ELDON JAMES

Validation Guide

SeriesLock™

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1.0 Validation Overview

1.1 Introduction

This Validation Summary is intended to provide users of the SeriesLock™ fittings, adapters, and connectors with the information necessary to assess the suitability of this product for use in their intended application.

Products are manufactured in compliance with ISO 9001 & ISO 13485 Standards. Products are controlled and inspected in accordance with our applicable product specifications and standard operating procedures.

These couplers are widely used in bioprocessing and medical device applications and are manufactured according to GMP standards and meet USP Class VI requirements (Polypropylene/PP, Polyvinylidene Fluoride/PVDF, and Polysulfone/PS) . All materials used are manufactured from animal free materials.

The information provided as requested is intended to be used for informational purposes only. The information is provided on a without prejudice basis and should not be viewed as giving technical advice, instruction, or otherwise. The information is furnished free of charge and is based on supplier knowledge and understanding. Eldon James Corporation makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any item, evaluation of any connector under end-use conditions prior to specification is essential as conditions such as pressure, temperature, chemicals and operating environment can affect the performance of couplings. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.

Couplings within this product line include inserts and bodies with hose barbs for $^{1}/_{16}$" to 1" internal diameter tubing.

This report is intended to document specifications of the SeriesLock series of couplings and the testing that has been performed on this series.

1.2 Effective Date

The information contained within this document is current as of October, 2023

1.3 Country of Origin

SeriesLock™ is manufactured in the U.S.A.

1.4 Product Manufacturer

These products are manufactured by:

SeriesLock
3420 Precision Drive
Fort Collins, CO 80528
United States of America

1.5 Manufacturing Facility Certifications

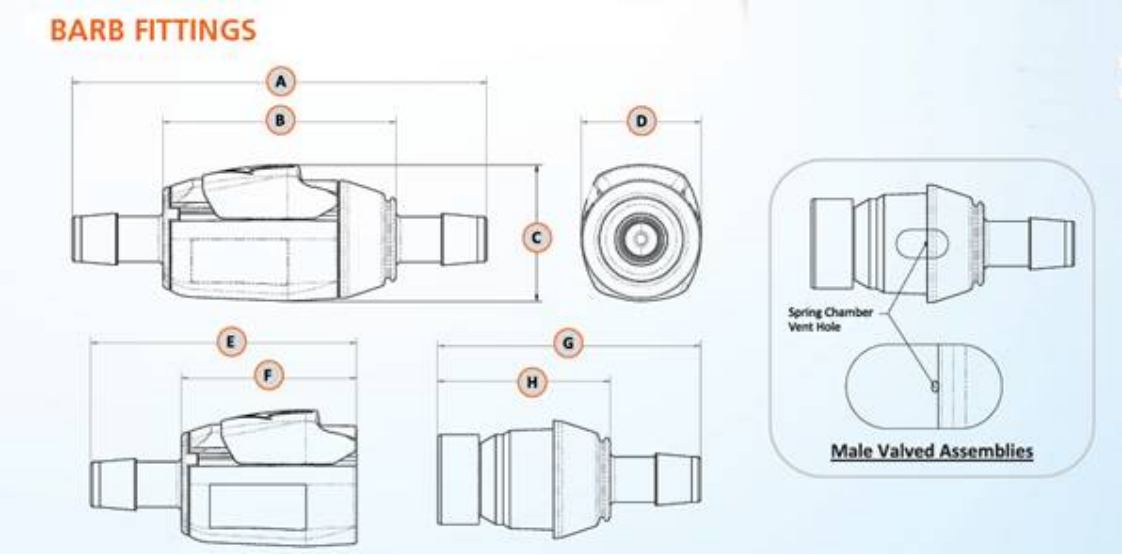
ISO 9001 and ISO 13485 Quality Standards, ISO Class 7 Cleanroom.

1.6 Shelf Life

Serieslock connectors in both polypropylene and Kynar housings have been tested to establish a shelf life of three (3) years. Each tested assembly utilized stainless steel springs and silicone 0- rings. Eldon James does not make any claims regarding Expiration Date because our customers use our products in many different applications and conditions. Eldon James cannot make any assessment or claims regarding expiration. Each individual condition and application must be tested by the customer to determine the limits of each product, material, and use.

2.0 Dimensions

2.1 Dimensions and Weights

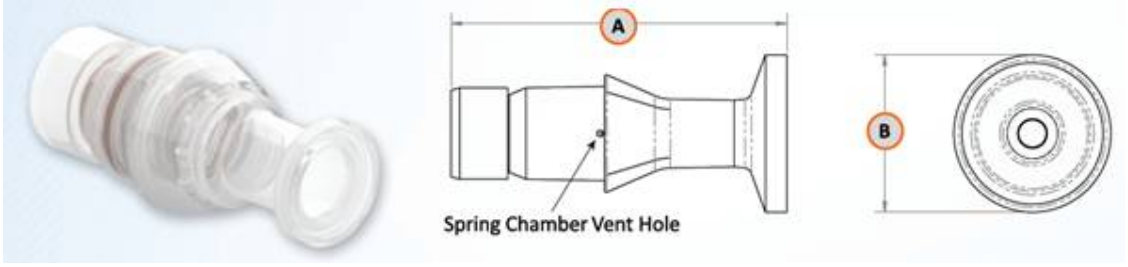


Tubing Size	Barb Fittings (Dimensions in Inches)							
	A	B	C	D	E	F	G	H
1/8"	2.60	1.80	.90	.84	1.85	1.44	1.70	1.30
3/16"	3.00	1.80	.90	.84	2.05	1.44	1.90	1.30
1/4"	3.46	1.98	1.12	.99	2.30	1.56	2.19	1.45
3/8"	3.66	1.98	1.12	.99	2.40	1.56	2.29	1.45
1/2"	4.58	2.57	1.50	1.32	2.93	1.93	2.90	1.90
3/4"	4.97	2.57	1.50	1.32	3.13	1.93	3.10	1.90

Tubing Size	Valved Assembly Weights (gr)					
	Female Assembly			Male Assembly		
	PP	PVDF	GFBN	PP	PVDF	GFBN
1/8"	7	12	11	4	6	6
3/16"	8	13	12	4	7	6
1/4"	11	18	17	6	9	9
3/8"	11	19	17	6	9	9
1/2"	25	42	38	15	25	22
3/4"	27	45	41	15	27	23

Tubing Size	Open Assembly Weights (gr)					
	Female Assembly			Male Assembly		
	PP	PVDF	GFBN	PP	PVDF	GFBN
1/8"	7	12	11	2	4	3
3/16"	8	13	12	2	4	3
1/4"	10	17	15	3	5	4
3/8"	10	18	16	3	6	4
1/2"	22	39	34	8	15	12
3/4"	24	42	37	9	18	14

MALE SANITARY FITTINGS



Dimensions in Inches Open and Valved Assemblies		Flange Size	Weights (gr)					
			Valved Assembly			Open Assembly		
A	B		PP	PVDF	GFBN	PP	PVDF	GFBN
2.04	1.14	Small (1/8" – 3/16")	6	9	8	4	7	6
2.24	1.14	Medium (1/4" – 3/8")	8	12	11	5	8	8
2.68	1.45	Large (1/2" – ¾")	16	28	17	9	18	10

2.2 Internal Surface Area

Small Body (-2 / -3)"	Internal Surface Area (square inches)	Medium Body (-4 / - 5 / - 6)"	Internal Surface Area (square inches)	Large Body (-8 / -10 / -12)"	Internal Surface Area (square inches)
Open Female	0.88	Open Female	1.64	Open Female	5.01
Valved Female	0.97	Valved Female	1.99	Valved Female	6.11
Open Male	2.67	Open Male	3.72	Open Male	8.99
Valved Male	1.55	Valved Male	2.37	Valved Male	6.36

3.0 Materials of Construction

Eldon James considers certain information concerning the manufacture of our products to be confidential trade secrets, such as, product raw materials and formulations.

These fittings, adapters, and connectors are manufactured using proprietary formulations of polypropylene, polyvinylidene fluoride, or polysulfone.

PRODUCT CONTACT	NON-PROUCT CONTACT
Main Body Components: Polypropylene (PP) Polyvinylidene fluoride (PVDF) Option Polysulfone **Seals:** Buna-N, EPDM, Platinum Cured Silicone and Viton Options **Lubricants:** PFPE (biocompatible, inert)	**Slide Button / Main Latch:** Polycarbonate **Springs:** Stainless Non-Magnetic Option

3.1 PP (Polypropylene)

All Eldon James polypropylene connectors are injection molded PVC-free, DEHP/BPA-free, are manufactured according to GMP and meet USP Class VI requirements.
The polypropylene is radiation stable and is resistant to solvents, chemicals, water and other inorganic environments. It resists most strong mineral acids and bases (however, it is subject to attack by oxidizing agents).

