Savillex
Science Contained

Savillex Life Sciences
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Savillex Life Sciences Brochure

CONTAINER + CONTAINMENT SOLUTIONS

WHO WE ARE

Savillex specializes in providing high-quality containers and containment designed for critical applications across a broad spectrum of pharmaceutical and biopharmaceutical processes. Our range of products ensures reliability and performance in the most demanding life science environments. Every product we sell is designed to help the scientific community to preserve sample integrity, ensure regulatory compliance, facilitate reliable data, and safeguard your assets.

WHY CHOOSE US

- Our operational footprint spans five locations across two continents, serving international container & containment needs.
- Our line of Purillex® containers are manufactured using injection and stretch blow molding to ensure the highest integrity seals.
- All Purillex containers are manufactured in the USA, from our ISO Class 7 cleanroom located in Eden Prairie, Minnesota.

OUR SOLUTIONS

Purillex® Containers

Designed for the most demanding applications, our Purillex PFA and PETG containers are the gold standard for ultra-pure storage - offering unmatched purity and performance for storing APIs, excipients, and high-value reagents.

Bioprocess Products

Single-use bags and assemblies engineered for reliability and scalability in both upstream and downstream bioprocessing, ideal for cell culture, gene therapies, tissue prep, and a variety of other applications.

ONFAB Containment

ONFAB is a leading provider of bespoke, single-use flexible pharmaceutical isolators for pharmaceutical process manufacturing - specializing in the containment of highly potent ingredients.

Want to shop our life sciences products online? Click here!

952.935.4100 | info@savillex.com | www.savillex.com

Purillex® PETG Square Media Bottles

Tailored for use in life sciences and meeting USP Class VI standards, Savillex introduces Purillex® PETG square media bottles - a premier solution for secure liquid media packaging and ingredient storage. These bottles are optimal for various critical applications in media manufacturing, research, drug development, and biopharmaceutical production.

DESIGN FEATURES

Crafted from heavy-duty PETG, these bottles feature a high-density polyethylene (HDPE) lugged closure engineered to deliver a leakproof seal. Their square, practical design, and optimal clarity facilitate easy labeling, storage, process handling, and pouring. These bottles exhibit excellent thread quality through precision injection molding, eliminating the need for secondary machining and mitigating the risk of particulate contamination. They boast a high-integrity seal without requiring secondary seals or inserts, ensuring suitability for manual and automated fill lines. Durable and shatter-resistant, these bottles seamlessly replace existing PETG media bottles. Additionally, they offer compatibility with industry-standard, off-the-shelf, single-use media bottle assemblies.

RESIN CHARACTERISTICS

Both Purillex PETG square media bottles and closures are proudly manufactured in the USA, ensuring stringent quality control and adherence to industry standards. The resin utilized in Purillex PETG square media bottles is RNase/DNase free, nonpyrogenic, non-cytotoxic, and recyclable. It results in an optically clear final product compatible with various chemicals and boasts a low leachable and extractable profile. PETG affords exceptional chemical and temperature resistance, which is particularly advantageous in freeze/thaw cycle applications. Moreover, it exhibits remarkable gas barrier properties, including reduced permeability to CO_2 and O_2.

AVAILABLE SIZES AND STERILITY

Purillex PETG bottles are offered in five sizes ranging from 125 mL to 2000 mL, each featuring molded graduations for precise measurement. All sizes are available in sterile configurations and validated to achieve a SAL of 10^{-6}, meeting requirements for aseptic applications.

LAB PACKS

The Purillex PETG square media bottle lab pack combines convenience, security, and material quality to meet the unique demands of laboratory and research settings. They are packaged with 50% fewer bottles than standard cases - making them a great option for smaller-scale laboratories requiring reduced inventory for limited usage. They are also ideal for R&D and pilot production batches where sterility and security are paramount. Bottles feature a tamper-evident band that provides visual assurance of product integrity and safety, meeting quality control and regulatory standards.

PACKAGING

Purillex PETG square media bottles are meticulously packaged for convenience and compliance with industry norms. They are arranged on individually shrink-wrapped trays, stacked and double-bagged, and placed in recyclable corrugated boxes. Labels are affixed to each tray, outer bag, and box, indicating part number, lot number, and expiration date. A Certificate of Conformance accompanies sterile and non-sterile bottles, while sterile bottles include a Certificate of Processing for added assurance.

