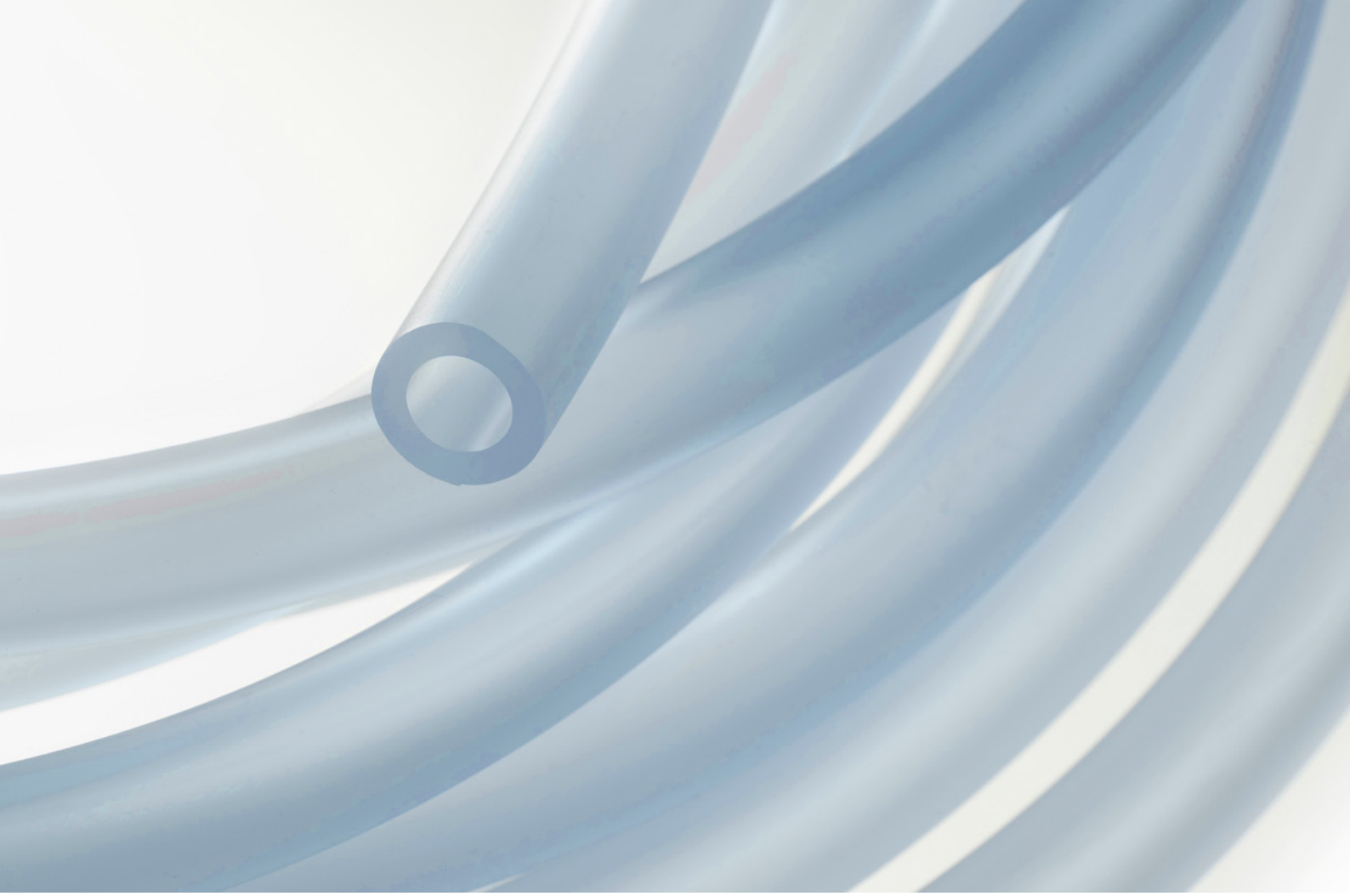
DUPONT

Liveo™

DuPont™ Liveo™ Pharma Advanced Pump Tubing (APT)

High-purity silicone tubing product selection guide for the Asia market



About silicone DuPont™ Liveo™ Pharma Tubing

High-purity, biomedical-grade, platinum-catalyzed silicone products designed for ultrapure fluid transfer applications for upstream and downstream processes of pharma and biopharma drug products

As tubing represents one of the largest surface areas in direct contact with drug substances during the drug-manufacturing process, pharma tubing needs to meet strict regulatory and quality requirements.

