pH measurement options: single-use sensor or reusable probe port
- Optional powder delivery system



Mobius® Single-use Mixing Systems

Mobius® FlexReady Solution for Buffer and Media Preparation +■

This system features a single-use flow path and specially designed hardware to hold pumps, instrumentation, filters and containers. It offers a choice of Millipore Express® or Durapore® filters, available in a variety of configurations and pore sizes to support your prefiltration, sterile filtration and mycoplasma control needs.



Mobius® FlexReady Solution for Buffer and Media Preparation

Millipore Express® Filters ■

- High capacity, high flux, hydrophilic PES membranes
- Chemical compatibility spans a wide pH range
- Multiple options are available to meet your process performance and operational efficiency goals

Durapore® Filters ■

- The industry standard for critical sterilizing filtration
- High throughput, hydrophilic PVDF membranes
- Low extractables and broad chemical compatibility
- Multiple configurations available to meet a wide variety of application needs



Opticap® Capsule Filters with Durapore® and Millipore Express® Membranes

- + Custom designs are available
- ▲ Configured design options are available
- Services available
- Cell culture media and critical raw materials services
- ◆ System automation
- ★ CCP® Ready for GMP manufacturing

Multi-use Fluid Handling



Mixers, valves, connectors and housings

NovAseptic® fluid handling components exceed the requirements for sanitary processing and ensure the safety, quality and purity of your product.





NovAseptic® GMP Mixer for low-shear blending

Recommended for critical applications



NovAseptic® USM Mixer for medium-shear blending

Recommended for a wide variety of common biopharmaceutical solutions



NovAseptic® HS Mixer

Recommended for difficult powder and solid dissolutions



NovAseptic® HSI Mixer

For high-shear mixing in-line, without a tank

NovAseptic® Advanced Mixing Solutions +▲■

NovAseptic® mixers offer a complete mixing solution; upstream to downstream.

- High-performance bottom-mounted mixers engineered for reliability and ease of maintenance
- Complies with the most stringent industry requirements for cleaning and sterilization

NovAseptic® Valves +▲■

Our valves and valve combinations provide a wide range of cost-effective solutions that comply with cGMP aseptic processing requirements.

- Shut off valves, take off valves and tank outlet valves
- No dead leg and minimal hold-up
- Solid diaphragms for long life: EPDM, silicone elastomers and PTFE
- Configured to meet your most critical applications

Housings +▲■

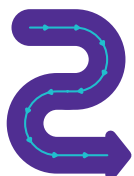
Supporting our world-class filtration devices, we offer a full range of high-quality single and multi-round housings for liquid, gas and venting applications.

- Series 3000™ 316 L stainless steel housings are available in T-line, C-line and in-line designs, in a variety of sizes and connections
- Designed to minimize dead volume and product loss and for quick and easy cleaning



Series 3000™ Single-round Housings and Durapore® Cartridge Filters

Sterile Sampling



Out-of-the-box, plug-and-play sterile

Accurate, sterile sampling of your product is critical. An imprecise or false positive result can lead to time-consuming investigations and costly delays. With our NovaSeptum® sampling system, you can sample with confidence.

NovaSeptum® Sterile Sampling System +■

From buffer and media preparation to final formulation and fill, the closed NovaSeptum® sterile sampling system gives you the freedom and security to sample processes wherever you need. Available in a wide variety of formats and volumes, NovaSeptum® sampling systems are easily integrated into your process for robust, reliable process monitoring.

- Flexible, pre-sterilized, disposable sampling options
- Ensures the security of the process, the operator and the sample
- Zero risk of cross-contamination
- Compliant with the most stringent regulatory and quality requirements
- Allows for accurate samples: 1 mL to 1000 mL

Preloaded, single-use NovaSeptum® holders eliminate the need to clean, assemble or disassemble



NovAseptic® Connectors +▲■

We offer a broad range of NovAseptic® connectors to improve the efficiency and robustness of your aseptic mixing process.