PP (Polypropylene)

Attribute	Nominal Value		Test Method
	English	(SI)	
Specific Gravity	0.902	0.900 g/cm^3	ASTM D792
Tensile Strength (yield)	4060 psi	28.0MPa	ASTM D638
Tensile Elongation (break)	>700%	>700%	ASTM D638
Notched Izod Impact (73°F, 23°C)	1.1 ft lb/in	60J/m	ASTM D256
Rockwell Hardness (R-Scale)	90	90	ASTM D785

Deflection Temperature Under Load (66psi – 0.45MPa unannealed)	194°F	90.0°C	ASTM D648
Flame Rating 1.5 mm 3.0 mm	 HB HB	 HB HB	 UL94

* Full Technical Datasheets available upon request.

3.2 PVDF (Polyvinylidene Fluoride)

PVDF (Polyvinylidene Fluoride) is transparent and can be used in food, bioprocess and medical device applications. It is biocompatible and has excellent chemical and abrasion resistance. PVDF connectors are manufactured according to GMP and meet USP Class VI requirements

Polyvinylidene Fluoride

Attribute	**Nominal Value (English / SI)**	
Density	**1.77 g/cm³ (1770 kg/m³)**	
Water Absorption (Equilibrium, 23°C, 50% RH)	0.015 %	
multiple autoclave cycles	Can be re-sterilized and reused	
Glass Transition Temperature	-40.0 °F (-40.0 °C)	
Heat Deflection Temperature	219.2 °F (104 °C)	
Tensile Stress (Yield)	7,251.89 psi (50.0 MPa)	
Nominal Tensile Strain at Break	>50%	
Flame Rating 1.5 mm 3.0 mm	 HB HB	 Test Method UL94 Test Method UL94

* Full Technical Datasheets available upon request.

3.3 Polysulfone (PS)

Polysulfone (PSU) has an amber tiny and it is a tough, rigid, high-strength thermoplastics suitable for continuous use and is also highly resistant to degradation by gamma or electron beam radiation. Polysulfone connectors are manufactured according to GMP and meet USP Class VI requirements

Polysulfone (PS)

Attribute	**Nominal Value (English / SI)**	
Density	**1.24 g/cm³ (1240 kg/m³)**	
Water Absorption (24hr)	0.30%	
Tensile Stress (Yield)	70.3 MPa	
Nominal Tensile Strain at Break	50-100%	
Flame Rating 1.5 mm, ALL 4.5 mm, NC	 HB V-0	 Test Method UL94
Pressure Range	Steam Position	Up to 35 psi, 2.4 Bar
	Flow Position	Up to 20 psi, 1.4 bar

* Full Technical Datasheets available upon request.

3.4 Platinum Cured Silicone (Seals)

Attribute	Nominal Value (English / SI)	Test Method
Color	Clear / translucent	
Tensile Strength	1340 psi	ASTM D412
Tensile Modulus	530 psi	ASTM D638
Elongation	580%	ASTM D412
Heat Deflection Temperature	219.2 °F (104 °C)	ASTM D256
High Tear	Yes	ASTM D790
Modulus	530 psi	ASTM D790
Operating Temperature High	450°F	
Operating Temperature Low	-80°F	
Hardness, Shore A	D74	D2240

* Full Technical Datasheets available upon request.

3.5 EPDM (Seals)

Attribute	Nominal Value (English / SI)	Test Method
Hardness	70+/-5	
Tensile Strength	2072 psi	
Elongation change	322 %	
Specific Gravity	1.13	
Heat Resistance – Hardness change	+3 PTS	ASTM D865 70hrs @125°C
Heat Resistance –Tensile strength change	+6.2%	ASTM D865 70hrs @125°C
Heat Resistance – Elongation Change	-10.3%	ASTM D865 70hrs @125°C
Compression Set	17.5	ASTM D395 22hrs @125°C
Water resistance – Volume change	+2.9%	ASTM D471 70hrs @100°C
Low temperature brittleness test	Pass	ASTM D2137 3min @-55°C

* Full Technical Datasheets available upon request.

3.6 BUNA N (Seals)

Attribute	Nominal Value	Test Method
Hardness	70	
Tensile Strength	14.0 MPA	
Elongation change	380 %	
Temperature Range	-35 – 250°F	
Heat Resistance – Hardness change	+5 PTS	ASTM D865 70hrs @100°C
Heat Resistance –Tensile strength change	+12%	ASTM D865 70hrs @100°C
Heat Resistance – Elongation Change	-24%	ASTM D865 70hrs @100°C
Compression Set	8	ASTM D395 22hrs @100°C
Water resistance – Volume change	+2.5%	ASTM D471 70hrs @100°C
Water resistance – Hardness change	-1 PTS	ASTM D471 70hrs @100°C
Fluid resistance oil #1– Hardness change	+4 PTS	ASTM D471 70hrs @100°C
Fluid resistance oil #1–Tensile strength change	+7%	ASTM D471 70hrs @100°C

Fluid resistance oil #1– Elongation Change	-4%	ASTM D471 70hrs @100°C
Fluid resistance oil #1 – volume change	-7%	ASTM D471 70hrs @100°C
Fluid resistance oil #3– Hardness change	-2 PTS	ASTM D471 70hrs @100°C
Fluid resistance oil #3–Tensile strength change	+7%	ASTM D471 70hrs @100°C
Fluid resistance oil #3– Elongation Change	-10%	ASTM D471 70hrs @100°C
Fluid resistance oil #3 – volume change	+7%	ASTM D471 70hrs @100°C
Low temperature brittleness test	Pass	ASTM D2137 3min @-40°C

* Full Technical Datasheets available upon request.

3.7 Viton (Seals)

Attribute	Nominal Value (English / SI)	Test Method
Color	Black	
Specific Gravity	1.8	ASTM D297
Hardness, Shore A	75 PTS	ASTM D2240
Elongation	225%	ASTM D1414
Modulus @ 50% elongation	875 psi	ASTM D1414
Modulus @ 100% elongation	2199 psi	ASTM D1414
Tensile Strength @ break	2600 psi	ASTM D1412
Temperature Range	-29 – 210°C / -20 – 410°F	
Compression Set @25% deflection	15	ASTM D395 Method B

* Full Technical Datasheets available upon request.

3.8 SeriesLock Fluorinated Oil

Attribute	Nominal Value
Name	SeriesLock oil
Type	Synthetic fluorinated oil
Food / Medical Grade	Medical Grade
Color	Colorless
Odor	Odorless
Biocompatability	ISO 10993 and/or USP Class VI standards to physical, chemical and toxicological standards
Chemical reactivity	Inert
Flammability	Non-flammable
Oxygen safety	Safe
Sterilization Methods	Gamma, e-beam, EyO, steam autoclave

4.0 SeriesLock Physical Specifications

4.1 Pressure Ratings

- 100 SeriesLock (small, medium, large, extra large housings – 1/8" to 1"):

  Vacuum up to 90psi, 6.2 bar (Liquid)

- 200 SeriesLock (MBO, MPMO, MBV, MPMV – 1/16" to ¼" and 3/8" MBO only:

  Vacuum up to 60psi, 4.12 bar (Liquid)

4.2 Service Temperature Range

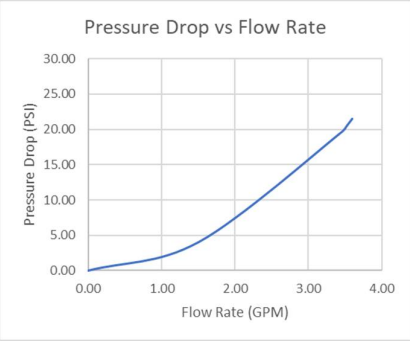
- Polypropylene body version: 32°F to 160°F (0°C to 71°C)
- PVDF body Version: 32°F to 250°F (0°C to 121°C)
- Polysulfone 39°F to 104°F (4°C to 40°C)

4.3 Spillage (at rated pressure)

- Small Housing (1/8" to 3/16" Tubing) <0.05cc per disconnect
- Medium Housing (1/4" to 3/8" Tubing) <0.05cc per disconnect
- Large Housing (1/2" to 3/4" Tubing) <0.1cc per disconnect

