DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing

Sterilizable, weldable TPE tubing for biopharmaceutical processing applications that require lower storage temperatures

Introducing DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing: This new thermoplastic elastomer tubing addresses the growing need for high-purity materials in single-use systems that can meet the industry's needs for lower storage temperatures. This new offering also can be welded to current TPE tubing solutions, simplifying usage and qualification requirements.

With the launch of DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing, DuPont is offering an additional TPE option for fluid transport and single-use bioprocessing applications and is facilitating adoption and compatibility with alternative TPE tubing offerings.

Our thermoplastic elastomer tubing product range – which also includes DuPont™ Liveo™ Pharma TPE Tubing – complements our silicone-based DuPont™ Liveo™ Pharma Tubing and Overmolded Assemblies product lines and is produced under the same high quality principles as the products our customers already know and trust.

Key features & benefits

- Improved elastomer toughness down to -86°C; decreased brittle failure; resistant to multiple freeze/thaw cycles
- Manufactured in ISO Class 7 cleanroom (U.S. sites)
- Designed to meet biopharma processing standards and low-temperature-resistance requirements
- High ductility; reduced brittle failure; resistant to bend, crush and impact at -80°C
- Thermoweldable and thermosealable using standard welder/sealer methods
- Good pumpability and low spallation
- Excellent burst resistance
- Comprehensive data package; numerous functional properties pre- and post-freezing
- Sterilizable:
  – Autoclave: Multiple cycles; 125°C/60 min
  – Gamma irradiation: Up to 50 kGy dose
- Excellent chemical resistance (including with DMSO)

Purity & regulatory data

- USP Class VI standards
- Extractables USP <665>
- Elemental impurities USP <232>
- Biocompatibility ISO 10993 (part 4, 5, 6, 10, 11)
- Food grade 21 CFR 177.2600 e) & f)
- Subvisible particulates USP <788>
- Bioburdens ISO 11737-1
- Endotoxins USP <85>
- Free from phthalates and heavy metals

Typical physical properties of DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing

Properties are based on DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing with an inner diameter (I.D.) of 3/8" (9.5 mm) and an outer diameter (O.D.) of 5/8" (15.9 mm).

	Property	Test standard	Mean value
	Durometer hardness	ASTM D2240	62 Shore A
	Specific gravity	ASTM D792	0.900
	Property	**Test standard**	**Mean value**
Steam (121°C/30 minutes)	Maximum elongation	ASTM D412 Die C	1030%
	Modulus at 200% elongation		1.88 MPa
	Maximum tensile strength		9.1 MPa
	Property	**Test standard**	**Mean value**
Gamma radiation (50 kGy)	Maximum elongation	ASTM D412 Die C	1256%
	Modulus at 200% elongation		1.90 MPa
	Maximum tensile strength		8.7 MPa

Specification writers: These values are not intended for use in preparing specifications. Please contact DuPont prior to writing specifications on this product.

Applications

- Biopharma cold chain logistics
- Advanced fluid management
- Freeze/thaw
- Monoclonal antibodies
- mRNA vaccines
- Viral vector vaccines
- Gene therapies

