

FluoroFlex®

Biocontainer Assemblies

Standards Guide
One-Touch® Single-Use Systems



Table of Contents

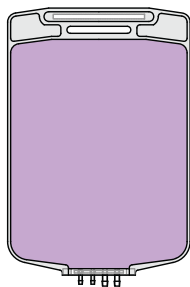
One-Touch® Basics	<u>3</u>
About FluoroFlex®	<u>4</u>
FluoroFlex® Standard Biocontainers (Without Filters)	
Small Volume 2D End-Ported Biocontainer Assemblies	<u>6</u>
Small Volume Plus 2D End-Ported Biocontainer Assemblies	<u>7</u>
Process Volume 2D End-Ported Biocontainer Assemblies	<u>8</u>
Filter Media Options	<u>9</u>
FluoroFlex® Standard Biocontainers with Filter	
Small Volume 2D End-Ported Biocontainer Assemblies	<u>11</u>
Process Volume 2D End-Ported Biocontainer Assemblies	<u>13</u>
Connector Guide	<u>15</u>
Tubing Selection	<u>20</u>
BioFlex® Fluid Path Assemblies	<u>21</u>

One-Touch®

Meissner Filtration Products, Inc. designs, develops, manufactures, and supplies high quality single-use systems. From film to filter, everything necessary to create clean, convenient biocontainer assemblies can be found under one roof.

One-Touch® Basics

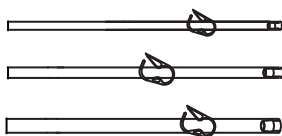
Meissner's adaptable, One-Touch® single-use systems are designed specifically for fluid management in the biopharmaceutical industry.



① Chamber

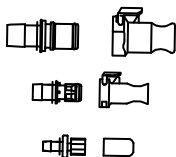
FluoroFlex® chambers are composed of Meissner's five layer PVDF-based FluoroFlex® film, which combines inherent purity with high gas barrier properties and industry-leading fluid integrity characteristics.

[Page 4](#)



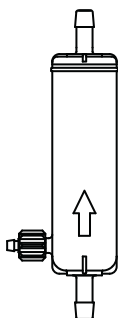
② Tubing

FluoroFlex® biocontainer assemblies come standard with either TPE or Platinum-cured silicone tubing. Tubing is available in a variety of lengths and diameters to suit customer specific needs. [Page 20](#)



③ Connectors

Meissner's FluoroFlex® biocontainers can be ordered with a wide range of connectors or end fittings to address the desired process connectivity. [Page 15](#)



④ Filters

Meissner's full line of single-use capsule filters are available for use with FluoroFlex® biocontainer assemblies. Compact and easy to use, capsule filters are engineered to satisfy the highest standards of filtration reliability and convenience. Capsule filters combine a full range of filter media, pore size ratings and surface areas to satisfy numerous applications. [Page 9](#)

About FluoroFlex®

One-Touch® Single-Use Systems

The One-Touch® single-use systems portfolio is built on a solid foundation of quality, technical capability and operational excellence, which is unparalleled in the industry. Our unique manufacturing approach employs pre-qualified dynamic single-use component libraries, and product quality certification is included for each assembly. Combined, these provide unprecedented levels of quality documentation and traceability for each fluid contact component. Comprehensive product quality certificates and serialization of each and every single-use product manufactured is one of our quality trademarks.

- Comprehensive Certificate of Quality
- Serialization of Every Single-Use Product
- Full Traceability

Technical Expertise

Meissner's single-use systems are designed by engineers proficient in liquid management applications, from development scale through production. Our polymer expertise, and the manufacture of many of the underlying components that go into our single-use assemblies, are Meissner's differentiating hallmarks. Our expanding repository of component and design knowledge allows us to value engineer the next generation of single-use assemblies to cater to your specific process needs. Meissner's comprehensive standards portfolio incorporates best practice designs with commonly requested functionalities. Our application engineering team is recognized for their design and scale-up expertise, process flow recommendations and validation support. Coupling this expertise with our streamlined manufacturing operations and support services allows Meissner to provide one of the shortest lead times in the industry for custom products.

- Value Engineered Designs
- Validation Support Services
- Fast Turnaround on Custom Products

FluoroFlex® Film

Property ¹	Test Protocol	Typical Values
Optical		
Haze	ASTM D1003-07	6.7%
Clarity	ASTM D1746-09	93%
Total luminous transmittance	ASTM D1003-07	94%

Barrier			
Water Vapor Transmission Rate ²	ASTM F1249-06	1.09 g/m ² • 24h	0.070 g/100 in ² • 24h
O ₂ Transmission Rate ³	ASTM F1927-07	0.75 cm ³ /m ² • 24h	0.049 cm ³ /100 in ² • 24h
CO ₂ Transmission Rate ⁴	ASTM F2476-05	<1.0 cm ³ /m ² • 24h	<0.06 cm ³ /100 in ² • 24h

Biocompatibility		
USP Class VI	USP <88>	Pass
Cytotoxicity	USP <87>	Pass
Non-volatile Residue	USP <661>	Pass
Residue on Ignition	USP <661>	Pass
Heavy Metals	USP <661>	Pass
Buffering Capacity	USP <661>	Pass

¹ Determined on samples gamma irradiated at 29.2 - 36.7 kGy.

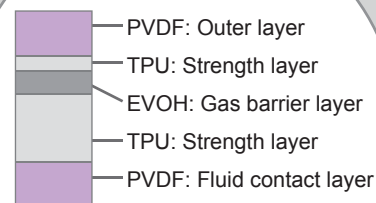
² RH test gas: 100%; RH carrier gas: 0%; 23°C

³ RH test gas: 50%; RH carrier gas: 100%; 23°C

⁴ RH test gas: 50%; RH carrier gas: 0%; 23°C

This technical information consists of typical product data and should not be used as a specification.

FluoroFlex® Film



Total thickness:
260 µm (10.2 mil)



FluoroFlex® Biocontainers

Meissner's polyvinylidene fluoride (PVDF) based FluoroFlex® film is a multi-layer coextruded film of an entirely new generation and is optimized to meet requirements within the pharmaceutical industry that are beyond the capabilities of polyolefin-based films. Because PVDF does not require additives, processing aids or stabilizers, it provides FluoroFlex® film its inherent purity and superior leachables and extractables profile. PVDF is also inert, has low adsorption and binding characteristics, and possesses non-stick qualities.

FluoroFlex® film retains the exceptional clarity and high gas barrier properties of Meissner's TepoFlex® polyolefin-based film. The combined attributes of inherent purity and high gas barrier mitigate the risk of degradation of process solutions and API's stored and processed in FluoroFlex® biocontainers.

Incorporating elastomeric thermoplastic polyurethane (TPU) strength layers in the patent-pending FluoroFlex® film structure renders it exceptionally strong, yet highly flexible. Our advanced welding technology maximizes the seam strength retention to ensure that FluoroFlex® biocontainers are the industry's most durable, reducing the risk of costly fluid integrity failures.