STERILIZATION AND WORKING TEMPERATURE RANGE

MATERIAL	STERILIZATION METHOD	WORKING TEMPERATURE RANGE
PETG	Gamma Irradiation	-121°F to 158°F (-85°C to 70°C)

PURILLEX PETG BOTTLE ORDERING INFORMATION

PART #	DESCRIPTION	QUANTITY
160-04-0125-S	125 mL Purillex® PETG Square Media Bottle, Sterile	24/Tray/4/Trays/Case/96
160-04-0125	125 mL Purillex® PETG Square Media Bottle, Non-Sterile	24/Tray/4/Trays/Case/96
160-04-0250-S	250 mL Purillex® PETG Square Media Bottle, Sterile	30/Tray/2/Trays/Case/60
160-04-0250	250 mL Purillex® PETG Square Media Bottle, Non-Sterile	30/Tray/2/Trays/Case/60
160-04-0500-S	500 mL Purillex® PETG Square Media Bottle, Sterile	20/Tray/2/Trays/Case/40
160-04-0500	500 mL Purillex® PETG Square Media Bottle, Non-Sterile	20/Tray/2/Trays/Case/40
160-04-1000-S	1000 mL Purillex® PETG Square Media Bottle, Sterile	12/Tray/2/Trays/Case/24
160-04-1000	1000 mL Purillex® PETG Square Media Bottle, Non-Sterile	12/Tray/2/Trays/Case/24
160-04-2000-S	2000 mL Purillex® PETG Square Media Bottle, Sterile	6/Tray/2/Trays/Case/12
160-04-2000	2000 mL Purillex® PETG Square Media Bottle, Non-Sterile	6/Tray/2/Trays/Case/12
160-04-0125-LP	125 mL Purillex® PETG Square Media Bottle, Sterile, Lab Pack	24/Tray/2/Trays/Case/48
160-04-0250-LP	250 mL Purillex® PETG Square Media Bottle, Sterile, Lab Pack	30/Tray/1/Trays/Case/30
160-04-0500-LP	500 mL Purillex® PETG Square Media Bottle, Sterile, Lab Pack	20/Tray/1/Trays/Case/20
160-04-1000-LP	1000 mL Purillex® PETG Square Media Bottle, Sterile, Lab Pack	12/Tray/1/Trays/Case/12
160-04-2000-LP	2000 mL Purillex® PETG Square Media Bottle, Sterile, Lab Pack	6/Tray/1/Trays/Case/6
670-038-05-PK	38-430 HDPE Retaining Ring - Pack of 10	Pack of 10
670-038-05-CS	38-430 HDPE Retaining Ring - Case of 10	Case of 100
670-053-05-PK	53B HDPE Retaining Ring, 10 Pack	Pack of 10
670-053-05-CS	53B HDPE Retaining Ring, 100 Pack	Case of 100

NOTE: All PETG bottles listed above include a size 38-430 lugged HDPE closure.

Purillex® Bioprocess PETG Bottle Assemblies

Purillex® Bioprocess PETG bottle assemblies redefine flexibility and performance in biopharmaceutical process development and manufacturing applications. Designed with precision for critical fluid handling, storage, and transfer applications, they provide superior durability and low extractables while maintaining compliance with the strictest industry standards.

APPLICATIONS

- Pilot production batches
- Process development fluid transfer requirements
- Buffer, culture media, and reagent preparation

AVAILABLE OPTIONS

- **Quality You Can Count On**
  - A variety of sizes, complete with tubing, hosebarbs, a dip tube, vent filter, and connector
  - Industry recognized components allowing for easy and efficient usage
- **Configurable Options, Customized for You**
  - In-stock components sourced from trusted manufacturers, providing a variety of choices to fit your needs
  - Significantly reduce lead time, cleaning, and validation requirements
- **From Vision to Reality: Custom Engineered Solutions**
  - Unmatched lead time from design to delivered assembly
  - Reduced downtime and lower facility setup expenses
  - Complete flexibility and integration into current biopharmaceutical process development footprints

DESIGN FEATURES

Crafted from heavy-duty PETG, these bottles feature a high-density polyethylene (HDPE) lugged closure engineered to deliver a leakproof seal. Their square, practical design, and optimal clarity facilitate easy labeling, storage, process handling, and pouring. These bottles exhibit excellent thread quality through precision injection molding, eliminating the need for secondary machining and mitigating the risk of particulate contamination. They boast a high-integrity seal without requiring secondary seals or inserts, ensuring suitability for manual and automated fill lines. Durable and shatter-resistant, these bottles seamlessly replace existing PETG media bottles.

A variety of options are available for tubing, vent filters, and connectors all of which are designed and manufactured to ensure successful fluid handling and storage. Each assembly is manufactured in an ISO Class 7 Cleanroom using USP Class VI components and are offered e-Beam irradiated for convenience and ease of use. Configurable options are available to meet unique customer requirements as well.