DuPont provides high-purity solutions resulting from the cleanliness – low extractables, no by-products, no additives – and biocompatibility of the silicone formulations used to produce the tubing. Products are rigorously tested, fully traceable, comprehensively documented, and thoroughly managed for contamination and change control, including customer notification of change.

To learn more, read our brochure titled ***"Exacting purity: Advancing single-use solutions for end-to-end purity, reliability and security"*** (Form No. 001-20372), available in the Resource Center at **liveo.dupont.com**.

Features & benefits of silicone DuPont™ Liveo™ Pharma Tubing

- Excellent flexibility
- Low extractables
- Contains no peroxide by-products, chlorophenyls or PCBs
- No organic plasticizers, phthalates or latex additives
- Easily sterilized
- Stable over a wide temperature range
- High resiliency
- No impaired taste or odor
- Non-wetting (hydrophobic) surface
- Made from biomedical-grade elastomer that exceeds United States Pharmacopeia (USP) Class VI Plastics Test Requirements
- Meets European Pharmacopoeia monograph 3.1.9. “Silicone elastomer for closures and tubing”
- Produced in an ISO 7 cleanroom and dedicated healthcare facility
- High purity quality (USP <788> Particulate matter for Injection, USP <85> Bacterial Endotoxins, ISO 11737-1 Bioburden, USP <665> Extractables and Leachables)
- FDA 21 CFR 177.2600 and USP <661> Physicochemical tests - Plastics
- Reduces risk of contaminating ultrapure liquids
- Complete traceability
- Consistent performance
- Rigorous change control

Silicone DuPont™ Liveo™ Pharma Tubing

DuPont™ Liveo™ Pharma 50 Tubing	DuPont™ Liveo™ Pharma 65 Tubing	DuPont™ Liveo™ Pharma 80 Tubing
• Durometer range: 45-55 Shore A • Suitable for most applications and for short-term pumping applications	• Durometer range: 60-70 Shore A • Increased pressure or vacuum resistance • Increased kinking resistance	• Durometer range: 75-85 Shore A • Higher pressure or vacuum resistance • Higher kinking resistance • Cost-effective alternative to reinforced tubing
DuPont™ Liveo™ Pharma Advanced Pump Tubing (APT)	**DuPont™ Liveo™ Pharma 65 Reinforced Tubing**	
• Durometer range: 45-55 Shore A • For specific long-term pumping applications • Provides 4-6x greater life in peristaltic pumps when compared to standard 50 durometer tubing	• Durometer range: 60-70 Shore A • Polyester fiber braid • Highest pressure or vacuum resistance	

This product selection guide is focused on DuPont™ Liveo™ Pharma Advanced Pump Tubing (APT). If you need more information about standard pharma-grade silicone DuPont™ Liveo™ Pharma Tubing and DuPont™ Liveo™ Pharma 65 Reinforced Tubing, please contact your DuPont representative.