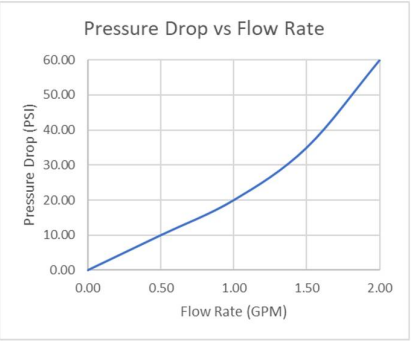
4.4 Flow Test

WATER FLOW – 1/8" Barb Fittings



FLOW RATE (GPM)	PRESSURE DROP (PSI)
0.00	0.00
0.60	16.08
0.90	31.01
1.10	43.20
1.20	54.24

WATER FLOW – 3/16" Barb Fittings



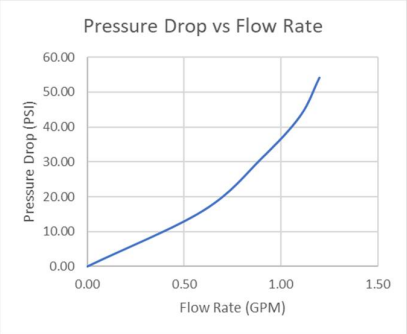
FLOW RATE (GPM)	PRESSURE DROP (PSI)
0.00	0.00
0.50	10.00
1.00	20.00
1.50	35.00
2.00	60.00

certified WBENC WOMEN'S BUSINESS ENTERPRISE

3486 Precision Drive · Fort Collins, CO 80528 (Headquarters)
3420 Precision Drive · Fort Collins CO 80528 SeriesLock® Facility
Phone 970.667.2728 · Fax 970.667.3204

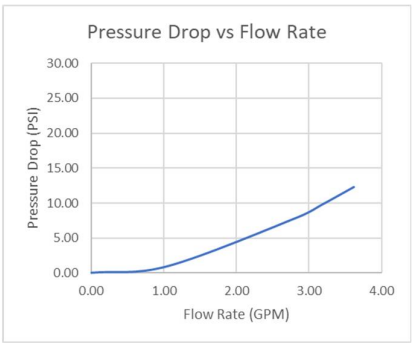
MADE IN USA

WATER FLOW – 1/4” Barb Fittings



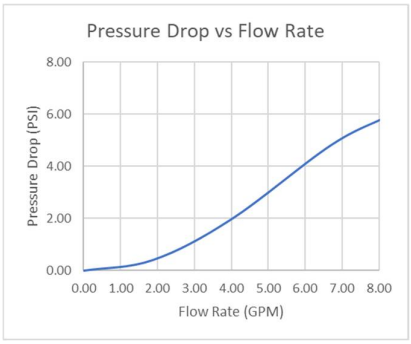
FLOW RATE (GPM)	PRESSURE DROP (PSI)
0.00	0.00
1.51	4.07
3.46	19.71
3.52	20.47
3.60	21.56

WATER FLOW – 3/8” Barb Fittings



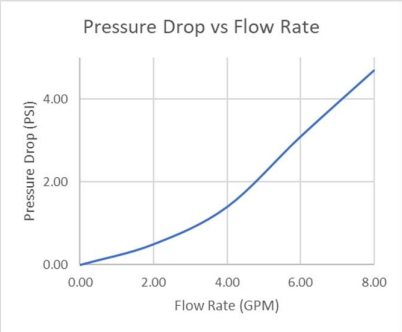
FLOW RATE (GPM)	PRESSURE DROP (PSI)
0.00	0.00
1.06	0.96
2.85	8.01
3.17	9.75
3.62	12.35

WATER FLOW – 1/2” Barb Fittings



FLOW RATE (GPM)	PRESSURE DROP (PSI)
0.00	0.00
1.88	0.41
4.00	1.97
6.70	4.81
8.30	5.96

WATER FLOW – 1/2" Barb Fittings



FLOW RATE (GPM)	PRESSURE DROP (PSI)
0.00	0.00
2.00	0.50
4.00	1.40
6.00	3.10
8.00	4.70

5.0 Animal Derivative Content & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Based on a review of the product composition, this product is not manufactured or formulated with ingredients of animal origin or associated with BSE/TSE infectivity.

6.0 Sterilization Methods

SeriesLock 100 Series Connectors (B, NPT, PM, PP, and SF) are available in a variety of housing materials. Each material has sterilization methods that are recommended and some that are not. Below is a table to illustrate the possible sterilization methods for each housing material. The end user should validate their own unique applications to verify sterilization effectiveness.

SeriesLock 200 Series Connectors (MBO, MBV, MPMO, and MPMV) are available in a variety of housing materials. Sterilization methods are limited to Gamma, E-Beam, and EtO methods. Gamma and E-Beam conditioning should be limited to 50 kGy cumulative. Autoclave sterilization is not recommended as the individual parts are small in volume and the heat introduced may distort the form of the parts thereby effecting performance and function.

	STERILIZATION METHODS				
	Gamma (1)	E-Beam (1)	ETO	Autoclave	
				121°C (4)	134°C (5)
Acetal	No	No	Yes	Yes (6)	No
Glass Filled Nylon	Yes	Yes	Yes	Yes	Yes
Kynar	Yes (2)	Yes (2)	Yes	Yes	Yes
Polypropylene	Yes (3)	Yes (3)	Yes	Yes	No
Polysulfone	Yes	Yes	Yes	Yes	Yes

NOTES:

(1) Typical radiation cycle <50 KGy (end user to verify their use environment and sterilization cycle validations).
(2) <50 kGy exposure tests completed (Silicone O-rings)

(3) <40 kGy exposure tests completed (Silicone O-rings)
(4) 121°C for 30 minutes (Gravity Displacement Method - unwrapped) followed by 15-30 minutes drying time.
(5) 134°C for 15 minutes (Gravity Displacement Method - unwrapped) followed by 15-30 minutes drying time.
(6) Proper ventilation required.

7.0 Regulatory Summary (Polypropylene, PVDF, and Polysulfone)

7.1 Food Contact Status

Polypropylene
21 CFR 177.1520(a)(3)(i) and (c)3.1a. According to our information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b).

This product does not meet the requirements of EU Regulation 10/2011 for food contact as it does not pass the 3.1.6 monographs for Polyolefins and Polypropylenes. The resin does pass all other testing of the 3.1.3 and 3.1.6 monographs.

PVDF
United States of America
Complies with the US Federal Food, Drug and Cosmetic Act. 21 CFR 177.2510(a)

China
Complies with National Standard of People's Republic of China "Hygienic Standard for Uses of Additive in Food Containers and Packaging Materials"

European Union
Complies with Regulation No. 10/2011 Compositional requirements.

Note: One chemical used as Polymer Production Aids (PPA) in the manufacture of this product is not listed in the annex I of the Regulation (EU) No 10/2011. However, based on our resin supplier's own risk assessment, the above-mentioned product is considered adapted for repeated used food contact applications. This product cannot be used for preparing packaging materials and articles intended to come into contact with foodstuff.

European Union (EU) Food Contact:
Polypropylene does not meet the requirements of EU Regulation 10/2011 for food contact as it contains an additive not included in Annex 1.

Polysulfone
Based on information provided by our supplier the resin, as manufactured, complies with Title 21 CFR Part 177.1655 promulgated under the Federal Food, Drug and Cosmetic Act (FFDCA). It is, therefore, permitted by FDA for food contact applications intended for repeated use under conditions of use A through H in Table

2 of 21 CFR Part 176.170 (c). It is, however, the responsibility of the customer to determine that all conditions and specifications outlined under the above-mentioned regulatory category are met, and that the products fabricated from these materials are acceptable to the FDA for use in their intended food-contact applications.

7.2 Allergens

These materials do not contain allergens. - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Soy, Peanuts, Tree Nuts - in the manufacture or formulation of this product and does not contain natural rubber latex or synthetic latex.

7.3 Plant Derived Components

Polypropylene - This product may contain one or more additives(s)/substances(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives/

PVDF - Product is not known or expected to contain vegetable or plant origin substances.

7.4 Ozone Depleting Chemicals (ODCs)

Compliant with Class I/Class II ozone layer depleting substances as listed in the Clean Air Act of 1990 and 1005/2009/EC in the manufacture or formulation of this product; not known or expected to be present based on the final product composition and raw ingredients.

7.5 Materials from Genetically Modified Organisms

Polypropylene

This product utilizes a component produced from material of unknown genetic origin in its formulation.

