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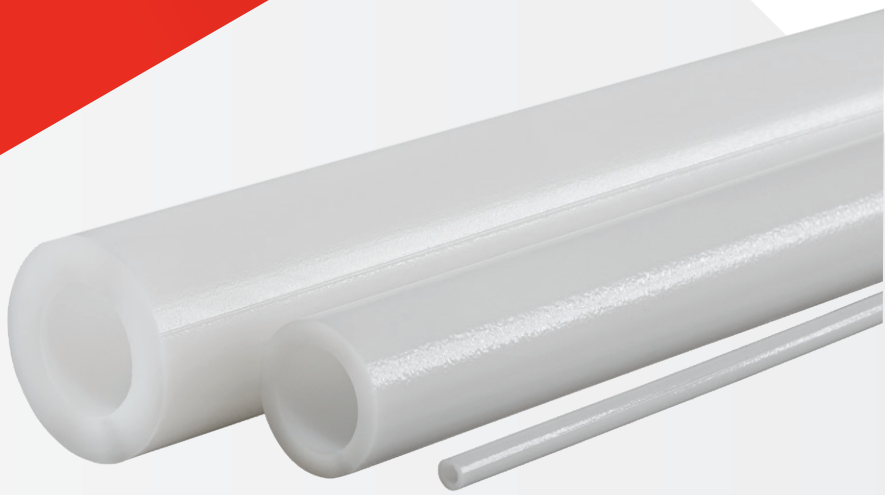
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*Together, improving life*

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

# VALIDATION GUIDE



Robust Peristaltic Pump Tubing
for Irradiated Assemblies used in
Single Use Bioprocessing

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# 1.0 Product Overview

## 1.1 Product Description

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (STA-PURE SU PRO Tubing) is a robust and radiation compatible tubing for use in peristaltic pumps. Flex-durable and resilient, this product enables extended fluid transfers with single-use tubing assemblies used in upstream and downstream biopharmaceutical manufacturing. The product delivers consistent flow rate and low incidence of rupture, even at operating pressures up to 4 bar or 60 pounds per square inch gauge (psig), thus enabling the pump to work reliably under challenging conditions. STA-PURE SU PRO Tubing achieves this performance via a unique combination of thermoplastic and elastomeric materials (Figure 1) and is compatible with gamma sterilization.

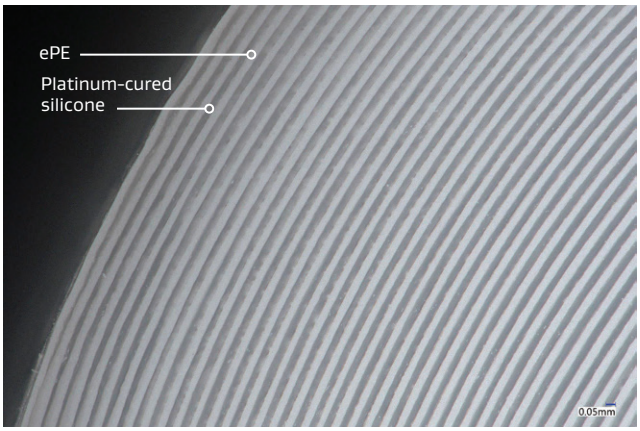



**Figure 1: Composite structure in detail**

## 1.2 Part Numbering

STA-PURE SU PRO Tubing is available in standard configurations as shown in Table 1 and Figure 2.

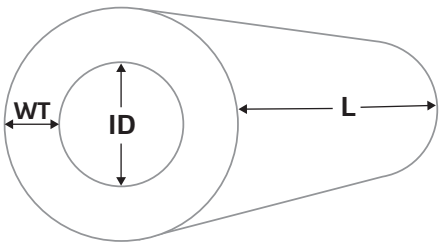
**Table 1: Part Number Description**

| Example | Z | B | 14 | RC |
|---|---|---|---|---|
| Attribute | Inner diameter (ID) | Wall thickness (WT) | Length (L) | **Radiation Compatible** |
| Nominal Range | 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) | |

Example: ZB14RC is STA-PURE SU PRO Tubing with a nominal ID of 3.2 mm (0.13 in.), WT of 2.4 mm (0.094 in.), and L of 355.6 mm (14 in.)

