



GORE[®] STA-PURE[®] Pump Tubing

SERIES PFL

*Durable, resilient, chemically resistant
tubing for peristaltic pump applications*



Validation Guide



GORE® STA-PURE® Pump Tubing

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1.0 Product Overview

1.1 Description

GORE® STA-PURE® Pump Tubing, Series PFL is a durable, resilient tubing product used in peristaltic pumps in pharmaceutical and biopharmaceutical manufacturing. The product delivers consistent flow rate and low incidence of rupture, even with aggressive chemicals. Series PFL enables the pump to work reliably at operating pressures up to 60 pounds per square inch gauge (psig). The product achieves this performance via a unique combination of thermoplastic and elastomeric materials (Figure 1).

1.2 Part Numbering

Series PFL is available in standard configurations as defined in Table 1 and Figure 2. See Appendix A for the standard part list.

Figure 1: Series PFL, Composite Structure in Detail

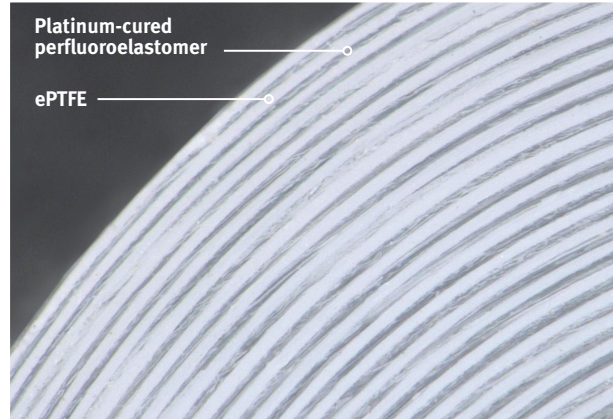
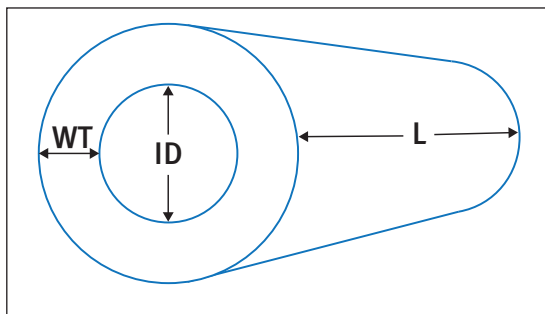


Table 1: Part Number Description

Example	Z	A	12	F
Format	Alphabetic	Alphabetic	Numeric	Alphabetic
Attribute	Inner diameter (ID)	Wall thickness (WT)	Length (L)	Series PFL
Range	1.6 – 25.4 mm (0.063 – 1.0 in.)	0.8 – 4.8 mm (0.031– 0.19 in.)	304.8 – 609.6 mm (12.0 – 24.0 in.)	F

Example: ZA12F is a Series PFL tube with a nominal ID of 3.2 mm (0.13 in.), WT of 1.6 mm (0.063 in.), and L of 304.8mm (12 in.).

Figure 2: Critical Dimensions of GORE® STA-PURE® Pump Tubing, Series PFL



ID Inner diameter
WT Wall thickness
L Length



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1.3 Materials of Construction

GORE® STA-PURE® Pump Tubing, Series PFL is a composite of expanded polytetrafluoroethylene (ePTFE) and a platinum-cured perfluoroelastomer material (Table 2). No peroxide curing agents are used in the formulation.

Table 2: Materials of Construction

Description	Material
Tubing	Composite of thermoplastic and perfluoroelastomer material
Thermoplastic material	ePTFE membrane
Elastomeric material	Platinum-cured perfluoroelastomer
Fluid contact surface	Platinum-cured perfluoroelastomer

1.4 Performance Specifications

Actual performance depends on the specific system in which the tubing is used and may vary depending on the design of the pump and how it is integrated into the drug manufacturing process. To simulate challenging, real-world applications, Gore tested Series PFL under rigorous conditions up to 60 psig.

1.4.1 Biocompatibility

Series PFL is verified annually to meet the requirements of the following tests:

- USP <87> Biological Reactivity Test In Vitro
- USP <88> Biological Reactivity Test In Vivo, Class VI

1.4.2 Physicochemical

The Series PFL tubing was evaluated against the Physicochemical Tests outlined in USP <661> Containers — Plastics and met the limits for each of the specified tests.