PVDF

None of the substances in this product are known or expected contain substances identified as GMOs, is not formulated with or have any intentionally added GMO's in the material.

8.0 United States of America Regulations

Polypropylene

Meets FDA requirements 21 CFR 177.1520(a)(3)(i) and (c)3.1a.

Polysulfone

complies with Title 21 CFR Part 177.1655 promulgated under the Federal Food, Drug and Cosmetic Act (FFDCA).

8.1 California Proposition 65

(Safe Drinking Water and Toxic Enforcement Act of 1986)

Polypropylene
Based on available information these products do not intentionally contain any components or chemicals at levels which would be subject to Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments.

PVDF
Based on the final composition of the NK7 fitting raw material, no known PROP65 substances defined in Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments have been identified.

Polysulfone
This product can expose you to chemicals including 4,4'- isopropylidenediphenol (CAS-No.: 80- 05-7) , which is/are known to the State of California to cause birth defects or other reproductive harm.

Warning for springs
Eldon James has been notified that the steel products (springs) contain one or more of the Proposition 65 listed chemicals and thus exposure to this material may result in exposure to a chemical known to cause cancer and /or reproductive harm. However, this product is not a product contact material.

Please contact Eldon James for further information

8.2 Conflict Materials

(Dodd-Frank Wall Street Reform and Consumer Protection Act)

To the best of our knowledge based upon data from our raw material supplier these products are not intentionally manufactured or formulated with the listed conflict Materials as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act

8.3 Heavy Metals – Polyethylene Coalition of Northeastern Governors (CONEG)

These products are not known to contain CONEG substances at or above the 100 ppm reporting threshold. Based on the information available from our raw material suppliers, they do not use cadmium, chromium, lead, or mercury in the manufacture or formulation of this product and do not intentionally contain any of the substances below. We do not specifically run any analysis on incoming raw materials or end products to measure for the presence of any of the substances below
Meets requirements of the Model Toxics in Packaging Legislation developed in 1989 by the CONEG (Coalition of Northeastern Governors, USA).

9.0 European Union Regulations

9.1 EU Directive 2015/863/EU Restriction of Hazardous Substances (RoHS 3) – Polypropylene and wire springs. PVDF, Platinum Cured silicone, EPDM, BUNA N, Viton

Based on the information provided by our resin suppliers and their formulation reviews, they have found that these products do not contain RoHS 3 substances above listed concentrations and would therefore be in compliance with substance restrictions

9.2 EU-Directive 2006/122/EC-RoHS (Polypropylene)

Restriction of the use of perfluorooctanoic acid and perfluorooctane sulfates. This product does not intentionally contain perfluorinated substances.

9.3 Phthalates

These products are not known or expected to contain substances that are identified as Phthalates.

9.4 Additional Substance Information – Polypropylene and PVDF

As with almost all polypropylenes, including these products, anti-oxidants (preservatives) are used to some degree to protect the polymer during conversion/processing. A phenolic anti-oxidant (phenyl group containing) is used in the formulation.

A list of substances not intentionally used within the manufacture or formulation of this products are included within the Eldon James validation documents for each specific material.

9.5 REACH 235 Substances (June 14th, 2023) – Polypropylene, PVDF, Polysulfone, EPDM, BUNA N and wire springs

Based on the information provided to us from our raw material supplier and their formulation reviews, they confirm that this product does not contain SVHC Candidate List Annex XIV materials above the applicable threshold (0.1%) as updated by the European Chemical Agency as of June 14th, 2023 (235 substances).

9.6 Heavy Metals (ELV Directive 2000/53/EC) – Polyethylene

This product has not been checked by tests, toxicologically and/or regulatory irrelevant extremely low trace levels of lead, mercury, cadmium and hexavalent chromium may unintentionally be present.

9.7 European Directive (94/62/EC) Packaging and Packaging Waste - Polypropylene & PVDF

EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE) Polypropylene, PVDF, Polysulfone

None of the substances listed in Annex VII are intentionally added or used in the formulation of this product and conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste with the following exception: these products are manufactured from a hydrocarbon; however, liquid hydrocarbons are not present in this product. Products are recyclable according to the recycle code 5.

European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE) Polypropylene and PVDF

These products are in compliance with European Union Commission Regulation 1895/2005/EC of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (repeals Directive 2002/16/EC & 2004/13/EC).

10.0 China Regulations

10.1 CHINA ROHS 2: PFDV

There are no listed substances known to be present above the reporting threshold as defined by the 2006 Chinese Ministry released Administrative Measures on the Control of Pollution Caused by Electronic Information Products (EIP) # 39.

11.0 Biological Safety, Particulates and Physio-Chemical Tests

11.1 Biocompatibility Tests:

- The polypropylene and PVDF materials were tested to USP Class VI USP <88>criteria.

Biocompatability Type	Polypropylene	PVDF
Biological reactivity *in vitro*	Compliant	Compliant
Cytotoxic studies	Compliant	Compliant
In Vitro hemolysis studies.	Compliant	Compliant

The PVDF materials were tested to USP <161> Transfusion and Infusion Assemblies and Similar Medical Devices and <661> Physicochemical.

PVDF This product has been assessed and certified under USP <661.1> Plastic Materials of Construction and USP <661.2> Plastic Packaging Systems for Pharmaceutical Use.

PVDF This product has been assessed and certified under USP Class VI Plastic (USP<88> and Systemic Toxicity; ISO 10993-11.

11.2 Polypropylene - Class VI testing, USP <88> / ISO 10993

This is a series of three tests that evaluate biological reactivity of animals to polymeric material: systemic toxicity, intracutaneous reactivity and implantation.

The Systemic Injection Test and the Intracutaneous test are designed to determine the systemic and local, respectively, biological responses of animals to plastics and other polymers by the single dose injection of specific extracts prepared from a sample.

The Implantation Test is designed to evaluate the reaction of living tissue to the plastic and other polymers by the implantation of the sample itself into animal tissue.

Eldon James has received the following conclusions from an outside test laboratory on these products:

General Procedure: The test article was prepared at a ratio of 60cm^2 : 20mL and extracted at 121^{o}C for one hour.

Test date	February 2009		
Test Article	Polypropylene fitting	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test - USP	**Extract Conditions**	121^{o}C for 1 hour

General Procedure: The extraction conditions were performed as stated above. The test article extracts, and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP. The animals were observed for signs of toxicity and skin reactivity post treatment. In addition, the test article was implanted into rabbit muscle for 7 days and observed macroscopically for signs of reaction.

Results:
USP Systemic Toxicity Study in the mouse. The test article was extracted as above and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extracts.

USP Intracutaneous Toxicity Study in the Rabbit. The test article was extracted as above and injected into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extracts.

USP Muscle Implantation Study in the Rabbit. The macroscopic reaction of the test article, implanted into rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

Conclusion: The test article meets the requirements of the guidelines for the Biological Test for Plastics Class VI in that it meets the requirements of the guidelines for the Biological Test for Plastics, Class VI, USP <88> Biological Reactivity Tests, *In Vivo.*

11.3 Polypropylene - Endotoxin

Test date	09/June/2015		
Test Article	Polypropylene fitting	**Vehicles**	Water for Injection
Study	LAL	**Extract Conditions**	37 +/- 1°C for 24 +/- 2 hours

Method

1 gram of sample was covered with 10mL of Water for Injection and placed in a 37°C shaker incubator for 40-60 minutes

Individual 0.1 mL portions of the test and control solutions were placed in sterile microplate wells and incubated at 37°C for 10 minutes in a Kinetic-Chromogenic Reader. Individual 0.1 mL portions of lysate, reconstituted per manufacturer's current directions, were then added to each well and testing was initiated. The concentration of the endotoxin was determined spectrophotometrically. A Positive Product Control solution (inhibition/enhancement control) was simultaneously prepared and tested to evaluate any possible interference by the test article on the lysate/endotoxin reaction.

All times and temperatures reported herein are approximate and within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

Test Acceptance Criteria

Type of Product	Current FDA Requirements*	Current USP Requirement
Medical Device	Less than or equal to 0.5 EU/mL	Less than or equal to 20.0 EU/device
Medical Device Contacting Cerebrospinal Fluid	Less than or equal to 0.06 EU/mL	Less than or equal to 2.15 EU/device
Water for Injection	Not applicable	Less than or equal to 0.25 EU/mL

*Based on an extract volume of 40 mL / device

Results

Test article Extract Dilution:	1
Positive Product Control Percent Recovery:	83% (between 50% and 200% is acceptable)
Test article extract:	<0.00500 EU/mL (Total Concentration) <0.0500 EU/g

REFERENCES

Association for the Advancement of Medical Instrumentation (AAMI) ST72: Bacterial Endotoxins - Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing (2011).