- Proven, innovative flush-mounted design for low hold-up volume
- Flexible aseptic design; available tank-connected or in-line
- Provides ease of access to critical areas for sampling prior to product release
- Adaptable to a wide range of equipment; easily and securely fitted to ensure system sterility

Process Chemicals for Storage and Cleaning +■●

You can order our GMP grade products in the volumes and concentrations you require. We can provide comprehensive Emprove® dossiers to simplify and speed your regulatory filings.

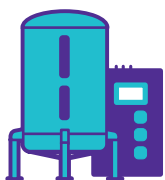


NovaSeal™ Crimping Tool allows you to securely crimp and disconnect your disposable assembly while maintaining sterility



**NovAseptic® Connectors
with NovaSeptum®
Sampling System**

Cell Culture Development and Scale Up



Proven platforms developed collaboratively with users, backed by long-term application expertise

Our upstream portfolio includes cell lines, cell culture media, media supplements, buffers, bioreactors and a full range of filtration products to ensure your process meets your yield and productivity targets, and is sterile and robust.



Millipore Express® Filters

Millipore Express® SHR 0.1µm Hydrophilic Filters ■

- Designed for sterilizing-grade performance and mycoplasma removal
- Optional on-board PES membrane prefilter for extended throughput
- Easy wetting and integrity testing
- Broad chemical compatibility (pH 1-14)

Mobius® Single-use Bioreactors +▲◆★

Mobius® Bioreactors are a scalable portfolio of single-use stirred tank bioreactors to suit suspension and adherent cell culture applications.

- Standalone systems easily integrate into your existing automation platform
- Fully jacketed vessels include integrated load cells for precise volume monitoring
- Bottom mounted magnetic levitating impeller with internal baffles and a 5:1 turndown ratio
- Demonstrated scalability from 3 L to 2000 L

Mobius® Single-use, Bench Scale Bioreactor +◆★

Eliminates the need to clean and autoclave.

- Pre-assembled and gamma irradiated
- Utilize your existing controller



2000 L, 1000 L, 200 L, 50 L and 3 L Bioreactors





Our team of experienced scientists and process development engineers can develop, optimize, validate and troubleshoot your upstream process, to meet your product quality, efficiency and speed to market goals.

CHOZN™ Expression Systems +■●



Our CHO Glutamine Synthetase knockout cell expression platform is provided as a cGMP banked cell line with a single expression vector and detailed protocols. Custom cell line engineering and development services are available.

Custom Cell Culture Media +■●

Whether developed by your team or ours, we can supply clinical to commercial scale media to exactly fit your specific cell line and process requirements. Our harmonized global Quality and Raw Material Management Systems and Manufacturing Technology ensures the safety, quality and performance you need.

Cell Culture Media and Feeds +■●

Our Cellvento™ CHO and EX-CELL® Advanced™ products are complete media platforms for CHO cells. They are chemically defined, of non-animal origin and proven to contribute to superior cell growth and productivity.



Cellvento™ CHO Platform

Cell Culture Supplements and Additives ●

We offer a comprehensive portfolio of non-animal origin cell culture supplements and additives to help you achieve consistent yields and simplify your regulatory process.

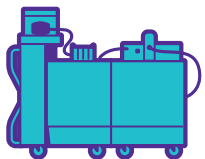


EX-CELL® Advanced™ Media Platform

Buffers +■●

We offer a complete range of GMP buffers for your upstream, purification and formulation steps with full traceability of our sourced raw materials to ensure the quality and consistency of your product. See page 18 for additional detail.

Clarification



With more than 40 years of clarification experience, we are committed to introducing innovative, easy-to-use technologies, like Millistak+® Pod and Clarisolve® disposable depth filters, to help you improve your productivity and process efficiency.

Millistak+® Pod Disposable Depth Filters ■

Millistak+® Pod is the industry standard for mAb and recombinant protein clarification, and is ideally suited to primary and secondary clarification applications. These disposable depth filters offer flexibility and ease of use through their unique modular design.