PURILLEX PETG BOTTLE ASSEMBLY ORDERING INFORMATION

PART #	DESCRIPTION	QUANTITY
990-02-94125	125 mL Purillex® Bioprocess PETG Bottle Assembly	1/EA
990-02-94250	250 mL Purillex® Bioprocess PETG Bottle Assembly	1/EA
990-02-94500	500 mL Purillex® Bioprocess PETG Bottle Assembly	1/EA
990-02-94001	1000 mL Purillex® Bioprocess PETG Bottle Assembly	1/EA
990-02-94002	2000 mL Purillex® Bioprocess PETG Bottle Assembly	1/EA

NOTE: All products listed above include a size 38-430 lugged HDPE closure.

Purillex® Bioprocess Bag Assemblies

Purillex® bioprocess bag assemblies redefine flexibility and performance in biopharmaceutical process development and manufacturing. Designed with precision for critical fluid handling, storage, and transfer, they provide superior durability and low extractables while complying with the strictest industry standards.

Featuring customizable configurations in size, film type, tubing, and connectors, Purillex bioprocess bag assemblies deliver unmatched scalability and versatility. Engineered for robustness, our assemblies are optimized for reliable performance in demanding applications, offering a high-integrity alternative to rigid systems without compromising clarity, low-temperature stability, or biocompatibility.

Purillex bioprocess bag assemblies are available in 2D and 3D versions, in sizes ranging from 1 L to 200 L.

APPLICATIONS

- Buffer preparation and storage
- Bulk intermediate product storage
- Cell culture media manufacturing
- Cell culture harvesting
- Fraction collection and storage

AVAILABLE OPTIONS

- **Quality You Can Count On**
  - A variety of sizes, complete with tubing, hosebarbs, a dip tube, vent filter, and connector
  - Industry recognized and accepted components allowing for easy and efficient usage
- **Configurable Options, Customized for You**
  - In-stock components sourced from trusted manufacturers, providing a variety of choices to fit your needs
  - Significantly reduce lead time, cleaning, and validation requirements
- **From Vision to Reality: Custom Engineered Solutions**
  - Unmatched lead time from design to delivered assembly
  - Reduced downtime and lower facility setup expenses
  - Complete flexibility and integration into current manufacturing footprint

OPTCLR FILM FOR PURILLEX BIOPROCESS BAG ASSEMBLIES

OpTCIR Film is a multilayer PE/EVOH based film for single use systems in biotechnology applications. It is designed for use in media storage bags, bioreactors, mixing systems and sampling, product storage containers, and other single use applications. These disposable pre-sterilized systems are increasingly considered 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 must fulfill the severe and strict product property requirements in critical biotechnology and pharmaceutical applications.

These disposable pre-sterilized systems are increasingly considered 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 must fulfill the severe and strict product property requirements in critical biotechnology and pharmaceutical applications.

OpTCIR barrier film offers a solution for these challenges:

- High oxygen barrier: <0.05cc/(m2.day.bar)
- Suitable for pillow bags and 3-D cubical bags
- Inert polyethyline fluid contact layer
- Superior clarity and flexibility and strength

The OpTClr film is produced under laminar flow conditions in an ISO class 7 clean room. The film fulfills test requirements of the various pharmacopoeia and applicable ISO 10993 standards.

OpTClr film is a coextruded film, comprising inert PE inner and outer layers and an oxygen barrier layer. Its high barrier properties offer significant advantages in the storage of oxygen sensitive products. The film is also resistant to a wide range of chemicals and exhibits extremely low leachables; a full leachable study is available upon request.

PURILLEX BIOPROCESS BAG ASSEMBLY ORDERING INFORMATION

Please click here to discuss your bag assembly design needs and receive a quote.

Purillex® Fluoropolymer Bottles

The Savillex Purillex® range of fluoropolymer bottles sets a new standards in cleanliness, safety, and performance. PFA and FEP bottles are crafted using a specialized stretch blow molding process adapted for fluoropolymer applications in the life sciences. These include autologous cell therapies, bulk drug storage & transport, formulation stability testing & storage, and many more.

INNOVATIVE DESIGN FEATURES

The proprietary manufacturing process we utilize for Purillex PFA and FEP bottles offers numerous advantages, including impeccably clean and smooth fluid contact surfaces, enhanced pourability, superior seal integrity, and more. Purillex bottles are indispensable in a wide array of critical applications, whether sterilized or non-sterilized. The wide-mouthed 45 mm diameter neck accepts a GL45 threaded closure (33 mm diameter neck and closure on 50 mL bottle). A closure is included with each bottle.