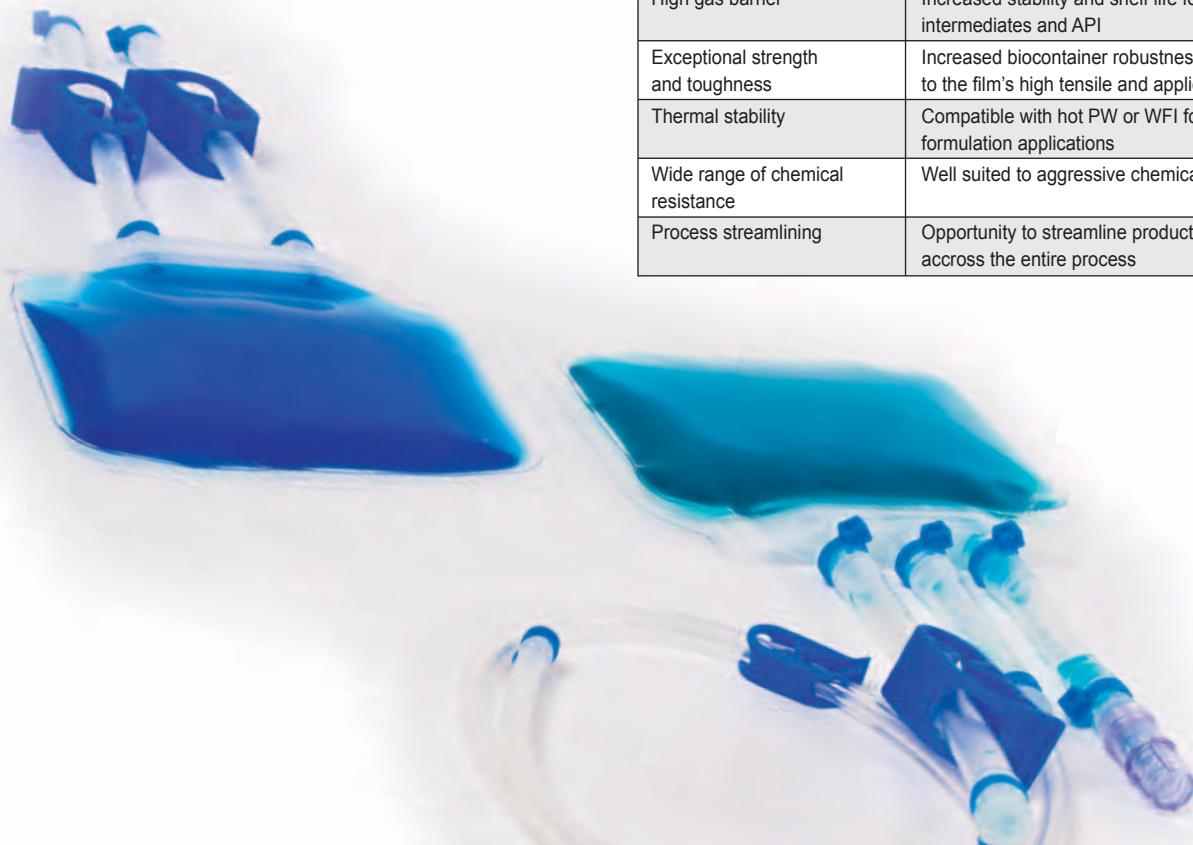
FluoroFlex® biocontainers provide superior performance benefits compared to polyolefin-based biocontainers with respect to thermal stability, chemical resistance and robustness. PVDF has an excellent performance history as a filter membrane medium and in pharmaceutical high purity water distribution systems. Extending this proven history of PVDF as a product contact material to FluoroFlex® biocontainers is a logical step in harnessing the highest benefits of single-use processing.

FluoroFlex® film is certified animal component free (ACF). The film is extruded, manufactured into biocontainers and packaged in ISO Class 7 cleanrooms.

FluoroFlex® biocontainers and BioFlex™ fluid path assemblies are supplied gamma-irradiated to ensure an SAL of 10^{-6} substantiated according to ISO 11137 methodology. FluoroFlex® film, biocontainers, and all components of single-use assemblies are supported by a comprehensive Qualification Guide. This guide brings together all relevant quality documentation and certification in one package, helping speed your qualification and validation process.

FluoroFlex® film combines inherent purity, inertness and high gas barrier properties to reduce potential product interference in the industry's most robust biocontainer.

FluoroFlex® Film Attributes	Single-Use Processing Benefits
Inherent purity of product contact layer	Very low leachables and extractables profile
Non adsorbing product contact layer	Low protein and lipid binding levels
Exceptional clarity	Opportunities for process monitoring
High gas barrier	Increased stability and shelf life for process solutions, intermediates and API
Exceptional strength and toughness	Increased biocontainer robustness and fluid integrity due to the film's high tensile and applied welding technology
Thermal stability	Compatible with hot PW or WFI for storage and formulation applications
Wide range of chemical resistance	Well suited to aggressive chemical solvents
Process streamlining	Opportunity to streamline product contact materials across the entire process



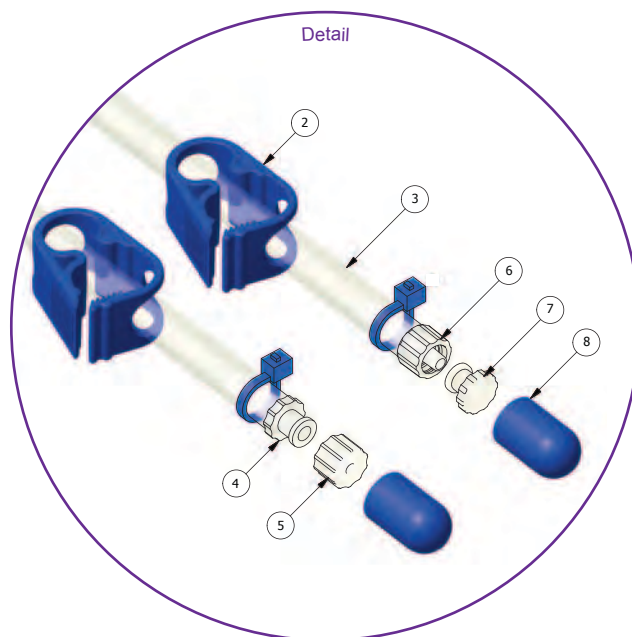
2D End-Ported Biocontainer Assemblies - Small Volume

Bill of Materials

Item	Description	Material	Qty
1	500 mL End-Ported Biocontainer	FluoroFlex®	1
2	Ratcheting Pinch Clamp, Medium	Polypropylene	2
3	¼" x ⅜" Tubing, 6" Length 6.4 mm x 9.5 mm Tubing, 15.2 cm Length	TPE or Plt. Silicone	2
4	¼" Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter	Polypropylene	1
5	Male Luer Plug	Polypropylene	1
6	¼" Hosebarb x Male Luer Adapter 6.4 mm Hosebarb x Male Luer Adapter	Polypropylene	1
7	Female Luer Plug	Polypropylene	1
8	Protective Cover, Small	Vinyl	2



- 500 mL biocontainer shown
- Packaged in quantities of 5



Standards

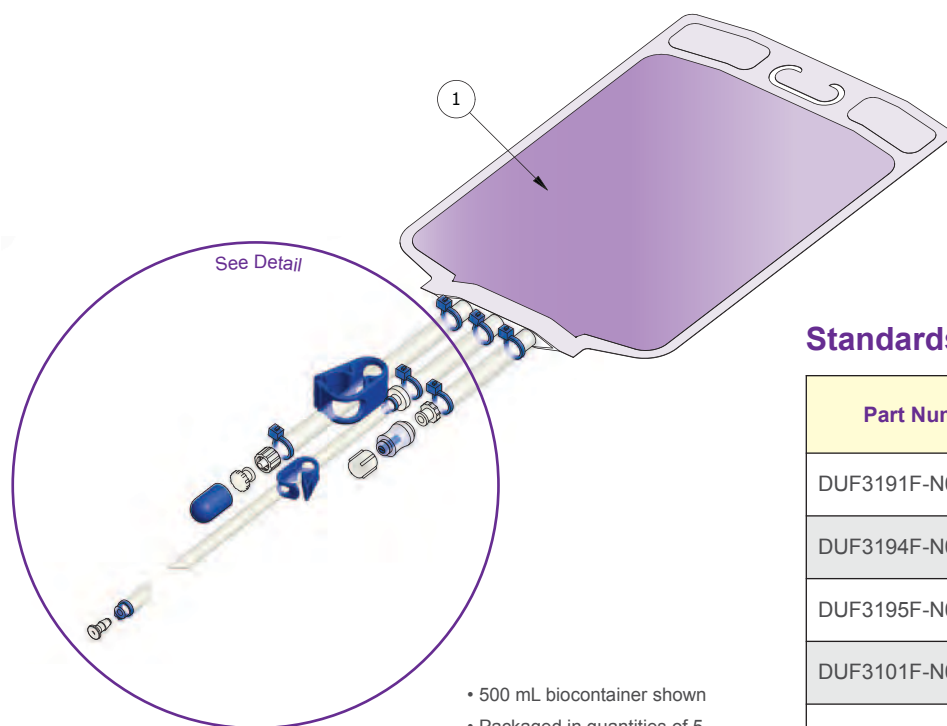
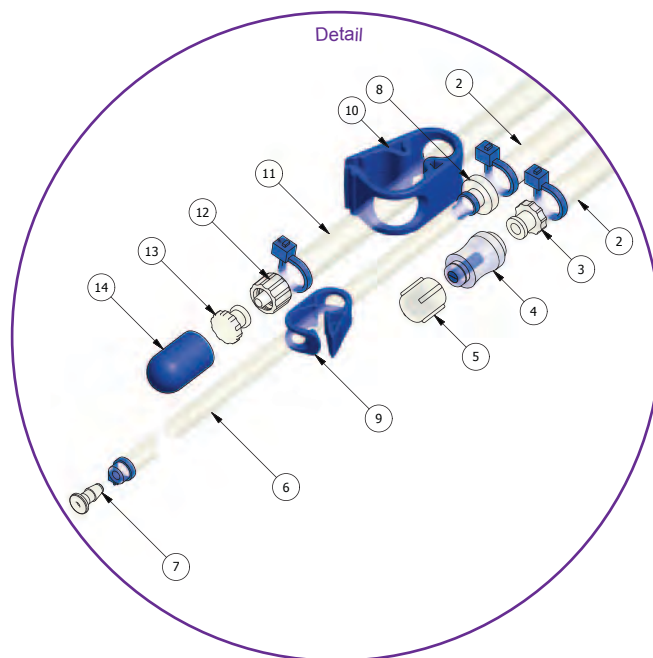
Part Number	Biocontainer		Tubing
	Volume	Dimensions	
DUF2191F-N00B01-00	50 mL	5.3" x 5.4" 13.3 cm x 13.7 cm	TPE
DUF2194F-N00B01-00	250 mL	6.0" x 7.9" 15.2 cm x 20.1 cm	TPE
DUF2195F-N00B01-00	500 mL	7.0" x 10.4" 17.8 cm x 26.4 cm	TPE
DUF2101F-N00B01-00	1 L	7.8" x 12.1" 19.8 cm x 30.7 cm	TPE
DUF2102F-N00B01-00	2 L	9.5" x 13.4" 24.1 cm x 34.0 cm	TPE

