SINGLE-USE SOLUTIONS

Standard and fully customized 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 customization to help ensure your success.

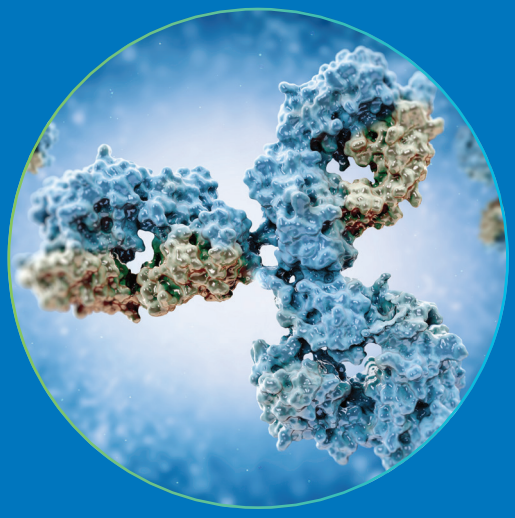
Our channel brand, VWR, part of Avantor, offers an integrated, seamless purchasing experience that is optimized for the way you do business. Through our global e-commerce platform, you can access our own brands as well as those from thousands of other manufacturers, so you can get exactly what you need 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 customizable manufacturing solutions, high-quality cGMP materials and specialized 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.

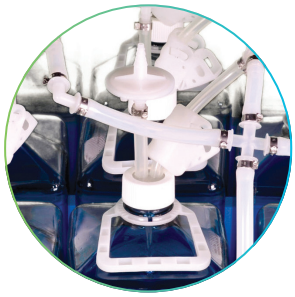
Our solutions enable bioprocessors to overcome complex regulatory demands and improve production efficiency and versatility, accelerating molecules through technical development and manufacturing launch to deliver new therapeutic breakthroughs.

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 choice of your systems
- Comprehensive Supplier Management Program with qualified first and second sources of key components
- Complete sterility validation program 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

CUSTOMIZATION

- Fully custom solutions designed for specific applications
- Ability to develop custom components and parts
- Customized 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 labor 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 programs
- Risk-based quality management approach

Complete regulatory compliance program

- 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 standardized 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 labor, 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.

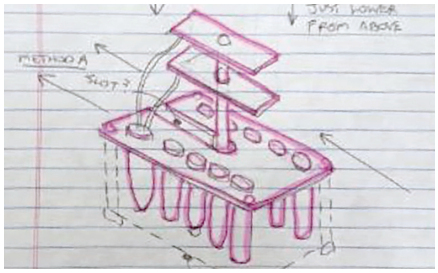
Custom single-use solutions

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.

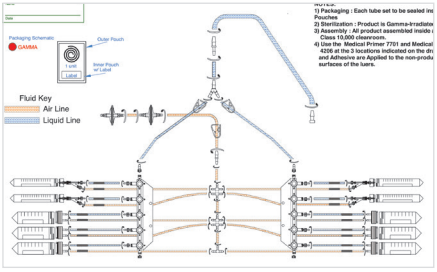
As an unbiased integrator of single-use solutions, Avantor's team of experts can work with you to understand your goals and design a custom single-use assembly that meets the needs of your application. From simple tubing sets to complex mixing systems, all assemblies can be made to your specifications.

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


EXIT

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 0.2µm 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 that 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 50mL to 50L.

JM BIOCONNECT® 3D CUBIC BAGS

JM BioConnect® 3D cubic bags are available in 200 L 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 2D and 3D 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 mold parting lines on all critical sealing surfaces
- Gamma-stable, 25-45 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.

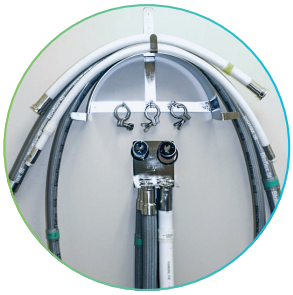
REINFORCED SILICONE HOSE AND ACCESSORIES

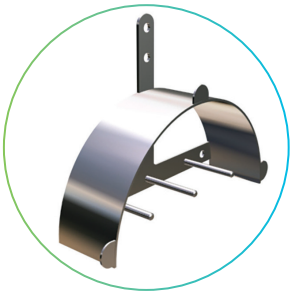
REINFORCED SILICONE HOSE AND LABELS

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.





Bioprocess media pooling case study

Simplifying sampling with a closed system solution

NEED

A biologic drug manufacturer was experiencing contamination issues due to an open media pooling process. The process required taking three 500mL media bottles into a biosafety cabinet, removing the caps, and open-transferring (pouring) media from the three bottles into one 2L bottle.

SOLUTION

Avantor worked with the customer to determine the best solution for the application. A sterile, closed-system was designed by Avantor to help reduce contamination in the biologic drug manufacturer's media pooling process. While aseptic connection/disconnection technology was considered, the customer was already comfortable using its existing welding/sealing process. The customer's existing tube welder coupled with sterile PETG bottle assemblies and tube sets sold through VWR, part of Avantor was determined to be the best choice. The manifold was created by welding the 500mL bottles (10830-296) to the Two Drop Clamp PP Tee (10830-694), and the 2L bottle (75835-988). Once all standard components were sterile-welded together, the transfer process could begin with use of a peristaltic pump.

RESULTS

The customer realized process efficiency by removing the need for a biosafety cabinet, and the operator was able to open and manipulate the pre-sterilized assemblies in a more comfortable, ergonomic setting. The desired configuration was welded and ready for use in less than 15 minutes. Process throughput was increased by eliminating the need for assembling the tubing sets and autoclaving, which could take over an hour for the autoclave cycle alone. The frequency of contaminations was significantly reduced by implementing the closed system solution and eliminating the media open pooling process.

Bioprocess sampling case study

Simplifying sampling with a closed system solution

NEED

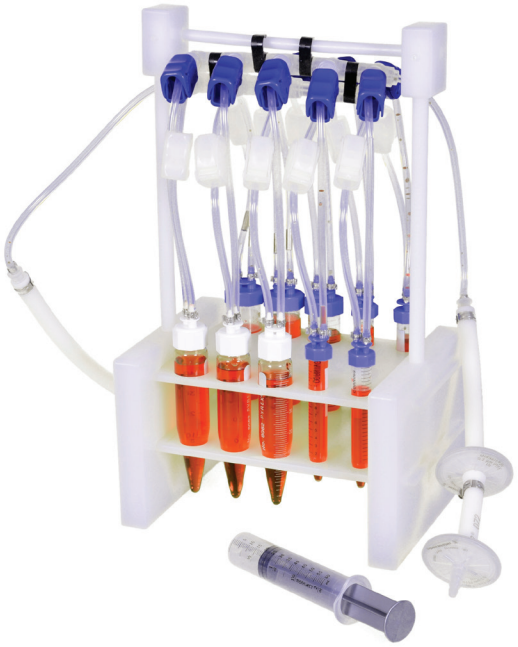
A vaccine manufacturer required a novel process sampling solution for taking multiple conical tube samples at varying time points. In order to provide the highest level of sterility assurance, samples would need to be taken in a closed manner without using a biological safety hood. Test methods required samples to be taken using multiple tube materials and at varying volumes.

SOLUTION

Avantor designed, prototyped, and commercialized a GMP-compliant, customized single-use solution, an OmniTop Sample Tubes® Manifold, that achieved all the benchmark requirements. A proprietary 10-leg, platinum-cured, silicone-molded manifold was used as the spine of the system, directing fluid to each of the conical tube collection vessels. Utilizing the latest technology in 3-D design and printing, Avantor engineering and development teams created a new conical tube cap design featuring ports to allow for fluid inlet and venting. Equally important to the design of the system, the user interface and method of sample collection was also considered in the design. A custom holder to protect the tubes and support the manifold was created using plastics that are washdown acceptable and GMP-compliant. This allowed for total fluid collection with zero hold-up.

RESULTS

The OmniTop Sample Tubes® Manifold was integrated into the customer's work stream and almost immediately, the customer saw an increase in process efficiency and sterility assurance. This platform sampling solution is capable of sampling at multiple points in their process and with the flexibility designed in to allow for a multitude of sampling options.



Avantor designed a GMP-compliant, customized single-use solution, an OmniTop Sample Tubes® Manifold, to meet a customer's closed system sampling requirements.

