WHITE PAPER 0131

High Durometer, High Burst Pressure Tubing

Sani-Tech® STHT®-80

BIOPROCESS SOLUTIONS | LIFE SCIENCES

SAINT-GOBAIN

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The comprehensive performance of Sani-Tech® STHT®-80, marked by its superior pulsation reduction, vacuum resistance, and burst pressure, sets it apart from other high-durometer silicone tubings.

Sani-Tech® STHT®-80 ensures exceptional reliability and safety in demanding fluid transfer processes.

INTRODUCTION

Selecting single-use tubing for pharmaceutical and bioprocessing applications depends on critical performance properties. The new Sani-Tech® STHT®-80, a high-durometer, non-reinforced silicone tubing, excels in key areas: pulsation reduction, vacuum resistance, and burst pressure. Its capabilities make it a clear choice for use in applications such as fill finish fluid transfer, PUPSIT (pre-use post-sterilization integrity testing), high-volume fluid transfers, high-viscosity flow, and hydrostatic pressure from very large vessels. Benchmarking STHT®-80 against comparable high-durometer silicone tubings demonstrates its superior performance and suitability for these demanding applications.

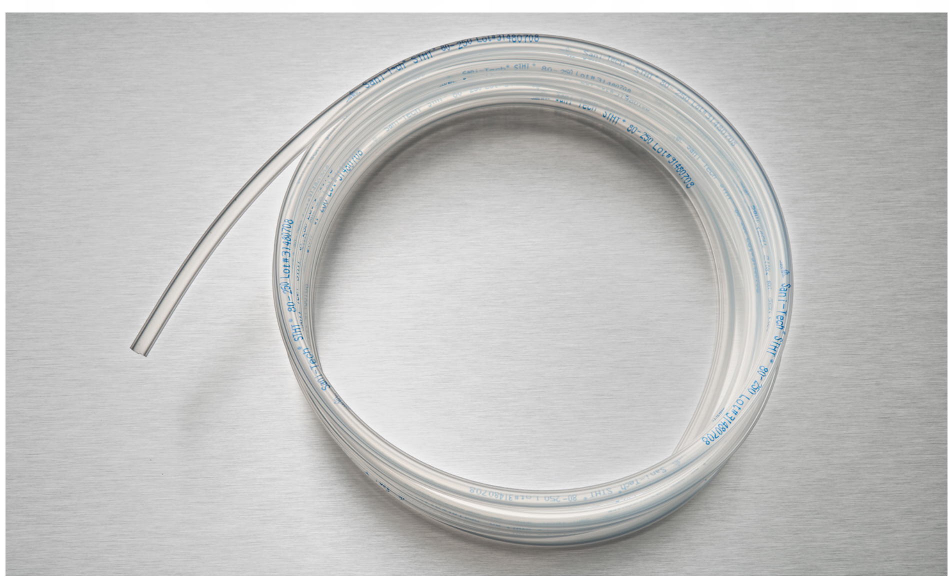
KEY PERFORMANCE ATTRIBUTES

Durometer

Durometer measures a material's hardness and is commonly cited as a core physical property of single-use tubing products. Sani-Tech® STHT®-80 has a higher nominal durometer than competing high-durometer silicone tubing products. A tubing with a higher durometer indicates a higher burst pressure capability than one with a lower durometer, but only for products within a single product family. This is because the precise formulation of the tubing will also impact its burst pressure. In this way, durometer can be a simple indicator – but not the sole indicator – of a tubing's pressure performance.

High Durometer Silicone Tubings	Durometer (Shore A)
Sani-Tech® STHT-80	78-88
Tube A	75-85
Tube B	78-85

Figure 1: Durometer ranges are listed on each product's datasheet. Sani-Tech® STHT®-80's durometer was measured according to ASTM D2240.



Pulsation

In pumping applications, the tubing being pumped and the tube set downstream of the pumping can experience varying degrees of pulsation depending on the type of tubing used and the pumping conditions. This can present difficulties, particularly in fill finish pumping operations, since pulsation can result in adverse effects such as poorer dosing accuracy and unintended fluid loss at the filling needle.

For these reasons, it can be very important to select transfer tubing for use downstream of pumping that will reduce pulsation to an absolute minimum.