United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <85>, Bacterial Endotoxins Test (2015).

United States Pharmacopeia 38, National Formulary 33 (USP), General Chapter <161>, Transfusion and Infusion Assemblies and Similar Medical Devices (2015).

11.4 Polypropylene - Cytotoxicity / ISO 10993-5

This test is a common cytotoxicity assessment designed to assess the toxicity to cells of leachable components of the material. The material is extracted in cell culture media (Minimum Essential Medium, or "MEM") at 37°C for 24 hours. Negative control reagent control and positive controls were similarly prepared.

Extracts are placed in contact with triplicate monolayers of L-929 mouse fibroblast cells. Cells are incubated in a controlled environment (37°C in the presence of 5% CO_2) for 48 hours after which they are examined microscopically for abnormal cell morphology and cellular degeneration.

Test date	04/08/2011		
Test Article	Polypropylene fitting	**Vehicles**	Serum-Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test - ISO	**Extract Conditions**	37 +/- 1°C for 24 +/- 2 hours

References: The study was conducted based on the following references: ISO 10993-5, 2009, Biological Evaluation of Medical devices – Part 5: Tests for *In Vitro* Cytotoxicity.

USP 32, NF27, General Chapter <87>, Biological Reactivity Tests, In Vitro (2009)

ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity

General Procedure: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control and negative control articles together with reagent control were prepared to verify the proper functioning of the test system.

The test extracts were not centrifuged, filtered or otherwise altered prior to dosing.

The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37 +/- 1 °C, in a humidified atmosphere containing 5 +/- 1% carbon dioxide. Biological reactivity (Cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity) as below.

Grade	Reactivity	Conditions of all cultures
0	None	Discreate intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no excessive cell lysis, not more than 50% growth inhibition observed.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed.
4	Severe	Nearly complete or complete destruction of the cell layers.

The test article met the requirements of the test if the negative control extracts must have had a reactivity of none (grade 0) and the positive control must have been a grade 3 or 4. None of the cultures exposed to the test article showed greater than a Mild reactivity (Grade 2).

Results: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48-hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48-hour observation.

Conclusion: The test article is considered non-cytotoxic and meets the requirements of the L929 MEM Elution Test ISO 10993-5, 1999 guidelines.

Note:
Although the above information was provided, only actual testing of the final medical device product will positively establish this status for your final product. Please note that meeting Class VI criteria is only the base starting point. The ultimate suitability for use in a medical device application would depend on the specifics of the final product, its specific end use application and meeting the USP or ISO testing criteria required for that specific end use application.
As Eldon James does not control the conditions under which our products are used in our customer's products, we are not in a position to warrant that the customer's products meet FDA or other regulatory requirements.

11.5 PVDF – Endotoxin

PVDF materials (material YO-6NK) have been tested to USP<85> standards and have been shown to meet USP<85> requirements.

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Sample collection Date	Sample Received Date	Completed Date	Requisition
12-11-2018	12-19-2018	12-21-2018	M38150

Customer	Eldon James Corp.
Street	10325 East 47th Avenue
City, State, Zip	Denver, CO 80238
Contact	Daryl Horiuchi
Email	Daryl.horiuchi@eldonjames.com

Laboratory Report
USP <85> Bacterial Endotoxins Test

Sample Identification	Lot Number	Sample Description
YO-6PP	1247482	Y-Connector
Endotoxin Release Limit:	Sample Concentration	Maximum Valid Dilution
N/A	as Provided	N/A

# of Samples Tested	Percent Recovery (50%-200% is Acceptable)	Endotoxin Concentration	Interpretation
1	83%	<0.5 EU/mL	N/A

Sample Identification	Lot Number	Sample Description
YO-6NK	1247483	Y-Connector
Endotoxin Release Limit:	Sample Concentration	Maximum Valid Dilution
N/A	as Provided	N/A

# of Samples Tested	Percent Recovery (50%-200% is Acceptable)	Endotoxin Concentration	Interpretation
1	99%	<0.5 EU/mL	N/A

NOVA BIOLOGICALS
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Laboratory Report
USP <85> Bacterial Endotoxins Test

Sample Identification	Lot Number	Sample Description
YO-6NN	1247484	Y-Connector
Endotoxin Release Limit:	Sample Concentration	Maximum Valid Dilution
N/A	as Provided	N/A

# of Samples Tested	Percent Recovery (50%-200% is Acceptable)	Endotoxin Concentration	Interpretation
I	67%	<0.5 EU/mL	N/A

Interpretation:
As tested, the sample meets the requirements of the test for USP Bacterial Endotoxin Testing if the Endotoxin Concentration is not greater than the Endotoxin Release Limit of 2 EU/mL supplied by the client.

References:

USP <85>, 2017. - U.S. Pharmacopoeia, National Formulary (USP 40-NF35)

QA Review: RMV

Approved by: Paul J. Pearce (SMP) Date: 12/21/2018
Paul J. Pearce, Ph.D.
Laboratory Director
Specialist in Microbiology (SM/ASCP Board of Certification)

11.6 Leachables and Extractables (Polypropylene)

Materials Tested

ITEM	DESCRIPTION
12000-00	FITTING, SANITARY TO HOSE BARB, PP, 3/4" SANITARY TO 3/8" BARB
11672-15	FITTING, BARBED REDUCER, PP, 3/4 X 3/8
11672-02	FITTING, REDUCER, 1/4 IN HB X 1/8 IN HB, PP
11811-03	STRAIGHT CONNECTOR 1/8", PP
11973-03	FITTING, BARBED CROSS, PP, 1/4"
12015-05	FITTING, TEE CONNECTOR, 1/4" HB X 3, PP
11673-01	PLUG, HOSE BARB, PP, 1/8"
11672-04	FITTING, BARBED REDUCER, PP, 3/8" X 1/8"
11673-04	PLUG, HOSE BARB, PP, 1/4
12015-02	FITTING, BARBED TEE, PP, 1/8"
12022-00	FITTING, SeriesLock™ QUICK CONNECT, IN LINE BARBED, PP, MALE, 3/4" BARB
12023-00	FITTING, SeriesLock™ QUICK CONNECT, IN LINE BARBED, PP, FEMALE, 3/4" BARB

An extractables study was performed to identify and to estimate the amounts of compounds that may be extracted from an assembly upon contact with model solvents.

Prior to extraction, the fitting assembly was sterilized using Gamma irradiation. During the sterilization process the delivered dose was monitored :

- Minimum delivered dose : 27.7 kGy
- Maximum delivered dose : 36.3 kGy

Each sample was analyzed by direct injection gas chromatography mass spectrometry (GC/MS) to screen for semi-volatile organic compounds and by headspace GC/MS to screen for volatile organic compounds. Liquid chromatography with ultraviolet and mass spectrometry detection (LC/UV/MS) was used to screen for non-volatile organic compounds.

An elemental analysis was performed using inductively-coupled plasma optical emission spectroscopy (ICP-OES).

Extraction Solvents

Sample ID	Solvent
Fittings Assembly NS-09600019	Water at pH 3
	Water at pH 10
	1/1 Ethanol/Water
	Water

For each solvent above, the assembly was filled with 4200ml (approximately half-full) of solvent and stored at 40ºC for 21 days, with agitation.

After the storage period, the sample extracts were transferred into glass containers for analysis by GC/MS and LC/UV/MS and polypropylene containers for analysis by ICP-OES. Control solutions for each solvent and condition were prepared in the same manner as the sample preparations.

The solutions to be analyzed by GC/MS and LC/UV/MS were then stored at 2°C to 8°C until analysis, and the solutions to be analyzed by ICP-OES were stored at ambient conditions until analysis.

Direct Injection GC/MS

The water at pH 3, water at pH 10, and water extracts and controls were exchanged to a 10 µg/mL phenanthrene-d10 solution in methylene chloride by combining 2.0 mL of each extract or control with 2.0 mL of a methylene chloride extraction solution. Each solution was vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes. A portion of each mixture's methylene chloride layer was transferred into a vial for analysis.

The 1/1 ethanol/water extracts and controls were exchanged twice to a 10 µg/mL phenanthrene-d10 solution in methylene chloride by combining 3.0 mL of each extract or control with two 1.5-mL aliquots of the 10 µg/mL phenanthrene-d10 solution. The first aliquot was combined with the extract or control and vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes before transferring the methylene chloride layer to a 3-mL volumetric flask. Then the second aliquot was combined with the extract or control and vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes before transferring the methylene chloride layer to the same volumetric flask as the first aliquot. As the ethanol made the volume greater than 3 mL, each solution was evaporated with nitrogen to less than 3 mL and was then brought back to volume with methylene chloride. A portion of each solution was transferred into a vial for analysis.

