

SINGLE-USE SOLUTIONS

Standard and fully
customised systems for your
bioprocessing applications



Setting science in motion to create a better world



WE ARE AVANTOR®

From discovery to delivery, Avantor is a global manufacturer and distributor of high-quality products, services and solutions to professionals in the life sciences and advanced technologies industries. We focus on the things that matter most to you, providing exceptional convenience, collaboration and customisation to help ensure your success.

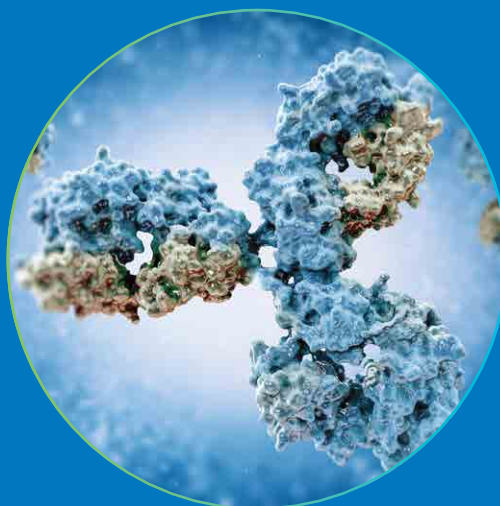
Our channel brand, VWR, part of Avantor, offers an integrated, seamless purchasing experience that is optimised for the way you do business. Through our global eCommerce platform, you can access our own brands as well as those from thousands of other manufacturers, so you can get exactly what you need to support your processes.

BIOPHARMACEUTICALS: ENABLING BREAKTHROUGHS IN BIOLOGICS

Today's biologics provide breakthrough solutions for many of the world's most challenging diseases and chronic conditions.

Avantor is a trusted supplier for some of the largest biopharmaceutical companies in the world. We provide the products, services and solutions these leading companies need to quickly move from the small-scale bench, scaling up in the pilot plant, to full production, reaching the market faster with new scientific breakthroughs in medicine.

When you work with Avantor, you gain a strategic partner with customisable manufacturing solutions, high-quality cGMP materials and specialised services. Backed by extensive regulatory and technical process expertise, we play a vital role in helping to increase drug yield, lot-to-lot consistency and, most importantly, drive results that benefit the world.



Combining innovation with efficiency to transform biologics production

As innovative new biologics become ready for production, biomanufacturing technology must be equal to the challenge. If long lead times and rigid assemblies are slowing you down, turn to Avantor for fast, flexible and innovative single-use solutions so you can scale up quickly and run your process, your way.

Our solutions enable bioprocessors to overcome complex regulatory demands and improve production efficiency and versatility, accelerating molecules through technical development and manufacturing launch to deliver new therapeutic breakthroughs.

Our capabilities are unique: Avantor is the only open-architecture, single-use provider to offer complete design, manufacturing and logistics to

support every stage of your biomanufacturing process—wherever your operations are located across the globe.

We supply what you need most for your bioprocessing applications:

- Expertise dedicated to solving your challenges using the latest single-use systems
- Efficiency that lets us custom fit our technology to your needs
- Quality combined with choice, so you have the right single-use products on hand when you need them
- Supply chain security and convenience to help produce critical therapies quickly and safely



Avantor offers an experienced, collaborative approach to designing single-use solutions that keep your production line running



QUALITY & CHOICE

- Open Architecture Model vertically integrated on bags, stoppers and fittings supporting your system choice
- Comprehensive Supplier Management Programme with qualified first and second sources of key components
- Complete sterility validation programme to mitigate risk



EXPERTISE

- Extensive fluid handling connectivity knowledge
 - Single-use facilities
 - Hybrid facilities
 - Conversion from Self-Assembled Parts
- Collaborative approach to designing your solution



CONVENIENCE

- Local single-use experts
- Expedited design and approval process
 - Designs < 5 days
 - Validation Packs < 5 days
- Global logistics footprint
- 100+ standard products



CUSTOMISATION

- Fully custom solutions designed for specific applications
- Ability to develop custom components and parts
- Customised skid systems with disposable fluid paths

Quality and supply chain security: Managing your risk

Single-use systems must meet rigorous quality standards related to component qualification, manufacturing operations, in-process testing and final product release. When choosing single-use solutions providers, you should evaluate the strengths and capabilities of their quality and risk management systems and practices.