We studied pulsation by measuring the change in the tubings' outer diameter (OD) with a pair of calipers. The test setup involved connecting the high burst tubings to pump tubing in a system where pressure would accumulate. For the pump tubing, a 36-inch section of Sani-Tech® SPT-60L pump tubing was placed in the Easy-Load® II pump head of a Cole-Parmer® Masterflex® pump. Then a 24-inch piece of the high burst pressure tubing was connected to the SPT-60L pump tubing via a hose barb fitting and cable ties. The size of the high burst pressure tubings was 1/4" ID by 3/8" OD.

Using calipers, an initial measurement (minimum OD) was taken in the center of the high burst pressure tubing while the pump ran without back pressure. Then, a ball valve downstream of the transfer tubing was actuated to create 60 psi of back pressure. At this point, the maximum OD measurement was taken. Then the % change from minimum to maximum OD was derived.

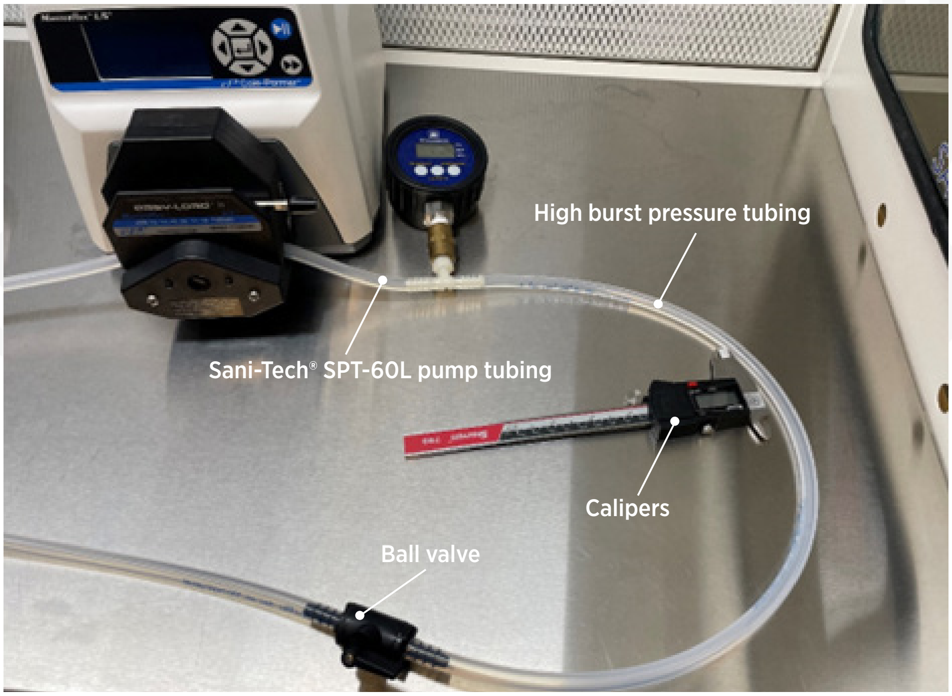
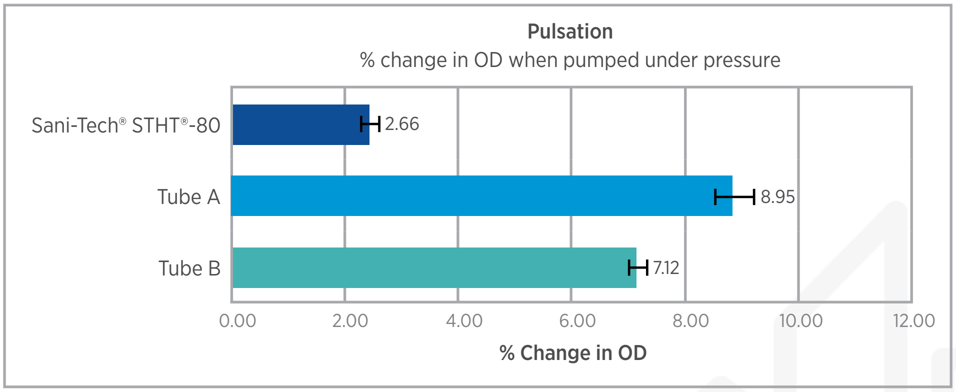


Figure 2: Test setup for measuring pulsation during pumping.