Sterilization methods

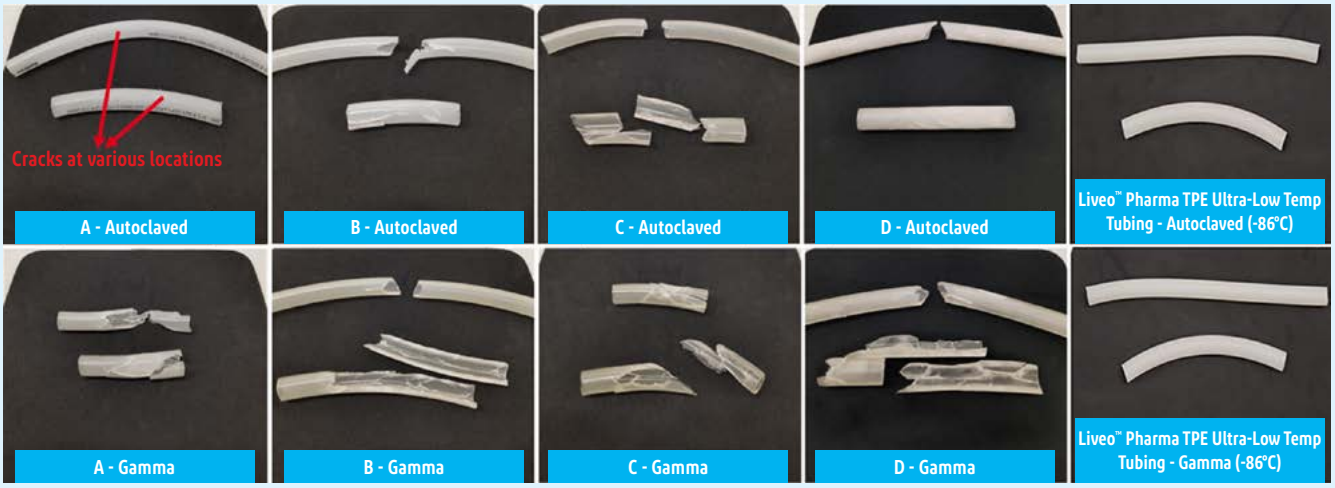
- Autoclave: Multiple cycles; up to 125°C/60 min
- Gamma irradiation: Up to 50 kGy dose

Performance data for DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing

Comprehensive studies were conducted on material in common sizes and using different sterilization methods, including steam and gamma radiation. The following is a review of analyses comparing DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing to industry benchmark tubing. Further testing data is available; please contact DuPont for more details depending on your application needs.

Competitive landscape: Incumbent TPE tubing fails low-temperature tests (-80°C)

Incumbent TPE tubing materials were subjected to testing after being frozen at -80°C. The specimens underwent bending, crushing and impact testing. None of the alternative materials tested were able to withstand these assessments, as they either broke completely, shattered into multiple pieces or developed cracks in various locations.

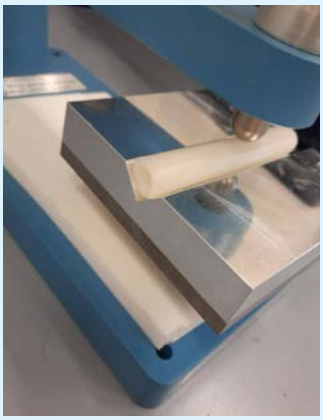


TEST PRINCIPLE

Evaluate low-temperature-resistance performance

Bend test – ISO 10619-2:2021

Frozen tubing specimen is bent for 5 seconds around a mandrel with a radius of 3 times the tubing's I.D., then visually inspected for failure (e.g., cracking, splitting, shattering, breaking).



Impact test – ASTM D2794

Frozen tubing specimen is impacted using Heavy-Duty Impact Tester BYK 5545 by dropping a 2 kg weight from a 10 cm height onto the tubing specimen, then visually inspected for failure (e.g., cracking, splitting, shattering, breaking).

Crush test – ISO 28702:2008

Frozen tubing specimen is compressed at 50% of tubing O.D. using a pneumatic press and warmed up to room temperature, then visually inspected for failure (e.g., cracking, splitting, shattering, breaking).

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Bend test results at -86°C

Multiple dimensions (I.D. x O.D.) of DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing specimens were tested after being sterilized and frozen at -86°C for several days. The pictures below highlight the results obtained by bending the tubing specimens while frozen. The benchmark TPE tubing broke very easily, while the Liveo™ Pharma TPE Ultra-Low Temp Tubing remained flexible.

After the low-temperature bend, crush and impact tests, the tubing specimens were then tested to measure the burst pressure resistance to detect any weakness following the mechanical constraints exercised at -86°C.

TPE benchmark
0.375" x 0.625"

DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing
0.375" x 0.625"

DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing:

- Meets traditional, typical functional performance (e.g., welding, pumping, burst resistance pressure)
- Passes -86°C bend, crush and impact tests with no loss of performance (weldability/sealability, pumping, burst pressure resistance, etc.)