1.5 Handling/Operating Specifications

As with other equipment and components, the user is most knowledgeable about the formulation of the working fluid. Therefore, the user is responsible for validating that the Series PFL is suitable for use with the specific formulation of the working fluid. The user is also responsible for validating that Series PFL is suitable for use in the process after sterilization, including determining the number of cycles and sterilization conditions.

1.5.1 Cleaning and Sterilization

Series PFL has been validated to operate after steam-in-place/clean-in-place (SIP/CIP) and autoclave sterilization.

Irradiation sterilization methods such as gamma or electron beam should never be used because they may damage or degrade the mechanical properties of the product.

1.5.2 Flow, Durability, and Operating Pressure

Series PFL maintains reliable and consistent flow up to 60 psig following sterilization.

1.5.3 Chemical Resistance

Series PFL maintains reliable and consistent flow in a peristaltic pump when tested with organic solvents commonly used as pharmaceutical feedstock chemicals.

1.5.4 Packaging

Each Series PFL tube is heat sealed in a single polyethylene bag. Each bag is labeled with the part number, lot number, product description, critical dimensions, and date of manufacture.

1.5.5 Product Shelf Life

The expiration date for Series PFL is four years from the date of manufacture. This date is based on an accelerated aging study to simulate storage of the product for four years at room temperature and applies to the product in its original packaging.

2.0 Compliance Statements

2.1 FDA-Regulated Status

Series PFL is neither classified nor regulated as a medical device and is not subject to FDA regulation. Series PFL is not intended to be used in medical device applications and is not certified to comply with food contact regulations.

2.2 Animal-Derived Materials

No materials of animal origin are used as raw materials or additives. No packaging materials of animal origin come in direct contact with Series PFL tubing.

2.3 Product Stewardship

Series PFL and its primary packaging materials are manufactured following the appropriate material and regulatory requirements. Please contact Gore for current compliance statements.



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3.0 Quality Control Statements

3.1 Manufacturing Environment

GORE® STA-PURE® Pump Tubing, Series PFL is manufactured and packaged in an environment that follows clean concepts principles in order to reduce particulates. In general, clean concepts include, but are not limited to, the use of hair nets, clean room gowns, designated shoes or booties, nitrile gloves, a changing room separate from the manufacturing area, and tacky mats before the changing room entrance. HEPA filters are used for supply air into the changing room and manufacturing area. The filters are changed out according to a preventative maintenance schedule.

3.2 Quality Management System

Series PFL is manufactured within a quality system that is certified to ISO 9001.

3.3 Traceability

Each lot of Series PFL is given a unique identifier to allow for traceability of all raw materials.

3.4 Lot Release Testing

The inner diameter, wall thickness, and length of the tubing are measured for each manufacturing lot per standard operating procedures. The product is checked to ensure that these dimensions meet tolerance specifications.

4.0 Performance Test Methods and Results

4.1 Biocompatibility

4.1.1 USP <87> Biological Reactivity Tests In Vitro

The purpose of this study of Series PFL was to determine the potential for cytotoxicity in accordance with USP <87> Biological Reactivity Tests In Vitro. The sample of Series PFL was extracted with single-strength Minimum Essential Medium (1X MEM) at 37°C (98.6°F) for 24 hours. Extracts from positive and negative control articles were similarly prepared. The results of this test verified that the Series PFL extract was non-cytotoxic and met the requirements of the USP standard.

4.1.2 USP <88> Biological Reactivity Tests In Vivo

Series PFL tubing was subjected to USP Plastic Class VI testing. Systemic toxicity and intracutaneous toxicity studies used extracting media for the Series PFL test article at 70°C (158°F) for 24 hours. In both studies, the test article extracts did not produce a significantly greater systemic or tissue reaction than the control extracts. For the muscle implantation study, the macroscopic reaction was not significant when compared to the control material. The results of the testing verified that Series PFL met the requirements of a USP Plastic Class VI.