Chart 1: The average maximum percent change of the tube's outer diameter under 60 psi pressure



Sani-Tech® STHT®-80 exhibited only a very small degree of pulsation when pumping under pressure with a 2.66% change in OD. The pulsation in STHT®-80 is approximately 2.7 to 3.4 times less than the competing high durometer tubings which makes STHT®-80 an excellent choice for tubing downstream of pumping.

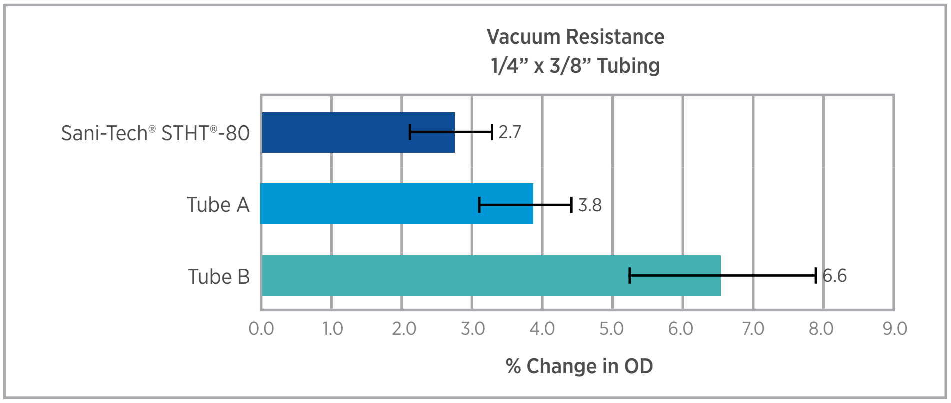
VACUUM RESISTANCE[1]

Very high flow rates can generate negative pressure, or a vacuum effect, in tubing. Many tubings cannot handle vacuum conditions and either partially or fully collapse as a result. This, in turn, can reduce or block fluid flow and potentially result in failures elsewhere in the system due to the blockage. Thus, a tubing's vacuum resistance capabilities can be very important.

The vacuum resistance of a tube is the ability to maintain its concentricity in 29.9 inHg, a perfect vacuum. The tube passes the test if the tube's OD changes less than 30% and then vacuum resistance is reported as ">29.9 inHg". If the tube's shape change is greater than 30% the vacuum is dropped to 25 inHg and the tube's OD is measured for % change once more.

Sani-Tech® STHT®-80 and the two competitor tubings tested passed this criteria for vacuum resistance and are rated as being vacuum resistant at >29.9 inHg. However, STHT®-80 had only a 2.7% shape change in the OD. For the competitor tubing, Tube A had a 3.8% change and Tube B had a 6.6% change in the OD. These results indicate STHT®-80's superior ability to maintain its shape and preserve a fully intact fluid pathway under vacuum conditions.

Chart 2: Percent change of OD at 29.9 inHg



[1] Akron WI-960-2-3-39 TR32721, TR32656, TR32918

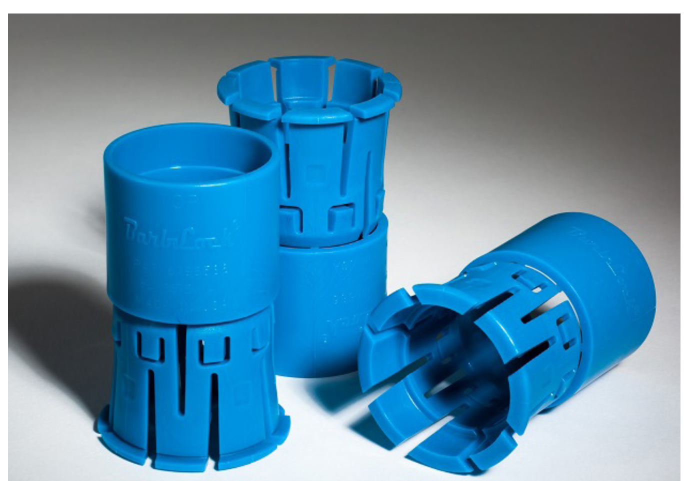
BURST PRESSURE

Pressure-intensive conditions are common in pharmaceutical and biopharmaceutical processing. Specifically, PUPSIT, high-volume fluid transfers, high-viscosity flow, and hydrostatic pressure from large vessels present significant pressure challenges. The components in the fluid handling system need to be able to safely handle these pressures without risk of bursting, which can cause costly downtime, product loss, and operator harm. Suppliers of single-use components and solutions can help end users assess fitness for use by defining the burst pressure capabilities of their products.