Avantor helps companies implement single-use technologies that reduce contamination risk, improve resource efficiency and lower labour and energy costs. Our documented quality systems are precisely managed using validated processes that help you manage your risk, and our global single-use manufacturing locations are certified and adhere to ISO standards. These systems and processes help ensure that you consistently receive products that you can trust.

KEY QUALITY AND REGULATORY COMPLIANCE SYSTEM ELEMENTS

Redundant cleanroom manufacturing facilities

- Certified ISO Class 7 assembly rooms
- Validated equipment and processes

Certified ISO 9001 quality system

- Compliant with FDA and EU cGMP requirements
- Robust and timely complaint handling and CAPA programmes
- Risk-based quality management approach

Complete regulatory compliance programme

- Animal origin-free or EMA/410/01 compliant materials
- Sterility validation per ANSI/AAMI/ISO 11137 (VDmax25)
- Sterile barrier shelf-life validation per ANSI/AAMI/ISO 11607
- ISO 11137 sterility validation
- Endotoxin USP <85> and particulate USP <788> lot release testing available
- BPOG standardised extractables testing protocol in use

Our product offering

Single-use bioprocessing technology plays a growing role in helping reduce contamination risk, improve resource efficiency and lower labour, energy and process validation costs. Avantor provides a complete offering of standard and custom single-use components, connections and assemblies to support sterile fluid transfer in upstream, downstream, and fill and finish process steps.

- Aseptic Sampling
- Bags: Pillow and 3D
- Bottle and Flask Assemblies
- Hose and Tubing Manifolds
- Specialty Connectors
- Tanks and Tank Liners



Integrator of components into single-use assemblies (SUA) that solve fluid handling challenges for biopharma manufacturers.



Designer and builder of skid systems (TFF, buffer dilution, etc.) with disposable fluid paths for specific unit operations.



Manufacturer of specialty single-use products (SUP) that are incorporated into SUAs or sold to other single-use OEMs.



Distributor of various fluid handling components and systems for the biopharma market.

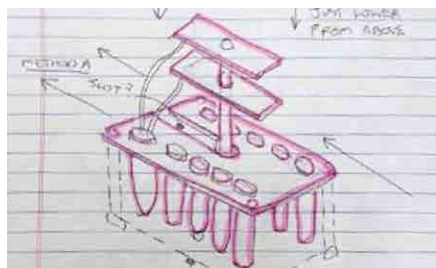
Custom single-use solutions

The number of methods available for interfacing with or interconnecting various process components in your system can make connecting your bioprocessing systems in a reliable, reproducible manner a significant challenge.

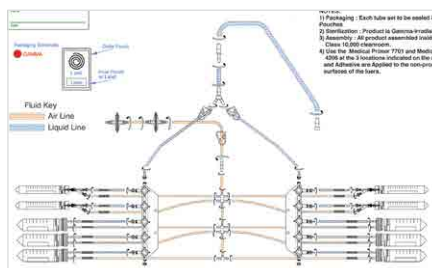
As an unbiased integrator of single-use solutions, Avantor's team of experts can work with you to understand your goals and design a custom single-use assembly that meets the needs of your application. From simple tubing sets to complex mixing systems, all assemblies can be made to your specifications.

Our experts can help create solutions such as:

- Product Development and Prototyping
- Custom Transfer Assemblies
- 3D Bags up to 3,500L
- Bag Mixing Systems
- Multi-Bag and Bottle Manifolds
- Custom Sampling Solutions
- Filtration Assemblies



Concept



Design



Prototype



Standard single-use solutions

Avantor single-use solutions provide the technology choices you need to navigate the fluid-handling challenges, component options and quality and regulatory compliance constraints of the single-use world. At Avantor, we can help solve unique problems in all areas of a biopharmaceutical manufacturing operation, to help keep your production line running.