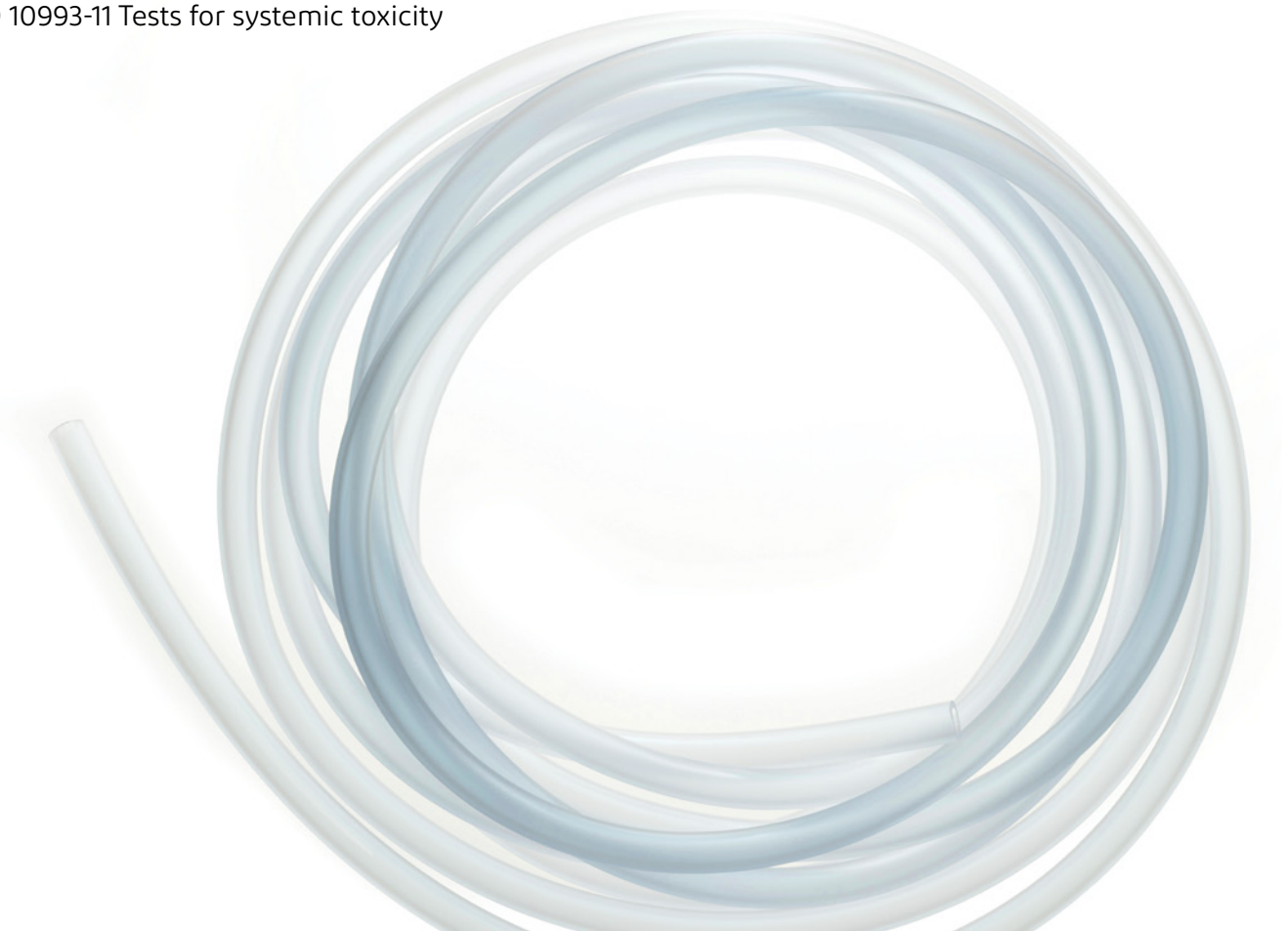
Product regulatory information

Compliance with:

- EP 3.1.9 Silicone Elastomers for Closures & Tubing
- USP <661> Physicochemical tests - Plastics
- FDA 21 CFR 177.2600 Rubber articles intended for repeated use
- JP XIV Section 11 – Plastic Containers for Pharmaceutical Products
- ISO 11737 – Part 1 Bioburden
- USP <665> Extractables and Leachables
- USP <788> Particulate Matter in Injections
- USP <88> Class VI (Biological reactivity tests, *in vivo*)
- USP <85> Bacterial Endotoxins
- USP <151> Pyrogen test
- ISO 10993-3 Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4 Selection of tests for interactions with blood (related to hemolysis)
- ISO 10993-5 Tests for *in-vitro* cytotoxicity (equivalent to USP <87> Biological reactivity tests, *in vitro*)
- ISO 10993-6 Tests for local effects after implantation
- ISO 10993-10 Tests for irritation and skin sensitization
- ISO 10993-11 Tests for systemic toxicity