Burst pressure is the pressure at which a product fails due to bursting. It can be measured in a standalone component, such as tubing, or in a more complex assembly with various connections and other components. It is very important to note that the burst pressure capability of a component can be very different from the capability of a system that it is a part of. Furthermore, certain actions such as engaging and disengaging clamps on tubing can affect burst pressure capabilities. To help illustrate this, we have measured the burst pressure of:

1. Standalone tubing
2. Simple tubing assemblies comprising:
    a. Couplers and tees
    b. Mechanical connections (via BarbLocks®) and overmolded connections
3. Standalone tubing after repeated clamping
4. Standalone tubing after autoclaving and prolonged clamping

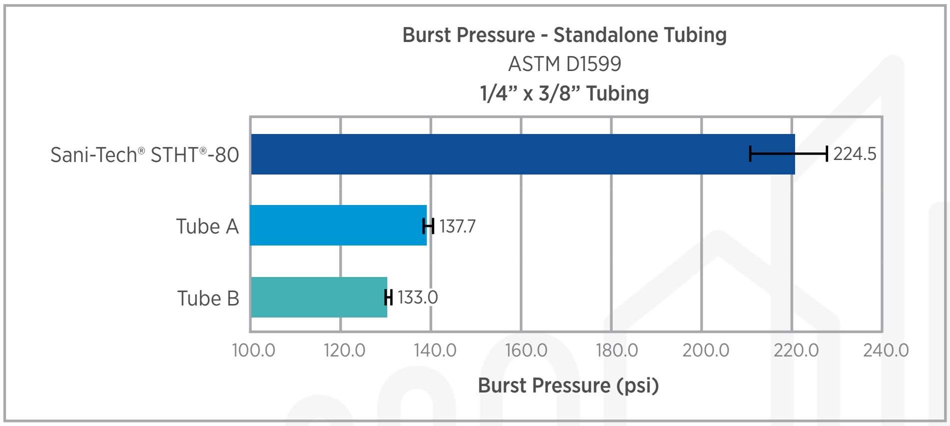
The burst pressure tests in this paper were conducted according to ASTM D1599 at room temperature with air as a test medium. All tubing used for this testing had dimensional measurements of 1/4" ID x 3/8" OD.



BURST PRESSURE OF STANDALONE TUBING[2]

The first series of burst pressure tests were conducted on standalone tubing – tubing on its own in isolation. Sani-Tech® STHT®-80 was tested alongside competitor high durometer silicone tubings.[3] Ten samples of STHT®-80 were tested and three samples of each competitor tubings were tested due to availability of product.

Chart 3: Burst pressure of standalone tubing at room temperature



In the standalone tubing tests, Sani-Tech® STHT®-80 demonstrated a burst pressure that is roughly 60% to 70% higher than competitor high-durometer tubing.

BURST PRESSURE OF SIMPLE TUBING ASSEMBLIES[4]

The second series of burst pressure tests were conducted on simple tubing assemblies of various design. High durometer tubing is used as a transfer tube in assemblies but the pressure capability of the assembly as a whole is only as strong as its weakest link, which is often the connection, whether mechanical or overmolded. Example assemblies (couplers and tees) were built to demonstrate the strength of both mechanical and overmolded connections using high durometer tubing. Saint-Gobain Life Sciences' BarbLock® was used for the mechanical connections and a 70 Shore A durometer liquid silicone rubber (LSR) was used for the overmolded connections. Assemblies constructed with Sani-Tech® STHT®-80 were compared to assemblies containing the competing tubings, Tube A and Tube B.