Part Number	Biocontainer		Tubing
	Volume	Dimensions	
DUF2191F-N00B11-00	50 mL	5.3" x 5.4" 13.3 cm x 13.7 cm	Platinum-Cured Silicone
DUF2194F-N00B11-00	250 mL	6.0" x 7.9" 15.2 cm x 20.1 cm	Platinum-Cured Silicone
DUF2195F-N00B11-00	500 mL	7.0" x 10.4" 17.8 cm x 26.4 cm	Platinum-Cured Silicone
DUF2101F-N00B11-00	1 L	7.8" x 12.1" 19.8 cm x 30.7 cm	Platinum-Cured Silicone
DUF2102F-N00B11-00	2 L	9.5" x 13.4" 24.1 cm x 34.0 cm	Platinum-Cured Silicone

2D End-Ported Biocontainer Assemblies - Small Volume Plus

Bill of Materials

Item	Description	Material	Qty
1	500 mL End-Ported Biocontainer	FluoroFlex®	1
2	1/4" x 3/8" Tubing, 3" Length 6.4 mm x 9.5 mm Tubing, 7.6 cm Length	TPE	2
3	1/4" Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter	Polypropylene	1
4	Swabable Valve / Needleless Injection Site	Polycarbonate / Silicone	1
5	Male Luer Cap	Polycarbonate	1
6	1/8" x 1/4" Tubing, 24" Length 3.2 mm x 6.4 mm Tubing, 61.0 cm Length	TPE	1
7	1/8" (3.2 mm) Hosebarb Plug	Polypropylene	1
8	1/4" x 1/8" Hosebarb Reduction Fitting 6.4 mm x 3.2 mm Hosebarb Reduction Fitting	Polypropylene	1
9	Ratcheting Pinch Clamp, Small	Polypropylene	1
10	Ratcheting Pinch Clamp, Medium	Polypropylene	1
11	1/4" x 3/8" Tubing, 6" Length 6.4 mm x 9.5 mm Tubing, 15.2 cm Length	TPE	1
12	1/4" Hosebarb x Male Luer Adapter 6.4 mm Hosebarb x Male Luer Adapter	Polypropylene	1
13	Female Luer Plug	Polypropylene	1
14	Protective Cover, Small	Vinyl	1



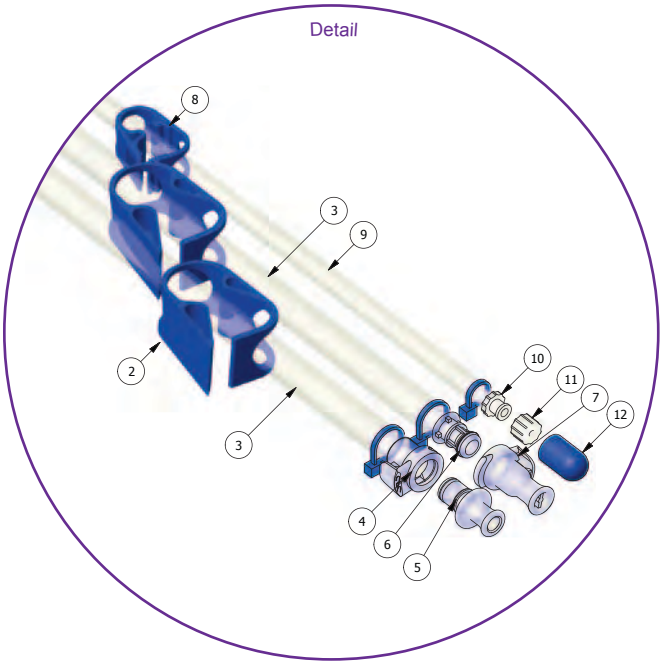
Standards

Part Number	Biocontainer		Tubing
	Volume	Dimensions	
DUF3191F-N00B01-00	50 mL	5.3" x 5.4" 13.3 cm x 13.7 cm	TPE
DUF3194F-N00B01-00	250 mL	6.0" x 7.9" 15.2 cm x 20.1 cm	TPE
DUF3195F-N00B01-00	500 mL	7.0" x 10.4" 17.8 cm x 26.4 cm	TPE
DUF3101F-N00B01-00	1 L	7.8" x 12.1" 19.8 cm x 30.7 cm	TPE
DUF3102F-N00B01-00	2 L	9.5" x 13.4" 24.1 cm x 34.0 cm	TPE

End-Ported Biocontainer Assemblies - Process Volume

Bill of Materials

Item	Description	Material	Qty
1	10 L End-Ported Biocontainer	FluoroFlex®	1
2	Ratchet Pinch Clamp, Large	PBT	2
3	3/8" x 3/16" Tubing, 12" Length 9.5 mm x 14.3 mm Tubing, 30.5 cm Length	TPE or Plt. Silicone	2
4	Coupling Body, 3/8" Hosebarb, MPC Coupling Body, 9.5 mm Hosebarb, MPC	Polycarbonate	1
5	Sealing Plug, MPC	Polycarbonate	1
6	Coupling Insert, 3/8" Hosebarb, MPC Coupling Insert, 9.5 mm Hosebarb, MPC	Polycarbonate	1
7	Sealing Cap, MPC	Polycarbonate	1
8	Ratchet Pinch Clamp, Medium	Polypropylene	1
9	1/4" x 3/8" Tubing, 12" Length 6.4 mm x 9.5 mm Tubing, 30.5 cm Length	TPE or Plt. Silicone	1
10	1/4" Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter	Polypropylene	1
11	Male Luer Plug	Polypropylene	1
12	Protective Cover, Small	Vinyl	1



• 10 L biocontainer shown

Standards

Part Number	Biocontainer		Tubing
	Volume	Dimensions	
DUF3104F-N00B01-00	5 L	13.0" x 15.5" 33.0 cm x 39.4 cm	TPE
DUF3105F-N00B01-00	10 L	15.0" x 22.0" 38.1 cm x 55.9 cm	TPE
DUF3106F-N00B01-00	20 L	17.3" x 27.0" 43.9 cm x 68.6 cm	TPE

Part Number	Biocontainer		Tubing
	Volume	Dimensions	
DUF3104F-N00B11-00	5 L	13.0" x 15.5" 33.0 cm x 39.4 cm	Platinum-Cured Silicone
DUF3105F-N00B11-00	10 L	15.0" x 22.0" 38.1 cm x 55.9 cm	Platinum-Cured Silicone
DUF3106F-N00B11-00	20 L	17.3" x 27.0" 43.9 cm x 68.6 cm	Platinum-Cured Silicone

Filter Media Options

SteriLUX® PVDF

SteriLUX® disposable capsule filters are absolute-rated PVDF membrane filters optimized for sterile filtration, prefiltration and clarification of pharmaceutical and biological solutions. The surface-modified SteriLUX® membrane filter is manufactured by Meissner's proprietary process to provide immediate water-wettability, unmatched flow, high mechanical strength, thermal and chemical stability, and ultra-low binding characteristics.