Avantor single-use solutions
Product informations

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Product introduction

Avantor Fluid Handling Disposable Bags

The Avantor Fluid Handling Disposables program consists of the following product lines:

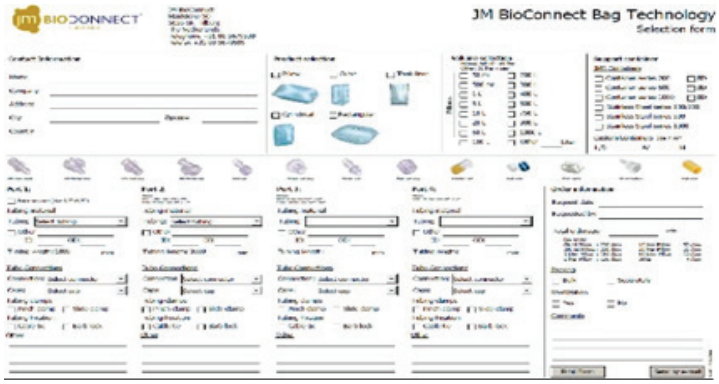
- Pillow Bags (50 ml - 50 L & Customizing)
- 3D Cubic or Cylindrical Bags (50 L - Customizing)
- Mixing Bags (50 L - Customizing)

All these products are manufactured by Avantor Fluid Handling in the Netherlands in an ISO certified and FDA approved cleanroom.

Through our flexible manufacturing organization, Avantor Fluid Handling can turn-around our customer's unique specification into custom designed and manufactured single-use solutions.

For these products Avantor Fluid Handling uses its own developed unique film, Avantor Fluid Handling Flex Film, which has the highest quality standards available in the market at this moment and has the highest clarity of all available films used for bag manufacturing. The film offers a solution for these challenges:

- Manufactured under laminar flow conditions in an ISO Class 7 cleanroom
- High oxygen barrier: 0.1 cc/(m2.day.bar)
- Suitable for pillow bags and 3-D cubical bags
- Resistant to gamma sterilization
- Inert polyethylene fluid contact layer
- High clarity and flexibility
- USP Class VI
- ISO 10993-4, 5, 6, 10 and 11
- EP 3.1.5



AVANTOR SINGLE-USE SOLUTIONS

Description	Capacity	Tubing length	Tubing connection	Tubing material	Tubing size	VWR Cat. No.	Unit
Pillow bag, 2 ports welding	50 ml	P1: 11.75"; P2: 11.75"	P1: Tube plug; P2: Tube plug	C-Flex	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-704**	**Case of 25**
Pillow bag, 2 ports Luer	50 ml	P1: 6"; P2: 6"	P1: Male luer and cap; P2: Female luer and cap	Platinum-cured silicone	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-706**	**Case of 25**
Pillow bag, 2 ports MPC	50 ml	P1: 6"; P2: 6"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug	Platinum-cured silicone	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-708**	**Case of 25**
Pillow bag, 2 ports welding	500 ml	P1: 11.75"; P2: 11.75"	P1: Tube plug; P2: Tube plug	C-Flex	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-710**	**Case of 20**
Pillow bag, 2 ports Luer	500 ml	P1: 6"; P2: 6"	P1: Male luer and cap; P2: Female luer and cap	Platinum-cured silicone	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-712**	**Case of 20**
Pillow bag, 2 ports MPC	500 ml	P1: 6"; P2: 6"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug	Platinum-cured silicone	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-714**	**Case of 20**
Pillow bag, 2 ports welding	1 L	P1: 11.75"; P2: 11.75"	P1: Tube plug; P2: Tube plug	C-Flex	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-682**	**Case of 15**
Pillow bag, 2 ports Luer	1 L	P1: 6"; P2: 6"	P1: Male luer and cap; P2: Female luer and cap	Platinum-cured silicone	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-684**	**Case of 15**
Pillow bag, 2 ports MPC	1 L	P1: 6"; P2: 6"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug	Platinum-cured silicone	P1: 1/4" ID x 3/8" OD; P2: 1/4" ID x 3/8" OD	**76358-686**	**Case of 15**
Pillow bag, 3 ports welding	5 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: Tube plug; P2: Tube plug; P3: Female luer and needleless swabable valve and cap	C-Flex	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-696**	**Case of 12**
Pillow bag, 3 ports MPC	5 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug; P3: Female luer and needleless swabable valve and cap	Platinum-cured silicone	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-698**	**Case of 12**
Pillow bag, 3 ports welding	10 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: Tube plug; P2: Tube plug; P3: Female luer and needleless swabable valve and cap	C-Flex	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-688**	**Case of 10**
Pillow bag, 3 ports MPC	10 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug; P3: Female luer and needleless swabable valve and cap	Platinum-cured silicone	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-690**	**Case of 10**
Pillow bag, 2 ports welding	20 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: Tube plug; P2: Tube plug; P3: Female luer and needleless swabable valve and cap	C-Flex	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-692**	**Case of 6**
Pillow bag, 3 ports MPC	20 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug; P3: Female luer and needleless swabable valve and cap	Platinum-cured silicone	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-694**	**Case of 6**
Pillow bag, 2 ports welding	50 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: Tube plug P2: Tube plug; P3: Female luer and needleless swabable valve and cap	C-Flex	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-700**	**Case of 4**
Pillow bag, 3 ports MPC	50 L	P1: 11.75"; P2: 11.75"; P3: 2"	P1: MPC insert (male) and cap; P2: MPC body (female) and plug; P3: Female luer and needleless swabable valve and cap	Platinum-cured silicone	P1: 3/8" ID x 5/8" OD; P2: 3/8" ID x 5/8" OD; P3: 1/4" ID x 7/16" OD	**76358-702**	**Case of 4**

Product introduction

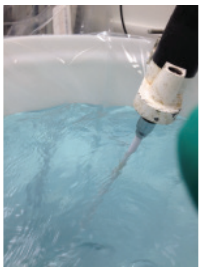
Avantor Fluid Handling Single-Use Liner

After installing the Tank Liner into a vessel and filling it with liquid, powder can be added to the vessel and the mixing process can start by using an overhead agitator. When mixing is finished, it's possible to pump the mixed liquid into sterile bags by using a sterile filter in order to have sterile media and buffers. The fluid contact layer is a medical grade LLDPE. To minimize gas diffusion, an EVOH layer is coextruded between the inner and outer layers. The outer, non-contact strength layer is formed from polyamide and is coextruded with polyethylene to create a bonding layer.

The film is USP Class VI and animal derived component free (ADCF).

- Designed to fit in cylindrical vessels
- No cleaning after media preparation
- Medical grade, multi-layer film
- For bioprocess applications
- USP Class VI and animal derived component free (ADCF)

Capacity, L (gal)	Cat. No.	Unit
2D Tank Liners		
19 (5)	**75874-384**	**Case of 20**
38 (10)	**75874-386**	**Case of 20**
50 (13.2)	**75874-388**	**Case of 20**
100 (26.4)	**75874-390**	**Case of 20**
200 (52.8)	**75874-392**	**Case of 20**
300 (79.2)	**75874-394**	**Case of 20**
560 (147.9)	**75874-396**	**Case of 20**
3D Tank Liners		
50 (13.2)	**75874-398**	**Case of 20**
100 (26.4)	**75874-400**	**Case of 20**
200 (52.8)	**75874-402**	**Case of 20**
300 (79.2)	**75874-404**	**Case of 20**
560 (147.9)	**75874-406**	**Case of 20**



Avantor Fluid Handling Flex Film layer

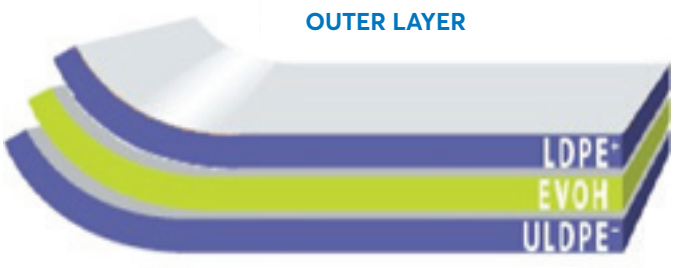
Flexible plastic disposable systems are more and more used as media storage bags, bioreactors, mixing systems and sampling- and product storage containers.

These disposable pre-sterilized systems are increasingly considered as a safer and less costly alternative to stainless steel equipment. This trend in the biotechnology industry is supported by exciting new developments in the plastic components of such flexible disposable systems. These components have to fulfill the severe and strict product properties that are required for critical biotechnology and pharmaceutical applications.

The Film is a co-extruded film, comprising inert PE inner and outer layers and an oxygen barrier layer. The high barrier properties of this film offer significant advantages in the storage of oxygen sensitive products. The film exhibits extremely low leachable and is resistant to a wide range of chemicals.

