

Flex-Durable and Resilient Pump Tubing for Irradiated Single-Use Assemblies

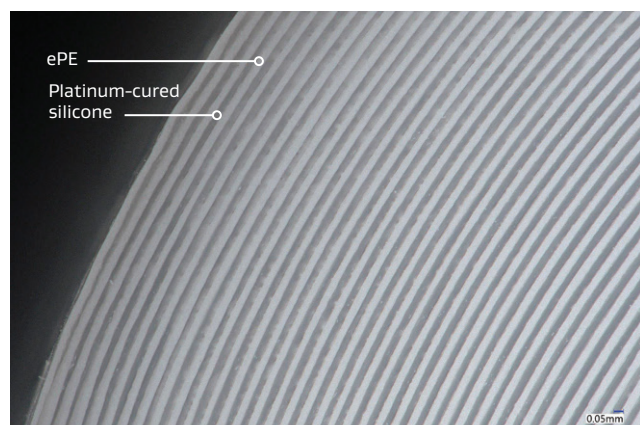
REDUCE RISK OF TUBING FAILURE

Product Description

Radiation compatible and robust peristaltic pump tubing is a requirement for single use systems to prevent loss of valuable drug substance and product. GORE® STA-PURE® SU PRO™ Transfer Pump Tubing significantly reduces risk of tubing failure in critical biopharmaceutical manufacturing operations. Its unique composite structure enables high flex durability and resilience for extending tubing life in challenging upstream and downstream applications, e.g. continuous bioprocessing. It is designed to achieve a minimum pump tube life of 60 days at low pressures (0-5 psig) and a minimum of 14 days at higher pressures up to 60 psig (4 bar), based on testing according to the test method described herein.

Tubing Design

Unlike conventional tubing, GORE STA-PURE SU PRO Transfer Pump Tubing is a composite of platinum-cured silicone, reinforced with expanded polyethylene (ePE) for added strength and resilience (patent pending). The silicone formulation is the same as GORE STA-PURE Pump Tubing, Series PCS, which has been used in biopharma for over 25 years.



The composite structure of GORE STA-PURE SU PRO Transfer Pump Tubing is represented here by a magnified, cross-section image of the tube wall.



Key Features and Benefits

Flex-Durable

- Reduce risk of batch loss
- Eliminate preventative measures to change or move position of tubing within the pump
- Extend tube life at low and high pressures

Resilient

- Maintain consistent flow rate
- Extend tube life by minimizing flow decay

Radiation Compatible

- Suitable for single use assemblies to reduce contamination risks
- Peristaltic pump performance demonstrated after exposure to 45 – 56 kGy of gamma radiation*

Available in Standard Sizes

- Suitable for industry-standard peristaltic pumps and pump heads

*The user is responsible for validating performance after exposure to their specific sterilization conditions

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing

Biocompatibility

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing was tested and meets the following requirements:

USP <87> Biological Reactivity Tests In Vitro

USP <88> Biological Reactivity Tests In Vivo Class VI

Performance Data Summary

Data and results herein are from durability testing in peristaltic pumps conducted over a wide range of discharge pressures according to the following:

- Continuous pumping of room temperature deionized water in Watson-Marlow 500 Series peristaltic pumps, with pump head speed of 220 rpm (two rollers)
- All GORE STA-PURE SU PRO samples were exposed to gamma radiation in the range of 45 – 56 kGy
- Tube life was measured as time until failure. Tube failure was defined as rupture, leakage, sustained flow reduction of 25 percent or more, or inability to sustain operating pressure.



Figures 1 and 2 show results at elevated pressure and compares GORE STA-PURE SU PRO Transfer Pump Tubing to a thermoplastic elastomer (TPE) tubing formulation used in bioprocessing applications.

Figure 1. Comparative Testing at a Pump Discharge Pressure of 4 bar (60 psig)

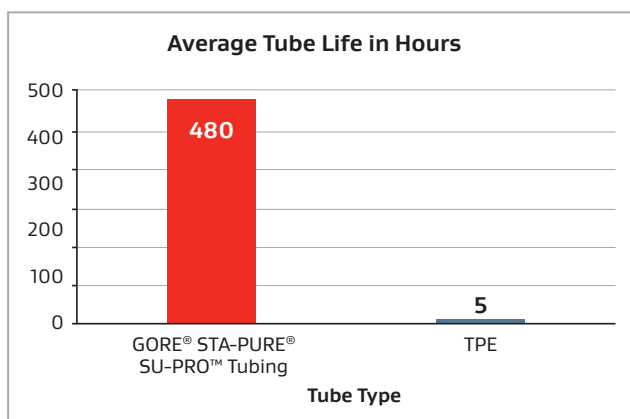
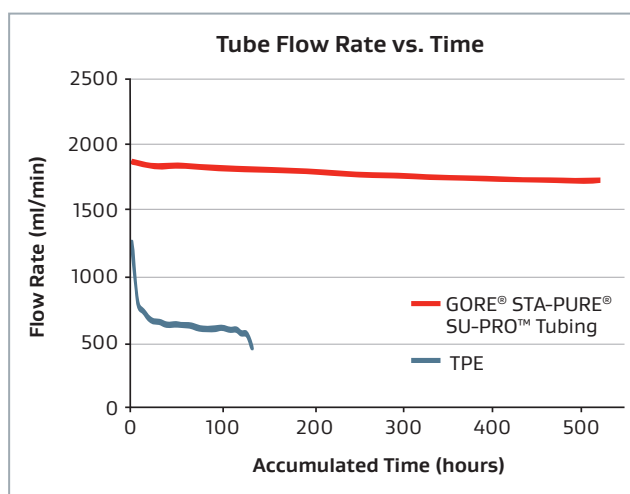