PFA/FEP RESIN ATTRIBUTES

- Temperature range: -328°F to 500°F for PFA (-200°C to 260°C), -328°F to 392°F for FEP (-200°C to 200°C)
- Extreme chemical resistance
- Low leachable and extractable profile
- Smooth interior surface
- Autoclavable

VERSATILE SIZING OPTIONS

Purillex fluoropolymer bottles are offered in six sizes ranging from 50 mL to 2000 mL, providing flexibility to suit diverse laboratory needs. Each bottle features a wide-mouthed 45 mm diameter neck compatible with GL45 threaded closures (33 mm diameter neck and closure on 50 mL bottles), and a closure is included for added convenience.

BOTTLE SIZE	PFA	FEP
50 mL	✓	✓
100 mL	✓	✓
250 mL	✓	✓
500 mL	✓	✓
1000 mL	✓	✓
2000 mL	✓	✓

STERILIZATION, CERTIFICATION, AND TESTING

All Savillex Purillex bottles are available sterilized and are individually double-bagged to maintain sterility before use. Sterilization processes are rigorously validated to achieve an SAL (Sterility Assurance Level) of 10^{-6}, meeting industry standards for aseptic applications. All of our PFA bottles have undergone compatibility testing for dry heat sterilization processes up to 250°C for two hours.

Furthermore, Purillex bottles have undergone a variety of additional comprehensive internal testing procedures, including assessments for drop resistance, leakproofness, vacuum resistance, and pressure bursts. They comply with Class VI standards and have undergone complete USP extractable and biocompatibility testing. Sterilized bottles come with manufacturing lot certification for added assurance.

TEST	NON-STERILIZED BOTTLES	STERILIZED BOTTLES
USP Class VI	✓	✓
USP <87> Cytotoxicity	✓	✓
USP <661.2>	✓	✓
BSE/TSE Free	✓	✓
Savillex Internal Leakproof Test	✓	✓
Bioburden		✓
USP <788> Particle		✓

PURILLEX FLUOROPOLYMER BOTTLE ORDERING INFORMATION

BOTTLE SIZE	CLOSURE	PFA PART # (STERILIZED)	PFA PART # (NON-STER.)	FEP PART # (STERILIZED)	FEP PART # (NON-STER.)
50 mL	33 mm	170-01-0050-A	170-01-0050	170-02-0050-A	170-02-0050
125 mL	GL45	170-01-0125-A	170-01-0125	170-02-0125-A	170-02-0125
250 mL	GL45	170-01-0250-A	170-01-0250	170-02-0250-A	170-02-0250
500 mL	GL45	170-01-0500-A	170-01-0500	170-02-0500-A	170-02-0500
1000 mL	GL45	170-01-1000-A	170-01-1000	170-02-1000-A	170-02-1000
2000 mL	GL45	170-01-2000-A	170-01-2000	170-02-2000-A	170-02-2000

Purillex™ Fluoropolymer Vials

Savillex presents a comprehensive range of Purillex™ vials tailored to support critical applications, including material validation and stability testing programs. These vials are particularly well-suited for cryogenic applications such as cell banking and long-term sample archiving, capable of enduring temperatures as low as liquid nitrogen conditions (-196°C) while preserving seal integrity.

DESIGN FEATURES

Available in 3 mL, 7 mL, and 15 mL sizes, Purillex vials accommodate a broad spectrum of stability test protocols, minimizing the consumption of precious final products for stability and materials testing and validation. These vials exhibit exceptional thread quality through precision injection molding, eliminating the need for secondary machining of the vial lip and significantly reducing the risk of particulate contamination. A robust seal is guaranteed without the necessity for secondary seals or inserts. Additionally, all vials feature round bottoms for effortless content removal.

CERTIFIED QUALITY

Purillex vials conform to USP Class VI standards and undergo rigorous USP testing. Every lot is manufactured using the same resin manufacturer and grade as Purillex PFA bottles, ensuring consistency and reliability. For regulatory compliance, each order includes full manufacturing lot certification - supporting seamless regulatory filing processes. Please see the table below for a summary of Purillex PFA vial testing procedures.

TEST	RESULT
Savillex Internal Product Testing	Passed
FDA 21 CFR 177.1550	Complies
USP <85> Bacterial Endotoxins Test	Passed
USP <87> Cytotoxicity Test	Passed
USP <88> Class VI Biological Reactivity	Passed
USP <661> Physiochemical Tests for Plastics	Passed
USP <788> Particulate Matter in Injections	Passed
BSE/TSE Free	Yes

STERILIZATION OPTIONS AND WORKING TEMPERATURE RANGE

All Savillex Purillex vials are available in sterilized configurations for added convenience and compliance with industry standards. Individually double-bagged to maintain sterility, these vials undergo validated autoclave sterilization processes, achieving an SAL (Sterility Assurance Level) of 10^{-6}, meeting requirements for life sciences applications.