Purity testing to accelerate qualification & validation

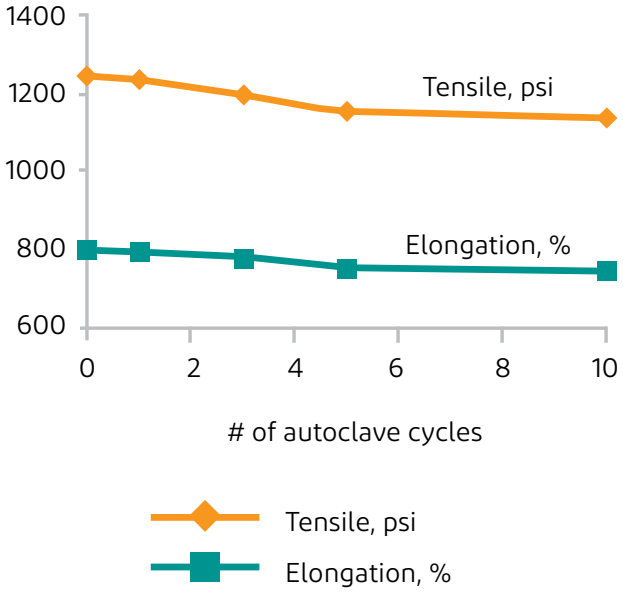
- **USP <788> Particulate Matter in Injections:** Solid particulate counts were substantially lower than the acceptance limits. Average counts: ≤0.3 particulate/ml (≥10 µm size), ≤0.1 particulate/ml (≥25 µm size).
- **USP <85> Bacterial Endotoxin Test:** Levels were below our stringent 0.125 EU/ml acceptance limit.
- **ISO 11737-1 for aerobic bacteria, yeast and spores:** No bioburden (0 CFU/ml) was detected. Molds are well below the limit of ≤0.1 CFU/ml for Sterile Biological Drug Products.
- **BPOG and USP <665> Extractables:** Available to meet the end user's requirements in accessing reliable, consistent data for faster implementation of the tubing.