- Produced under laminar flow conditions in an ISO class 7 clean room
- High oxygen barrier
- Suitable for Pillow Bags, 3-D Cubical Bags and Special Designs
- Resistant to Gamma Sterilization
- Inert polyethylene fluid contact layer
- High clarity and flexibility
- Compatible with the PE based tubing and PE injection molding compound
- USP Class VI
- ISO 10993-4, 5, 6, 10, 11
- Extractable Study
- EP 3.1.5
- Bacterial Endotoxins
- Break at cold temperature: -45°C (ISO8570)

Physical Property	Test Protocol	Typical values
Optical		
Haze	ASTM D1003-07	5%
Clarity	ASTM D1746-03	98%
Total luminous transmittance	ASTM D1003-07	93%
Barrier		
Water Vapor Transmission Rate	ASTM F1249-06	0,35 g/m2
O_2 Transmission Rate3	ASTM F1927-07	0,05 cm3/m2
CO_2 Transmission Rate4	ASTM F2476-05	<0,2 cm3/m2
Fluid integrity		
Film strength retained in seam	ASTM D882-02	>95%
Biocompatibility		
USP Class VI	USP <88>	Pass
Cytotoxicity	USP <87>	Pass
Bacterial Endotoxin	USP <85>	Pass
Non-volatile Residue	USP <661>	Pass
Residue on Ignition	USP <661>	Pass
Heavy Metals	USP <661>	Pass
Buffering Capacity	USP <661>	Pass
Cytotoxicity	ISO 10993-5	Pass
Intramuscular Implantation	ISO 10993-6	Pass
Intracutaneous Injection	ISO 10993-10	Pass
Kligman Maximization	ISO 10993-10	Pass
Systemic Toxicity	ISO 10993-11	Pass
Conformity Analysis	EP 3.1.5.	Pass

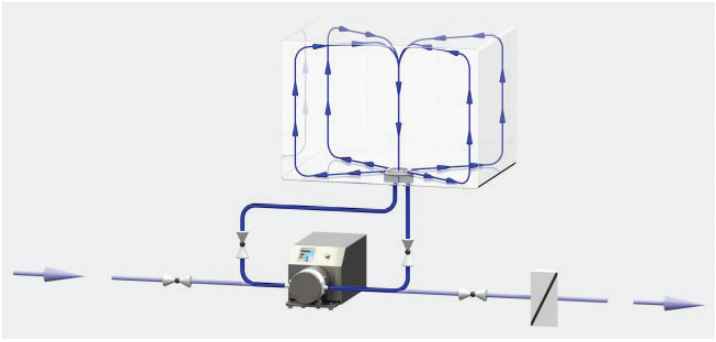


Product introduction

16 Outlet noozles

Connect with pump in-and out outley

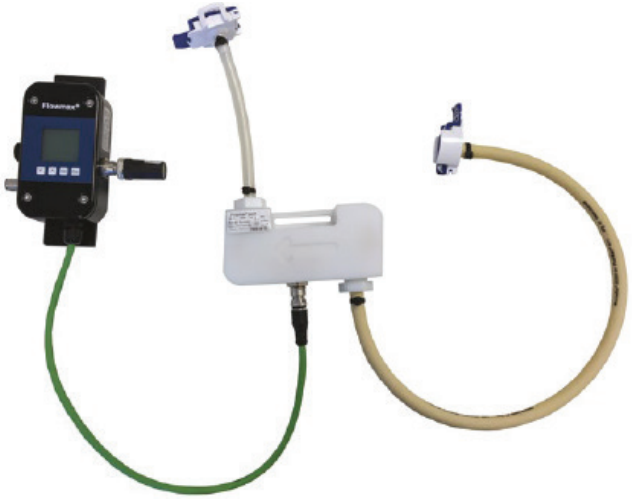
Avantor Fluid Handling QuattroMix Bag



Avantor Fluid Handling QuattroMix is a innovative Single-Use Mixing System on the market. In combination with a pump-system the Avantor Fluid Handling Quattro Mix Mixing System becomes a multi-purpose system for: Mixing solutions by recirculation without rotating wetted parts Filling and emptying of the bag without an additional pump Post-mixing processes like sterile filtration, TFF, flow through chromatography and more Integration of in-line sensors (pH, conductivity, temperature, UV) Integration of heat exchanger for cooling / heating of the media.

Avantor Fluid Handling Ultrasonic Flowmeter

FLOWMAX 242I
Flowmax 242i is a flowmeter calculating the volume flow of liquids. Based on the ultrasonic technology Flowmax 242i can measure conductive and non-conductive liquids contact free. Flowmax 242i has no moving parts and is absolutely free of wear. It is very suitable for single-use application like; MF and UF / DF applications, feed control of bioreactors and PID control systems in combination with pumps. Flowmax 242i is characterized by its high measurement accuracy and repeatability. Empty pipe detection is integrated. The calculated flow is provided with a response rate of a few milliseconds on the outputs. Flowmax 242i is suitable for operation with as well piston diaphragm pumps, as peristaltic pumps. Thus, even lower flowrates can be measured for pulsating flow.



Disposable Measuring Housing:

- Material: PE-HD
- Protection class: IP65
- Medium temperature: 0°– 50°C
- Measuring range: 0.012 – 24.0 L/min
- Nominal pipe diameters: 3, 5, 7 or 10
- DN Nominal max. pressure: 7 bar

Avantor Fluid Handling Containers & Trolleys & Equipment

Avantor Fluid Handling Containers are designed for the safe and robust storage and mixing of biopharmaceutical fluids contained in Avantor Fluid Handling 3D Bags and Mixing Bags. Inherent to the bags, are the containers available up to 3.000 L volume and can be delivered in PP, PE and stainless steel. Containers can be supplied with different options as; double jacket (cooling / heating), on wheels for transporting or with integrated devices for Mixing Bags. Containers can work as a stand-alone product without movement necessity. Only often, to be flexible in space occupancy and for ease of handling, a Trolley is needful. Trolleys are available with several options to support customer's production. A common design is the Weighing Trolley, which is equipped with load cells.

TFF system

Continuos clarification system after USP

Virus inactivation system

50L double jacket container on weighing trolley

200L container designed for JetMixer™ Bags

Two 500L containers stacked on weighing trolley

Product introduction

BioShell™ Suspension Pack (UFP)

Frozen Bag Protection System, advances bag protection through a unique suspension design. Bags are enveloped tightly in a durable film that suspends products within a polycarbonate shell. The suspension film absorbs shocks during impact allowing bags to move within a cushion of air. This prevents damage by eliminating contact with the shell.

Unparalleled versatility/Purpose

- Fill to any level
- Allows use of varying number of tubes, lengths, clamps, or filters without sacrificing protection
- Compatible with bags from all manufacturers
  - Hyclone
  - Applied Bioprocess Containers (ABC)
  - Pall
  - Advanced Scientifics (ASI)
  - GE Healthcare
  - Meissner
  - Charter
  - Sartorius Stedim
  - Xcellerex
  - Parker Mitos
  - Millipore

* For other bags that fit, please conact us

- Position bags in any orientation
- Serves as a liquid bag handling, storage and transport unit as well—simply remove the suspension system
- Acts as process tray for carts and benches

Freeze/Thaw times

- Thermally conductive construction allows contents to quickly freeze and thaw
- The contents within the shipper can be stored as low as -80°C
- Suitable for water baths