Figure 2. Comparative Testing at a Pump Discharge Pressure of 4 bar (60 psig)



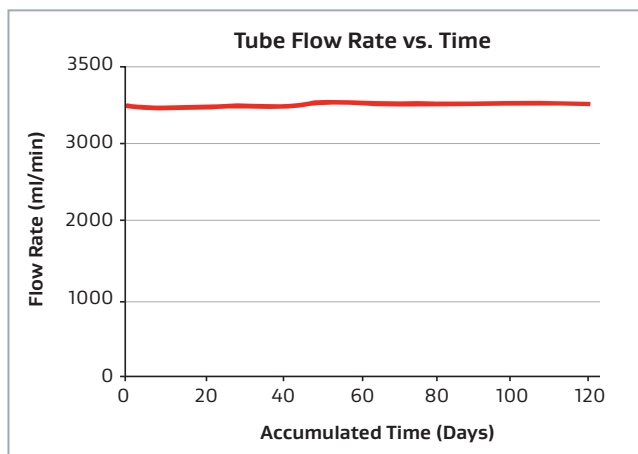
NOTES (testing at elevated pressure)

- Sample size of six (6) for each tube type
- The data is a representative sampling, may not be indicative of future results, and does not constitute creation of a specification
- Nominal tube size: 6.4 mm (inner diameter) x 2.4 mm (wall thickness)
- Minimum observed tube life for an individual GORE STA-PURE SU PRO sample at 4 bar (60 psig): 415 hours
- Minimum observed tube life for an individual TPE sample at 4 bar (60 psig): 1.6 hours
- All TPE samples were not irradiated
- Average tube life for STA-PURE SU PRO Tubing in Figure 1 is based on 3 of 6 samples reaching end-of-test due to tube failure. The remaining 3 samples performed without failure until the test was terminated at 504 hours (21 days).

Gore® STA-PURE® SU PRO™ Transfer Pump Tubing

Figure 3 shows test results at low pressure for Gore STA-PURE SU PRO Transfer Pump Tubing.

Figure 3. Testing at a Pump Discharge Pressure of 0.3 bar (5 psig)



NOTES (testing at low pressure)

- Sample size of six (6)
- The data is a representative sampling, may not be indicative of future results, and does not constitute creation of a specification
- Nominal tube size: 9.5 mm (inner diameter) x 2.4 mm (wall thickness)
- All samples performed without failure until the test was terminated at 2,866 hours (119 days).

Particulates

Subvisible inherent particulates within the fluid path of as-manufactured, non-irradiated tube samples was determined. The flow imaging method of USP <1788> was used to measure particle count with an extraction method that met qualification criteria of ASTM E3230-25. Results are presented in Figure 4 for a nominal tube size of 9.5 mm ID x 2.4 mm WT x 406 mm L.

Figure 4. Average Particulate Per Lot

Lot Number	Number of Samples	Particles/mL (≥10 μm)	Particles/mL (≥25 μm)
1	3	1.48	0.30
2	3	0.41	0.15
3	3	0.82	0.00

Bacterial Endotoxins

Non-irradiated, whole-product tube samples were tested to determine the level of bacterial endotoxins. The test method utilized was validated per guidance provided in USP<85> and ANSI/AAMI ST72. Figure 5 contains the test results for three lots, each of a different tube size.

Figure 5. Bacterial Endotoxin Per Lot

Lot Number	Nominal Tube Size, mm (ID x WT x L)	Number of Pooled Samples	Endotoxin Level (EU/mL)
1	1.6 x 1.6 x 356	3	<0.01
2	25.4 x 4.8 x 610	3	<0.01
3	17.0 x 4.0 x 381	3	<0.01

Manufacturing Environment and Quality

GORE STA-PURE SU PRO Transfer Pump Tubing 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. The product is 100% 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.

Product Stewardship/Regulatory Compliance

GORE STA-PURE SU PRO Transfer Pump Tubing is manufactured following relevant material and regulatory requirements. Compliance statements are available from Gore.

Extractables

Extractables testing results are available based on Extractables Testing of Polymeric Single-use Components used in Biopharmaceutical Manufacturing (Biophorum, 2020). Contact Gore for details.

Tubing Dimensions

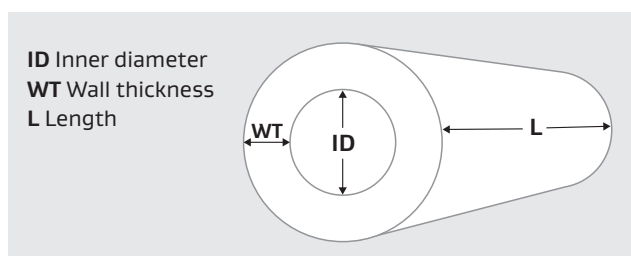
Nominal Range of Critical Tubing Dimensions

Inner diameter (ID) ¹	Wall thickness (WT) ²	Length (L)
1.6 – 25.4 mm (0.063 – 1.0 in)	1.6 – 4.8 mm (0.063 – 0.189 in)	208.0 – 660.4 mm (8.2 – 26.0 in)

1. Nominal ID available at initial commercial launch (April 2026):

1.6 mm, 3.2 mm, 4.8 mm, 6.4 mm, 8.0 mm, 9.5 mm

2. Nominal WT available at initial commercial launch (April 2026): 2.4 mm



Gore PharmBIO Products

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

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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