**Figure 2: Critical Dimensions of GORE STA-PURE SU PRO Transfer Pump Tubing**

**ID** Inner diameter
**WT** Wall thickness
**L** Length



## 1.3 Materials of Construction

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing is a composite of expanded polyethylene (ePE) and platinum-cured silicone (Table 2). No peroxide-based curing agents are used in the formulation.

**TABLE 2: Description of Materials of Construction**

| Description | Material |
|---|---|
| Tubing | Composite of thermoplastic and elastomeric materials |
| Thermoplastic material | Expanded polyethylene (ePE) membrane |
| Elastomeric material | Platinum-cured silicone |
| Fluid contact surface | Platinum-cured silicone |

## 1.4 Performance Testing

Actual product performance depends on the specific system and process 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 STA-PURE SU PRO Tubing under rigorous conditions up to 60 psig (4 bar).

### 1.4.1 Pump Tube Life

STA-PURE SU PRO Tubing 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. Following gamma radiation, samples were tested for durability in peristaltic pumps where mean pump tube life exceeded the performance benchmarks of 60 days at 5 psig and 14 days at 60 psig. See Section 4.1 for specific test data and information.

## 1.5 Handling and Operating Information

As with other equipment and components, the user is the most knowledgeable about the formulation of the working fluid. In addition, the performance of the product can only be fully assessed when all necessary operating data is available. Therefore, the user is responsible for validating that STA-PURE SU PRO Tubing is suitable for use with the specific formulation of the working fluid and in the specific application.

### 1.5.1 Sterilization Compatibility

STA-PURE SU PRO Tubing has been tested for operation in peristaltic pumps after gamma irradiation. Sterilization is not performed on the product supplied by Gore. Users of the product are responsible for performing sterilization and any associated sterility claims.

### 1.5.2 Packaging and Labeling

STA-PURE SU PRO Tubing is packaged unsterilized in linear low-density polyethylene (LLDPE) bags. Each finished good, i.e., each tube, is double-bagged. The inner and outer bags are heat-sealed. The inner bag is labeled with the part number, lot number, product description, quantity, date of manufacture, and expiration date. A Certificate of Compliance is provided with each lot of tubing.

### 1.5.3 Product Shelf Life

The expiration date is one year from the date of manufacture. This time period is based on pump tube life test data from a one-year accelerated aging study. See Section 4.2 for specific information on this study. (Three- and four-year accelerated aging studies are in progress. An update to the product shelf life is planned once these studies are completed. Real time aging was started in parallel with the accelerated aging studies.)

## 2.0 Compliance and Regulatory Information

### 2.1 FDA-Regulated Status

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing is neither classified nor regulated as a medical device and is not subject to FDA regulation. It is not intended for use in medical device applications, and it is not certified to comply with food contact regulations.

### 2.2 Product Stewardship

STA-PURE SU PRO Tubing and its primary packaging materials are manufactured following appropriate material and regulatory requirements. Please contact Gore for current compliance statements.

### 2.3 Particulates

Sub-visible inherent particulate within the fluid path of as-manufactured, non-irradiated product 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. See Section 5.1 for specific test data and information.

### 2.4 Bacterial Endotoxins

Representative product samples were tested to determine the level of bacterial endotoxins. See Section 5.2 for specific test data and information.

### 2.5 Biocompatibility

STA-PURE SU PRO Tubing was verified to meet the requirements of the following standardized biocompatibility tests:

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

See Section 5.3 for specific test data and information.

### 2.6 Extractables

Extractables studies were performed by an independent laboratory based on Extractables Testing of Polymeric Single-use Components used in Biopharmaceutical Manufacturing (Biophorum, 2020). Please contact Gore for details related to the test method and results.

## 3.0 Manufacturing Environment and Quality Control

### 3.1 Manufacturing Environment

STA-PURE SU PRO Tubing is manufactured and packaged in an ISO 14644-1 Class 7 cleanroom. Routine viable and non-viable environmental monitoring is performed.

### 3.2 Quality Management System

STA-PURE SU PRO Tubing is manufactured and packaged 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 13485.2016 and ISO 15378.2017.