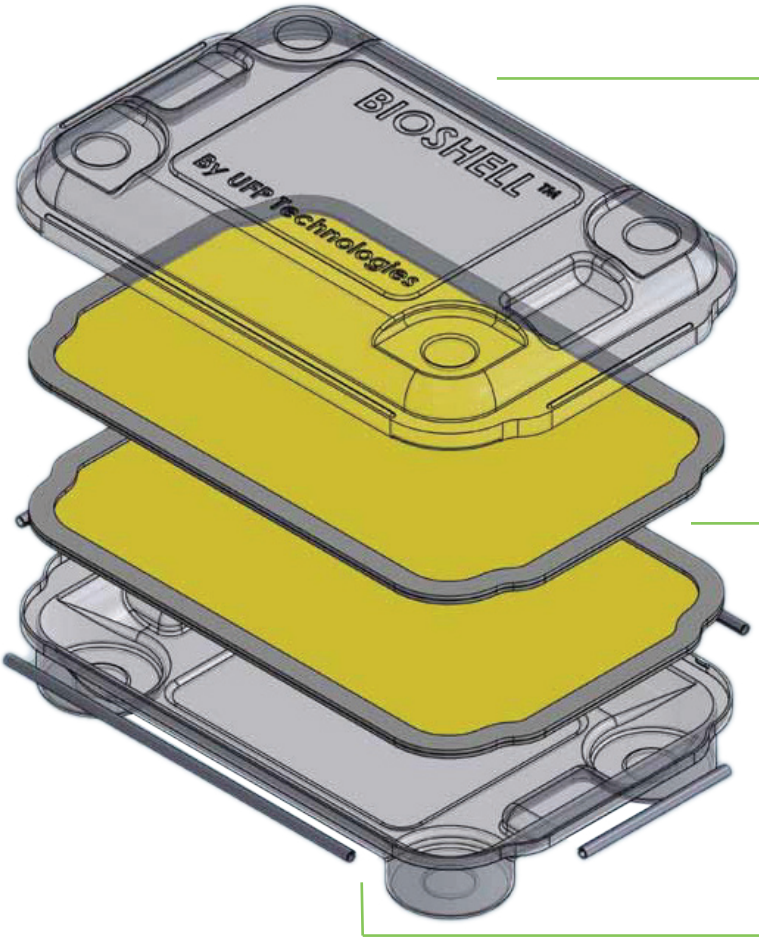
Test description	Item	Result
Freeze/Thaw		
This test compares the freeze/ thaw times of a freestanding bag to a bag enclosed within a BioShell.	Bag size	20 L
	Fill level	16 L
	Freezer type	Harris Upright Freezer Model: HLT-32V-8551D39
	Freezer temp.	-70 °C
	Ambient Room temp.	21 °C
	Time to freeze to -70 °C: Freestanding Bag	30 hrs
	Time to freeze to -70 °C: Bag in BioShell	39 hrs
	Time to freeze to Room temp: Freestanding Bag	70 hrs
	Time to freeze to Room temp: Bag in BioShell	73 hrs
Bench Drop		
This test is meant to simulate an accidental drop of a BioShell. The BioShell was removed from the freezer and immediately dropped from a height of 36" onto a concrete floor.	Bag size	20 L
	Fill level	16 L
	Temp.	-70 °C
	Drop height	36 inches
	Result (Frozen)	Passed
	Result (Thawed)	Passed
ISTA 2A		
The following tests were performed by placing a BioShell unit at -70 °C, complete with a filled bag, inside a palletized BioShell Insulated Shipper. The tests were performed according to ISTA 2A configurations.	Bag size	20 L
	Fill level	16 L
	Freezer type	Harris Upright Freezer Model: HLT-32V-8551D39
	Freezer temp.	-70 °C
	Rotational edge drop	8 inches
	Vibration test	240 CPM at 4.0Hz for 60 minutes (Passed)
	Compression test	272 lbs for 96 hours (Passed)
	Weight of Unit	13 lbs

Space saving/Reusable

- Stackable/Nestable
- Designed to maximize part density in industry standard freezers
- Each component is fully recyclable

Customizable

- The entire system or select features are fully customizable

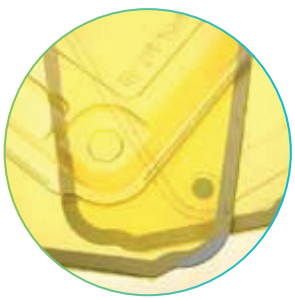


UV protective shell and film.
Protect sensitive products.
Available in all black as well.

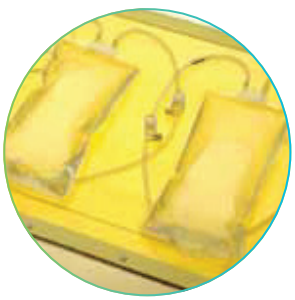
Visibility.
Bags, tubes, accessories are in plain sight.
Possible kinks and/or stress point are in view for quick correction.

Simplicity. Easy open/close. No assembly.

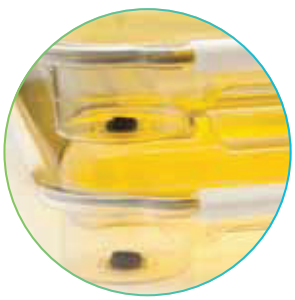
BioShell™ Suspension Pack



Protection



Versatility



Fast cycles

Quality & Regulatory Compliance System to Mitigate Risk

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 programs
- Risk-based quality management approach

Complete Regulatory Compliance Program

- 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> & Particulate USP <788> lot release testing available
- BPOG Standardized Extractables Testing Protocol in us

Minimizing The Complexity Of Your Supply Chain Security

- **Quality and Change Control:** through our own internal Quality Assurance team and Change Control systems to ensure compliance. Visit **vwr.com** to view our Change Notification video to learn about new enhancements!
- **Collaborative Planning, Forecasting, and Replenishment (CPFR):** enabling then demonstrating through service level reports on assurance of supply through the Critical Materials Care team who directly engage with our customers
- **Documentation:** ensuring availability on **vwr.com** such as Certificates of Conformance, Quality, or Analysis and making them available with the SDS's
- **Local Support:** by leveraging VWR's field-based technical experts across 5 continents who will help you match your requirements to high-quality suppliers of bioprocessing materials
- **Supplier Auditing & Integrity:** conducting risk based audits enables us to understand the capabilities of new suppliers and collaborate effectively to promptly address CAPA's corrective and preventative actions if the need arises

Certificate of Compliance

Certificate of Quality

avantor™

Part Number	1002537
Part Revision	A
Lot Number	
Part Description	20L Pillow Bag, 3 Ports MPC
Date of Manufacture	
Gamma Process Run ID	
Expiration Date	
Country of Origin	USA

Quality System Compliance

- This assembly was manufactured in an ISO 9001 certified and FDA cGMP-compliant facility.
- This assembly was manufactured in a certified ISO Class 7 (10,000) clean room.

Inspection & Testing

This product was subjected to inspection in accordance with our Standard Inspection Procedures by qualified inspectors and released by the Quality unit.

Product Specifications & Compliance

Sterilization Validation: VDmax25 Sterilization Validation to the requirements of ANSI/AAMI/ISO-11137 has demonstrated achievement of a Sterility Assurance Level (SAL) of 10^{-6} for gamma-irradiated assemblies.

USP<88> Class VI: Product contact material(s) used in this assembly have been tested to USP protocols and found to comply with the requirements of USP<88> Class VI Plastics based on USP testing performed by component manufacturer(s).

Animal Origin Statement: The product contact material(s) in this assembly are certified to be animal-derived component free (ADCF)

Storage & Shelf-Life

- Storage in original packaging, at ambient conditions and away from direct sunlight, is recommended.
- Expiration for this gamma-irradiated product is shown in the header above, and is based on:
  1. The manufacturer's sterile barrier packaging validation to the requirements of ANSI/AAMI/ISO-11607, and;
  2. The recommended shelf-life of integrated component(s) specified by the component manufacturer(s).

Certified by:

_____ _____

Quality Assurance *Date*

Avantor Fluid Handling, LLC, 29 Saratoga Boulevard, Devens, MA 01434 USA
Manufacturing Location: 29 Saratoga Boulevard, Devens, MA 01434 USA

Certificate of Compliance

BIOCONNECT DISPOSABLES

BIOCONNECT

50L 3D Tankliner
1 pc. JMSCUA0V006100
NON PYROGENIC / PYROGENFREI
SINGLE USE
Do not use if package is damaged, caps are loose or if any leak is found
Nicht verwenden, falls Verpackung beschädigt ist, der Verschluss lose oder das Produkt ausgetreten ist

Sterile | Gamma

LOT 20171011-2
2017/10
2020/10

Certificate No.: 20171011-2

Good Manufacturing Practices
This product was manufactured in a facility that adheres to Good Manufacturing Practices.

ISO Quality Standard
This product was manufactured in a facility who's Quality Management System is approved by an accredited notified body to the ISO9001:2008 and ISO13485:2003.

Validated manufacturing process
This product was manufactured, according to the product specifications, using a validated manufacturing process. Principles of statistical process control and determination of process capability have been applied to critical variables in the manufacturing process. In-process controls are in place to assure stability of the process.

Cleanroom specifications
This product was manufactured in an ISO Class 7 Cleanroom. Monitoring of the Cleanroom is performed according to ISO14644-1.

Validation JM BioConnect Film and components
The JM BioConnect Film is:
- compliant to European Pharmacopoeia ed. IV, 3.1.5;
- compliant to ISO 10993-4,-5,-6,-10,-11;
- USP class VI; USP <87>; USP<88>;
- USP<661> for plastic containers;
- animal derived component free (ADCF).

The used fluid path components:
- meet the USP class VI requirements for plastics;
- are animal derived component free (ADCF);
- are fabricated from medical grade materials in compliance with the US/FDA Regulations (21 CFR part 820);

The tubing material used is in compliance with CFR 21 177.2600.

Sterilization
The components applied are compatible with gamma irradiation.

Quality Assurance Manager: Tilburg, Date: 08-NOV-2017

Commissioned by JM Separations BV, Tilburg

JM BioConnect
Maidstone 50 • 5026 SK Tilburg • The Netherlands
T +31 88 5679500 • F +31 88 5679599 • info@jmbioconnect.com • www. jmbioconnect.com
CoC 24271752 • VAT NL803779781B01 • Bank Account 17.06.28.442 • IBAN NL51RABO0170628442

make the connection

Avantor Fluid Handling Flex film validation

ISO 0993 compliancy

Hemolysis -Human Blood (ISO 10993-4)
Purpose: to assess the hemolytic activity of the test article, Avantor Fluid Handling Flex Film gamma sterilized, in direct contact with human blood.