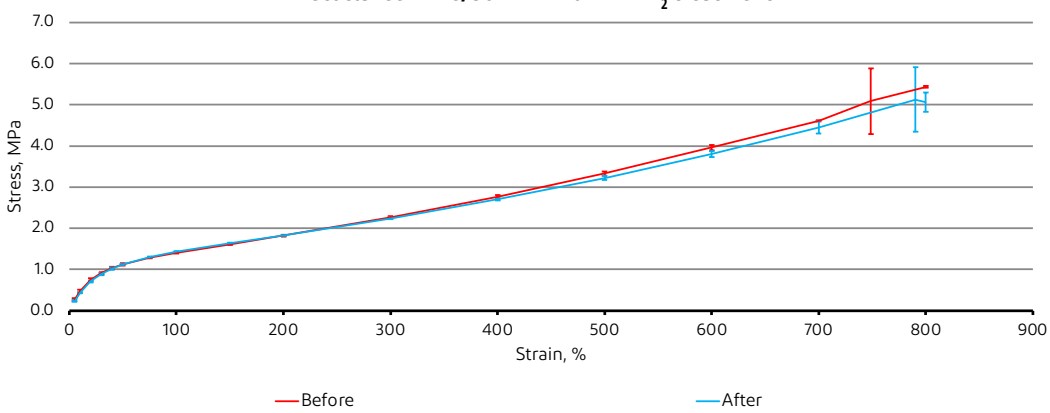
Welding before & after liquid nitrogen treatment[1]

The goal of this experiment was to evaluate potential impact on the weldability of DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing following low-temperature treatment and a thermal shock using liquid nitrogen (LN_2).

Tubing specimens were left in LN_2 for 10 minutes. No bubbling was observed after 30 seconds, confirming that the temperature of the tubing specimens matched that of the LN_2.

3/8" I.D. x 5/8" O.D., autoclaved beforehand (121°C/30 minutes) – 10 minutes in liquid nitrogen (LN_2)

Stress/strain of 3/8" I.D. x 5/8" O.D. welded Liveo™ Pharma TPE Ultra-Low Temp Tubing
Autoclaved 121°C/30 min – 10 min LN_2 treatment



After LN_2 treatment:

- The tubing specimens were welded with various standard welding methods and tested to measure the tensile strength of the weld
- The tensile strength of the weld remains unchanged

[1]These results were obtained by testing autoclaved tubing specimens. However, similar results are observed on gamma-irradiated tubing material.

Performance data for DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing
(continued)

Clamped tubing: Accelerated aging in liquid nitrogen

In these experiments, the tubing specimens were clamped with Pure-Fit® clamps before being immerged in liquid nitrogen (LN_2) for 14 continuous days to simulate accelerated aging.

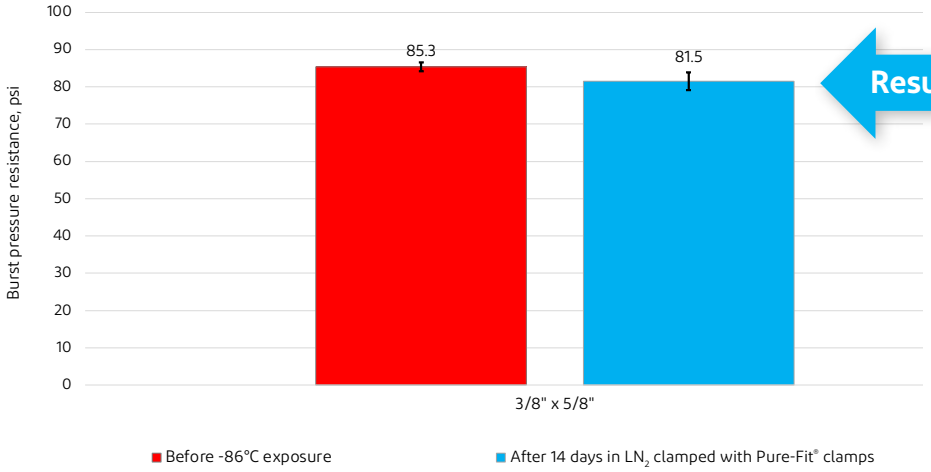
After the freezing period, the tubing specimens were removed from the LN_2, left to thaw back to room temperature, visually checked (lumen of the tubing), and tested for burst pressure resistance and functional properties.

