GORE® STA-PURE® Pump Tubing
Series PFL

Durable, resilient, chemically resistant tubing for peristaltic pump applications

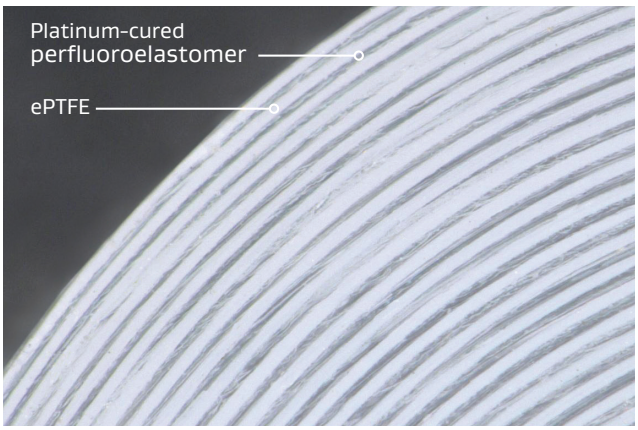
RELIABILITY WITH AGGRESSIVE CHEMICALS

Product Description

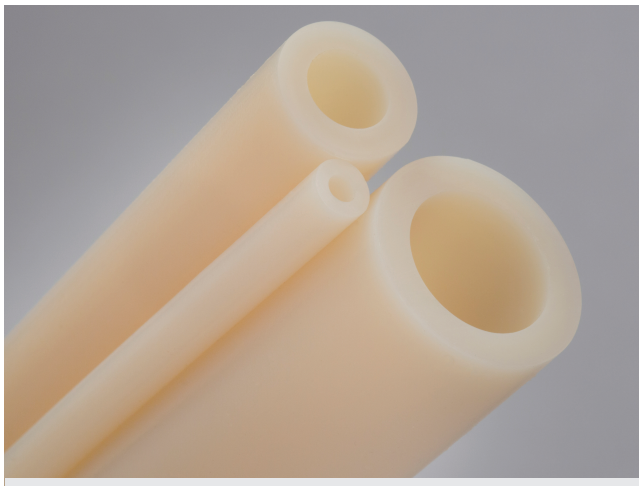
GORE STA-PURE Pump Tubing Series PFL enables reliable peristaltic pump operation in critical pharmaceutical and biopharmaceutical processing applications that include aggressive chemicals. The unique, chemically inert composite of Series PFL increases its durability for greater security against catastrophic failure due to rupture or chemical attack. In addition, the patented structure of the composite enables consistent flow rates over extended production cycles up to 60 psig.

Available in standard sizes, Series PFL withstands the rigors of clean-in-place and steam-in-place (CIP/SIP) processing, which helps simplify sterile fluid processing applications.

Tubing structure in detail



Unlike conventional tubing, Series PFL is manufactured with a patented composite structure of platinum-cured perfluoroelastomer and expanded polytetrafluoroethylene (ePTFE) for increased reliability with aggressive chemicals in peristaltic pumps.



Key Features and Benefits

Chemical Resistance

- Provides better chemical compatibility than silicone and thermoplastic elastomer (TPE) tubing
- Performs reliably with common organic solvents
- Minimizes incidence of premature rupture

High Resilience

- Maintains process stability
- Delivers consistent flow rate

Standard Sizes

- Retrofits easily to commonly used peristaltic pumps

Compatible with CIP/SIP and autoclave sterilization

- Provides a flexible solution for industry-standard cleaning/sterilization procedures
- Supports sterile fluid processing

Together, improving life

GORE® STA-PURE® Pump Tubing

Series PFL

Biocompatability

GORE STA-PURE Pump Tubing Series PFL meets the following requirements*:

USP <87> Biological Reactivity Tests In Vitro
USP <88> Biological Reactivity Tests In Vivo Class VI

* Results are verified annually.

Performance Data Summary

GORE STA-PURE Pump Tubing Series PFL was tested for durability in peristaltic pumps over a wide range of discharge pressures (see following table).