The methodology followed for these burst pressure tests are basically the same method as burst pressure tests on standalone tubing. Box clamps are used to connect two sides of the tubing assembly to the equipment. Any additional leg on the assembly is clamped off and burst pressure is tested along the straight length of the assembly. Figure 3 below gives a graphical depiction of the test setup.

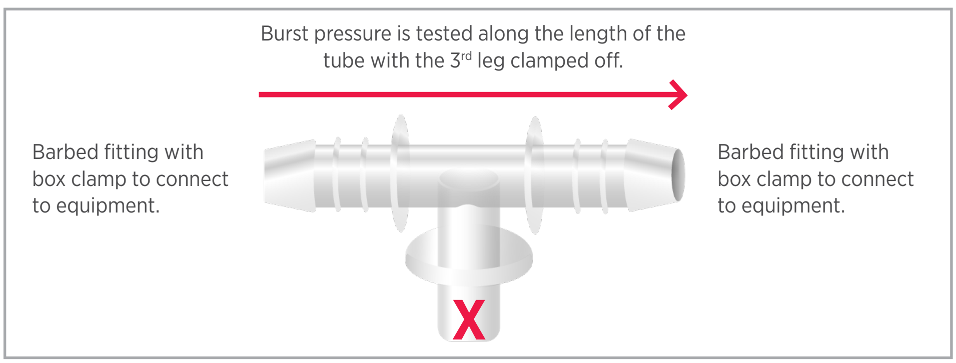


Figure 3: Depiction of a tee assembly for burst pressure testing.

[2]Test Report Competitor's TR32414 and TR32254
[3]Competitor's tubing was tested over several different lots and the lot-to-lot variability of their tubing appears in the results of this paper
[4]Test Report: TR32898, TR32884, TR32911