Mass spectra were compared to reference spectra found in the Wiley2010/NIST2011 (W10/N11) database and a proprietary Eurofins database to determine plausible identities. When confident matches to the database were not found, compounds were classified as accurately as possible. The results for the direct injection GC/MS analysis are shown below.

Direct Injection GC/MS Results for Water at pH 3 Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	1,3-Bis(1,1-dimethylethyl)-benzene	0.2	668.8
	1-Decanol	< 0.1	207.7
	Unknown (Ions: 177, 220, 41)	0.1	298.2
	2,4-Bis(1,1-dimethylethyl)-phenol	2.2	9082.6
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the direct injection GC/MS analysis, no compounds were reportable in the water at pH 3, water at pH 10, or water extracts of the fittings. Four compounds (1,3-bis(1,1-dimethylethyl)-benzene, 1-decanol, 2,4-bis(1,1dimethylethyl)-phenol, and an unknown) were reportable in the 1/1 ethanol/water extracts of the fittings.

Headspace GC/MS

Internal standards were added to the water at pH 3, water at pH 10, and water extracts and controls directly by combining 1.0 mL of each extract or control with 4.0 mL of a 1.25 µg/mL 1,4-dichlorobenzene-d4 spiking solution in water in 10 mL headspace vials. This spiking yielded a final concentration of approximately 5 µg/vial.

Internal standard was added to the 1/1 ethanol/water extracts and controls directly by combining 0.5 mL of each extract or control with 5.0 mL of a 0.5 µg/mL 1,4-dichlorobenzene-d4 spiking solution in water in 10 mL headspace vials. This spiking yielded a final concentration of approximately 2.5 µg/vial.

Mass spectra were compared to reference spectra found in the Wiley2010/NIST2011 (W10/N11) database and a proprietary Eurofins database to determine plausible identities. The results for the headspace GC/MS analysis are shown below.

Headspace GC/MS Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	1,3-Bis(1,1-dimethylethyl)-benzene	0.3	1336.1
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the headspace GC/MS analysis, no compounds were reportable in the water at pH 3, water at pH 10, or water extracts of the fittings. One compound (1,3-bis(1,1-dimethylethyl)-benzene) was reportable in the 1/1 ethanol/water extract of the fittings.

LC/UV/MS

Each of the extracts and controls was transferred directly into a vial for analysis.

LC/MS MM^+ Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	Tris(2,4-di-tert butylphenyl)phosphate (Ion 663.4551)	1.3	5291.0
1/1 Ethanol/Water	Bis(2,4-di-tert butylphenyl)phosphate (Ion 475.2971)	0.4	1660.0
	Irganox 245 (Ion 604.3799)	0.3	1216.3
	Dilauryl Thiodipropionate (oxidized) (C30H58O5S) (Ion 531.4082 [M+H]+)	0.5	2053.1
	Tris(2,4-di-tert butylphenyl)phosphate (Ion 663.4549)	0.4	1841.0
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

LC/MS MM- Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	Bis (2,4-di-tert butylphenyl)phosphate (Ion 473.2839)	1.4	6007.5
1/1 Ethanol/Water	Irgafos 168 degradant (C14H23O3P) (Ion 269.1322 [M-H]-)	0.1	577.9
	Bis (2,4-di-tert butylphenyl)phosphate (Ion 473.2840)	3.6	15054.1
	C28H43O5P (Ion 489.2781 [M-H]-), Irganox 245 (Ion 585.3438), and related to Bis (2,4-di-tert butylphenyl)phosphate (Ion 473.2831)	0.2	661.8
Water	Bis (2,4-di-tert butylphenyl)phosphate (Ion 473.2845)	0.4	1690.1

NA = Not applicable; RL = Reporting limit

LC/UV Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	Bis (2,4-di-tert butylphenyl)phosphate	0.4	1677.3
1/1 Ethanol/Water	Unknown	1.8	7668.8
	Bis (2,4-di-tert butylphenyl)phosphate	1.1	4479.1
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the LC/UV/MS analysis, no compounds were reportable in the water at pH 3 extract of the fittings. Several Irgafos 168 degradants and a few unknown compounds were reportable in the water at pH 10, 1/1 ethanol/water, and water extracts.

ICP-OES

System suitability standards were prepared from purchased stock standards. Two standards were prepared at approximately 1 µg/mL in the 5% nitric acid / 5% hydrochloric acid matrix and contained all reported elements. One standard was used for system calibration while the

other was used as a check standard. A sensitivity solution was prepared at approximately 0.1 µg/mL in the 5% nitric acid / 5% hydrochloric acid matrix and contained all reported elements. In addition, an internal standard containing 3 µg/mL yttrium was prepared in the 5% nitric acid / 5% hydrochloric acid matrix. This internal standard was mixed with each standard and sample online by the instrument in order to eliminate issues associated with the differences in physical properties between the standard and sample solutions, such as viscosity, which can affect the mobility of the test solutions passing into the spray chamber and through the ICP-OES system.

Each water at pH 3, water at pH 10, and water extract and control were prepared by adding 0.5 mL of nitric acid and 0.5 mL of hydrochloric acid to a digestion vessel containing the extract or control. The solutions were then brought to a volume of 10.0 mL, each with the appropriate extract or control. For the preparation of the 1/1 ethanol/water extracts and controls, 10 mL of each was evaporated to near dryness and then reconstituted with an equivalent volume of 5% nitric acid / 5% hydrochloric acid.

The following elements were evaluated:

1. Ag	11. Hg	21. Ru
2. Al	12. Ir	22. Sb
3. As	13. Li	23. Se
4. Au	14. Mo	24. Sn
5. Ba	15. Ni	25. Ti
6. Cd	16. Os	26. Tl
7. Co	17. Pb	27. V
8. Cr	18. Pd	28. W
9. Cu	19. Pt	29. Zn
10. Fe	20. Rh	30. Zr

Reportable results for a given element in a sample were calculated by subtracting the concentration of the element in the associated control from the concentration of the element in the sample. The concentration the reporting limit corresponded to in-sample as a result of any dilutions performed during sample preparation are shown below.

ICP-OES Results for Extracts

Solvent	Element	Corrected Est. Conc. (µg/mL)	Corrected Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	NA	< RL	< RL
Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

Note: Spectral interference was observed in the water at pH 10 extract and control solutions for As, Hg, Ir, Pb, Sb, Se, and Tl.
Note: Cr was detected in the water at pH 10 extract and control solutions above the reporting limit (but was not reportable due to control correction). This response is likely due to the presence of P in the extraction solvent because P is known to interfere with Cr at the analyzed wavelength.

In the ICP-OES analysis, no elements were reportable in the extracts of the fittings.

Conclusion

In the direct injection GC/MS analysis, no compounds were reportable in the water at pH 3, water at pH 10, or water extracts of the fittings. Four compounds (1,3-bis(1,1-dimethylethyl)-benzene, 1-decanol, 2,4-bis(1,1dimethylethyl)-phenol, and an unknown) were reportable in the 1/1 ethanol/water extracts of the fittings.

In the headspace GC/MS analysis, no compounds were reportable in the water at pH 3, water at pH 10, or water extracts of the fittings. One compound (1,3-bis(1,1-dimethylethyl)-benzene) was reportable in the 1/1 ethanol/water extract of the fittings.

In the LC/UV/MS analysis, no compounds were reportable in the water at pH 3 extract of the fittings. Several Irgafos 168 degradants and a few unknown compounds were reportable in the water at pH 10, 1/1 ethanol/water, and water extracts.

In the ICP-OES analysis, no elements were reportable in the extracts of the fittings.

11.7 Leachables and Extractables (PVDF)

Materials Tested

- Polyvinylidene Fluoride Plastic Moulded Fittings

An extractables study was performed to identify and to estimate the amount of compounds that may be extracted from the fittings upon contact with model solvents.

Each sample was analyzed by direct injection gas chromatography mass spectrometry (GC/MS) to screen for semi-volatile organic compounds and by headspace GC/MS to screen for volatile organic compounds. Liquid chromatography with ultraviolet and mass spectrometry detection (LC/UV/MS) was used to screen for non-volatile organic compounds.

An elemental analysis was performed using inductively-coupled plasma optical emission spectroscopy (ICP-OES).