### 3.3 Traceability

Each lot of STA-PURE SU PRO Tubing 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 and verified to ensure that the dimensions meet tolerance specifications.

### 3.5 Visual Inspection

STA-PURE SU PRO Tubing is 100% visually inspected for contamination and for defects in materials and workmanship.

# 4.0 Performance Test Methods and Results

## 4.1 Pump Tube Life

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing was tested for durability in peristaltic pumps. Pump tube life was defined as either the time to reach the end of test due to tube failure or a stop of the test after a considerable amount of time without failure. Gore defined tube failure as any of the following:

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

Non-aged samples were subjected to gamma radiation at a target of 50 kGy before pump testing. Sets of samples were prepared according to tube size as shown in Table 3.

**TABLE 3**

| Tubing Set | Sample size | Nominal inner diameter, mm | Nominal wall thickness, mm |
|---|---|---|---|
| 1 | 6 | 6.4 | 2.4 |
| 2 | 6 | 9.5 | 2.4 |

Each set of samples underwent continuous pumping of deionized (DI) water at room temperature in Watson Marlow 500 Series pumps at maximum speed with two-roller pump heads according to the parameters listed in Table 4 below.

**TABLE 4**

| Tubing Set | Pump Discharge Pressure, psig (bar) | Speed, rpm |
|---|---|---|
| 1 | 60 (4) | 220 |
| 2 | 5 (0.3) | 220 |

Pump tube life results are presented in Table 5 which demonstrate performance that exceeds the benchmarks of 60 days at 5 psig and 14 days at 60 psig.

**TABLE 5**

| Tubing Set | Mean Pump Tube Life, Hours (Days) | Minimum Pump Tube Life, Hours (Days) |
|---|---|---|
| 1 | 480 (20)[1] | 415 (17)[1] |
| 2 | >2,866 (119)[2] | N/A[2] |

1. Value 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).

2. Value based on 0 of 6 samples reaching end-of-test due to tube failure. All 6 samples performed without failure until the test was terminated at 2,866 hours (119 days).

## 4.2 Product Shelf Life

An accelerated aging study was conducted with representative samples per ASTM F1980-21. Testing was conducted to evaluate pump tube life characteristics. After accelerated aging, the samples underwent a single gamma sterilization dose at a target of 50 kGy.

The samples then underwent continuous pumping of deionized (DI) water at room temperature in Watson Marlow 500 Series pumps at 220 rpm with two-roller heads. As in the case of the testing in Section 4.1, the samples consisted of two tube sizes with each size tested at a different pump discharge pressure. Samples with a nominal tube size of 6.4 mm ID x 2.4 mm WT were tested at 60 psig, and samples with a nominal tube size of 9.5 mm ID x 2.4 mm WT were tested at 5 psig.

The pump tube life achieved met the following mean performance benchmarks: 60 days at 5 psig and 14 days at 60 psig.

## 5.0 Compliance Test Methods and Results

### 5.1 Particulates

Testing was completed on nine (9) total samples of non-irradiated product. Three (3) individual samples were selected from three (3) different lots. The nominal tube dimensions of each sample were 9.5 mm ID x 2.4 mm WT x 406 mm L. The average subvisible inherent particulate for each lot is presented in Table 6.

**TABLE 6**

| 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 |

### 5.2 Bacterial Endotoxins

Non-irradiated, whole product samples were tested using the Limulus Amebocyte Lysate (LAL) Kinetic-Turbidimetric Method to determine the level of bacterial endotoxin contamination. The test method/extraction process was validated per guidance provided in USP<85> and ANSI/AAMI ST72, to demonstrate that STA-PURE SU PRO Tubing does not cause inhibition, enhancement, or otherwise interfere with the accuracy and sensitivity of the test. Table 7 contains the test results for three lots, each of a different tube size.