Purillex PFA vials possess a working temperature range of -328°F to 500°F (-200°C to 260°C), while Purillex FEP vials possess a working temperature range of -328°F to 392°F for FEP (-200°C to 200°C).

PACKAGING OPTIONS

Purillex PFA vials can be purchased individually, in racks of ten, or as an eco-friendly bag refill. The racked version (see image to right) ensures effortless access to individual vials and streamlines inventory management for enhanced efficiency. Alphanumeric labeling simplifies identification, enabling swift retrieval and minimizing errors in bustling pharmaceutical settings.

PURILLEX FLUOROPOLYMER VIAL ORDERING INFORMATION

PART #	VIAL SIZE	CLOSURE SIZE	MATERIAL	STERILIZED?
271-01-003-20	3 mL	23 mm	PFA	No
271-01-003-20-A	3 mL	23 mm	PFA	Yes
271-02-003-20-A	3 mL	23 mm	FEP	Yes
271-01-007-20	7 mL	24 mm	PFA	No
271-01-007-20-A	7 mL	24 mm	PFA	Yes
273-01-007-20-100	7 mL (racked)	24 mm	PFA	No
271-01-007-20-50	7 mL (rack refills)	24 mm	PFA	No
271-01-015-20	15 mL	33 mm	PFA	No
271-01-015-20-A	15 mL	33 mm	PFA	Yes
273-01-015-20-100	15 mL (racked)	33 mm	PFA	No
271-01-015-20-50	15 mL (rack refills)	33 mm	PFA	No

Purillex™ Fluoropolymer Jars

The Savillex Purillex™ line of molded PFA jars meticulously crafted to meet the exacting demands of life sciences applications. These jars guarantee the secure collection, transport, and storage of samples, prioritizing container integrity above all else. All Purillex jars meet USP Class VI standards and undergo comprehensive USP testing, accompanied by manufacturing lot certification for utmost quality assurance.

INNOVATIVE DESIGN FEATURES

Crafted from virgin resin through precision injection molding, Purillex jars are made with the same resin grade as Purillex® bottles and other Savillex containers utilized across various scientific disciplines. Their seamless construction, rounded interior, smooth inner surface, and wide-mouth design facilitate effortless transfer and complete content removal. Purillex jars excel in applications demanding unfettered access to contents, reliable chemical stability, and impeccable cleanliness.

ENGINEERING FEATURES AND WORKING TEMPERATURE RANGE

All Purillex jars include a robust leakproof closure. The injection molding process ensures impeccable thread quality, eliminating the need for secondary machining of the jar lip and significantly reducing the risk of particulate contamination. A robust seal is guaranteed without the necessity for additional seals or inserts. Moreover, all jars feature rounded bottoms for effortless content extraction. Boasting a temperature range of -328°F to 500°F (-200°C to 260°C), Purillex jars maintain seal integrity even under extreme conditions.

VERSATILE SIZING AND STERILIZATION OPTIONS

Choose from Purillex PFA jars available in 60 mL, 120 mL, and 240 mL capacities to suit diverse laboratory needs. All are available sterilized via autoclave with up to a two-year shelf life. Jars are individually double-bagged to ensure sterility is maintained before use. All sterilization processes are validated to provide a SAL (Sterility Assurance Level) of 10^{-6}, the industry standard for use in aseptic applications.

JAR SIZE	CLOSURE SIZE	PFA PART # (STERILIZED)	PFA PART # (NON-STERILIZED)
60 mL	53 mm	171-01-0060-01	171-01-0060-01-A
120 mL	70 mm	171-01-0120-01	171-01-0120-01-A
240 mL	70 mm	171-01-0240-01	171-01-0240-01-A

HarvestMax® Filter Reservoir System

The HarvestMax® is a filter reservoir system designed for one-step cell harvest clarification. It functions as a single use, drop-in unit for the prefilteration, clarification, and final filtration of difficult-to-filter cell culture harvests, conditioned media, and other critical materials.

Representing the first true 250 mL to 1 L one-step processing, the HarvestMax is designed to significantly reduce the risk of premature plugging of vacuum membrane filler units. More importantly, it reduces harvest clarification time and eliminates the need for centrifugation - which opens up laboratory floor space and helps simplify your workflow.

The HarvestMax family of special filters are available as complete vacuum filler systems, in stock and ready to use. They can also be customized to your particular application.