4.2 Physicochemical

The purpose of this study was to describe the physicochemical attributes of Series PFL. A sample of Series PFL was extracted at 70°C (158°F) for 24 hours in purified water. A control of purified water without a Series PFL sample was similarly prepared. Non-volatile residue, residue on ignition, heavy metals, and buffering capacity were determined for the Series PFL sample. Test results confirm that Series PFL meets the limits for USP <661> Containers — Plastics, Physicochemical Tests.

5.0 Handling/Operating Test Methods and Results

5.1 Flow, Durability, and Operating Pressure

Series PFL was tested for flow stability and durability in a peristaltic pump to ensure reliable performance. For this testing, Gore defined failure as any of the following:

- Rupture
- Leakage
- Sustained reduction in flow of 25 percent or more
- Inability to sustain desired operating pressure

5.1.1 Cleaning and Sterilization

Samples of Series PFL were subjected to CIP/SIP conditions before and during pump testing. Each CIP cycle consisted of two chemical rinse cycles — one with Steris CIP 100® Alkaline Process and Research Cleaner and the other with Steris CIP 200® Acid-Based Process and Research Cleaner. The cleaning agents were recirculated through the tubing at 82°C (180°F) for 30 minutes. Each SIP cycle was conducted at 125°C (257°F) for 30 minutes. Five CIP/SIP cycles were employed in conjunction with pump testing at 10 psig, and one cycle was employed with pump testing at 60 psig.



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5.1.2 Test Method Summary

Starting at room temperature, cleaned and sterilized GORE® STA-PURE® Pump Tubing Series PFL tube elements underwent continuous pumping of deionized (DI) water until they failed.

Six Series PFL samples were tested in Watson-Marlow 600 Series two-roller peristaltic pumps at a discharge pressure of 10 psig and a pump speed of 165 revolutions per minute (rpm). Taken from multiple manufacturing lots, these samples had an inner diameter (ID) of 12.7 mm and a wall thickness (WT) of 3.2 mm.

Eighteen additional Series PFL samples were tested in Watson-Marlow 500 Series two-roller pumps at 60 psig and 220 rpm. Also taken from multiple manufacturing lots, these samples had a 6.4 mm ID and 2.4 mm WT.

5.1.3 Test Results

The 12.7 mm x 3.2 mm tubing elements were tested at 10 psig until they failed. Based on a one-sided lower-limit prediction interval, there is a 95 percent probability that any tube will perform without failure for at least 95 hours, with the average tube performing for 194 hours. Just prior to failure, the flow rate was 2 percent less on average than the initial flow rate.

The 6.4 mm x 2.4 mm tubing elements were tested at 60 psig until they failed. Based on a one-sided lower-limit prediction interval, there is a 95 percent probability that any tube will perform without failure for at least 76 hours, with the average tube performing for 130 hours. Just prior to failure, the flow rate was 15 percent less on average than the initial flow rate.

5.2 Chemical Resistance

Series PFL was tested for flow stability and durability in a peristaltic pump to ensure reliable performance with aggressive chemicals. For this testing, Gore defined failure as described in Section 5.1.

5.2.1 Test Method Summary

Three sets of Series PFL samples were taken from multiple manufacturing lots and tested in a Watson-Marlow 600 Series two-roller peristaltic pump at a discharge pressure of 10 psig and pump speed of 165 rpm. All three sets consisted of two samples with an ID of 12.7 mm and WT of 3.2 mm. As described in Section 5.1.1, all samples were subjected to CIP/SIP conditions for five cycles.

- One set ran with acetic acid (99% concentration) as the working fluid
- One set ran with acetone (99% concentration) as the working fluid
- One set ran with ethanol (99% concentration) as the working fluid

Starting at room temperature, the cleaned and sterilized samples underwent continuous pumping of the organic solvents until they failed.

5.2.2 Test Results

Based on a statistical comparison (using an alpha of 0.05), the overall performance of the samples that underwent pumping of organic solvents was not significantly different from the performance of the samples that underwent pumping of DI water at 10 psig (Sections 5.1.2 and 5.1.3). For each organic solvent, the samples' average operating life was equal to or greater than 194 hours, which was the average life of all samples that underwent pumping with DI water at 10 psig.