- Broad range of 23 media types; offered in single and multilayer products
- Compact design maximizes product yield and minimizes facility footprint
- Scalable from 5 to 12,000 L feed streams
- Disposable Pod device protects operators from exposure to biohazards and eliminates the cost of housings, CIP and cleaning validation



Millistak+® Pod Disposable Depth Filters



Clarisolve® Disposable Depth Filters

Clarisolve® Disposable Depth Filter ■

The innovative Clarisolve® depth filter is a fast and efficient way to clarify challenging, high density cell culture feed streams that require pre-treatment.

- Eliminates the need for a centrifuge and reduces flush volumes from 50% to 93%, depending on the media grade, versus traditional depth filters
- Enables single stage clarification; go directly from the bioreactor to downstream sterile filtration



pDADMAC

pDADMAC ■

Our GMP-purified cationic polymer flocculation reagent, polydiallyldimethylammonium chloride (pDADMAC), is a powerful pre-treatment for high density feed streams. In combination with Clarisolve® depth filters, it provides an effective solution for clarifying mammalian cell harvest and may eliminate the need for centrifugation.



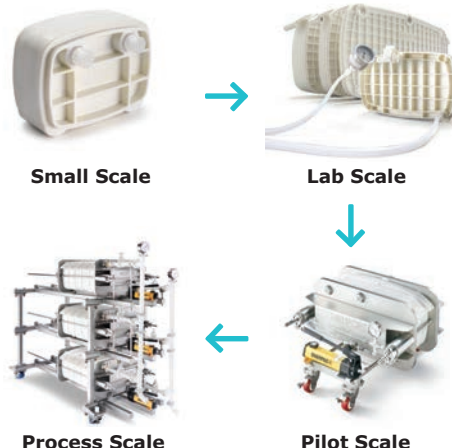
Mobius® FlexReady Solution for Clarification +▲■

Our easy to use Mobius® FlexReady clarification systems can support your clarification needs; process development to large-scale commercial manufacturing.

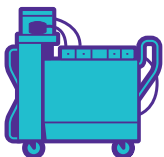
- Optimized single-use flow path for maximum adaptability
- Compatible with Millistak+® Pod and Clarisolve® disposable depth filters

Unparalleled Scalability

Millistak+® Pod Holders are easy to use and are available with disposable adapters to eliminate the need for cleaning validation.



Virus Safety



For over 20 years our application, process development and virology experts have addressed your regulatory, filtration and scale-up needs. We can support every phase of your viral clearance implementation, providing you with security and peace of mind.

Mobius® FlexReady Solution for Virus Filtration +▲■◆

Mobius® FlexReady Solution for Virus Filtration provides an ideal combination of single-use assemblies, innovative separation devices, and specially designed hardware that conveniently holds pumps, instrumentation, and filters.

- Mobius® FlexReady assemblies include a fully disposable flow path
- Optimized for use with state-of-the-art Viresolve® Pro devices
- Onscreen P&ID enables real time process monitoring and control loops
- Automated data management and recording of active parameters and event history



Mobius® FlexReady Solution for Virus Filtration delivers robust parvovirus clearance across many scales

- 0.2-13 L/h or 2.4-130 L/h @ 30 psi
- 30-2400 L/h @ 30 psi



Solvent Detergent

Visit [merckmillipore.com/empv](https://www.merckmillipore.com/empv) for a complete list of our Emprove® grade bioprocessing chemicals

Viresolve® Pro Solution ■

The Viresolve® Pro Solution represents a major leap forward in membrane technology with five patents granted for unparalleled viral clearance assurance. The combination of a Viresolve® Pro Shield in-line with a Viresolve® Pro device enables increased process robustness and high productivity while maintaining high parvovirus LRV, capacity and flux.

- ≥ 4.0 log removal of parvovirus
- Devices 100% tested with air/water diffusion and patented Binary Gas Test
- Viresolve® Pro Shield and Viresolve® Pro devices are fully disposable and caustic stable for *in situ* sanitization
- Available with Viresolve® Pro/Pro+ Magnus Holders

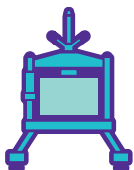
Viral Inactivation

Our portfolio of high-quality solvent detergents and low pH viral inactivation agents can help you avoid microbial contamination and meet regulatory requirements. We offer comprehensive Emprove® dossiers to simplify and speed your regulatory filing.