Advantages

- Available in 0.1 µm and 0.2 µm ratings with standard biocontainer assemblies
- Qualifies as a sterilizing grade filter per ASTM F838-05 liquid bacterial challenge
- High flow rates at low pressure drops
- Ultraclean – no additives or surfactants
- 100% integrity tested
- Hydrophilic PVDF membrane
- Fully integrity testable in water
- High thermal and hydrolytic stability

- Extremely low protein and preservative binding
- Extremely low extractables
- Cleanroom manufactured

Applications

SteriLUX® capsule filters can be used to filter microbiological growth media, cell and tissue culture media and additives, bulk pharmaceutical chemicals, acids, bases, organic solvents, pharmaceutical preparations and active ingredients, parenterals, biopharmaceuticals, vaccines, serum, blood products, ophthalmic solutions, orals, topicals, protein solutions, buffers, salts, diluents, diagnostics, cosmetics and toiletries, solvent/product mixtures, reagents, water for injection (WFI), and compressed gases.

Specifications

Filter Media: Polyvinylidene Fluoride (PVDF) Membrane

Bacterial Retention:

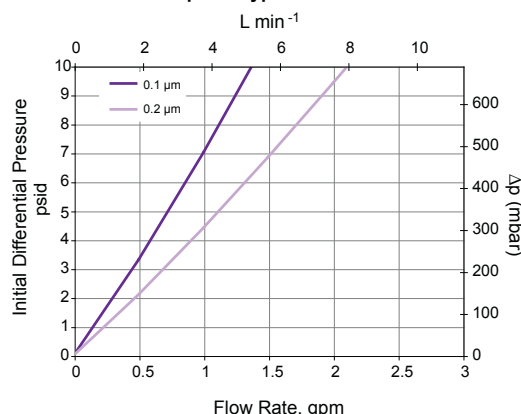
ASTM F838-05 Challenge

0.1 µm, 0.2 µm > 10⁷ LRV/cm²

Brevundimonas diminuta

0.1 µm and 0.2 µm meet the FDA definition of a sterilizing grade filter

SteriLUX® Capsule Typical Water Flow Rates



STyLUX® PES

STyLUX® disposable capsule filters are absolute-rated, polyethersulfone membrane filters designed to provide greater bacteria and particle removal at high flow rates and extremely low pressure drops. STyLUX® capsules contain an asymmetric membrane which offers the greatest assurance of filtration performance, stability and service life for controlling contaminants in demanding environments. The highly porous polyethersulfone membrane is permanently hydrophilic, has exceptional flow rates, and provides excellent compatibility and extremely low extractables in a wide range of fluids and applications.

Advantages

- Available in 0.1 µm and 0.2 µm ratings with standard biocontainers
- Qualifies as a sterilizing grade filter per ASTM F838-05 liquid bacterial challenge
- Extremely high flow rates at low pressure drops
- Ultraclean – no additives, surfactants, or post treatments
- 100% integrity tested during manufacture

- Fully integrity testable in water
- Permanently hydrophilic membrane
- High thermal and hydrolytic stability
- Wide chemical compatibility through pH range 1-14
- Highly passive to protein adsorption, low binding
- Reliable integrity under severe process conditions
- Cleanroom manufactured

Applications

STyLUX® capsule filters offer the greatest security for high quality filtration in a wide variety of applications. STyLUX® capsules are designed for removal of particulates, colloids and microorganisms from a broad range of pharmaceutical and biological liquids. Typical liquids include pharmaceutical preparations, antibiotics, vaccines, protein solutions, immunologicals, virus suspensions, radiodiagnostics, enzymes, ophthalmic solutions, reagents, salt solutions, nutrients, tissue culture media, serum and blood-based products, biologicals and many more.

Specifications

Filter Media: Polyethersulfone (PES) Membrane

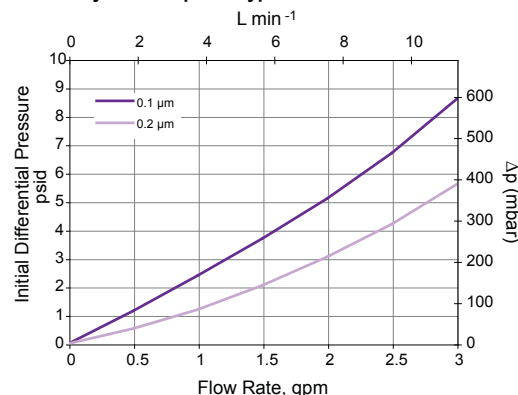
Bacterial Retention:

ASTM F838-05 Challenge

0.1 µm, 0.2 µm > 10⁷ LRV/cm²

Brevundimonas diminuta

STyLUX® Capsule Typical Water Flow Rates



EverLUX® PES

The EverLUX® polyethersulfone (PES) capsule filter is designed for very high contaminant capacity, extended service life and high flow with low pressure drop in a wide range of biological fluids. Optimized for sterile filtration, prefiltration and clarification applications, the permanently hydrophilic EverLUX® membrane offers up to 2.5 times higher flow rates than other PES membranes. Its asymmetric structure extends the membrane's capacity and service life by withstanding higher particle loads and protein concentrations. Increased membrane thickness allows the EverLUX® to retain its sterilizing properties, while its tapered pore structure allows more contaminant capacity than even conventional PES membranes. The fast-flowing, high-throughput, low-binding and bacteria-retentive properties of the EverLUX® PES membrane make it a very reliable, cost effective and time saving filter.

Advantages

- Available in 0.2 µm ratings for standard biocontainers
- Pharmaceutical validated, sterilizing grade
- Unique, patented PES membrane with very high flow rates and exceptional service life

- Minimum pressure drop
- Chemical compatibility across pH 1-14
- Low adsorption, high transmission of proteins, active ingredients, and preservatives
- Superior throughput in high contaminant fluids, including growth media, serum and protein-containing solutions.
- Lower filtration costs through increased service life and contaminant-holding capacity
- Fully integrity testable in water
- 100% integrity tested during manufacture
- Cleanroom manufactured

Applications

EverLUX® capsules are frequently used for buffers, blood products, complex biologicals, serum, cell and tissue culture media, process intermediates, supernatants, vaccines and ophthalmic solutions.

Specifications

Filter Membrane: Polyethersulfone (PES)

EverLUX® capsules are made with filter media which meets the criteria for a non-fiber releasing filter as defined in 21 CFR 210.3 (b)(6). EverLUX® capsule

components are biosafe in compliance with USP Class VI Plastics biologicals reactivity tests. All materials of construction are FDA approved for food contact use per CFR Title 21,177.

Bacterial Retention:

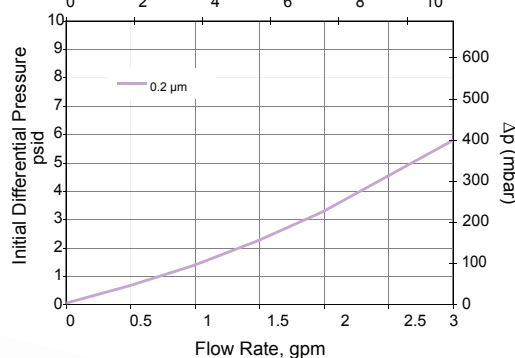
ASTM F838-05 Challenge:

STW 0.2 µm > 10⁷ cfu/cm²

Brevundimonas diminuta

STW 0.2 µm meets the FDA definition of a sterilizing grade filter.