References (amongst others):

- ISO 10993-4, 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006
- ISO 10993-12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

Conclusion: the test article exhibited 0,0% hemolysis. The test article is considered non-hemolytic under the experimental conditions employed.

Assessment of Cytotoxicity (ISO 10993-5)
Purpose: to assess if the test article, Avantor Fluid Handling Flex Film gamma sterilized, meets the requirements described in the Solmed® Cytotoxicity Test Method.

References:

- ISO 10993-5, Test for Cytotoxicity, In vitro
- ISO 10993-12: Sample Preparation and Reference Materials
- USP<87> Biological Reactivity Tests, In vitro

Conclusion: the test article meets the requirements described in the Solmed® Cytotoxicity Test Method.

Intramuscular Implementation Test (ISO 10993-6)
Purpose: to evaluate the test article, Avantor Fluid Handling Flex Film gamma sterilized, for the potential to induce local toxic effects after implementation in the muscle tissue of albino rabbits.

References (amongst others):

- ISO 10993-6, 1994, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implementation
- ISO 10993-12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

Conclusion: the test article was implanted in the paravertebral muscle tissue of New Zealand White rabbits for a period of 2 weeks. The results indicate that the test article does not demonstrate any remarkable difference as compared to the control implant sites (Bioreactivity Rating of 0.1) when implanted for 2 weeks.

Kligman Maximization Test (ISO 10993-10)
Purpose: to evaluate the allergenic potential or sensitizing capacity of the test article, Avantor Fluid Handling Flex Film gamma sterilized. The study was used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it did not establish the actual rick of sensitization.

References (amongst others):

- ISO 10993-10, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed- Type Hypersensitivity
- ISO 10993-12, 2002, Biological Evaluation of Medical Devices

– Part 12: Sample Preparation and Reference Materials
– Magnusson, B. and A.M. Kligman, Allergic Contact Dermatitis in the Guinea Pig, Identification of Contact Allergens, Springfield, IL.: Thomas, 1970

Conclusion: the skin treated with the test article extracts exhibited no reaction to the challenge (0% sensitization), following an induction phase. Therefore, as defined by the scoring system of Kligman, this is a Grade I reaction and the test article extracts are classified as having weak allergenic potential. Based on the criteria of the protocol, a Grade I sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.

Intracutaneous Injection Test (ISO 10993-10)
Purpose: to screen solutions and test article, Avantor Fluid Handling Flex Film gamma sterilized, extracts for potential irritation effects as a result of an intracutaneous injection in New Zealand White rabbits.

References:

– ISO 10993-10, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
– ISO 10993-12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
– ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

Conclusion: the test article did not show a significantly greater biological reaction than the sites injected with the control article and therefore meets the requirements of the Intracutaneous Test, ISO- 10993-10 guidelines using extracts prepared with NaCl and CSO.

Systemic Injection Test (ISO 10993-11)
Purpose: to screen solutions and test article, Avantor Fluid Handling Flex Film gamma sterilized, extracts for potential toxic effects because of a single-dose systemic injection in mice.

References:

– ISO 10993-11, 1993, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
– ISO 10993-12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
– ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

Conclusion: the animals treated with the test article extracts did not exhibit biological reactions greater than the controls. Therefore, the test article meets the requirements of the ISO 10993-11 guidelines for the Systemic Injection Test.

USP Class VI & European Pharmacopeia (EP)

Class VI Test (USP)
Purpose: to determine the biological response of animals to direct and indirect contact with the test article, Avantor Fluid Handling Flex Film gamma sterilized, or injection of the test article extract.

References:

- United States Pharmacopeia 29, National Formulary 24, 2006. <88> Biological Reactivity Tests, In Vivo
- Draize Scale for Scoring Skin Reactions, Draize, J.H. "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics – Dermal Toxicity, pp. 49-52. Association of Food and Drug Officials of the United States, Topeka, Kansas, 1965
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

Conclusion: the USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH) and Polyethylene Glycol 400 (PEG) extracts of the test article and the test article did not produce a biological response following intramuscular implantation in rabbits, or systemic injection in mice. Therefore, the test article meets the requirements of the USP guidelines, for Class VI Plastics - 50°C.

European Pharmacopeia conformity analysis
Purpose: to determine if the test article, Avantor Fluid Handling Flex Film gamma sterilized, meets the relevant test requirements described in the European Pharmacopeia 3.1.5.

Reference:

- European Pharmacopeia 5th edition 3.1.5., 2005, Materials based on Polyethylene for containers and closures for preparations and for parenteral and ophthalmic use

Conclusion: the test article meets the relevant test requirements described in the European Pharmacopeia 5th edition, Monograph 3.1.5., 2005.

ADCF Statement
Herewith we state that the Avantor Fluid Handling Flex Film does not contain any components of animal origin (not intentionally added, nor knowingly present). Furthermore, no components of animal origin are added to the raw materials in the production process of the abovementioned Avantor Fluid Handling Flex Film.

PE Based materials
In this paragraph the physic- chemical material properties for polyethylene (PE, LDPE, VLDPE, ULDPE) based materials is summarized.

Resistance to solvents/ fluids:

- Good resistance to many chemicals
- Good resistance to polar solvents (alcohols, esters)
- Limited resistance to a-polar solvents (hydrocarbons, aromatic fluid substances, chlorinated hydrocarbons), esp. at elevated temperatures
- Very low water sorption
- Water pH = 2.5 to 11 compatibles

Avantor Fluid Handling Films Leachable / extractable study

The following study was performed on the Avantor Fluid Handling Flex Film: "91 days leachable study on gamma irradiated articles made of Solmed® polyethylene-based materials" Normative basis:

- ISO 10993-17, and -18 [Chemical Characterization of Medical Devices]
- European Pharmacopoeia, 5th Edition (2005 + supplements)

This study has been set up with the aim to provide our customers and the final users with information regarding the extractables coming from this material at well-defined and rigorous conditions with standard extractants (contact fluids). It remains the responsibility of the customer or end user to make sure that articles made of these materials are suited for the intended purpose or use and are in compliance with any applicable law, regulation or ordinance. Here below is a summary of the leachable extractable study as it was performed in June 2007.

Study outline

In co-operation with a well-known bags maker articles made of Solmed® Avantor Fluid Handling Flex Film, Tubeflex tubing and Granuflex injection moulding compound were manufactured, gamma sterilized (25 kGy) and sent to Toxikon Europe to be filled with one of 7 contact fluids:

- Water for Injection (WFI)
- WFI- phosphate buffer solution pH3
- WFI- phosphate buffer solution pH11
- NaCl 3M
- Ethanol 96%
- 1% Tween 80
- 10% DMSO

The filled bags were climatized at 40°C-75% Relative Humidity and samples were taken at T=0, T=30 days and T=91 days. The bags were filled according to a surface to content ratio of 2 cm^2/mL. Various analytical methods were used, aiming for different groups of molecules, e.g. ICP-AES for metals, Headspace gaschromatography/ Mass Spectography for volatiles, etc. All analytical assays were performed against a blank (in glass container).

Results: Examples of molecules found are reaction products of antioxidants, oligomers from the Polyethylene articles, and their reaction products. As expected, the Ethanol, Tween and DMSO contact fluids showed the most extractables, but the highest concentration of any extractable found in this study was approx. 5.3 ppm for 1,3-Di-tert-butylbenzene (a reaction product coming from certain phenolic antioxidants). Based on the findings from this study we can say, that the 30 days and the 91 days test results only revealed extractable chemical entities that were expected, with most concentrations in the 100 ppb – 1 ppm range.

Aggregated Table of Findings – 2007 study.

Extractant:	WFI	WFI-pH3	WFI-pH11	NACL 3M	96% ETHANOL	1% TWEEN 80	10% DMSO
Levels:							
2-10 ppm					1,3 di-tert-butylbenzene (5.3 ppm)		
1-2 ppm	TOC (1.3 ppm C/L)	TOC (1.1 ppm C/L)			C8 Alkenes (<2 ppm)		
100 ppb - 1 ppm		Acetate exanal	TOC (0.5 ppm C/L)	Fatty acids	Acetate AOx degradation Alkenes (C_{9+})	1 Octene C8 Alkenes Methyl-cyclopen-thane 1.3 di-tert butylben-zene	1.3 di-tert butylben-zene AOx
10-100 ppb	Acetate AOx degradation di-tert buty-ilphenol	AOx degradation di-tert buty-ilphenol	2 Methyl-1 propene di-tert butylphenol	Di-tert butylphenol	Alkanes		
5-10 ppb	2 Methyl-1 propene 2 octanone		Antioxi-dants	Hexanal			
<5 ppb	Antioxi-dants			Antioxidants 2-methyl 1-propene			

Follow-up study (2011)
A follow-up extractables study, essentially identical to the 2007 study except for the Granuflex part, was therefore, performed on bags made of Avantor Fluid Handling Flex Film and Tubeflex. This 2011 extractables/ leachable study shows that the levels of extractables found are very low, with 1,3-di-tert-butylbenzene being the highest (4.6 ppm, Ethanol 96%, volatiles). Most findings are in the concentration range < 1 ppm and tend to be lower than those found in the 2007 study.