FEATURES

- More prefilteration filler area allows for faster flow and higher throughput through the membrane filler
- Universal design which can be used with most 250 mL, 500 mL, and 1 L vacuum filler units commonly found in the laboratory
- Utilizes a convenient, quick-connecting vacuum cradle ring stand clamp
- Reduces protein exposure to proteases, minimizing degredation
- PES (polyethersulfone) vacuum unit membranes measure 90 mm in diameter and are available in 0.1 µm, 0.2 µm, or 0.45 µm
- Enables the connection of multiple units for concurrent filtration

APPLICATIONS

- Antibody preparations
- CHO-Hybridoma-293 & HEK whole harvests
- Conditioned media or buffers
- Biological preparations
- Reagents
- Prefiltration of sterile media feeds
- Antifoam additions
- Transfected cells
- Crop protection
- Bacterial harvests
- Food digestion preparations
- Protein solutions
- Viral, vaccine, tissue preps

HARVESTMAX ORDERING INFORMATION

PART #	DESCRIPTION	QUANTITY
990-02-88052	250 mL – 0.2 µm PES	1/EA
990-02-88055	500 mL – 0.2 µm PES	1/EA
990-02-88051	1000 mL – 0.2 µm PES	1/EA
990-02-88042	250 mL – 0.45 µm PES	1/EA
990-02-88045	500 mL – 0.45 µm PES	1/EA
990-02-88041	1000 mL – 0.45 µm PES	1/EA
990-02-HMV1	4” HMV Pleated Depth Filter	1/EA
990-02-HMV2	2” HMV Pleated Depth Filter	1/EA
990-02-88044L	3 Place Vacuum Manifold, AL/S.S.	1/EA

XpressVent Liquid Handling Systems

XpressVent liquid handling systems are disposable assemblies designed to ease liquid handling for various addition, storage, and processing steps. They are collapsible, less expensive than rigid bottles, and available in LDPE with or without a cardboard outer box making it suitable for shipment.

XpressVent containers offer a new level of convenience to replace glass, rigid PETG, PE, or PP bottles, and SS stopper assemblies commonly found in laboratories, pilot plants, and R&D laboratories. All containers are customized for your purposes with short lead times, far faster than with competing products. XpressVent assemblies are made from well characterized biocompatible low density polyethylene.

FEATURES

- 100% recyclable
- Hydrophilic and hydrophobic filter options allows for sterile filling and draining of process fluids

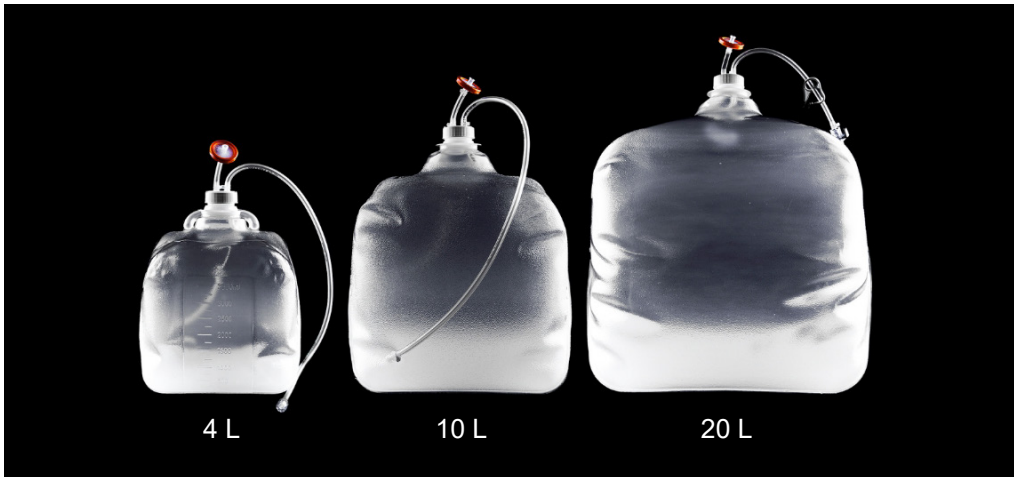
- Pre-made assemblies which significantly reduce risk of repetitive motion injury
- 10:1 lower greenhouse gas emissions in transport, 90% fewer CO_2 emissions in film manufacturing process, no chemicals or water for cleaning, low energy, no labor
- Nesting of collapsed vessels saves storage space before and after use
- Tubing-welder compatible

APPLICATIONS

- Pre-production
- Cell culture
- Process development and optimization
- Buffers
- Liquid storage
- Acid-base and sterile antifoam additions
- Sterile media feeds
- Sample preparation
- Aseptic sampling
- Cell banking
- Seeding
- Stem cells aseptic transfer
- Transfection and transduction
- Protein expression

XPRESSVENT ORDERING INFORMATION

PART #	CONTAINER TYPE	FILTER TYPE
271-01-003-20	3 mL	23 mm
271-01-003-20-A	3 mL	23 mm
271-02-003-20-A	3 mL	23 mm
271-01-007-20	7 mL	24 mm



SeptaVent® Bioreactor Spin Tubes

SeptaVent® is a 50mL bioreactor spin tube ideal for those working in cell line development, protein expression, and cell culture media optimization where automated systems are used to minimize manual intervention.