Extraction Solvents

Sample ID	Solvent
Fittings	Water at pH 3
	Water at pH 10
	1/1 Ethanol/Water

For each solvent above, the component was covered with 34mL of solvent and stored at 40ºC for 21 days.

After the storage period, the sample extracts were transferred into glass containers for analysis by GC/MS and LC/UV/MS and polypropylene containers for analysis by ICP-OES. Control solutions for each solvent and condition were prepared in the same manner as the sample preparations.

The solutions to be analyzed by GC/MS and LC/UV/MS were then stored at 2°C to 8°C until analysis, and the solutions to be analyzed by ICP-OES were stored at ambient conditions until analysis.

Direct Injection GC/MS

The 1:1 EtOH:water extracts and controls were exchanged twice to a 10 µg/mL phenanthrene-d10 solution in methylene chloride by combining 5.0 mL of each extract or control with two 2.5-mL aliquots of the 10 µg/mL phenanthrene-d10 solution. The first aliquot was combined with the extract or control and vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes before transferring the methylene chloride layer to a 5-mL volumetric flask. Then the second aliquot was combined with the extract or control and vortex-mixed for 1 minute, and the layers were allowed to separate and settle for at least 10 minutes before transferring the methylene chloride layer to the same volumetric flask as the first aliquot. As the EtOH made the volume greater than 5 mL, each solution was evaporated with nitrogen to less than 5 mL and was then brought back to volume with methylene chloride.

A portion of each solution was transferred into a vial for analysis.

Mass spectra were compared to reference spectra found in the Wiley2010/NIST2011 (W10/N11) database and a proprietary Eurofins database to determine plausible identities. When confident matches to the database were not found, compounds were classified as accurately as possible. The results for the direct injection GC/MS analysis are shown below.

Direct Injection GC/MS Results

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/cm²)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	Triethyl borate	0.1	<0.1
	1,3-Diethoxy-1,1,3,3-tetramethyl-disiloxane	0.1	<0.1

NA = Not applicable; RL = Reporting limit

In the direct injection GC/MS analysis, no compounds were reportable in the acidic water, pH 3 or the basic water, pH 10 extracts of component A. In the 1:1 EtOH:water extracts, triethyl borate and a siloxane were reportable.

Headspace GC/MS

Internal standards were added to the water at pH 3, water at pH 10, and water extracts and controls directly by combining 1.0 mL of each extract or control with 4.0 mL of a 1.25 µg/mL 1,4-dichlorobenzene-d4 spiking solution in water in 10 mL headspace vials. This spiking yielded a final concentration of approximately 5 µg/vial.

Internal standard was added to the 1/1 ethanol/water extracts and controls directly by combining 0.5 mL of each extract or control with 5.0 mL of a 0.5 µg/mL 1,4-dichlorobenzene-d4 spiking solution in water in 10 mL headspace vials. This spiking yielded a final concentration of approximately 2.5 µg/vial.

Mass spectra were compared to reference spectra found in the Wiley2010/NIST2011 (W10/N11) database and a proprietary Eurofins database to determine plausible identities. When confident matches to the database were not found, compounds were classified as accurately as possible.

Headspace GC/MS Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/cm²)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the headspace GC/MS analysis, no compounds were reportable in the acidic water, pH 3; basic water, pH 10; or the 1:1 EtOH:water extracts of the component.

LC/UV/MS

Each of the 1:1 EtOH:water; acidic water, pH 3; and basic water, pH 10 extracts and controls were transferred directly into a vial for analysis.

Mass spectra and retention times were compared to a proprietary Eurofins database to determine plausible identities. Tables 20 through 28 present the results for each mode of the LC/UV/MS analysis.

LC/MS MM^+ Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/cm²)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

LC/MS MM^- Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/cm²)
Water at pH 3	Fluoro-alkyl sulfonic acid (tridecafluorooctane sulfonic acid)	0.5	0.1
Water at pH 10	Fluoro-alkyl sulfonic acid (tridecafluorooctane sulfonic acid)	0.3	<0.1
1/1 Ethanol/Water	Fluoro-alkyl sulfonic acid (tridecafluorooctane sulfonic acid)	1.5	0.3

NA = Not applicable; RL = Reporting limit

LC/UV Results for Extracts

Solvent	Tentative Identification	Est. Conc. (µg/mL)	Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the LC/UV/MS analysis, only tridecafluorooctane sulfonic acid was reportable for the 1:1 EtOH:water; acidic water, pH 3; and basic water, pH 10 extracts of component A with a molecular ion weight of 426.97 m/z. This fluoroalkyloctane sulfonic acid is different than PFOS (perfluorooctane sulfonic acid) which has a molecular weight of 500.13 g/mole.

ICP-OES

System suitability standards were prepared from purchased stock standards. Two standards were prepared at approximately 1 µg/mL in the 5% nitric acid / 5% hydrochloric acid matrix and contained all reported elements. One standard was used for system calibration while the other was used as a check standard. A sensitivity solution was prepared at approximately 0.1 µg/mL in the 5% nitric acid / 5% hydrochloric acid matrix and contained all reported elements. In addition, an internal standard containing 3 µg/mL yttrium was prepared in the 5% nitric acid / 5% hydrochloric acid matrix. This internal standard was mixed with each standard and sample online by the instrument in order to eliminate issues associated with the differences in physical properties between the standard and sample solutions, such as viscosity, which can affect the mobility of the test solutions passing into the spray chamber and through the ICP-OES system.

Each acidic water, pH 3 and basic water, pH 10 extract and control was prepared by adding 0.5 mL of nitric acid and 0.5 mL of hydrochloric acid to a digestion vessel containing the extract or control. The solutions were then brought to a volume of 10.0 mL, each with the appropriate extract or control. For the preparation of the 1:1 EtOH:water extracts and controls, 10 mL of each was evaporated to near dryness and then reconstituted with an equivalent volume of 5% nitric acid / 5% hydrochloric acid.

The following elements were evaluated:

11. Ag	11. Hg	21. Ru
12. Al	12. Ir	22. Sb
13. As	13. Li	23. Se
14. Au	14. Mo	24. Sn
15. Ba	15. Ni	25. Ti
16. Cd	16. Os	26. Tl
17. Co	17. Pb	27. V
18. Cr	18. Pd	28. W
19. Cu	19. Pt	29. Zn
20. Fe	20. Rh	30. Zr

Reportable results for a given element in a sample were calculated by subtracting the concentration of the element in the associated control from the concentration of the element in the sample. The concentration the reporting limit corresponded to in-sample as a result of any dilutions performed during sample preparation are shown below.

ICP-OES Results for Extracts

Solvent	Element	Corrected Est. Conc. (µg/mL)	Corrected Est. Conc. (µg/assembly)
Water at pH 3	NA	< RL	< RL
Water at pH 10	NA	< RL	< RL
1/1 Ethanol/Water	NA	< RL	< RL

NA = Not applicable; RL = Reporting limit

In the ICP-OES analysis, no elements were reportable in any extracts of the component.

Conclusion

In the direct injection GC/MS analysis, no compounds were reportable in the acidic water, pH 3 or the basic water, pH 10 extracts of component A. In the 1:1 EtOH:water extracts, triethyl borate and a siloxane were reportable.

As a reference standard, a sample of perfluorooctanesulfonic acid or PFOS was analyzed by direct injection GC/MS to compare with extracted ion analysis. Perfluorooctane sulfonic acid (PFOS) cannot be recovered by direct inject analysis, but its analysis yielded 4 related compounds. These are likely degradants of the perfluorooctanesulfonic acid.

When comparing the extracts for the polymer tested, none of these 4 compounds were identified in any of the extracts of component A. Therefore, no PFOS was detected in the extracts of component A.

In the headspace GC/MS analysis, no compounds were reportable in the water, pH 3; the water, pH 10; or the 1:1 EtOH: water extracts of component A.
In the LC/UV/MS analysis, only tridecafluoroooctane sulfonic acid was reportable for the 1:1 EtOH: water; acidic water, pH 3; and basic water, pH 10 extracts of component A. This compound is a fluoro-alkyloctane sulfonic acid with a molecular weight of 428.16 g/mole. This compound is not perfluorooctanesulfonic acid, which has a molecular weight of 500.13 g/mole.

In the ICP-OES analysis, no elements were reportable in any extracts of component A.

11.8 Aerosolized Testing

Materials Tested

- B-FV-PO-SS-8 (Polypropylene) Female Coupling
- B-MV-P-SS-8 (Polypropylene) Male Coupling
- Silicone O-rings

Purpose

Assessing the connection's integrity against bacterial ingress.