Aggregated Table of Findings – 2011 study.

Extractant:	WFI	WFI-pH3	WFI-pH11	NACL 3M	96% ETHANOL	1% TWEEN 80	10% DMSO
Levels:							
2-10 ppm					1,3 di-tert-butylbenzene (4.6 ppm)		
1-2 ppm					AOx degr.prod. (1.6 ppm) C_8 Alkenes (2 ppm) Alkene (1.5 ppm)		
100 ppb - 1 ppm	TOC Acetate oligometers (apolar comp)		Unknow		Unknow Methylcycle pentane	C_8 Alkenes, alkenes 1,3 di-tert butylben-zene	
10-100 ppb		3-methyl 3-epthanol, unknow	Fatty acids, Zn ions, unknow	Oligomers (apolar comp)	2,2,4,4,6,6-penta methyleptane	Methylcy-clopentane	Metylcy-clo-pen-thane
<10 ppb	Methylcy-clopentane, AOx degr. prod.	Methylcy-clopentane 2.6-di-tert butylphenol, AOx degr. prod.	AOx degr. prod. (2.4 di-tert bu-tylphenol, unknow	Unknow		2,2,4,4,6,6-penta methylep-tane	Isobuty-lene

The nature of the chemical entities found, and their quantities are in line with the test results of the 2007 E/L study on bags made of Avantor Fluid Handling Flex Film and Tubeflex and tend to be slightly lower per chemical entity. This follow-up study was due to the replacement of one of the polymers used in the Avantor Fluid Handling Flex Film formulation a re-validation was deemed necessary, inclusive a new extractables/ leachable study.

Bag manufacturing: in-process controls

This section outlines a summary of the In-Process-Control procedures JM Separations implements during bag manufacturing. Products are sampled on basis of the ISO-2859 procedure and guidelines unless stated otherwise. Paragraph 3.1 provides general information about the pillow bags, 3D bags (cubic, rectangular, cylindrical) manufactured from Avantor Fluid Handling Flex Film. Then follow paragraphs 3.2.and 3.3 about resp. pillow bags and 3D bags.

Pillow bags / 3D bags
General requirements:

Application	Pillow bags/3D bags: bags for storage of fluids like: buffers, intermediates product. Jeimixer bags: bags for mixing of fluids.
REACH	This product does not contain substances as listed in Annex XIV to the European Regulation N° 1907/2006.
Local Regulatory Requirements	Compliance with local regulatory requirements that may apply to this product in the country of use is the responsibility of the customer.
Blocompatibility	The compatibility of the pillow bag with the solutions it will contain during use is to be determined by the customer.
Environmental aspects	- Materials and processes must comply with relevant regulations - Materials and processes must preferably be low energy consuming - The use of materials will be reduced as far as reasonably possible without compromising the clinical safety of the product - Materials must preferably be suitable for re-use - Materials must not contain hazardous substances

Packaging, storage, and transport:

Protection sharp objects	Product will be protected by using PE layer wrapped around the components.
Primary packaging (over wrap)	Each product will be individually double packed in sealed PA/PE bags unless stated otherwise.
Secondary packaging (box)	Products will be packed in an export quality double wall comugated carton box. Amount of products per box depends on product size and will be deter-mined per product.
Labeling	Label on the products and packaging stating product name, part number batch number, production date and shelf life. Label on the box also stated the amount per box. A gamma indicator is placed on carton box label.
Certificate of Compliance	A Certificate of Compliance for the product will be delivered with each shipment.
Storage requirements	Store in dry and dark place under warehouse conditions (preferably between 2°C and 30°C).
Transport information	Material should be protected to heat over 40°C and cold below - 20°C.

Pillow bags (≤ 50 liters)

Pillow bag components:

Components description	Material	Additional classification
JMS Flex Film	PE, EVOH compound	USP Class Vi, USP<87>, USP<661> EP. 3.1.5 EP. 3.2.2.1 15010993-5, 1S010993-12
Bio boat	PE, compound 4301	USP Class VI
Labels	Vinyl	No contact with fluid pathway
Carton box	Paper	No contact with fluid pathway

In process control specifications for pillow bags:

Subject	Test method	Sample level	Reference
Visual check	Visual check to drawing	100%	No missing components Right configuration Good welding picture
Functional test	1 Bar Pressure test bag	$3	Quality of seal
	Dry leak test	100%	No leaks
	Strength boat connector by peel test	<100 pcs S2 >100 pcs S3	Strength of connector seal
	Static tensile strength	<100 pcs S2 >100 pcs S3	Strength of assembled connections
Dirt	Visual check to inclusions	100%	Details in Product Specs.
	Measurement according to drawing	100%	Details in Product Specs.
	Visual check	100%	Details in Product Specs.
Dimensions	Visual check	100%	Position of components Length/ width of product
Packaging	Visual check	S2	No dirt Labels right No damaged packaging

3D bags

3D bag components:

Components description	Material	Additional classification
JMS Flex Film	PE, EVOH compound	USP Class VI, USP<87>, USP<661> E.P.3.1.5,E.P. 3.2.2.1 1SO10993-5,15010993-12
Port plates	LDPE	USP Class VI
Labels	Vinyl	No contact with fluid pathway
Carton box	Paper	No contact with fluid pathway

In process control specifications for 3D bags:

Subject	Test method	Sample level	Reference
Visual check	Visual check to drawing	100%	No missing components Right configuration Good welding picture
Functional test	1 Bar Pressure test bag	1 pcs	Quality of seal
	Peel test port plates	1 pcs	No leaks
	Seal strength test	1 pcs	Quality of seal >70N
	Static tensile strength test	s2	Strength of assembled connections
	Dry leak test	100%	No leaks
Contamination	Visual check to internal dirt	100%	Details in Product Specs.
	Visual check to external dirt	100%	Details in Product Specs.
	Visual check to inclusions	100%	Details in Product Specs.
Dimensions	Measurements according to drawings	Depends on batch quantity	Position of components Length/ width of product
Packaging	Visual check	S2	No dirt Labels right No damaged packaging

Validation of sterilization procedure

General information
The validation is based on AAMI TIR27:2001 method "Sterilization of Health Care Products" - Radiation Sterilization - Substantiation of 25 kGy as a Sterilization Dose - Method Vdmax. Sterility is an absolute term and the assurance that any given item is sterile is a probability function. The Sterility Assurance Level (SAL) is defined as the probability of any given unit being non-sterile after exposure to a validated sterilization process. The Vdmax method is used to substantiate the use of 25 kGy as a routine dose. This method substantiates using a verification dose of a SAL of 10-1 to attain a SAL of 10-6 and may only be applied to products whose bioburden is on average below 1000 cfu's. The Vdmax methodology is an alternative approach to substantiation of 25 kGy as an appropriate sterilization dose to attain a SAL of 10-6. The application of this method is not limited by batch size or production frequency, and the number of products units irradiated in the verification dose experiment, remains constant. The methods employ as its basis the standard distribution of resistances (SDR) on which Method 1 is also founded and embodies the following three principles:

- Existence of a direct link between the outcome of the verification dose experiment and the attainment of a SAL of 10-6 at a sterilization dose of 25 kGy
- Possession of a level of conservativeness at least equal to that of the SDR
- For a given bioburden, use a maximum verification dose (Vdmax) commensurate with substantiation of 25 kGy

Sterility study by JM Separations
Here below is a summary of the validation study carried out on the sterilization process for JM Separations Biocontainers manufactured from Avantor Fluid Handling Flex Film. This study was performed according to the GMP-GCLP principles. This statement concerns the final report on the following study:

"Validation of a sterility and bioburden test and sterilization process in conformity with AAMI TIR33:2005 method Vdmax30 by gamma-irradiation of Biocontainers."

The report accurately reflects the raw data generated during this study. There have been no circumstances detected that might have affected the quality and integrity of the results obtained.