PRODUCTS FOR ASEPTIC SAMPLING

OMNITOP™ SAMPLE TUBES

OmniTop™ single-use sampling and small volume transfer tubes can be used for the sampling and transfer of biopharmaceutical products and reagents in a closed system. Aseptically weld onto bioreactors and aseptically disconnect using the Genesis sealer. Choose from a range of sizes and materials that come with a pre-attached 0,2 µm vent filter and 18" of C-Flex. Custom configurations available.

WFI SAMPLER: SIMPLIFYING WATER SAMPLING

A convenient solution to obtain fluid samples from a WFI water drop. Each WFI Sampler is double-poly pouched for cleanroom use and irradiated. Designed exclusively with the SterilEnz®-II/AT pre-attached gasket fittings allow for quick and secure attachment to water systems or equipment while also increasing your sterility assurance.



BOTTLE AND FLASK ASSEMBLIES

STERILE PETG SINGLE-USE BOTTLE ASSEMBLIES

Sterile containers are available in PETG or polycarbonate, each with weldable tubing to provide the maximum amount of flexibility and reliability. Polycarbonate bottle assemblies are able to withstand temperatures from -20 to 65 °C (-4 to 149 °F) without losing integrity.

STERILE PETG SINGLE-USE BOTTLE WITH ASEPTIC CONNECTOR

A version of our sterile PETG bottles features an aseptic connector to help reduce contamination risk and save time by eliminating the need for a laminar hood or additional equipment. Bottle assemblies are manufactured in a certified ISO Class 7 cleanroom and available in multiple bottle sizes for process-specific flexibility.

STERILE POLYCARBONATE SINGLE-USE BOTTLE ASSEMBLIES

Sterile polycarbonate containers with weldable tubing provide the maximum amount of flexibility and reliability. Sterile bottles come individually bagged and process ready and are available in a variety of sizes, allowing for process-specific flexibility. Bottles are gamma irradiated to Sterility Assurance Level (SAL) 10^{-6} .

STERILE POLYCARBONATE SINGLE-USE FLASK ASSEMBLIES

Assembled in an ISO Class 7 cleanroom and manufactured from USP Class VI materials, polycarbonate flasks feature weldable tubing to provide the maximum amount of flexibility and reliability. Custom-configuration possibilities are endless when used with our line of tube sets.



BOTTLE AND FLASK ASSEMBLIES

JM BIOCONNECT® DISPOSABLE PILLOW BAGS

Designed for hanging to facilitate complete fluid recovery and ease of handling, JM BioConnect Disposable Pillow Bags are made from proprietary JMS Flex Film that has a polyethylene inner and outer layer and a high oxygen barrier layer. This offers high clarity and flexibility while being resistant to a wide range of chemicals. Available in sizes ranging from 50 ml to 50 l.

JM BIOCONNECT® 3D CUBIC BAGS

JM BioConnect® 3D cubic bags are available in 200 and 500 l volume with two ports on top of the bag consisting of silicone platinum tubing with MPX-connectors. 3D cubic bags are made from a proprietary film with a polyethylene inner and outer layer, and a high oxygen barrier layer, that is resistant to a wide range of chemicals. Designed to fit in existing support containers, 3D cubic bags can also be supplied together with a matching container made of plastic or stainless steel.

JM BIOCONNECT® DISPOSABLE TANK LINERS

JM BioConnect® disposable tank liners feature an open top designed to fit in cylindrical vessels to avoid cleaning after media and buffer preparation. The tank liners are made of a clean medical grade multi-layer film designed for bioprocess applications. Available in both 2-D and 3-D styles, the tank liners are delivered gamma-irradiated and ready-to-use.