The Viresolve® Pro+ Magnus Holder

Chromatography



Scalable single and multi-use chromatography systems, and a full portfolio of resins, to meet your purification and process efficiency needs

Chromabolt® Prepacked Chromatography Columns ■

Chromabolt® validated, prepacked chromatography columns are designed for clinical stage manufacturing.

- Ready to use
- 10 cm, 20 cm, 32 cm diameters available

Chromabolt®
Prepacked
Chromatography
Columns



Established market leader for more than 25 years, ProSep® and Eshmuno® Chromatography Resins



Mobius® FlexReady Solution with smart Flexware® Assemblies for Chromatography + ▲ ■ ◆ ★

The Mobius® FlexReady Solution for Chromatography is an innovative single-use system designed for the separation of mAbs, vaccines, plasma and therapeutic proteins. These fully-automated systems feature our robust CCP operating software and unique Flexware® single-use flow paths, which minimize dead space and provide a high level of processing control and reproducibility. These versatile systems utilize a standard hardware platform that can switch between chromatography and TFF.

- Available in 2.2 L/min and 8 L/min maximum flow rate
- Disposable flowpath is gamma irradiated
- Mixing at an accuracy of +/- 2% over a 10 - 90% gradient mix range
- Suited to a wide range of chromatographic separation techniques and column sizes

Resins ■

We offer a comprehensive portfolio of chromatography resins to meet your process needs. Under the well-known brand names of Eshmuno®, designed specifically to address emerging purification challenges, Fractogel®, PharmPrep® P and ProSep® resins, we can help you increase productivity and process efficiency for:

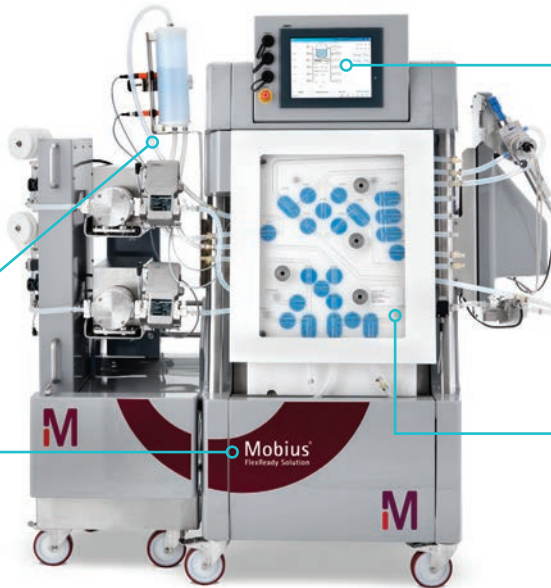
- Affinity Chromatography
- Ion Exchange Chromatography
- Reversed Phase / Normal Phase Chromatography
- Size Exclusion Chromatography

Mobius® FlexReady Solution with smart Flexware® Assemblies for Chromatography

+▲◆◆★

Flexware® assemblies are available with factory calibrated UV and conductivity single-use sensors.

The cart is the heart of the system and houses the single-use flow path clamshell and automation software.



Our Common Control Platform® (CCP®) automation software centrally controls all pumps and valves, and allows recipe editing, storing and sharing. CCP® software is fully compliant with GAMP 5 recommendations for automation software and FDA 21 CFR Part 11 requirements for electronic records and signatures.

Our smart Flexware® assemblies utilize a combination of keyed assemblies and clear labeling for easy, error-free installation.

K-Prime® Chromatography Systems +▲◆◆★

K-Prime® multi-use chromatography systems are designed for separating and purifying proteins and bio-engineered products. Our K-Prime® product line spans a wide range of flow rates and delivers best-in-class separations from pilot through commercial production.

