

Durable and resilient tubing for high-pressure peristaltic pump applications

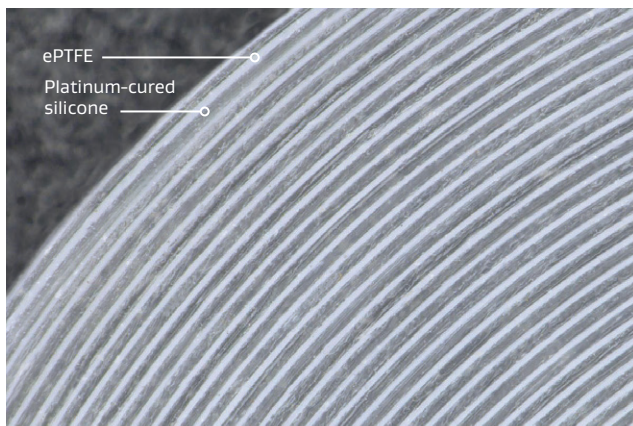
REDUCE RISK THROUGH GREATER PROCESS SECURITY

Product Description

GORE STA-PURE Pump Tubing Series PCS enables reliable peristaltic pump operation in critical pharmaceutical and biopharmaceutical processing applications. The unique composite structure of the tube adds strength and high flex durability for greater security against rupture under challenging conditions, up to 100 psig. Additionally, this highly resilient structure supports consistent flow rate over extended production cycles, helping to maintain process stability.

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

Tubing structure in detail



Unlike conventional tubing, Series PCS is manufactured with a patented composite of platinum-cured silicone rubber, reinforced with expanded polytetrafluoroethylene (ePTFE) for added strength and resilience.



Key Features and Benefits

High Flex Durability

- Enables long production cycles
- Minimizes incidence of rupture at high pressures

High Resilience

- Maintains process stability
- Delivers consistent flow rate

Standard Sizes

- Retrofits easily to industry-standard peristaltic pumps

Compatible with CIP/SIP and autoclave sterilization

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

GORE® STA-PURE® Pump Tubing

Series PCS

Biocompatibility

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

Series PCS Tube Life at End of Test^a

Discharge Pressure (psig)	Tube Life (hours)
10	> 2,160 ^b
100	106 ± 48 ^c

a. Continuous pumping of room temperature deionized water in Watson-Marlow 500 Series peristaltic pumps, with pump head speed of 220 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 = 9.5 mm (ID) x 2.4 mm (WT). When testing was terminated at 2,160 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 cycles before testing and 2 cycles during testing).

c. Tube size = 3.2 mm (ID) x 2.4 mm (WT). Six tubing 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 52 hours. Before testing, tubing was subjected to conditions similar to 1 CIP/SIP cycle.

Sterilization

Series PCS has been validated to operate after 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 PCS 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 PCS 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 PCS

Storage/Shelf Life

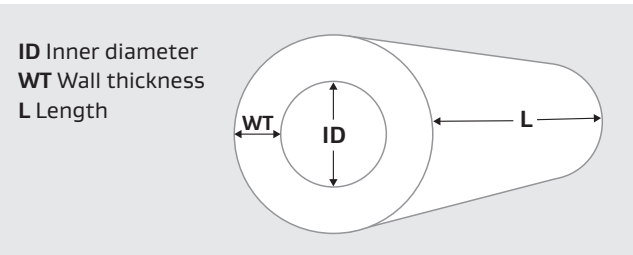
The expiration date is four years from the date of manufacture based on an accelerated aging study. The product should be stored in its original packaging at room temperature.

Ordering Information

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

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

Dimensions



Part Number Description

Example	Z	A	12	ME
Attribute	Inner diameter (ID)	Wall thickness (WT)	Length (L)	Series PCS
Nominal Range	1.6 – 25.4 mm (0.063 – 1.0 in)	0.8 – 9.0 mm (0.031 – 0.354 in)	304.8 – 796.0 mm (12.0 – 31.3 in)	ME

Example: ZA12ME is a Series PCS tube with a nominal ID of 3.2 mm (0.13 in.), WT of 1.6 mm (0.063 in.), and L of 304.8 mm (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.

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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