



GORE® STA-PURE® Pump Tubing

SERIES PCS

*Durable and resilient
tubing for high-pressure
peristaltic pump applications*

Reduce risk through greater process security

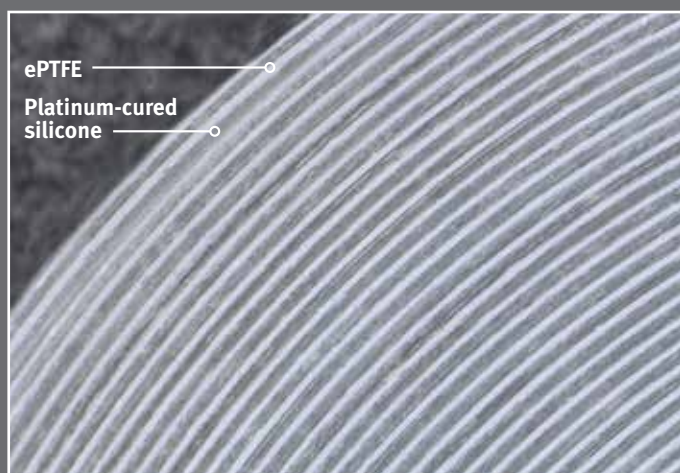
Product Description

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, GORE® STA-PURE® Pump Tubing — 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

Biological and Physicochemical Testing

GORE® STA-PURE® Pump Tubing — Series PCS meets the following requirements:

Biological Testing	USP <88> Biological Reactivity Tests in Vivo, USP Plastic Class VI
	USP <87> Biological Reactivity Tests in Vitro, USP Elution Cytotoxicity Study
Extractables Testing	USP <661> Containers — Plastics, Physicochemical Tests (Aqueous)

Results are verified annually.



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Performance Data Summary

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

Series PCS Tube Life and Flow Decay at End of Test^a

Discharge Pressure (psig)	Tube Life (hours)	Loss of Initial Flow Rate (%)
10	> 2,160 ^b	5.6
100	28 ^c	4.1

^a Continuous pumping of room temperature water in Watson-Marlow 500 Series peristaltic pumps, with pump head speed of 220 rpm (two rollers).

^b Tube size = 9.5 mm (inner diameter) x 2.4 mm (wall thickness). When testing was terminated at 2,160 hours, all 6 samples were performing without rupture, leakage, flow reduction of 25 percent or more, or inability to sustain operating pressure. Tubing was subjected to conditions similar to five CIP/SIP cycles (three cycles before testing and two cycles during testing).

^c Tube size = 3.2 mm (inner diameter) x 2.4 mm (wall thickness). All 18 tubing samples were tested until failure. Prior to testing, tubing was subjected to conditions similar to one CIP/SIP cycle. 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 28 hours.

Sterilization

GORE® STA-PURE® Pump Tubing — Series PCS has been validated to operate after CIP/SIP or autoclave sterilization; however, users must validate their own sterilization process. Radiation sterilization should never be employed.

Ordering Information

GORE® STA-PURE® Pump Tubing — Series PCS products are available in standard sizes through select channel partners. Please contact Gore for more information.

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

Manufacturing Environment and Quality

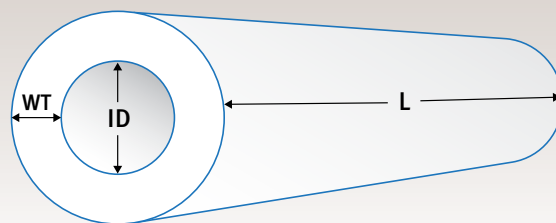
GORE® STA-PURE® Pump Tubing — Series PCS is produced in a facility certified to ISO 9001 and is manufactured in an environment that follows clean concept principles to reduce particulates. Every Series PCS product is visually inspected for contamination and for defects in materials and workmanship. The inner diameter, wall thickness, and length of the tubing are measured for each manufacturing lot and checked to ensure conformance to specifications.

Storage

Storage – It is recommended to store tubing in its original packaging at room temperature.

Shelf Life – When properly stored, the tubing should be used within four years.

Dimensions



Example	Z	A	12	M
Format	Alphabetic	Alphabetic	Numeric	Alphabetic
Attribute	Inner diameter (ID)	Wall Thickness (WT)	Length (L)	Series PCS
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)	M

Example: ZA12M is a Series PCS tube 12 inches long with a nominal inner diameter of 3.2 mm and a wall thickness of 1.6 mm.

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 PCS 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.

gore.com/pharmbio

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Not intended for use in medical device or food contact applications or with radiation sterilization

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