Objective
The objective of this study was to verify that an irradiation dose of 25 kGy is adequate to guarantee a sterility assurance level (SAL) of 10-6 for Biocontainers, for the inside as well as the outside of the Biocontainer. The irradiation sterilization validation was performed according to ISO 11137-2 method Vdmax25. In this study it should be proven that 5 l Biocontainers do not represent a worst-case situation and are therefore not representative for larger Biocontainers (the bioburden on 200 l Biocontainers is not comparable to the bioburden on 5 l Biocontainers). The bioburden on 200 l and 5 l Biocontainers was determined on a Sample Item Portion (SIP). To determine the bioburden on a SIP of a 200 l or 5 l Biocontainer, the bioburden recovery was determined on both

Biocontainers. After the determination of the bioburden recovery, the bioburden on 10 times 5 l and 10 times 200 l Biocontainers were determined and compared. The SIP used for the determination of the bioburden on the 200 l Biocontainers was validated based on ISO 11137-2. The suitability of the method to determine the bioburden on a SIP of a 200 l Biocontainer was determined conform European Pharmacopoeia 2.6.12 and ISO 11737-1. The suitability of the method to determine the sterility of a 200 l Biocontainer was determined conform European Pharmacopoeia 2.6.1 and ISO 11737-2. Hereafter it was verified that an irradiation dose of 25 kGy is enough to sterilize the Biocontainers according to ISO 11137-2 method Vdmax25. Hereto, the bioburden was determined on 3x10 SIPs of 200 l Biocontainers (10 Biocontainers of 3 different batches) conform the validated method. 10 Biocontainers were sterilized with an irradiation dose based on the found bioburden. Hereafter the sterility of the ten irradiated Biocontainers was determined using the validated method.

Conclusion

On basis of the results of this study, it is concluded that routine irradiation of 200 l Biocontainers with 25 kGy is not sufficient to sterilize the Biocontainers. An average bioburden of 2320 cfu's was found on a 200 l Biocontainer and therefore Vdmax25 conform ISO 11137-2 cannot be used. It was decided to use AAMI TIR33:2005 Vdmax30, to prove that 30 kGy is sufficient to sterilize 200 l Biocontainers. The results of this study proves that 30 kGy is sufficient for the sterilization of 200 l Biocontainers to guarantee sterility of the inside as well as the outside of the 200 l Biocontainer. The bioburden recovery from SIPs of 200l Biocontainers was 59%, as determined conform ISO 11737-1, leading to a bioburden correction factor of 1.7. The bioburden recovery from SIPs of 5 l Biocontainers was 83%, as determined conform ISO 11737-1, leading to a bioburden correction factor of 1.2. The method to determine the bioburden on SIPs of 200 l Biocontainer was proven suitable. The suitability test to determine the validity of the method to determine the bioburden was found to be in accordance with the European Pharmacopoeia 2.6.12 and ISO 11737-1: the number of microorganisms enumerated after the test in the presence of the product was within the acceptable limits from the positive control. The method to determine the sterility of SIPs of 200 l Biocontainer was proven suitable. The suitability test to determine the validity of the sterility test method was found to be in accordance with the European Pharmacopoeia 2.6.1 and ISO 11737-2: growth promotion was proven for all microorganisms tested.

Extractables/ leachable study of Solmed®

Introduction
Solmed® plastic products are being used worldwide for the manufacture of medical devices and pharmaceutical packaging such as infusion bags, blood bags, biotech reactors, etc. An extractables study has been performed on the Solmed® newly developed TPE based flexible tubing, aimed for use in biotechnological processes and for biopharmaceutical applications:

SOLMED® TUBEFLEX (TX) 4502
This study has been set up with the aim to provide our customers and the final users of systems made of a.o. TX 4502 with information regarding the extractables coming from this material at well-defined and rigorous conditions with standard contact fluids. However, it remains the responsibility of our customer, or the end user to make sure that articles made of our materials are suited for the intended purpose or use and are following any applicable law, regulation, or ordinance.

Study Outline
Sample Description
Tubing made of Formulation 4502 with an inner diameter of 6.35mm, gamma sterilized at minimum 25 kGy, was sent to Toxikon Europe NV (Toxikon) to be filled with the respective contact fluids at a surface to content ratio of 5.6 cm2/mL After filling with the respective contact fluids the bags were put in a climate chamber (at 40°C and 75% RH for 91 days. Samples for analysis were taken at t = 0 and t = 91 days. Contact fluids in clear glass bottles were used as blanks.
Extraction or Contact Fluids
The following contact fluids were chosen:

- WFI (Water for Injection, pH 7)
- WFI – Phosphate buffer solution (PBS) pH 3
- WFI – Phosphate buffer solution (PBS) pH 11
- Ethanol 96%

Analytical methods and Chemical Entities aimed for Various analytical methods were used: GC-MS, GC-MS headspace, LC-MS, ICP, TOC, pH, organic acids, etc.

- **Acidity / Alkalinity – pH measurement:** Detection of extractables that could change the pH of the fluid.
- **Conductivity:** Detection of molecules that could conduct electric current through the fluid, mostly inorganic ions.
- **Total Organic Carbon (TOC):** Measurement of the Total of Organic Components leaching into the contact fluid. This is the sum mass balance of all other analytical methods aimed at discovering organic molecules. The method first purges inorganic carbon from the sample, then converts the remaining carbon into Carbon Dioxide (CO_2); measurement with Infrared Absorption Spectroscopy.
- **Metal ions – ICP-OES:** Metals may come from e.g. the catalysts used for the polymerization processes of the polymers. They may also come from certain additives used in these polymers. Metals are best analyzed using Atomic / Optical Emission Spectroscopy with an inductively coupled plasma (ICP-AES or ICP-OES).

Target metals:

Ag	Silver	Cr	Chrtomium	Mg	Magnesium	Si	Silicium
Al	Aluminium	Cu	Copper	Mn	Manganese	Sr	Strontium
Ba	Barium	Fe	Iron	Na	Sodium	Ti	Titanium
Ca	Calcium	Hf	Hafnium	Ni	Nickel	Vi	Vanadium
Cd	Cadmium	K	Potassium	Pb	Lead	Zn	Zinc
Co	Cobalt	Li	Lithium	Pt	Platinum	Zr	Zirconium

- **Acetate/Formate - Ion Chromatography:** Acetates and Formates can be found in small quantities everywhere in plastic products, either coming from raw materials used or being the smallest degradation molecules from larger organic molecules. The most sensitive method to analyze their presence is the use their different polarity and therefore their

different affinity to polar adsorbents (ion chromatography).

- **Volatile Organic Compounds – Headspace GC/MS:** Volatile organic molecules may come from a host of sources, such as monomers and oligomers, residual solvents from various production steps, additives, residues form polymer treatment, degradation products. Volatile molecules can be analyzed by means of headspace Gas Chromatography coupled with e.g. Mass Spectrograph.
- **Semi-volatile Organic Compounds – GC/MS:** Many compounds are not volatile enough to be analyzed by Headspace GC/MS but are still volatile enough to be analyzed by "standard" GC/MS. These compounds may comprise solvents with higher boiling points, lubricants, plasticizers, antioxidants and many others.
- **Non-volatile Organic Compounds - Liquid Chromatography LC/MS:** If the molecules cannot be properly analyzed in their gaseous state a different form of chromatography is used, dissolving the compound in a liquid mobile phase:
- Liquid chromatography again coupled with a Mass Spectrograph. Typically, compounds such as the widely used phenolic antioxidants can be analyzed by means of this method.
- **Derivation GC/MS:** Some groups of organic compounds, e.g., organic acids need to be treated differently compared with Par.A.3.7. for generating a sufficient signal in the GC/MS assay. Derivatization comprises treatment with BF3 and Butanol. This method esp. shows the presence of fatty acids, e.g., palmitic acid, stearic acid.

Identification

The Mass Spectrometer as detector coupled onto a GC or LC analytical device makes use of a huge library of molecules (> 190,000) and tries to match the found signal with the most probable chemical entity in the library. IC = Identified Compound ("100%" fit) MPC = Most probable Compound (>80% fit) TIC = Tentatively Identified Compound (>50% fit)

Quantification (see also e.g., European Pharmacopoeia, Chapter 2.2.46)

All analytical methods have their limitations and, although today we can really find low quantities of molecules, we must take into account the following:

- **Noise:** any analytical system base line is not a straight line, when magnification factor is high enough Signal to noise ratio - does the analytical signal emerge from the base line noise?
- **Detection limit:** signal to noise ratio is 3
- **Quantitation limit:** signal to noise ratio is 3x detection limit
- **Disregard limit:** specification for "impurity" in monograph of pharmaceutical raw material (active ingredient or excipient).
- **Reporting limit:** 10% of the analytical response of the internal standard used. Furthermore, the analytical system chosen must be suitable, i.e., peak shape, retention times, must comply with certain specifications. For "in-line" suitability an internal standard is used.