Method

1. Prior to any testing, all system components are autoclaved at 134°C for 30-45 minutes.
2. The solutions are autoclaved at 121°C for 15-20 minutes before being subjected to the testing.
3. For the staph solution in this aerosol test, the concentration is (1 vial of staph: 250 mL of nutrient broth)
4. The fittings were challenged with the staph solution for 1 hour. The connection was sprayed every 5 minutes for 1 hour. At each spray point, 5 sprays occurred.
5. Following the aerosol challenge, TSB was flowed through the tubing and collected
6. 10ml of the TSB was collected
5. Sampling occurred upstream of the valve and downstream of the valve.
7. Before solution: samples of 1:10 concentration, 1:100 concentration and 1:1,000 concentration are plated onto 3M petrifilm plates. 1 mL of each concentration is plated separated on the petrifilm, and are incubated for 24 hours at 35°C. Following this incubation period, each of the plates are counted for growth.
8. After solution: the same protocol is followed.
   For the staph solution, it is plated at ratios of 1:10, 1:1,000 and 1:10,000.

Results

Bacterial Growth		
Sample	**Before**	**After**
1	No	No
2	No	No
3	No	No

The SeriesLock connectors had no bacterial intrusion during the aerosol testing. Although a less aggressive test than the 30-minute full submersion, this test confirms that the SeriesLock connector product is robust to stand up against intrusion from liquid and from mist.

Conclusion

Three replicates were tested, and each connector experienced NO ingress of the staph solution.

11.9 Submersion Testing

Materials Tested

- B-FV-PO-SS-8 (Polypropylene) Female Coupling
- B-MV-P-SS-8 (Polypropylene) Male Coupling
- Silicone O-rings

Purpose

Assessing the connection's integrity against bacterial ingress.

Method

1. Prior to any testing, all system components are autoclaved at 134°C for 30-45 minutes.
2. The solutions are autoclaved at 121°C for 15-20 minutes before being subjected to the testing.
3. TSB (tryptic soy broth) is placed in the starting flask.
4. TSB is sampled from the starting valve, before (upstream) of the SeriesLock test valve that is being challenged with the staph.
5. For the staph solution in this submersion test, the concentration is (3 vial of staph: 750 mL of nutrient broth)
6. The SeriesLock valve is submerged for 30 minutes in the staph solution.

   Note: the TSB is only flowed through system enough that it fills the SeriesLock connection parts and is saturated.

7. Following the 30 minutes, the TSB flows through and a sample downstream is taken.
8. Following collection of the TSB that has flowed through the valve during the testing:

   - 10 mL of TSB are collected
   - There are 3 vials that have 9 mL of buffer
   - Before solution: samples of 1:10 concentration, 1:100 concentration and 1:1,000 concentration are plated onto 3M petrifilm plates. 1 mL of each concentration is plated separated on the petrifilm and are incubated for 24 hours at 35°C. Following this incubation period, each of the plates are counted for growth.
   - After solution: the same protocol is followed.

- For the staph solution, it is plated at ratios of 1:10, 1:1,000 and 1:10,000.

Results

Bacterial Growth		
Sample	**Before**	**After**
1	No	No
2	No	No
3	No	No

The SeriesLock connectors blocked all egress, on all tested samples, for a 30-minute submersion. This is considered the worst-case test scenario and provides confidence that the connection fidelity is adequate to block out intrusion from bacteria.

Conclusion

Three replicates were tested, and each connector experienced NO ingress of the staph solution.

11.10 Ingress Testing

Materials Tested

- B-FV-PO-SS-8 (Polypropylene) Female Coupling
- B-MV-P-SS-8 (Polypropylene) Male Coupling
- Silicone O-rings

Purpose

Test with the objective of assessing the connection's integrity against bacterial ingress.

Method

1. Prior to any testing, all system components are autoclaved at 134°C for 30-45 minutes.
2. The solutions are autoclaved at 121°C for 15-20 minutes before being subjected to the testing.
3. The female and male end were connected in the system and were submerged in a spore suspension containing Geobacillius stearothermophilus ATCC 7953 in 0.1% Carboxy-Methyl Cellulose for 30 seconds.
4. The soiled assembly was placed in a laminar flow cabinet to air dry at ambient temperature for 12 hours.
5. 1 L TSB (tryptic soy broth) was placed in Bag 1.
6. Using a peristaltic pump, the TSB was transferred from Bag 1 to Bag 2 5 times to simulate general fluid transfer and exposure through the connector.
7. After the 5 transfers, the TSB was equally split between Bag 1 and Bag 2

8. The bags were incubated at 55°C for 14 days.
9. Following the 14-day incubation period:
   a. There are 3 vials that have 9 ml of buffer
   b. Bag 1 solution: samples of 1:10 concentration, 1:100 concentration and 1:1,000 concentration are plated onto 3M petrifilm plates. 1 mL of each concentration is plated separated on the petrifilm and are incubated for 24 hours at 35°C. Following this incubation period, each of the plates are counted for growth.
   c. Bag 2: the same protocol is followed.
13. The same procedure was done without a connector, as a control.

Results

Bacterial Growth		
Sample	**Bag 1**	**Bag 2**
Control	No	No
1	No	No
2	No	No
3	No	No

Summary

This testing further confirmed, in conjunction with the submersion and aerosol insult testing, that the connection of the male and female fittings is robust against bacterial intrusion.

Conclusion

Three replicates and a control were tested, and each sample experienced NO ingress of the Geobacillius solution.

11.11 Cyclic Study

Materials Tested

Polypropylene and Kynar housings with EPDM O-rings

Purpose

To illustrate what the customer will expect with respect to cycles before failure of the seals and the housing materials. These results should be viewed as a reference as different fluids flowing through the connector can influence these results and as such, SeriesLock recommends that internal testing be completed on a specific fluid flow

Method

SeriesLock cyclic testing was completed on product with polypropylene and Kynar housings with EPDM O-rings. The goal was to determine the usable cycle count that a customer would expect when using a SeriesLock connector.
Testing was replicated three (3) times using the following female/male combinations:

Polypropylene Housings / EPDM O-Rings:
B-FV-PO-ES-3 / B-MV-P-ES-2
MBV-FV-PO-ES-4 / MBV-MV-P-E-4

Kynar Housings / EPDM O-Rings:
B-FV-KO-ES-3 / B-MV-K-ES-2
MBV-FV-KO-ES-4 / MBV-MV-K-E-4

The small housings (B-) where chosen for the Series 100 connectors as they present the greatest o-ring challenge with the most stretch and compression when compared to the medium (sizes -4 thru -6) and large (sizes -8 thru -12) housings. The micro housings (MBV) have only one option.

The test included a series of two-hundred connection/disconnection/connection cycles with leak testing and female to male latch engagement testing every two hundred (200) cycles. Additionally, button function and return and connection audible click presence was inspected every cycle.

Results

Polypropylene Housings / EPDM O-Rings:

Female	Male	Cycles Complete
B-FV-PO-ES-3	B-MV-P-ES-2	5000
MBV-FV-PO-ES-4	MBV-MV-P-E-4	5000

1. All polypropylene housings survived 5000 cycles without failure.
2. The 5000-cycle life limit will be extended to the following POLYPROPYLENE part code families since the inner components are all common:
   All B, PM, SF12, SF24, NPT1/8", NPT1/4", NPT3/8", NPT1/2" and PP families.
   MBO, MBV, MPMO and MPMV families.

Kynar Housings / EPDM O-Rings:

Female	Male	Cycles Complete
B-FV-KO-ES-3	B-MV-K-ES-2	5000
MBV-FV-KO-ES-4	MBV-MV-K-E-4	2600

1. Kynar small housings survived 5000 cycles without failure.
2. The 5000-cycle life limit will be extended to the following KYNAR part code families since the inner components are all common:
   All B, PM, SF12, SF24, NPT1/8", NPT1/4", NPT3/8", NPT1/2" and PP families.

3. Kynar MBV (micro) housings survived 2600 cycles without failure. The female to male latch engagement was the limiting factor with this combination. No leaks were reported when disconnected, however, up to 5000 cycles.
4. The 2600 cycle life limit will be extended to the following KYNAR part code families since the inner components are all common:

   All MBO, MBV, MPMO and MPMV families.

Conclusion

All polypropylene and small Kynar housings survived 5000 cycles without failure. The Kynar MBV (micro) housings survived 2600 cycles without failure. The female to male latch engagement was the limiting factor with this combination. No leaks were reported when disconnected, however, up to 5000 cycles.