Chart 4: The average burst pressure of couplers made with BarbLock® connections

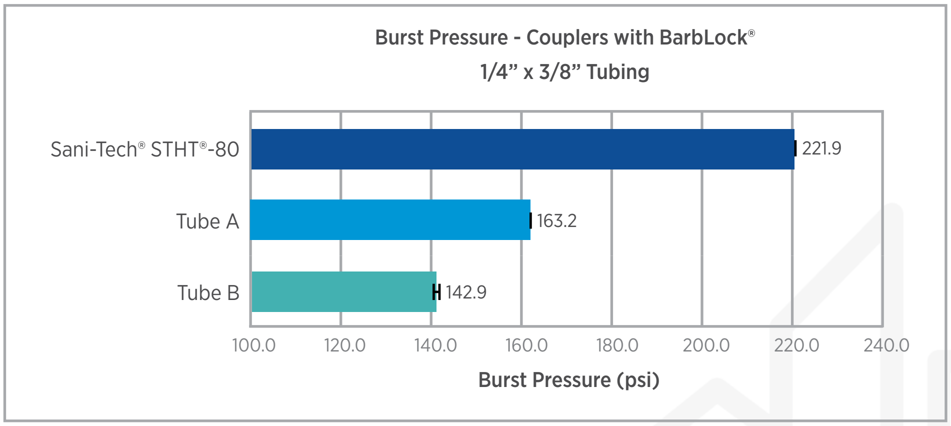


Chart 5: The average burst pressure of couplers made with overmolded connections

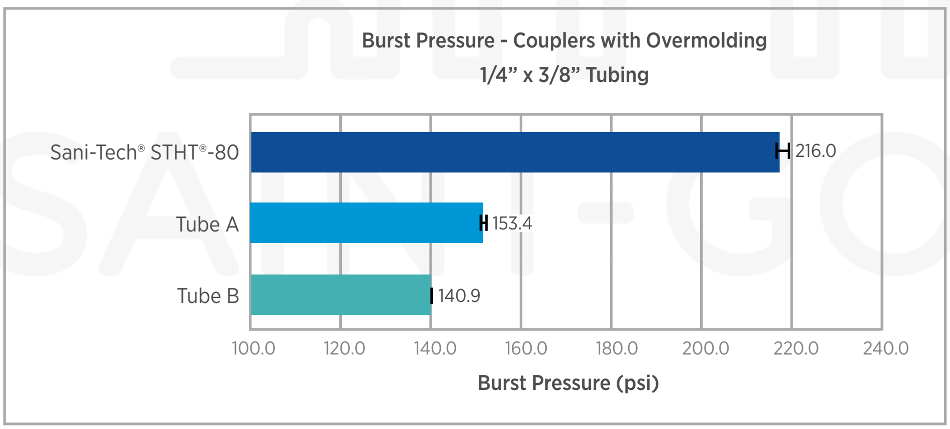


Chart 6: The average burst pressure of tees made with BarbLock® connections

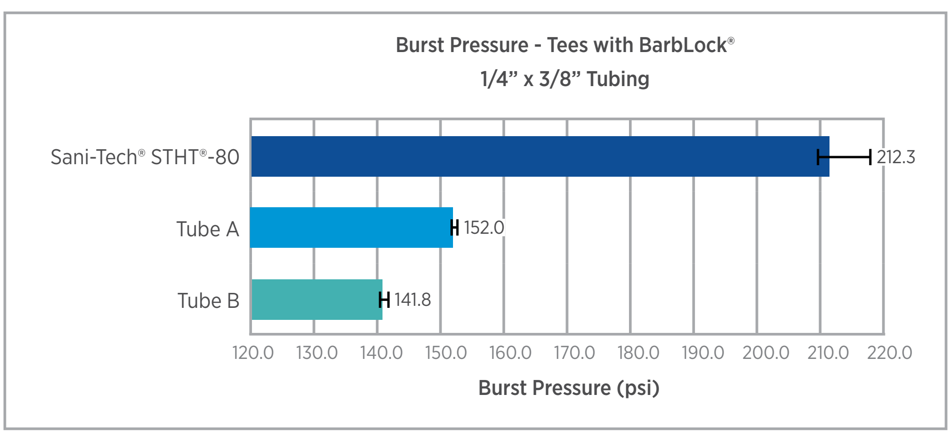
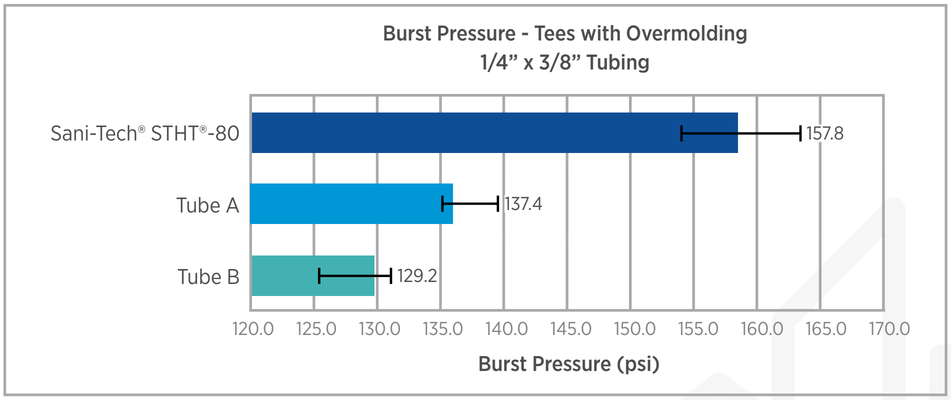