3/8" I.D. x 5/8" O.D., autoclaved beforehand (121°C/30 minutes) – 14 days in liquid nitrogen (LN_2); tubing specimens clamped with Pure-Fit® clamps

14-day LN_2

Burst

Results



After accelerated aging in LN_2:

- The lumen remains open (within the first 10 minutes)
- Burst pressure resistance before and after clamping in LN_2 remains statistically unchanged
- No loss of tubing performance (welding, sealing, pumping)

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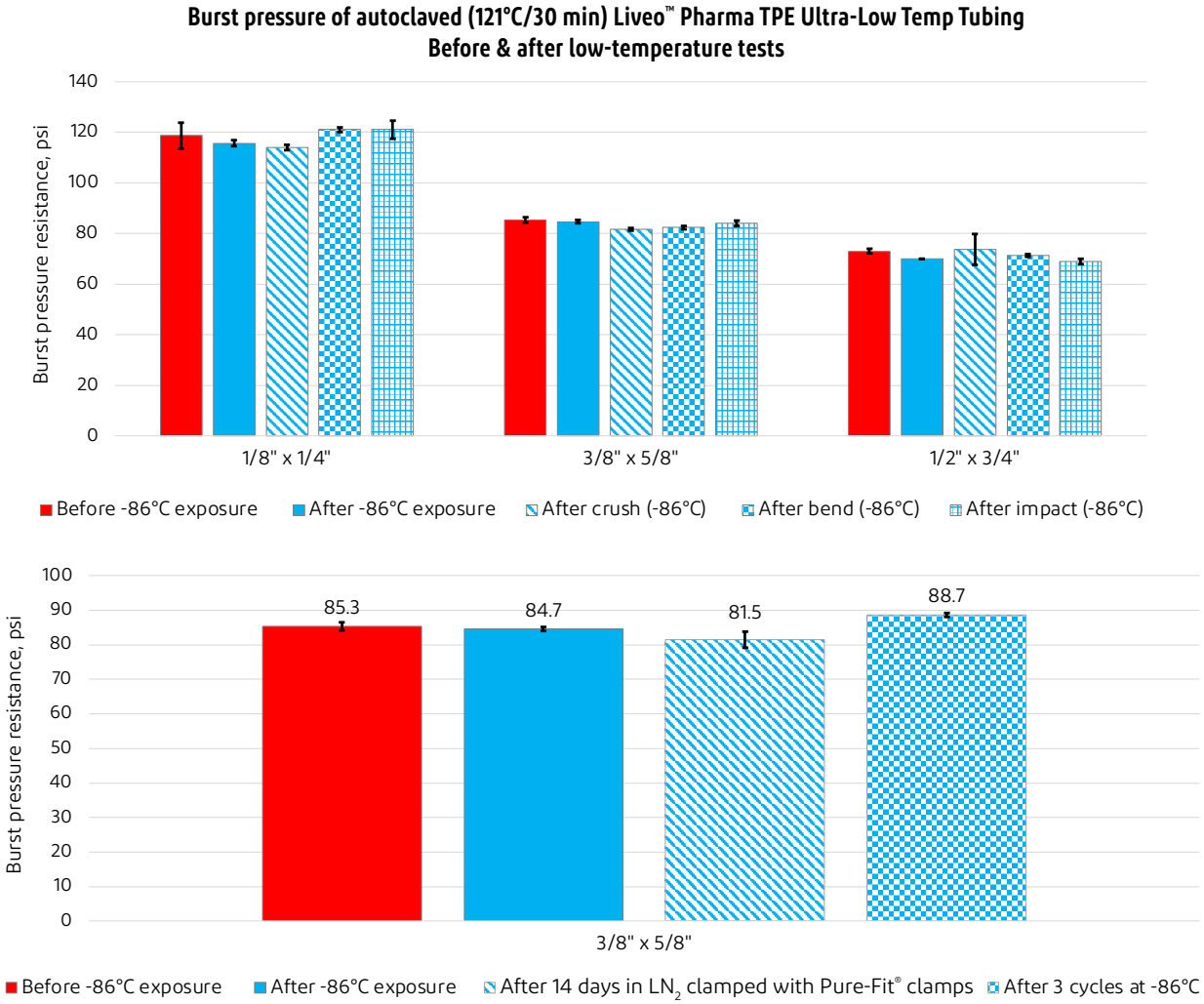
Thermal stability (burst pressure resistance) of autoclaved tubing