Series PFL Tube Life at End of Test[a]

Discharge Pressure (psig)	Tube Life (hours)
10	> 330[b]
60	85 ± 48[c]

a. Continuous pumping of room temperature deionized water in Watson-Marlow 500 and 600 Series peristaltic pumps. The 500 Series pumps were used for testing at 60 psig with pump head speed of 220 rpm (two rollers). The 600 Series pumps were used for testing at 10 psig with pump head speed of 165 rpm (two rollers). Samples selected represent the worst-case configuration of pump and tube size based on mechanical stresses imposed by the pump on the tube.

b. Tube size = 12.7 mm (ID) x 3.2 mm (WT); When testing was terminated at a minimum of 330 hours, all 6 samples were performing without failure. Failure is defined as rupture, leakage, sustained flow reduction of 25 percent or more, or inability to sustain operating pressure. Tubing was subjected to conditions similar to 5 CIP/SIP cycles (3 before and 2 during testing).

c. Tube size = 6.4 mm (ID) x 2.4 mm (WT); 6 samples were tested until failure as defined in (b) above. The operating life until failure is presented as the average and standard deviation for all samples. The minimum observed value was 28 hours. Before testing, tubing was subjected to conditions similar to 1 CIP/SIP cycle.

Chemical Resistance

Series PFL was also tested to ensure reliable performance with aggressive chemicals as compared to deionized (DI) water. Twelve (12) samples were tested in a Watson-Marlow 600 Series two-roller peristaltic pump at a discharge pressure of 10 psig and speed of 165 rpm. The samples had a nominal ID of 12.7 mm and nominal WT of 3.2 mm. The samples were subjected to CIP/SIP conditions for 5 cycles (3 before and 2 during testing). Working fluids consisted of DI water (6 samples), and 99% concentrations of acetic acid, acetone, and ethanol (2 samples each). The mean tube life of the samples that underwent pumping of organic solvents was not significantly different from the samples that underwent pumping of DI water.

Sterilization

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

Manufacturing Environment and Quality

Series PFL is manufactured and packaged in an ISO 14644-1 Class 7 cleanroom in a manner that adheres to relevant current Good Manufacturing Practices (cGMP) as defined in the Gore PharmBIO Products' quality system which is certified to ISO 13485 and ISO 15378. Every Series PFL product is visually inspected for contamination and for defects in materials and workmanship. The inner diameter, wall thickness, and length of the tubing are measured for each manufacturing lot and checked to ensure conformance to specifications.

GORE® STA-PURE® Pump Tubing

Series PFL

Storage/Shelf Life

The expiration date is four years from the date of manufacture based on an accelerated aging study. The product should be stored in its original packaging at room temperature.

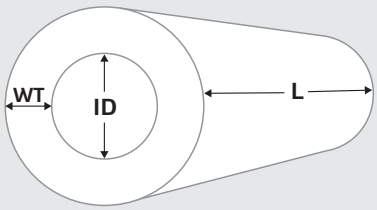
Ordering Information

Series PFL products are available in standard sizes through select channel partners. Please contact Gore for more information.

GORE STA-PURE Pump Tubing Series PFL Validation Guide is available upon request.

Dimensions

ID Inner diameter
WT Wall thickness
L Length



Part Number Description

Example	Z	A	12	FE
Attribute	Inner diameter (ID)	Wall thickness (WT)	Length (L)	Series PFL
Nominal 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)	FE

Example: ZA12FE 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).

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, and medical device manufacturers. GORE STA-PURE Pump Tubing, 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.

Americas | W. L. Gore & Associates, Inc.
402 Vieve's Way, Elkton, MD 21921 • USA
T +1 410 506 1715 Toll-free (US) 1 800 294 4673
Email pharmbio@wlgore.com

Europe | W. L. Gore & Associates, GmbH
Wernher-von-Braun-Strasse 18, 85640 Putzbrunn, Germany
T +49 89 4612 3456 Toll free 0 800 4612 3456
Email pharmbio_eu@wlgore.com

gore.com/pharmbio

PB4630-R2-DSH-US-JUL24