Chart 7: The average burst pressure of tees made with overmolded connections

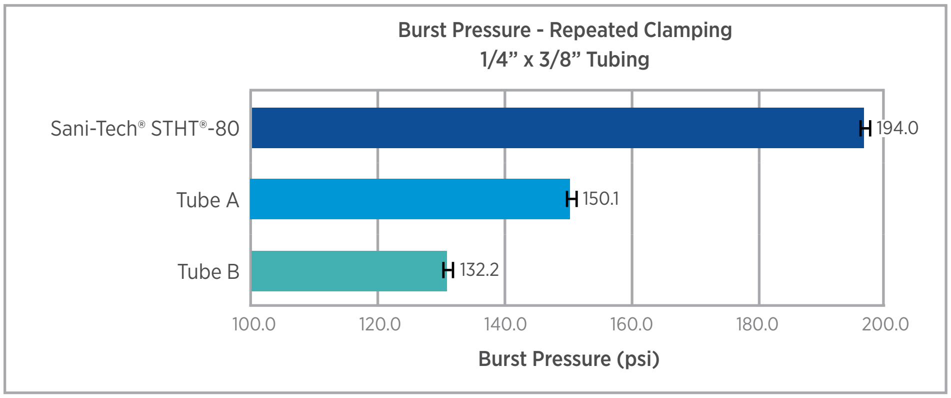


Assemblies built with Sani-Tech® STHT®-80 show a higher burst pressure in all configurations compared to assemblies built with competitor tubing. Couplers of either mechanical or over-molded connections show only a small drop in pressure when compared to standalone tubing. Burst pressure in the tees revealed a more substantial drop in pressure capability compared to standalone tubing with the overmolded connections performing significantly worse than the BarbLock® connections. Despite the drop in burst pressure in these assemblies, the burst pressure of assemblies with STHT®-80 still maintain a significant advantage over assemblies with competitor tubing.

BURST PRESSURE OF STANDALONE TUBING AFTER REPEATED CLAMPING[5]

Since some applications call for repeated engaging and disengaging of tube clamps during operation, we set out to explore what impact this might have on Sani-Tech® STHT®-80 and the competitor high durometer tubings. 1/4" x 3/8" tubing was subjected to repeated clamping and unclamping four times per hour for eight hours with a Saint-Gobain Life Sciences' Pure-Fit® TC Tube Clamp (PFTC750PVDF). This resulted in a total of 32 cycles of clamping. Between each cycle, the clamp was left closed and engaged on the tubing. After the 32 cycles were completed, the clamps were removed and burst pressure was measured. This process was completed three separate times to generate the results shown below.

Chart 8: Burst pressure after cyclic clamping of 1/4" x 3/8" tubing



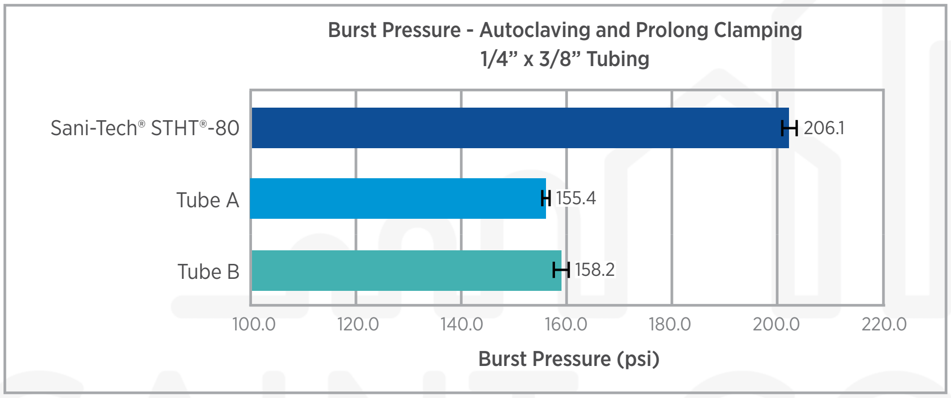
The effects of repeated clamping resulted in a slight reduction in burst pressure compared to standalone tubing. Despite the decrease, Sani-Tech® STHT®-80 maintained a significantly higher burst pressure compared to the competitor tubings.

[5] *Test Report: TR32851*

BURST PRESSURE OF STANDALONE TUBING AFTER AUTOCLAVING AND PROLONGED CLAMPING

We also studied the effect of prolonged clamping with autoclave exposure to assess the impact on the tubings' burst pressure capabilities. 1/4" x 3/8" tubing was clamped with a Saint-Gobain Life Sciences' Pure-Fit® TC Tube Clamp (PFTC750PVDF), placed in an autoclave at 121°C for 30 minutes, and allowed to sit with the clamp engaged for 60 hours. The clamps were removed, and then burst pressure was tested. Sani-Tech® STHT®-80 and the competitor high-burst tubings were tested. This process was completed three separate times to generate the results shown below.