SeptaVent is a novel integration of two common technologies into a single device. The SeptaVent spin tube allows for easy access and small volume fluid handling while maintaining a sterile and uncompromised environment via septum and filter membrane technology. The resealable septum facilitates the use of various syringes, pipettes, injection needles, pipette tips, and cannulae for easy access to samples without compromising sterility for repeated or intermittent sampling.

The 0.2 µm PTFE filter membrane maintains a sterile environment while allowing for proper airflow and gas exchange. With its hydro-oleophobic properties, the vent filter resists wetting with water or low surface tension fluids.

FEATURES

- Enables maintenance of a “closed system” during sample manipulation
- Hydro-oleophobic vent filter resists wetting with water or low surface tension fluids
- Suitable for low pressure, gravity feed or pump transfer of media and cells
- Optional filter luer available for SeptaVent 50 Plus, allowing for real time microfluidic cell culture additions
- Available irradiated or non-irradiated, and for use on other single-use containers
- Caps available separately

APPLICATIONS

SeptaVent is offered with an optional custom rack designed for use with an automated liquid handling platform or robot. Using the rack allows for scaling of production while reducing contamination risks associated with opening and closing the cap to obtain samples. Users are able to perform multiple experiments at the same time, maximizing productivity and achieving greater efficiency. Key applications include:

- Mini production
- Cell culture development
- Culture media optimization
- Seeding
- Stem cell separation
- Hair follicles
- Criminology
- Transfection and transduction
- Whole blood
- Binding experiments for chromatography
- Contamination control of specimens

SEPTAVENT ORDERING INFORMATION

PART #	DESCRIPTION	QUANTITY
990-02-95025	SeptaVent 50 mL Bioreactor Spin Tube	25/PK, 600/CS
990-02-95021	SeptaVent 50 mL Cap Only	25/PK

OPTI-Tube Sampling Assembly

The OPTI-Tube sampling assembly is a single-use device for cell culture sampling, allowing for simple access to small volume handling. Standard centrifuge tubes commonly used in the laboratory may be enhanced by integrating ports and venting into their caps - which then facilitates use for other applications including filtration, storage, sampling, and additions.

OPTI-Tube style 1-port (15 mL) and 2-port (50 mL) caps can also be added to any 15mL or 50mL available centrifuge tube containers commonly found in the lab, including those from Corning®, Nalgene, and other manufacturers. No assembly is required prior to using the OPTI-Tube - simply remove the product from its container and begin using immediately.

FEATURES

- Low-cost sampling system
- Eliminates expensive sampling methods
- Samples can be pulled using a syringe vacuum
- Luer or barb connection ports
- Enables maintenance of a “closed system” during sample manipulation
- Ideally suited for low pressure, gravity feed, or pump transfer of media and buffers
- Can be provided irradiated or non-irradiated
- Weldable tubing that eliminates the need to remove caps during sampling
- Dip tube allows for maximum recovery of fluids

APPLICATIONS

- Mini production
- Sampling
- Stem cell manipulation
- Transfection and transduction
- Process development
- Seeding
- Additions
- Cell banking
- Binding experiments for chromatography media
- Whole blood
- Transfers
- C.S.I. bioburden and contamination control of specimens

OPTI-TUBE ORDERING INFORMATION

PART #	DESCRIPTION	QUANTITY
990-02-94015	15 mL OPTI-Tube Sampling Assembly (1-port)	20
990-02-94050	50 mL OPTI-Tube Sampling Assembly (2-port)	10

ONFAB Flexible Isolators

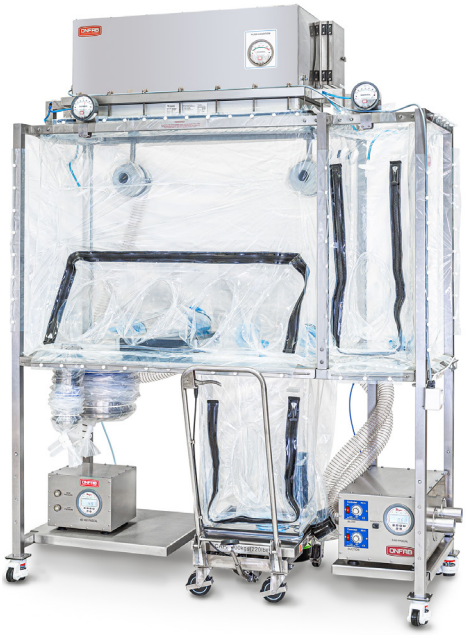
ONFAB Process Containment

Founded in 2004, ONFAB specializes in the design, manufacture, and installation of flexible containment technology used in the pharmaceutical manufacturing process and drug discovery - especially involving high potent active pharmaceutical ingredients (HPAPIs) or improving GMP conditions.