EverLUX® Capsule Typical Water Flow Rates
L min⁻¹



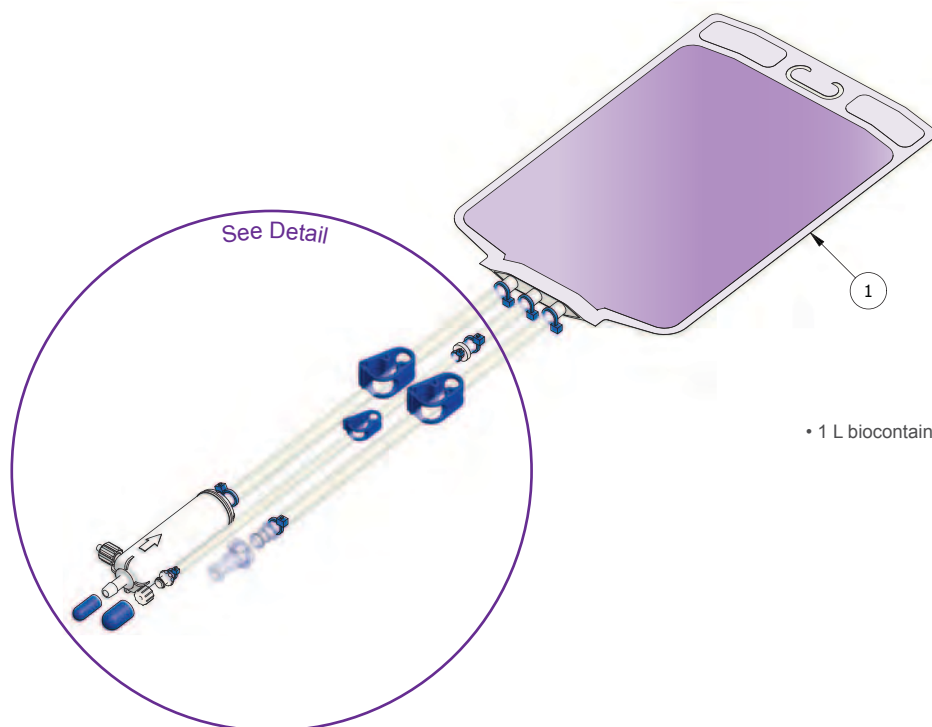
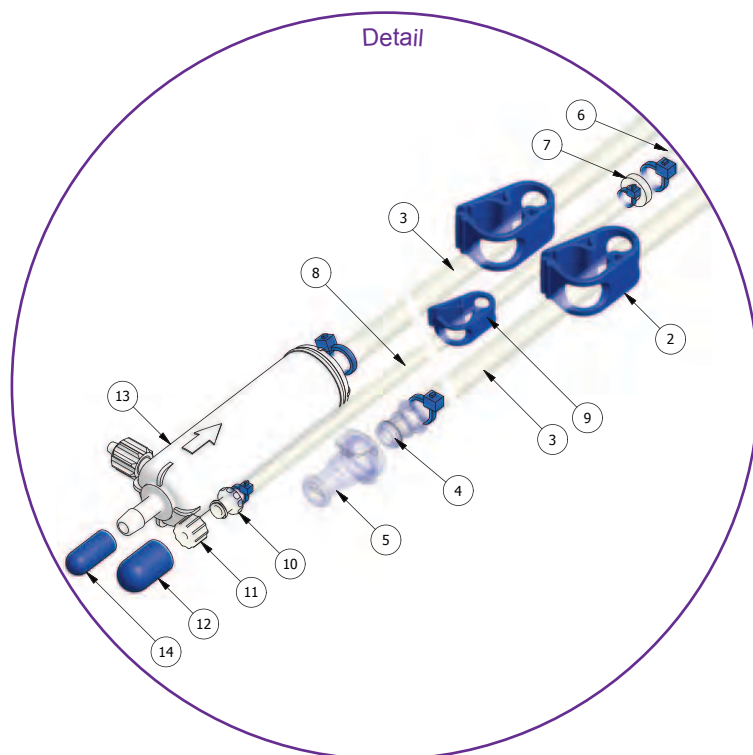
* The filter media listed are available with standard bicontainer assemblies, but for custom assemblies other filters may be ordered.

* To view Meissner's full range of filter media, please visit www.meissner.com.

2D End-Ported Biocontainer Assemblies - Small Volume with Filter

Bill of Materials

Item	Description	Material	Qty
1	1 L End-Ported Biocontainer	FluoroFlex®	1
2	Ratchet Pinch Clamp, Medium	Polypropylene	2
3	1/4" x 3/8" Tubing, 12" Length 6.4 mm x 9.5 mm Tubing, 30.5 cm Length	TPE or Plt. Silicone	2
4	Coupling Insert, 1/4" Hosebarb, MPC Coupling Insert, 6.4 mm Hosebarb, MPC	Polycarbonate	1
5	Sealing Cap, MPC	Polycarbonate	1
6	1/4" x 3/8" Tubing, 3" Length 6.4 mm x 9.5 mm Tubing, 7.6 cm Length	TPE or Plt. Silicone	1
7	1/4" x 1/8" Hosebarb Reduction Fitting 6.4 mm x 3.2 mm Hosebarb Reduction Fitting	Polypropylene	1
8	1/8" x 1/4" Tubing, 12" Length 3.2 mm x 6.4 mm Tubing, 30.5 cm Length	TPE or Plt. Silicone	1
9	Ratchet Pinch Clamp, Small	Polypropylene	1
10	1/8" Hosebarb x Female Luer Adapter 3.2 mm Hosebarb x Female Luer Adapter	Polypropylene	1
11	Male Luer Plug	Polypropylene	1
12	Protective Cover, Small	Vinyl	1
13	Meissner Capsule Filter	See options on p. 12	1
14	Protective Cover, 1/4" (6.4 mm) Hosebarb	Vinyl	1



• 1 L biocontainer shown

2D End-Ported Biocontainer Assemblies - Small Volume with Filter (continued)

Standards

Part Number	Filter	Filter Part Number	Tubing	Biocontainer	
				Volume	Dimensions
DSR3101F-E02B01-00	EverLUX™ 0.2 µm	CMSTW0.2-115	TPE	1 L	7.8" x 12.1" 19.8 cm x 30.7 cm
DSR3101F-E02B11-00	EverLUX™ 0.2 µm	CMSTW0.2-115	Plt. Silicone		
DSR3101F-S01B01-00	STyLUX® 0.1 µm	CMST0.1-115	TPE		
DSR3101F-S01B11-00	STyLUX® 0.1 µm	CMST0.1-115	Plt. Silicone		
DSR3101F-S02B01-00	STyLUX® 0.2 µm	CMST0.2-115	TPE		
DSR3101F-S02B11-00	STyLUX® 0.2 µm	CMST0.2-115	Plt. Silicone		
DSR3101F-V01B01-00	SteriLUX® 0.1 µm	CMVTH0.1-115	TPE		
DSR3101F-V01B11-00	SteriLUX® 0.1 µm	CMVTH0.1-115	Plt. Silicone		
DSR3101F-V02B01-00	SteriLUX® 0.2 µm	CMVTH0.2-115	TPE		
DSR3101F-V02B11-00	SteriLUX® 0.2 µm	CMVTH0.2-115	Plt. Silicone		

