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# Long Term Pumping Assessment With Tuflux<sup>®</sup> Sil

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## Abstract

A comprehensive long term pumping study has been performed on Sartorius Tuflux<sup>®</sup> SIL platinum cured silicone tubing under test conditions that represent a typical biopharmaceutical fed batch process feeding a bioreactor. Test methods were developed to observe visual changes, particles, thickness changes and burst pressure. The results prove that Sartorius Tuflux<sup>®</sup> SIL platinum cured silicone tubing is recommended for similar long term pumping applications.

 **For more information, visit**

[www.sartorius.com/en/products/fluid-management/transferring-sampling/tuflux-tubing](http://www.sartorius.com/en/products/fluid-management/transferring-sampling/tuflux-tubing)

# Introduction

The purpose of this application note is to present the excellent mechanical resistance of Tuflux® SIL, the Sartorius standard platinum cured silicone tubing, for long-term pumping application. This study has been performed by our Confidence® validation service.

# Materials

- Gamma-irradiated Transfer Sets (TS) made of 20 m Tuflux® SIL  $\frac{3}{8}$ " x  $\frac{5}{8}$ " (ID x OD) (FSA117428)
- Counter 9064, Sensor HRLD150, Sampler 3000A (ALB-C-009)
- Profile projector (ALM-C-052)
- Water for Injection (WFI)
- Watson Marlow peristaltic pump 620 UN R(060.414N.020)



Silicone Tubing

# Methods

## 1. Visual Inspection

The tubing section installed in the peristaltic pump is inspected for visual testing of the plastic material after the 20 days of continuous pumping.

## 2. Particles Counting (Subvisible and Visible)

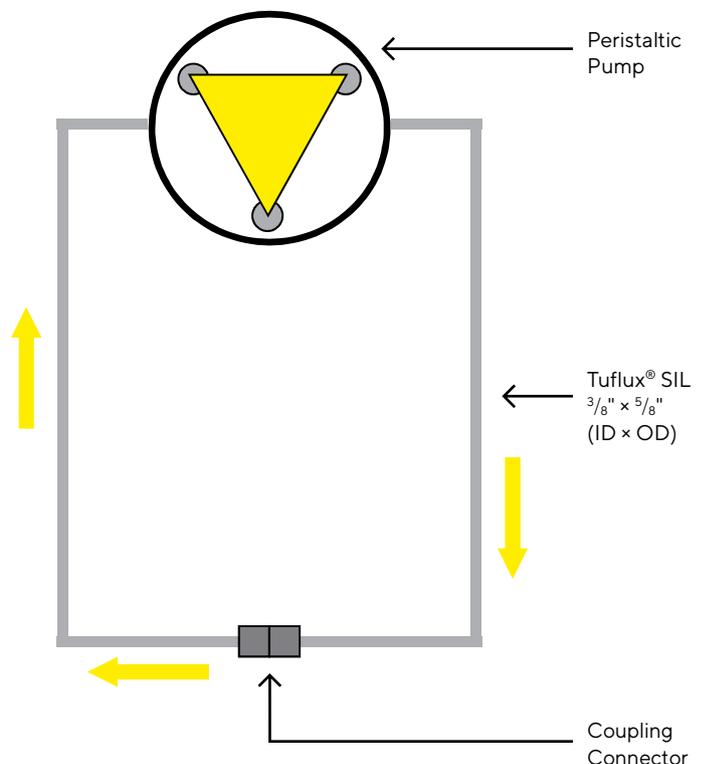
The quantity of subvisible particles is determined in the WFI which is in contact with the tubing after the 20 days of pumping in order to evaluate the compliance of WFI with USP <788> by light obscuration method. Visible particles are also counted in the same test.

## 3. Tubing Thickness Measurement

The tubing is cut at three different locations on the section that was inside the peristaltic pump after 20 days of pumping. The section of tubing was measured with the profile projector and compared to its initial dimensions.

## 4. Burst Pressure Test

The test is performed on the part of the tubing installed on the peristaltic pump according to the international standard NF EN ISO 1402 after the 20 days of pumping. The tubing cut length is installed on the test line. The pressure is measured until the tubing bursts.



Experimental set-up in closed circuit

# Results

## 1. Particles Counting (Subvisible and Visible)

### Subvisible Particles

Results of subvisible particles counting in tubing after 20 days of pumping under test conditions (950 mL, closed circuit)

| Particle Size | Blank Result [particles/mL] | Results at 20 Days [particles/mL] |
|---------------|-----------------------------|-----------------------------------|
| Size ≥ 10 µm  | <1                          | 54                                |
| Size ≥ 25 µm  | <1                          | 3                                 |

Concentration of subvisible particles extrapolated to process step representing a 1,000 L fed-batch application (WFI 1,000 L, opened circuit)

| Particle Size | Extrapolation to a Process Step of 1,000 L Bioreactor [particles/mL] | USP 788 or EP 2.9.19 Acceptance Criteria [particles/mL] | Pass   Fail |
|---------------|--|---|-------------|
| Size ≥ 10 µm  | <1   | 25  | Pass        |
| Size ≥ 25 µm  | <1   | 3   | Pass        |

### Visible Particles

Results of visible particles counting in tubing after 20 days of pumping under test conditions (950 mL, closed circuit)

| Results for the Blank Sample [particles/mL] | Results at t=20 Days [particles/mL] | Extrapolation to Process Condition of 1,000 L Bioreactor [particles/mL] |
|---|-------------------------------------|---|
| 0   | 0                                   | 0   |

## 2. Tubing Thickness

The tubing thickness measurement is performed after 20 days of pumping on three tubing sections located in the peristaltic pump. This data is compared to the tubing dimensions of a gamma-irradiated sample before any pumping.

The average values of three measurements at t=0 and t=20 days are used to calculate the variation of the wall thickness overtime.

| Tubing Dimension        | Variation of Wall Thickness (t=0 – t=20 days) |
|-------------------------|---|
| Tuflux® SIL 3/8" x 5/8" | < 1.5%  |

## 3. Burst Pressure Test

Results of the burst pressure test after 20 days of pumping

| Results for the Reference Sample at t=0 | Variation of Burst Pressure Over Time [%] |
|---|---|
| 5.4 bar                                 | ≤ 6                                       |

## Conclusion

Tuflux® SIL has been exposed to test conditions representing a typical fed-batch process feeding a bioreactor for 20 days at a flow rate of 2 L/h.

The analysis of visual inspection, particle count, tubing thickness measurement, and burst pressure resistance, performed after 20 days of pumping proves that Tuflux® SIL shows excellent mechanical resistance and is therefore recommended for similar long-term pumping applications.

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