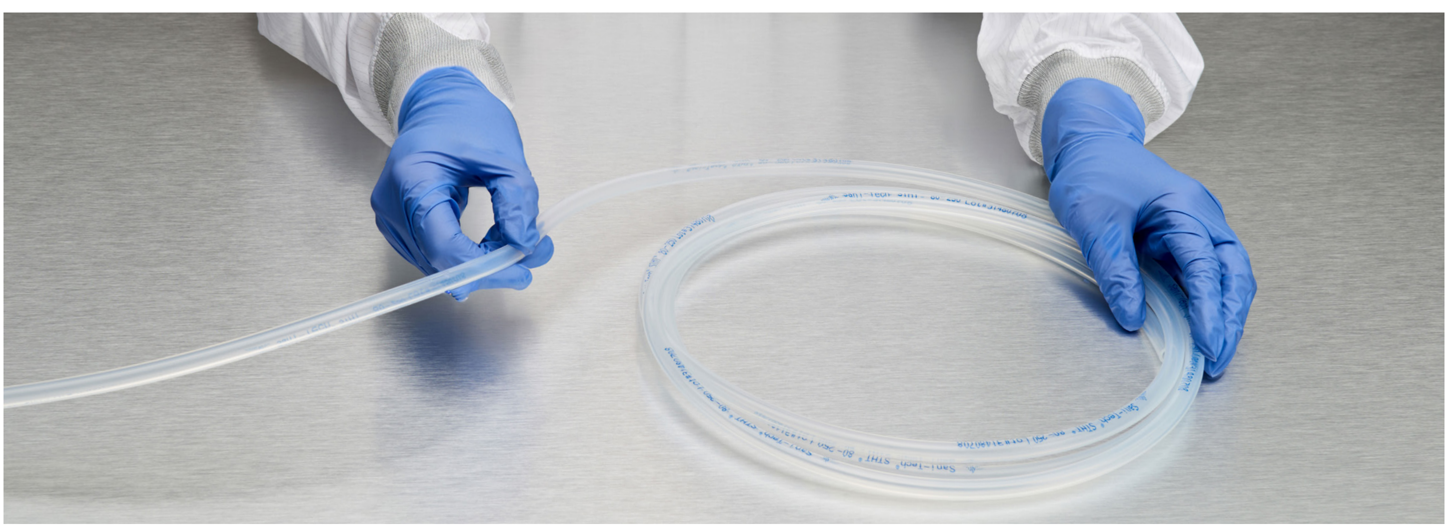
Chart 9: Burst pressure after being clamped and autoclaved of 1/4" x 3/8" tubing



The effects of prolonged clamping resulted in a slight reduction in burst pressure compared to standalone tubing. However, the decrease was smaller than what was seen in the repeated clamping tests, likely due to the increase in burst pressure due to the autoclaving. Nonetheless, despite the small decrease, Sani-Tech® STHT®-80 maintained a significantly higher burst pressure compared to the competitor tubings.

CONCLUSION

The comprehensive performance of Sani-Tech® STHT®-80, marked by its superior pulsation reduction, vacuum resistance, and burst pressure, sets it apart from other high-durometer silicone tubings. This translates to a distinct advantage across a spectrum of critical applications, whether used as standalone tubing, within complex assemblies, or subjected to repeated and prolonged clamping. This ensures exceptional reliability and safety in demanding fluid transfer processes.



About

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Heidi has an MS in Materials Process Engineering from Worcester Polytechnic Institute and a BSE in Chemical Engineering from the University of Massachusetts in Amherst. She has spent 19 years specializing in silicone formulations and application specific testing. Her current research is focused on tubing used in final fill drug manufacturing.

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Nils has a Master of Business Administration from the University of St. Thomas. He has worked for Saint-Gobain Life Sciences in several marketing roles since 2015 and is currently the product manager of all silicone tubing and hose products within the Bioprocess Solutions sub-division.

Saint-Gobain Life Sciences

The Bioprocess Solutions business of Saint-Gobain Life Sciences is an industry-leading provider of materials science-based solutions for single-use fluid management, including TPE and silicone tubing, connection and flow control components, bioprocess and cell culture bags, filtration products, sensors, and over-molded technology, all available in customized assemblies that are produced in 20 manufacturing facilities located around the world. To find out more about Saint-Gobain Life Sciences and to learn how we can assist you with your application needs, visit our website.

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