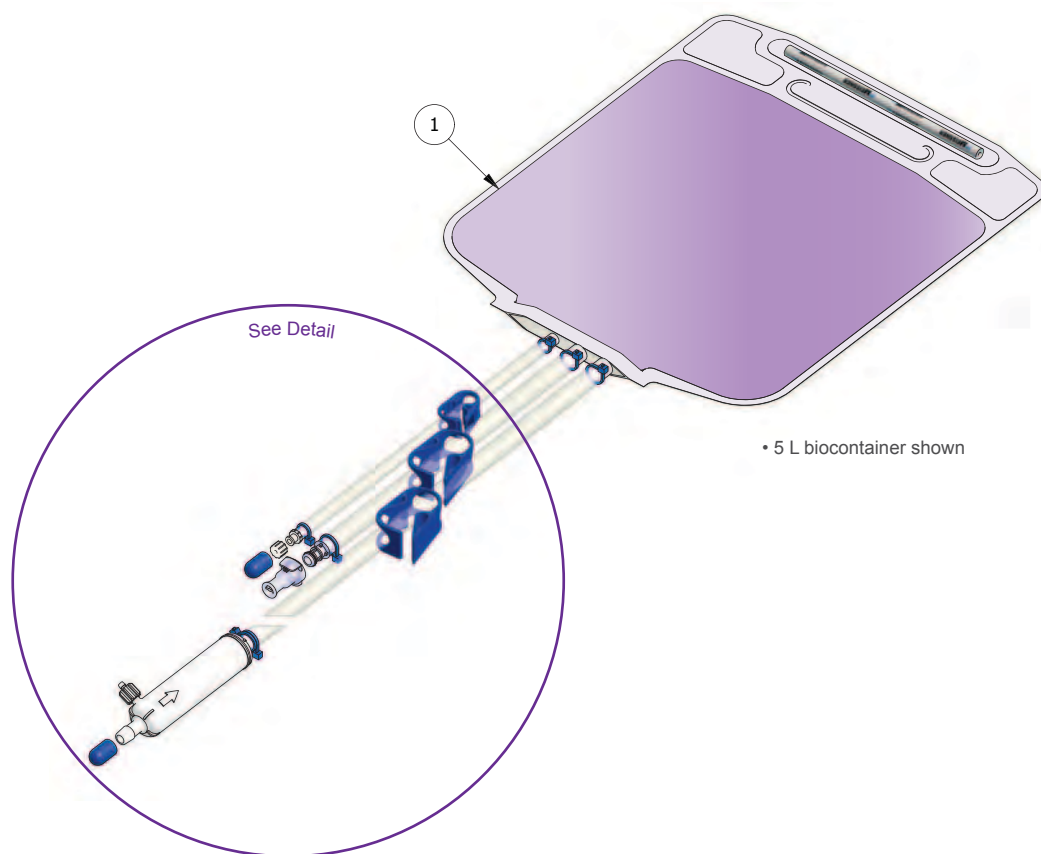
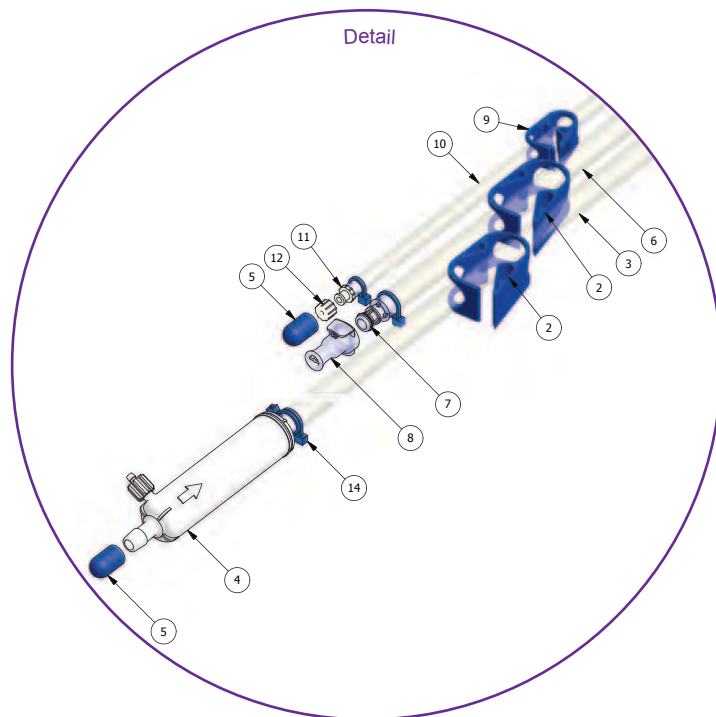
Part Number	Filter	Filter Part Number	Tubing	Biocontainer	
				Volume	Dimensions
DSR3102F-E02B01-00	EverLUX™ 0.2 µm	CMSTW0.2-115	TPE	2 L	9.5" x 13.4" 24.1 cm x 34.0 cm
DSR3102F-E02B11-00	EverLUX™ 0.2 µm	CMSTW0.2-115	Plt. Silicone		
DSR3102F-S01B01-00	STyLUX® 0.1 µm	CMST0.1-115	TPE		
DSR3102F-S01B11-00	STyLUX® 0.1 µm	CMST0.1-115	Plt. Silicone		
DSR3102F-S02B01-00	STyLUX® 0.2 µm	CMST0.2-115	TPE		
DSR3102F-S02B11-00	STyLUX® 0.2 µm	CMST0.2-115	Plt. Silicone		
DSR3102F-V01B01-00	SteriLUX® 0.1 µm	CMVTH0.1-115	TPE		
DSR3102F-V01B11-00	SteriLUX® 0.1 µm	CMVTH0.1-115	Plt. Silicone		
DSR3102F-V02B01-00	SteriLUX® 0.2 µm	CMVTH0.2-115	TPE		
DSR3102F-V02B11-00	SteriLUX® 0.2 µm	CMVTH0.2-115	Plt. Silicone		



2D End-Ported Biocontainer Assemblies - Process Volume with Filter

Bill of Materials

Item	Description	Material	Qty
1	5 L End-Ported Biocontainer	FluoroFlex®	1
2	Ratchet Pinch Clamp, Large	PBT	2
3	3/8" x 3/16" Tubing, 24" Length 9.5 mm x 14.3 mm Tubing, 61 cm Length	TPE or Plt. Silicone	1
4	Meissner Capsule Filter	See options on p. 14	1
5	Protective Cover, Small	Vinyl	2
6	3/8" x 3/16" Tubing, 12" Length 9.5 mm x 14.3 mm Tubing, 30.5 cm Length	TPE or Plt. Silicone	1
7	Coupling Insert, 3/8" Hosebarb, MPC Coupling Insert, 9.5 mm Hosebarb, MPC	Polycarbonate	1
8	Sealing Cap, MPC	Polycarbonate	1
9	Ratchet Pinch Clamp, Medium	Polypropylene	1
10	1/4" x 3/8" Tubing, 12" Length 6.4 mm x 9.5 mm Tubing, 30.5 cm Length	TPE or Plt. Silicone	1
11	1/4" Hosebarb x Female Luer Adapter 6.4 mm Hosebarb x Female Luer Adapter	Polypropylene	1
12	Male Luer Plug	Polypropylene	1



2D End-Ported Biocontainer Assemblies - Process Volume with Filter (continued)

Standards

Part Number	Filter	Filter Part Number	Tubing	Biocontainer	
				Volume	Dimensions
DSR3104F-E02B01-00	EverLUX™ 0.2 µm	CKSTW0.2-225	TPE	5 L	13.0" x 15.5" 33.0 cm x 39.4 cm
DSR3104F-E02B11-00	EverLUX™ 0.2 µm	CKSTW0.2-225	Plt. Silicone		
DSR3104F-S01B01-00	STyLUX® 0.1 µm	CKST0.1-225	TPE		
DSR3104F-S01B11-00	STyLUX® 0.1 µm	CKST0.1-225	Plt. Silicone		
DSR3104F-S02B01-00	STyLUX® 0.2 µm	CKST0.2-225	TPE		
DSR3104F-S02B11-00	STyLUX® 0.2 µm	CKST0.2-225	Plt. Silicone		
DSR3104F-V01B01-00	SteriLUX® 0.1 µm	CKVTH0.1-225	TPE		
DSR3104F-V01B11-00	SteriLUX® 0.1 µm	CKVTH0.1-225	Plt. Silicone		
DSR3104F-V02B01-00	SteriLUX® 0.2 µm	CKVTH0.2-225	TPE		
DSR3104F-V02B11-00	SteriLUX® 0.2 µm	CKVTH0.2-225	Plt. Silicone		

Part Number	Filter	Filter Part Number	Tubing	Biocontainer	
				Volume	Dimensions
DSR3105F-E02B01-00	EverLUX™ 0.2 µm	CKSTW0.2-225	TPE	10 L	15.0" x 22.0" 38.1 cm x 55.9 cm
DSR3105F-E02B11-00	EverLUX™ 0.2 µm	CKSTW0.2-225	Plt. Silicone		
DSR3105F-S01B01-00	STyLUX® 0.1 µm	CKST0.1-225	TPE		
DSR3105F-S01B11-00	STyLUX® 0.1 µm	CKST0.1-225	Plt. Silicone		
DSR3105F-S02B01-00	STyLUX® 0.2 µm	CKST0.2-225	TPE		
DSR3105F-S02B11-00	STyLUX® 0.2 µm	CKST0.2-225	Plt. Silicone		
DSR3105F-V01B01-00	SteriLUX® 0.1 µm	CKVTH0.1-225	TPE		
DSR3105F-V01B11-00	SteriLUX® 0.1 µm	CKVTH0.1-225	Plt. Silicone		
DSR3105F-V02B01-00	SteriLUX® 0.2 µm	CKVTH0.2-225	TPE		
DSR3105F-V02B11-00	SteriLUX® 0.2 µm	CKVTH0.2-225	Plt. Silicone		