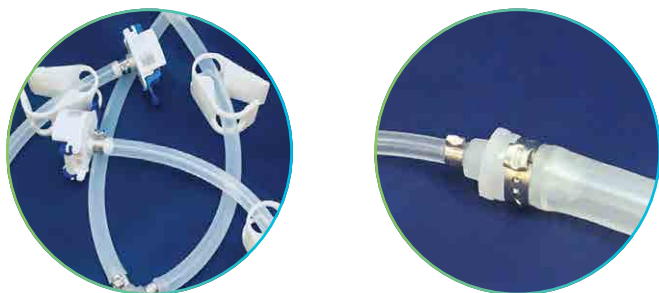
TUBING ASSEMBLIES

SINGLE-USE C-FLEX® ADAPTERS AND EXTENSIONS

Sterile C-Flex® adapters and extensions are designed to facilitate and expedite the on-site construction of single-use fluid transfer assemblies. Manufactured from USP Class VI materials and supplied gamma irradiated to sterility assurance level (SAL) 10⁻⁶, they are offered with custom size and configuration capabilities.

SINGLE-USE SILICONE TUBING ASSEMBLIES

Designed for use in a broad range of applications, platinum-cured silicone assemblies available in straight, cross or tee configurations with aseptic connectors on each end make these tubing assemblies a superior alternative to market offerings.



PRE-GASKETED CONNECTORS & CAPS

STERILENZ®-II/AT: PRE-GASKETED SANITARY FITTINGS FOR SINGLE-USE SYSTEMS

SterilEnz®-II/AT are the only single-use connectors that come with a platinum-cured, medical-grade silicone gasket mechanically attached to the fitting face.

Standard sanitary clamp fitting, per ASME BPE Specifications.

- USP Class VI and ADCF Compliant materials; certificate included
- Zero mould parting lines on all critical sealing surfaces
- Gamma stable, 25 to 45 kGy
- Suitable for autoclave use at 123 °C for 30 minutes

STERILENZ®-II/EC: PRE-GASKETED POLYPROPYLENE END CAPS

Featuring a standard sanitary clamp fitting per ASME BPE specifications and suitable for autoclave use at 123 °C for 30 minutes, SterilEnz®-II/EC are the only end caps that come equipped with a medical grade silicone gasket pre-attached to the fitting face. This helps prevent contamination risks that come from the misalignment or mishandling of gaskets during assembly. process-specific flexibility.



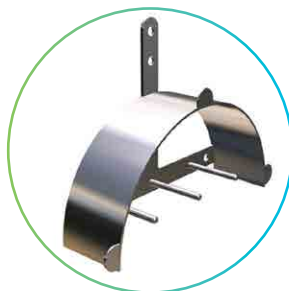
REINFORCED SILICONE HOSE & ACCESSORIES

REINFORCED SILICONE HOSE & LABELS

Ideal for biopharmaceutical and biomedical applications, reinforced silicone hose and labels feature excellent bend radius and kink resistance. CLEAR-mark® hose labels are available upon request for easy traceability.

STAINLESS STEEL HOSE RACKS

The arch-style, wall-mounted hose racks were designed to enhance safety and eliminate clutter in the workplace. Design ideal for cleanroom environment and stores hose and components in one convenient location. Ensures 100% drainage and extends hose life.



NOTES

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Enabling your success with innovative choices

PRODUCTION CHEMICALS

- Amino acids
- Antioxidants
- Biological buffers
- Carbohydrates
- Chromatography resins
- Cytokines and growth factors
- Mineral salts
- Peptones/hydrolysates
- Surfactants
- Vitamins

CULTURE REAGENTS

- Media
- Sera
- Supplements

SINGLE-USE SOLUTIONS

- Aseptic sampling
- Bags
- Connectors
- Filtration systems
- Manifolds
- Tank liners
- Tube sets
- 2-D and 3-D bags
- Mixing bags
- Supporting hardware and control systems
- Containers
- Media preparation systems
- Bottle assemblies

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