5.3 Product Shelf Life

To ensure that the Series PFL meets its functional requirements for the labeled shelf life of four years, a product shelf-life study of representative samples was conducted. The evaluation within this study focused on Series PFL after accelerated aging per ASTM F1980-07. Testing was conducted to evaluate mechanical, physicochemical, and cytotoxic functionalities.

To simulate the potential impact of shipping and handling prior to aging, all samples were pre-conditioned at worst-case hot and cold transit conditions. They were also subjected to simulated, worst-case distribution cycles in accordance with ASTM D4169-09.

Accelerated aging was conducted in an environmentally controlled chamber at 90°C (194°F), based on ASTM F1980-07 using a Q10 = 2 aging model. Material characterization studies confirmed that 90°C (194°F) was acceptable. Assuming a room temperature of 23°C (73°F), the accelerated aging time of 14 days was considered equivalent to a real-time aging period of four years. After accelerated aging, the samples underwent a single autoclave cycle of 121°C (250°F) for 30 minutes.

Acceptance criteria were met for all samples upon completion of the following tests:

- Burst pressure per ASTM D380-94
- USP <661> Containers — Plastics, Physicochemical Tests
- USP <87> Biological Reactivity Tests In Vitro

The results of the accelerated aging study support an expiration date of four years from the date of manufacture.



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Appendix A: GORE® STA-PURE® Pump Tubing, Series PFL Part List

Gore Part Number	Inner Diameter (mm)	Wall Thickness (mm)	Length (mm)
XZ14F	2.80 ± 0.20	0.8 ± 0.1	355.6 ± 3.0
YA12F	1.60 ± 0.20	1.6 ± 0.2	304.8 ± 3.0
YA14F	1.60 ± 0.20	1.6 ± 0.2	355.6 ± 3.0
ZA12F	3.20 ± 0.25	1.6 ± 0.2	304.8 ± 3.0
ZA14F	3.20 ± 0.25	1.6 ± 0.2	355.6 ± 3.0
AA12F	4.80 ± 0.25	1.6 ± 0.2	304.8 ± 3.0
AA14F	4.80 ± 0.25	1.6 ± 0.2	355.6 ± 3.0
BA12F	6.40 ± 0.25	1.6 ± 0.2	304.8 ± 3.0
BA14F	6.40 ± 0.25	1.6 ± 0.2	355.6 ± 3.0
CA12F	8.00 ± 0.25	1.6 ± 0.2	304.8 ± 3.0
CA14F	8.00 ± 0.25	1.6 ± 0.2	355.6 ± 3.0
YB14F	1.60 ± 0.20	2.4 ± 0.2	355.6 ± 3.0
ZB14F	3.20 ± 0.25	2.4 ± 0.2	355.6 ± 3.0
AB14F	4.80 ± 0.25	2.4 ± 0.2	355.6 ± 3.0
BB14F	6.40 ± 0.25	2.4 ± 0.2	355.6 ± 3.0
CB14F	8.00 ± 0.25	2.4 ± 0.2	355.6 ± 3.0
DB24F	9.50 ± 0.25	2.4 ± 0.2	609.6 ± 3.0
BC24F	6.40 ± 0.25	3.2 ± 0.2	609.6 ± 3.0
DC24F	9.50 ± 0.25	3.2 ± 0.2	609.6 ± 3.0
EC24F	12.70 ± 0.25	3.2 ± 0.2	609.6 ± 3.0
FC24F	15.90 ± 0.50	3.2 ± 0.2	609.6 ± 3.0
LH15F	12.00 ± 0.25	4.0 ± 0.4	381.0 ± 3.0
NH15F	17.00 ± 0.50	4.0 ± 0.4	381.0 ± 3.0
ED24F	12.70 ± 0.25	4.8 ± 0.4	609.6 ± 3.0
FD24F	15.90 ± 0.50	4.8 ± 0.4	609.6 ± 3.0
GD24F	19.10 ± 0.50	4.8 ± 0.4	609.6 ± 3.0
HD24F	25.40 ± 0.50	4.8 ± 0.4	609.6 ± 3.0



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Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers.

GORE® STA-PURE® Pump Tubing, Series PFL products, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

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