Part Number	Filter	Filter Part Number	Tubing	Biocontainer	
				Volume	Dimensions
DSR3106F-E02B01-00	EverLUX™ 0.2 µm	CKSTW0.2-225	TPE	20 L	17.3" x 27.0" 43.9 cm x 68.6 cm
DSR3106F-E02B11-00	EverLUX™ 0.2 µm	CKSTW0.2-225	Plt. Silicone		
DSR3106F-S01B01-00	STyLUX® 0.1 µm	CKST0.1-225	TPE		
DSR3106F-S01B11-00	STyLUX® 0.1 µm	CKST0.1-225	Plt. Silicone		
DSR3106F-S02B01-00	STyLUX® 0.2 µm	CKST0.2-225	TPE		
DSR3106F-S02B11-00	STyLUX® 0.2 µm	CKST0.2-225	Plt. Silicone		
DSR3106F-V01B01-00	SteriLUX® 0.1 µm	CKVTH0.1-225	TPE		
DSR3106F-V01B11-00	SteriLUX® 0.1 µm	CKVTH0.1-225	Plt. Silicone		
DSR3106F-V02B01-00	SteriLUX® 0.2 µm	CKVTH0.2-225	TPE		
DSR3106F-V02B11-00	SteriLUX® 0.2 µm	CKVTH0.2-225	Plt. Silicone		

Connector Guide

PC Quick Disconnect Couplings (QDC) - MPC Series



Materials

- Polycarbonate (PC)
- Animal Component Free (ACF)

Common Vernacular

- Coupling Body
 - Female QDC or MPC body
- Sealing Plug
 - Male / QDC / MPC Plug
- Coupling Insert
 - Male QDC or MPC Insert
- Sealing Cap
 - Female QDC or MPC Cap



Typical Usage and Applications

- Industry standard quick connect
- Buffer and culture media transfer lines
- Filter and tubing sets
- More economical than polysulfone series

Connectivity

- Coupling Body
 - 1/4" (6.4 mm) or 3/8" (9.5 mm) HB
 - Female quick connect interface
- Sealing Plug
 - Male quick connect interface
- Coupling Insert
 - 1/4" (6.4 mm) or 3/8" (9.5 mm) HB
 - Male quick connect interface
- Sealing Cap
 - Female quick connect interface

Gamma Irradiation

- Blue in color pre-gamma irradiation
- Grey to clear post-gamma
- Up to 50 kGy



PC Large Bore Quick Disconnect Couplings - MPX Series



Materials

- Polycarbonate (PC)
- Animal Component Free (ACF)

Common Vernacular

- Coupling Body
 - Female QDC or MPX Body
- Sealing Plug
 - Male / QDC / MPX Plug
- Coupling Insert
 - Male QDC or MPX Insert
- Sealing Cap
 - Female / QDC / MPX Cap



Typical Usage and Applications

- Industry standard large bore quick connect
- Buffer and culture media transfer lines
- Filter and tubing sets
- More economical than polysulfone series

Connectivity

- Coupling Body
 - 1/2" (12.7 mm) HB
 - Female large bore quick connect interface
- Sealing Plug
 - Male large bore quick connect interface
- Coupling Insert
 - 3/8" (9.5 mm) or 1/2" (12.7 mm) HB
 - Male large bore quick connect interface
- Sealing Cap
 - Female large bore quick connect interface



Gamma Irradiation

- Blue in color pre-gamma irradiation
- Grey to clear post-gamma
- Up to 50 kGy

Connector Guide (continued)

Luer Fittings



Materials

- Polypropylene (PP)
- Animal Component Free (ACF)

Common Vernacular

- Luer-Lok™

Typical Usage and Applications

- Sampling operations
 - Small volume sample chambers
 - Syringe sampling
- Industry standard small flow connectivity



Principle Components

- Luer x HB Adapters
- Luer Caps

Connectivity

- 1/8" (3.2 mm) to 1/4" (6.4 mm) HB
- Female and Male Luer Connections

Gamma Irradiation

- Up to 50 kGy



Tubing Clamps



Common Vernacular

- Pinch Clamp
- Ratchet Pinch Clamp

Typical Usage and Applications

- When activated stops or constricts flow on given tubing line

Connectivity

- Large Clamp – Tubing up to 3/4" (19.0 mm) in diameter
- Medium Clamp – Tubing up to 7/16" (11.1 mm) in diameter
- Small Clamp – Tubing up to 1/4" (6.4 mm) in diameter

Materials of Construction

- Large Clamp – PEI
- Medium and Small Clamps – Polypropylene

Protective Covers



Typical Usage and Applications

- For protection of components during shipping and storage, not intended for in process use.

Materials of Construction

- Vinyl



TC Fittings



Materials

- Polypropylene (PP)
- Platinum-cured silicone (TC Gaskets)
- Animal Component Free (ACF)

Common Vernacular

- Sanitary Fittings
- Tri-Clamp® Fittings

Typical Usage and Applications

- Single-use / multi-use process equipment connectivity
- Large volume drain / fill lines
- High flow rate applications



Principle Components

- TC x Hose Barb Adapters
- TC Gaskets
- TC Blind Caps
- TC Clamps

Connectivity

- 1/4" (6.4 mm), 3/8" (9.5 mm), 1/2" (12.7 mm), or 3/4" (19.0 mm) HB
- TC Sizes: 3/4" (19.0 mm), 1" - 1 1/2" (25.4 - 38.1 mm)

Gamma Irradiation

- Up to 50 kGy

PSU Quick Disconnect Couplings (QDC) - MPC Series



Materials

- Polysulfone (PSU)
- Animal Component Free (ACF)

Common Vernacular

- Coupling Body
 - Female QDC or MPC Body
- Sealing Plug
 - Male / QDC / MPC Plug
- Coupling Insert
 - Male QDC or MPC insert
- Sealing Cap
 - Female / QDC / MPC Cap

Typical Usage and Applications

- Industry standard quick connect
- Buffer and culture media transfer lines
- Filter and tubing sets
- Higher temperature rating than polycarbonate makes it more suitable to applications where autoclaving may be required



Connectivity

- Coupling Body
 - 1/4" (6.4 mm) or 3/8" (9.5 mm) HB
 - Female quick connect interface
- Sealing Plug
 - Male quick connect interface
- Coupling Insert
 - 1/4" (6.4 mm) or 3/8" (9.5 mm) HB
 - Male quick connect interface
- Sealing Cap
 - Female quick connect interface

Gamma Irradiation

- Up to 50 kGy
- Minimal color shift post-gamma; Yellow in color



PSU Large Bore Quick Disconnect Couplings - MPX Series



Materials

- Polysulfone (PSU)
- Animal Component Free (ACF)

Common Vernacular

- Coupling Body
 - Female QDC or MPX Body
- Sealing Plug
 - Male / QDC / MPX Plug
- Coupling Insert
 - Male QDC or MPX Insert
- Sealing Cap
 - Female / QDC / MPX Cap

Typical Usage and Applications

- Industry standard large bore quick connect
- Buffer solution and cell culture media transfer lines
- Filter and Tubing sets
- Higher temperature rating than polycarbonate makes it more suitable to applications where autoclaving may be required

Connectivity

- Coupling Body
 - 1/2" (12.7 mm) HB
 - Female large bore quick connect interface
- Sealing Plug
 - Male large bore quick connect interface
- Coupling Insert
 - 3/8" (9.5 mm) or 1/2" (12.7 mm) HB
 - Male large bore quick connect interface
- Sealing Cap
 - Female large bore quick connect interface