Results/Findings

Here are the results on chemical parameters aggregated for all four contact fluids:

Contact fluid	WFI/Blank	PBS pH3/Blank	PBS pH3/Blank	PBS pH3/Blank
TOC Value (ppm C/L)	23/0.1	21/14	37/12	N.A.
pH	4.30/6.37	2.93/2.97	9.94/9.72	N.A.
Conductivity	<50/<50	15.9/15.6	16.7/16.3	N.A.

TABLE 1: Chemical parameters

The following paragraphs present the analytical results (in ppm, where applicable) per Contact Fluid.

Water for Injection (WFI)

If at all extracted compounds were quantifiable, the concentrations for most of them were found to be in the micrograms per Liter range (ppb).

Phosphate Buffer Solution pH 3.0

If at all extracted compounds were quantifiable, the concentrations for most of them were found to be in the micrograms per Liter range (ppb).

Analysis	Unity concentration	Compound/Chemical entity	Blank after 91 days	Tube after 91 days
Ions and Organic acids	ppm	Acetate	<0.05	0.39
		Formate	<0.07	1.30
		Chloride	0.08	0.09
		Phosphate	<0.04	0.21
Metals	ppm	Silicium (Si)	0.06	0.17
		Sodium (Na)	0.03	0.07
		Potassium (K)	<20	0.05
		Calcium (Ca)	0.004	0.02
		Other metals b.d.		
Volatile organic compounds	ppm	Acetone		0.04*
		Tert-Butanol		0.03*
Semi-volatile organic compounds	ppm	2-ethythexanoic acid		0.28*
		3,5-Di-tert-butyl-4-hydroxy-phenylpropionic acid		0.16*
		2,2-Dimethylpropanoic acid		0.07*
		7,9-Di-tert-butyl-1-oxaspiro(4,5) deca-6,9-diene-2,8dione		0.04*
Non-volatide organic compounds	ppm	All under method detection limit	-	-

- = non detected * = after substraction of blank result

Phosphate Buffer Solution pH 3.0

If at all extracted compounds were quantifiable, the concentrations for most of them were found to be in the micrograms per Liter range (ppb).

Analysis	Unity concentration	Compound/Chemical entity	Blank after 91 days	Tube after 91 days
Ions	ppm	Acetate	<0.50	1.90
		Formate	<0.70	2.30
Metals	ppm	Potassium (K)	0.41	0.70
		Silicium (Si)	0.03	0.22
		Calcium (Ca)	0.02	0.06
		Magnesium (Mg)	0.004	0.01
Volatile organic compounds	ppm	Acetone		0.04*
		tert-Butanol		0.02*
Semi-volatile organic compounds	ppm	2-Ethylhexanoic acid		0.19*
		2.2-Dimethylpropandic acid		0.08*
		Unknow		0.06*
		3,5-Di-tert-butyl-4-hydroxy-phenylpropionic acid		0.05*
		7,9-Di-tert-butyt-1-oxaspiro(4,5) deca-6,9-diene-2,8-dione		0.03*
		2-Phenoxyethanol		0.02*
		2-(2-buthoxyethoxy)-Ethanol		0.02*
		1,1,2,2-tetrachloroethane		0.02*
		Benzoic acid		0.02*
		4-hydroxy-3-methoxybenzal-dehyde(or vanillin)		0.01*
		Phenol		0.01*
		Unknow		0.01*
Non-volatide organic compounds	ppm	Virtually all under method detection limit	-	0 (0.001)
		Oleamide	-	
Organic acids	ppm	-	-	

- = non detected * = after substraction of blank result

Phosphate Buffer Solution pH 11.0

If at all extracted compounds were quantifiable, the concentrations for most of them were found to be in the micrograms per Liter range (ppb).

Analysis	Unity concentration	Compound/Chemical entity	Blank after 91 days	Tube after 91 days
Ions	ppm	Acetate	<0.50	2.70
		Formate	<0.70	3.40
Metals	ppm	Kalium (Potassium) (K)	1.70	0.70
		Silicium (Si)	-	0.42
Volatile organic compounds	ppm	Acetone		0.04*
		tert-Butanol		0.03*
Semi-volatile organic compounds	ppm	7,9-Di-tert-butyl-1-oxaspiro(4,5) deca-6,9-diene-2,8-dione		3.50*
		2-ethyl Hexanoic acid		1.02*
		n-Hexadecanoic acid		0.32*
		3,5-Di-tert-butyl-4-hydroxy-phenylpropionic acid		0.24*
		Octadecanoic acid		0.10*
		2,2-Dimethylpropanoic acid		0.09*
		Unknown		0.09*
		Unknown		0.09*
		Unknown		0.08*
		Tetradecanoic acid		0.07*
		Unknown mass		0.05*
		Nonanoic acid		0.05
		Unknown		0.04*
		Unknown		0.04*
		2-(2-buthoxyethoxy)-Ethanol		0.04*
		2,6-Di-tert-butyl-p-benzo-quinone		0.03*
		Benzoic acid		0.03*
		Unknown		0.03*
		Unknown		0.03*
		4-hydroxy-3-methoxybenzal-dehyde(or vanillin)		0.02*
		Unknown mass		0.02*
		2-Phenoxyethanol		0.02*
		Phenol		0.02*
		Unknown		0.02*
		Unknown		0.02*
		3,5-di-tert-Butyl-4-hydroxy-benzaldehyde		0.02*
		Unknown		0.02*
Non-volatide organic compounds and organic acid	ppm	Palmitic acid	0.01	0.98
		Stearic acid	-	0.51
		Myristic acid	traces	0.28
		Oleic acid	-	0.03

- = non detected * = after substraction of blank result
Traces = reported concentration is < quantification limit for this compound, or not quantifiable

Ethanol 96%

If at all extracted compounds were quantifiable, the concentrations for most of them were found to be in the micrograms per Liter range (ppb). As expected, this contact fluid shows more extractables than the water- based contact fluids.

Analysis	Unity concentration	Compound/Chemical entity	Blank after 91 days	Tube after 91 days
Ions	ppm	Acetate	<0.500	3.20
		Chloride	0.300	1.00
		Sulphate	1.90	3.30
Metals	ppm	Calcium (Ca)	0.02	0.08
		Magnesium (Mg)	<0.003	0.01
		Natrium (Sodium) (Na)	0.18	0.15
		Kalium (Potassium) (K)	<0.02	0.03
Volatile organic compounds	ppm	1,3-Di-tert-butylbenzene		0.41*
		Alkene (probably $C_{12}H_{24}$)		0.36*
		2,6-di(tert-butyl)benzo-1,4-quinone		0.36*
		Acetone		0.16*
		2-methyl-1-propene		
		1,1-Diethoxy-ethane		0.08*
		Tetradecane		0.07*
Semi-volatile organic compounds	ppm	3,5-Di-tert-butyl-4-hydroxy-benzaldehyde		2.40*
		7,9-Di-tert-butyl-1-oxaspiro(4,5) deca-6,9-diene-2,8-dione		1.50*
		2 6-di(tert-butyl)benzo-1,4-quinone		1.40*
		1-Ethylhexanoic acid		0.55*
		Fragments of antioxidant		4.10*
		Fragments of antioxidant		1.20*
		Fragments of antioxidant		0.81*
		Fragments of antioxidant		0.56*
Non-volatide organic compounds	ppm	Pentaerythrityl tetratkis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate)	-	56.9
		N,N-Ethylenedialkanamide	-	17.5
		2,2',2".6,6',6"-hexa-tert-butyl-4,4',4"-((2,4,6-trimethyl-1,3,5benzene-triyljtrismethylene)triphenol	-	15.8
		Tris(2,4-di-tert-butylphenyl) phosphite (oxidated)	-	1.30
		Erucamide	-	1.15
Organic acids	ppm	Myristic	-	0.94
		Paimitic	-	4.00
		Stearic acid	-	6.15

- = non detected * = after substraction of blank result

* antioxidant = Pentaerythrityl tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]

Conclusion

Tubing samples made of Solmed® Tubeflex Formulation 4502 (batch 831XP), after gamma irradiation (minimum 25kGy) were filled with 4 different contact fluids. The analysis after 91 days, revealed low concentrations of extractables as compared with a blank, see for details the tables under B.1. – B.4. Most findings are in the concentration range up to 1 ppm. A limited number of extracted chemical entities was extracted at 1 – 10 ppm (mainly fragments or reaction products of one of the antioxidants) and two antioxidants and EBS (ethylene bis-stearamide) were extracted with Ethanol 96% at higher concentrations up to 57ppm:

- Pentaerythrityl tetratkis[3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate] [57 ppm]
- N, N'-Ethylenedialkanamide [17.7 ppm]
- 2,2',2'',6,6',6''-hexa-tert-butyl-4,4',4''-[(2,4,6-tri-methyl-1,3,5benzene-triyl) trismethylene] tri- phenol [15.8 ppm]

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