- Scalable from 20 mL/min to 10 L/min
- Fully configurable and customizable up to 200 L/min
- Automated linear and step gradient
- Conforms to GAMP and FDA 21 CFR Part 11



K-Prime® Chromatography System

QuikScale® Chromatography Columns ▲◆

QuikScale® chromatography columns maximize process yields, boost productivity, and shorten time-to-market.

- High linear velocity for maximum productivity
- Easy to pack and unpack
- Rapid scale up: column sizes from 70 mm to 630 mm
- Easy to change tube material and height



QuikScale® Chromatography Column

IsoPak® Chromatography Columns +▲◆

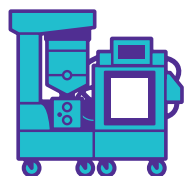
IsoPak® chromatography columns deliver consistent chromatographic results for process scale applications.

- Easy to clean and maintain
- Unique valve design allows automated column packing and unpacking without removing the top flow cell
- Available options: axial hydraulic packing, choice of stainless steel grade, up to 1400 mm ID



IsoPak® Chromatography Column

Ultrafiltration



Recognized as the worldwide leader in ultrafiltration

Customers around the globe have trusted their most critical, high-value ultrafiltration applications to us for more than 50 years. Our industry-leading Pellicon® cassettes and UF/DF systems consistently and reliably deliver purity assurance at every stage of your drug development and manufacturing process.

Cogent® Process Scale Tangential Flow Filtration System

Available Scales:

- 1.5-50 L/min, 2.5-5.0 m² with 50, 100 or 200 L tank
- 2-120 L/min, 5.0-15 m² with 50, 100 or 200 L tank



Cogent® Process Scale Tangential Flow Filtration Systems +▲◆★

From process development to commercial production, we provide a range of scalable ultrafiltration systems to meet your needs for concentration and diafiltration with maximum recovery of product.

- Fully-automated, configurable, multi-use TFF systems are suited for cGMP manufacturing
- Low system hold up maximizes product concentration and recovery
- Modular standard options meet your process requirements and minimize upfront investment
- Custom engineered systems are available upon request



Cogent® μScale System



Cogent® M1 System

Tangential Flow Filtration Systems for Process Development & Pilot Manufacturing ◆

Cogent® μScale and Cogent® M1 benchtop systems are designed to facilitate your TFF development work. These easy to use, semi-automated systems enable data capture and extraction for inclusion in your batch records.

Buffers

We offer a complete range of GMP buffers for your upstream, purification and formulation steps with full traceability of our sourced raw materials to ensure the quality and consistency of your product. We can provide a comprehensive, regulatory documentation package for our Emprove® and PharmaGrade buffers to simplify your regulatory filing.



Mobius® FlexReady Solution with smart Flexware® Assemblies for Tangential Flow Filtration

+ ▲ ■ ◆ ★

Our fully-automated systems feature a robust operating software and unique smart Flexware® single-use flow paths which eliminate moving parts, minimize dead space and provide a high level of processing control and reproducibility. These versatile, scalable systems utilize a standard hardware platform that can easily switch between chromatography and TFF.

- Suited to demanding applications including high protein viscosity, low final volume and high purity
- Validated for a feed flow capacity up to 40 L/min
- Integrated load cells, mixer, and temperature sensors
- Disposable flow path is easily installed by a single operator

Pellicon® 3 Cassettes ■

Recommended for the most demanding ultrafiltration processes, Pellicon® 3 cassettes consistently deliver high protein yield, flux and product quality.

- Choose from Biomax® polyethersulfone membrane or Ultracel® composite regenerated cellulose membrane
- Leading-edge, void-free membranes provide unbeatable performance, consistency, high retention and high product yield
- Optimized channel configuration increases flux and reduces membrane area requirements
- Scalable from bench to commercial scale



Mobius® FlexReady Solution



Pellicon® 3 Cassettes



Pellicon® Holders can be easily built in levels, for simple membrane area expansion in a compact footprint. Hydraulic closures are available.