Gamma Irradiation

- Up to 50 kGy
- Minimal color shift post-gamma; Yellow in color



Sampling and Injection Sites



Materials

- Needleless Injection Site
 - Polycarbonate
 - Silicone
- Traditional Injection Site (Latex Free)
 - ABS
 - PVC
 - Polyisoprene

Common Vernacular

- Septum Port
- Swabable Valve
- Sample Port

Typical Usage and Applications

- Sampling operations
 - Small volume sample chambers
 - Syringe sampling
- Industry standard small flow connectivity



Connectivity

- Needleless Sample/Injection Site
 - Connection – Male Luer
 - Sample/Injection Site – Female Luer
- Traditional Sample/Injection Site
 - Connection – Male Luer
 - Sample/Injection Site – Needle

Connector Guide (continued)

Hose Barb Fittings



Materials

- Polypropylene (PP)
- Animal Component Free (ACF)

Typical Usage and Applications

- Sampling systems
- Tubing manifolds

Connectivity

- 1/8" → 3/4" Hose Barbs
(3.2 mm → 19.0 mm)

Gamma Irradiation

- Up to 50 kGy

Quick Disconnect Couplings with Integrated Valves - HFC Series



Materials

- Polysulfone (PSU)
- Seals – Silicone
- Animal Component Free (ACF)

Common Vernacular

- HFC fitting
- QDC with shut-off valve
- Aseptic Disconnect

Typical Usage and Applications

- Disconnections without the possibility of spilled process fluid
- Disconnections aseptically outside of controlled areas
- Commonly used in lieu of tube sealer or where tubing material, e.g., silicone, cannot be heat sealed



Connectivity

- Coupling Body
 - 1/4" (6.4 mm), 3/8" (9.5 mm), or 1/2" (12.7 mm) HB
 - Female quick connect with integrated valve interface
- Coupling Insert
 - 1/4" (6.4 mm), 3/8" (9.5 mm), or 1/2" (12.7 mm) HB
 - Male quick connect with or without integrated valve interface

Gamma Irradiation

- Up to 50 kGy

Single-Use / Multiple-Use Interface



Materials

- Polysulfone (PSU)
- Seals – Silicone
- Animal Component Free (ACF)

Common Vernacular

- STC Fitting
- Steam-Thru® Connection
- Steam Fitting

Typical Usage and Applications

- Sterile connection of a pre-sterilized single-use system to conventional fixed, e.g., stainless steel equipment
- Harvest from bioreactor to pre-sterilized single-use systems
- Feed from single-use systems to bioreactors

Connectivity

- To single-use system: 3/8" (9.5 mm) or 1/2" (12.7 mm) HB
- To process equipment: 3/4" (19.0 mm) or 1 1/2" (38.1 mm) TC Connection
- To steam trap: 3/4" (19.0 mm) TC

Gamma Irradiation

- Up to 50 kGy



Tubing Selection

For Standard Biocontainer Assemblies



Platinum-Cured Silicone

Meissner uses top quality platinum-cured silicone manufactured specifically for use within the biopharmaceutical and pharmaceutical markets. This ultraclean tubing comes standard in 50A durometer, is certified Animal Component Free (ACF), and is compatible with peristaltic pumping operations.



Thermoplastic Elastomer Tubing

TPE allows for the integration of thermal welding (aseptic connection) and sealing (aseptic disconnection) connectivity steps into your biopharmaceutical process. Meissner incorporates 374 C-Flex® 62A durometer TPE tubing into many standard product offerings.

Also Available



AdvantaFlex® TPE

This 69A durometer, ACF, TPE tubing is very similar to the 374 C-Flex® with the added advantage of increased compatibility with peristaltic pumping operations and a very low extractables and leachables profile.

PVC

Meissner offers medical grade radiation stable PVC tubing for applications where RF weldability, tubing clarity, and/or process economics are primary drivers.

High Durometer and Extended Life

Higher Durometer and Extended Pump Life Silicone Tubing – Meissner offers silicone tubing in a higher durometer formulation, 65A, for applications where tubing resilience may be required, such as in extended time peristaltic pumping applications (e.g., recirculation mixing, TFF applications, etc.).

Other

Meissner can accommodate custom tubing requirements as necessary, e.g., Sta-Pure®, Tygon®, etc. Please contact Meissner for further details.

BioFlex® Fluid Path Assemblies

Meissner's BioFlex® single-use fluid path assemblies provide secure fluid transfer in critical biopharmaceutical processing applications. The assemblies reduce process risk while providing an enhanced level of convenience that maximizes flexibility in the deployment of single-use systems, as well as conventional systems.

Customizable to process requirements, the assemblies are available with a range of connectivity, tubing and accessory component options to achieve the functionality necessary for your process. Fluid path assemblies can be integrated with filter capsules in a selection of surface areas and media to cater to applications ranging from process stream sterilization and clarification to sterile venting applications. Meissner has extensive experience in single-use system design and implementation and can deliver customized designs using pre-qualified components in some of the industries' shortest lead times.

Meissner's BioFlex® fluid path assemblies are supplied with comprehensive documentation and traceability. Each assembly is serialized, which may reduce batch record requirements in some cases. When the fluid path assembly includes a filter, the filter serial number is linked to the assembly's serial number. Meissner provides a single cohesive certification package for the complete fluid path assembly which includes component specific lot number information, TSE risk and qualification status as well as applicable filter certification material and specific gamma irradiation dosage information.

Sterilization

Meissner fluid path assemblies are supplied gamma irradiated at a dosage which has been substantiated as a sterilizing dosage via ANSI/AAMI/ISO 11137-2:2006 methodology.

Assembly Design, Components and Filters

The fluid path assembly configurations on page 22 illustrate a variety of common applications, although they have unlimited permutations. Assemblies are configured from our comprehensive library of pre-qualified components. For applications which require filtration, Meissner offers capsule filters for processing volumes from 10 mL to over 10,000 L in a wide variety of filtration media.

BioFlex® Fluid Path Assemblies (continued)

Connecting Stainless Steel Process Equipment to Stainless Steel Process Equipment



CRVTH0.1-1T0C4 →
Steam Through Connector



Steam Through Connector →
Steam Through Connector

Connecting a Single-Use System to Stainless Steel Process Equipment



Quick Connect → CSST0.2-224
→ Steam Through Connector



Aseptic Connector →
Steam Through Connector

Connecting a Single-Use System to a Single-Use System



Quick Connect → CFST0.1-33B4
→ TPE Tubing & Plug



Quick Connect →
Quick Connect

Connecting Stainless Steel Process Equipment to a Single-Use System



Tri-Clamp Fitting →
CLVTH0.2-224 → Quick Connect



Steam Through Connector
→ Aseptic Connector

Filling Assemblies and Manifolds



CLVTH0.2-024 → Four Line
Manifold Terminating in Luers



Luer Fitting → Pump-Y
→ Filling Needle

Fluid Transfer with Sampling and/or Flushing Functionality



CRST0.2-2T0C4 → T to Flush
Biocontainer → MPX



Quick Connect → T to Sampling
Line → Quick Connect

Notes:

- → Arrows indicate flow direction
- Steam Through Connectors provide aseptic connectivity between SUS and stainless steel process equipment
- TPE (Thermo Plastic Elastomer) Tubing + Plug is for use in conjunction with tubing welders
- Aseptic Connectors are designed to allow sterile connections to be made outside of controlled environments
- Quick Connects can be manipulated aseptically under a laminar flow hood



Meissner Filtration Products • 1001 Flynn Rd, Camarillo, CA 93012
800.391.9458 • int'l +1 805.388.9911 • fax 805.388.5948 • www.meissner.com

SteriLUX, STyLUX, EverLUX, UltraCap, TepoFlex, FluoroFlex, BioFlex and One-Touch are registered trademarks of Meissner Filtration Products. © 2014 Meissner Filtration Products. All Rights Reserved.

Steam-Thru® is a registered trademark of Colder Products Company
C-Flex® is a registered trademark of Saint-Gobain Performance Plastics
Tygon® is a registered trademark of Saint-Gobain Performance Plastics
Luer-Lok™ is a trademark of Becton, Dickinson and Company

Sta-Pure® is a registered trademark of W.L. Gore and Associates
AdvantaFlex® is a registered trademark of NewAge Industries AdvantaPure
Tri-Clamp® is a registered trademark of Alfa Laval