For this experiment, sterilized tubing specimens were tested in various conditions: before and after low-temperature treatment; after low-temperature bend, crush and impact tests; after being clamped in liquid nitrogen (LN_2); and after multiple freeze/thaw cycles.



Thermal stability:

- Burst pressure remains similar, regardless of the treatment (before and after low-temperature exposure and low-temperature tests such as bend, crush and impact tests)

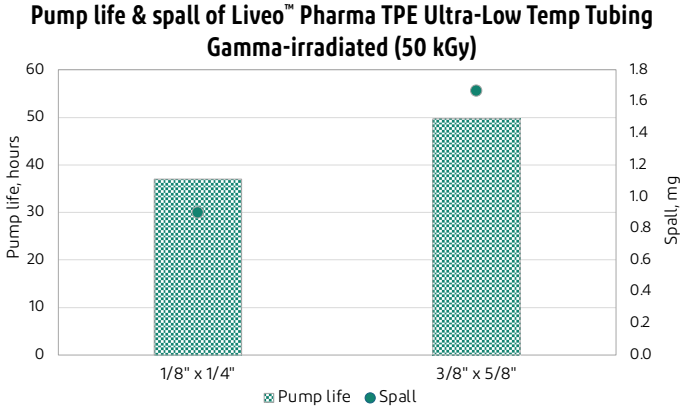
Pump & spallation tests of gamma-irradiated tubing

Sterilized DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing specimens of various dimensions were tested to determine the maximum pump life (before breakage occurs), as well as to evaluate the amount of particles generated throughout the pump life of the tubing.

To do so, peristaltic pumps from Watson-Marlow and Cole-Parmer were used and set at moderate speed, without backpressure, while circulating ultrapure water with no control on the temperature of the media. Given the small size of the water reservoir, the temperature of the media increased between 25°C up to 40°C, depending on the peristaltic pump model used. The graph at right shows the typical pump life and amount of spall expected in these conditions using DuPont™ Liveo™ Pharma TPE Ultra-Low Temp Tubing.

Test method:

- Tested in triplicate; gamma-irradiated tubing (50 kGy)
- 3/8" x 5/8" tubing: 400 RPM Cole-Parmer® I/P® pumping pure water without backpressure
- 1/2" x 3/4" tubing: 150 RPM Watson-Marlow® 630U/620R (counterclockwise) pumping pure water without backpressure
- Filtration of spall on 3 µm filter membrane



About DuPont™ Liveo™ Healthcare Solutions

DuPont™ Liveo™ is a globally recognized leader in technology for a broad range of innovations in medical devices, biopharmaceutical processing and pharmaceutical solutions. DuPont high-performance materials help create safer healthcare environments and protect the health of patients and healthcare providers worldwide. We help enable smarter healthcare and positive patient outcomes.

For more information about DuPont™ Liveo™ Biopharmaceutical Processing Solutions

Visit **liveo.dupont.com** – or scan the QR code at right to be taken directly to our biopharma processing web page, where you'll find details on the full portfolio of biopharma solutions, including tubing and overmolded assemblies for critical fluid transport, as well as processing aids such as antifoams and defoamers.

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To learn more about DuPont™ Liveo™ Healthcare Solutions, visit **liveo.dupont.com**.

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Positive Patient Outcomes.

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