With manufacturing facilities in the UK, USA, and Spain, ONFAB works with global pharmaceutical, biopharmaceutical, and contract manufacturing organizations around the world. Their cost-effective flexible systems protect users from exposure to hazardous substances typically to a performance of < 30ng/m^3 down to 1ng/m^3, while also reducing cleaning and cleaning validation times. Learn more about some of their top solutions below, and explore their full portfolio of offerings at onfab.co.uk.

STANDALONE ISOLATORS

Recent developments in the pharmaceutical industry have led to increasingly higher usage of toxic compounds working predominantly in OEB 4, 5, and 6 banding. This has created an expanded need for containment measures that can reliably protect manufacturing personnel against these potentially harmful ingredients.



In response to this uptick in demand, flexible containment solutions are drawing increasing appeal due to the cost advantages they provide over their rigid counterparts. ONFAB's flexible standalone isolator range allows for the safe handling of these highly potent materials, ensuring new drug modularities can be developed and manufactured safely and efficiently. They provide an ergonomic, fully contained environment for many different processing requirements, including weighing and dispense operations, in process control applications, drum transfer processes, and aseptic processing. They are also idea for the enclosing of small, tabletop powder handling equipment such as mills, sieves, and blenders.

Key features of ONFAB Standalone Isolators include:

- Nanogram-level containment - up to OEB 5
- Lower investment costs and reduced cleaning and validation costs compared to rigid isolators
- Integrates seamlessly into existing SOPs, requiring minimal changes to current workflows
- Ideal for enclosing of small, tabletop powder handling equipment, including mills and blenders
- Heavy duty polyurethane film with anti-static coating and high tear resistance
- Available gamma irradiated in multiple configurations
- Short delivery lead times and simple installation

POP UP ISOLATOR

Obtain fast, safe handling of high potent pharmaceuticals with the ONFAB Pop Up Isolator. This instant, benchtop flexible containment system transforms your lab into a safe, enclosed working environment for handling potentially dangerous pharmaceutical ingredients.

Featuring incredibly quick and easy setup (usually less than two minutes), the Pop Up Isolator is ideal for small scale powder, liquid, instrument, and inert-gas operations. It offers dual glove port access, an integrated P3 filter for added protection, and a large gas-proof zipper for material/equipment introduction and removal. With a typical size of 30.3” long x 24.4” wide x 29.1” high, it can easily fit on most laboratory benchtops and tabletops.

ANTIBODY-DRUG CONJUGATE (ADC) ISOLATOR

Antibody-drug conjugates (ADCs) are rapidly emerging as powerful therapies in the fight against cancer - but the high potency of their ingredients presents unique safety challenges for manufacturers. Trust ONFAB’s ADC Isolator with your most complex and sensitive ADC compounding needs. Deploying multiple components and features that facilitate a broad spectrum of applications, it installs quickly, is easy to use, and delivers nanogram-level performance while reducing costs and risk associated with cleaning protocols (compared to rigid isolator technology).

The ONFAB ADC Isolator can be utilized for a wide variety of ADC manufacturing applications. Providing a dedicated space for the removal of raw materials from bulk containers, it’s ideal for weighing & dispensing, toxin linker compounding, and ADC containment & transfer.

FLEXIBLE PROCESS ISOLATORS

ONFAB’s Flexible Process Isolators are designed to be retrofit to your existing manufacturing equipment and quickly get your team ready to safely handle HPAPIs. They can be tailored to fit within the unique layout of your production facility - ensuring your products are properly contained with minimal disruption to established processes. working with you and your site-based teams to develop the correct solution. As flexible solutions, they allow for the upgrading and modification of yout production capabilities with minimal downtime and re-engineering.

Some of the specific types of Flexible Process Isolator we offer include our Weighing & Dispensing Isolator, Sizing Isolator, Milling & Compacting Isolator, Drying Isolator, API Synthesis Isolator, and many more.

[Click here to learn more about our containment solutions on the ONFAB website.]

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