**TABLE 7**

| 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 | 17.0 x 4.0 x 381 | 3 | <0.01 |
| 3 | 25.4 x 4.8 x 610 | 3 | <0.01 |

### 5.3 Biocompatibility

#### 5.3.1 USP <87> Biological Reactivity Tests In Vitro

The purpose of this study was to determine the potential for cytotoxicity in accordance with USP <87> Biological Reactivity Tests In Vitro. The product test article was first gamma sterilized at a target of 50 kGy and then extracted with single-strength Minimum Essential Medium at 37°C (98.6°F) for 24 hours. Extracts from positive and negative control materials were similarly prepared and analyzed. The results of this test verified that the product extract was not cytotoxic and met the requirements of the USP standard.

#### 5.3.2 USP <88> Biological Reactivity Tests In Vivo

STA-PURE SU PRO Tubing was subjected to USP Plastic Class VI testing after gamma sterilization at a target of 50 kGy. Systemic toxicity and intracutaneous toxicity studies used extracting media for test articles 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 defined in USP <88>. The results of the testing verified that the product met the requirements of USP Plastic Class VI.

## Appendix A: Available Parts as of Initial Commercial Launch (April 2026)

| GORE® STA-PURE® SU PRO™ Transfer Pump Tubing, Gore Part Number | Nominal Tube Size | | Dimensional Specifications | | |
|---|---|---|---|---|---|
| | Inner Diameter (mm) | Wall Thickness (mm) | Inner Diameter (mm) | Wall Thickness (mm) | Length (mm) |
| YB8RYC* | 1.6 | 2.4 | 1.52 ± 0.20 | 2.50 ± 0.20 | 208.0 ± 3.0 |
| YB14RC | 1.6 | 2.4 | 1.52 ± 0.20 | 2.50 ± 0.20 | 355.6 ± 3.0 |
| ZB8RYC* | 3.2 | 2.4 | 3.03 ± 0.25 | 2.50 ± 0.20 | 210.1 ± 3.0 |
| ZB14RC | 3.2 | 2.4 | 3.03 ± 0.25 | 2.50 ± 0.20 | 355.6 ± 3.0 |
| AB8RYC* | 4.8 | 2.4 | 4.62 ± 0.25 | 2.50 ± 0.20 | 210.1 ± 3.0 |
| AB14RC | 4.8 | 2.4 | 4.62 ± 0.25 | 2.50 ± 0.20 | 355.6 ± 3.0 |
| AB16RC | 4.8 | 2.4 | 4.62 ± 0.25 | 2.50 ± 0.20 | 406.4 ± 3.0 |
| AB26RC | 4.8 | 2.4 | 4.62 ± 0.25 | 2.50 ± 0.20 | 660.4 ± 3.0 |
| BB8RYC* | 6.4 | 2.4 | 6.19 ± 0.25 | 2.50 ± 0.20 | 214.9 ± 3.0 |
| BB14RC | 6.4 | 2.4 | 6.19 ± 0.25 | 2.50 ± 0.20 | 355.6 ± 3.0 |
| BB16RC | 6.4 | 2.4 | 6.19 ± 0.25 | 2.50 ± 0.20 | 406.4 ± 3.0 |
| BB24RC | 6.4 | 2.4 | 6.19 ± 0.25 | 2.50 ± 0.20 | 609.6 ± 3.0 |
| BB26RC | 6.4 | 2.4 | 6.19 ± 0.25 | 2.50 ± 0.20 | 660.4 ± 3.0 |
| CB8RYC* | 8.0 | 2.4 | 7.75 ± 0.25 | 2.50 ± 0.20 | 214.9 ± 3.0 |
| CB14RC | 8.0 | 2.4 | 7.75 ± 0.25 | 2.50 ± 0.20 | 355.6 ± 3.0 |
| DB8RYC* | 9.5 | 2.4 | 9.13 ± 0.25 | 2.50 ± 0.20 | 214.9 ± 3.0 |
| DB14RC | 9.5 | 2.4 | 9.13 ± 0.25 | 2.50 ± 0.20 | 355.6 ± 3.0 |
| DB16RC | 9.5 | 2.4 | 9.13 ± 0.25 | 2.50 ± 0.20 | 406.4 ± 3.0 |
| DB24RC | 9.5 | 2.4 | 9.13 ± 0.25 | 2.50 ± 0.20 | 609.6 ± 3.0 |

* Part number consists of a pair of individual tube pieces for double-Y assemblies. Specifications apply to each tube piece.

## 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. 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.

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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