Formulation, Final Filtration and Filling



Trusted for the most critical applications, with over 280 billion sterile doses, our single-use final fill assemblies reduce risk of cross-contamination and deliver greater process flexibility and productivity without compromising product sterility or process security.

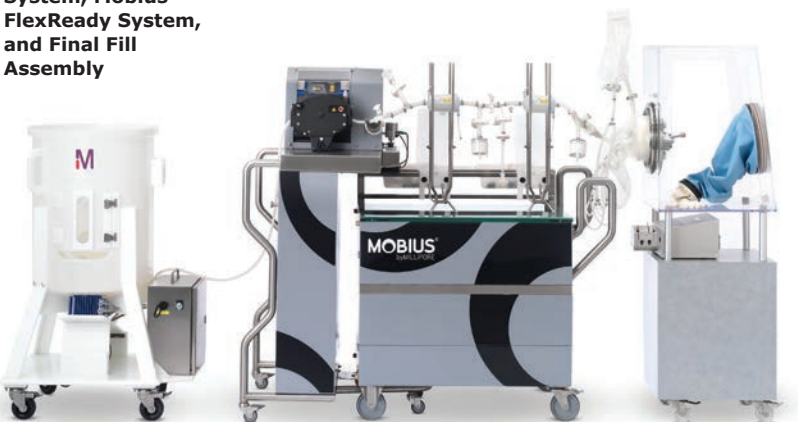


Sterilizing-grade Cartridge and Opticap® Capsule Filters + ■

We offer a wide range of cartridges, capsules and stacked-disc devices under the industry-leading brand names of Durapore®, Millipore Express® and Aervent®

- Gamma-compatible and presterilized capsules simplify your process without compromising product safety
- Validated per ASTM F838 and 100% integrity tested
- Available in single or multilayer format for bacteria and mycoplasma retention

Mobius® Mixing System, Mobius® FlexReady System, and Final Fill Assembly



Mobius® Single-use Final Fill Assemblies + ■

Using Mobius® products, you'll be able to reduce the time spent from initial cleaning and set-up to final filling from 36 hours to 12 hours at 10,000 vials per hour. Mobius® single-use final fill assemblies provide flexibility to accommodate a variety of fill volumes.

- Decreased risk of cross-contamination
- Fast set-up and process turnaround
- Reduced validation time and cost
- 100% integrity tested by a validated method based on ASTM® F2095



Integrating single-use into your final fill operation can reduce your campaign fill time by 75%.

BioReliance® assays and comprehensive services help ensure the quality and purity of your in-process materials and final biological product.

FDA and EMA guidelines require integrity testing filters that will be used for processing sterile solutions. They also require testing documentation be included with batch records.



Sterilizing-grade Millipak® Disposable Filters ■

- Unique stacked disk design minimizes hold-up and protein binding – ideal for high value applications
- 100% integrity tested in manufacturing
- Made with Durapore® PVDF membrane which provides high throughput, low extractables, broad chemical compatibility and low particle shedding
- Millipak® Barrier filters feature separate hydrophilic and hydrophobic layers, enabling simplified in-line pre-use integrity testing without a flush bag

Integritest® 4 Series Automated Filter Integrity Test Instrument ■◆

This portable, fully automated system provides accurate and reliable filter integrity test measurements. This system leverages a proven test algorithm to perform bubble point, diffusion, and HydroCorr™ water intrusion tests over a wide range of filter types and formats, including: disks, cartridges, TFF filters, virus filters, and asymmetric membrane filters.



- Compliant with the most stringent regulatory and quality requirements, including 21 CFR Part 11 for electronic records and signatures
- Available as a standalone system, or networked for centralized reports and printing
- Intuitive touch screen and context-sensitive help
- Available in multiple languages



Formulation Excipients

We offer an extensive portfolio of excipients for liquid formulation encompassing buffers, pH-adjustment and tonicity agents, stabilizers and preservatives. Our Emprove® branded products provide a comprehensive regulatory documentation package to simplify and speed regulatory filings.

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