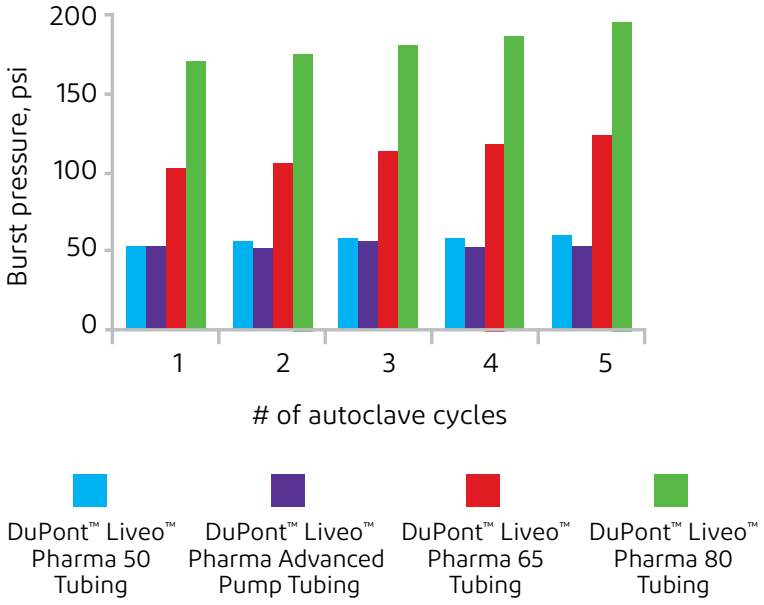
Sterilization methods

- Silicone tubing is easily sterilized because of silicone's stability
- Sterility can be achieved via heat, irradiation or chemical agents
- Common sterilization procedures include:
  - Autoclave (steam)
  - Gamma radiation
  - Ethylene oxide (EtO)
  - X-ray radiation
- Example: Repeated sterilizations with autoclave
- Typical gamma radiation dosages: up to 50 kGy
- Example: 50 kGy irradiation causes no significant alteration in:
  - Tensile, elongation or modulus
  - Shore A durometer
  - Extractables
- Repeated gamma sterilization and/or higher doses of radiation may change some of the physical properties of the elastomer

Effect of autoclaving on DuPont™ Liveo™ Pharma 50 Tubing



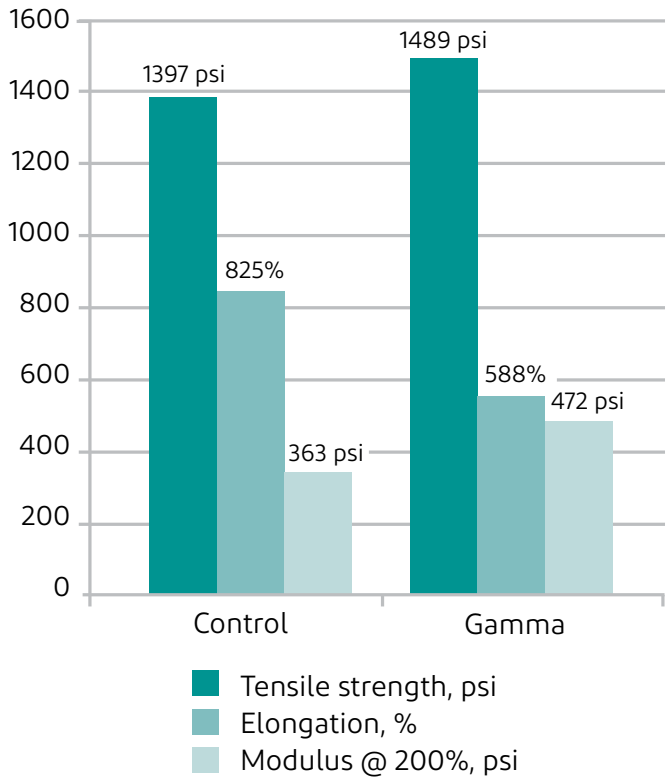
Effect of autoclaving on burst pressure



Storage & stability

Shelf life is 60 months from the date of manufacture when stored in the original unopened containers.

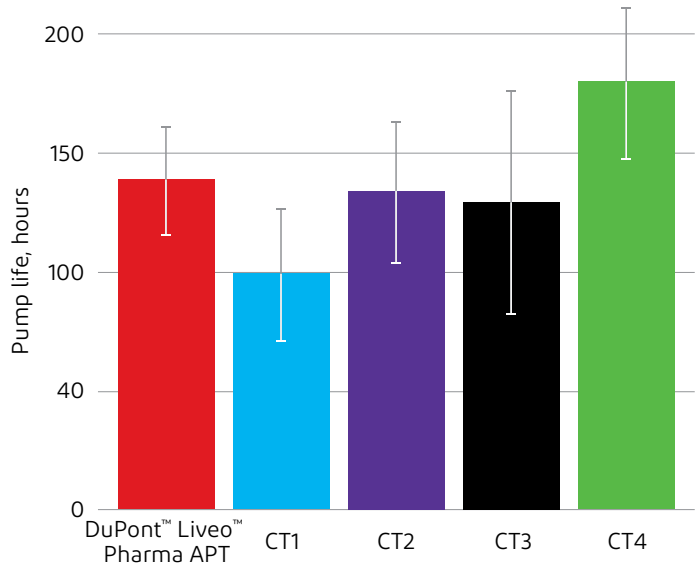
Effects of gamma radiation sterilization



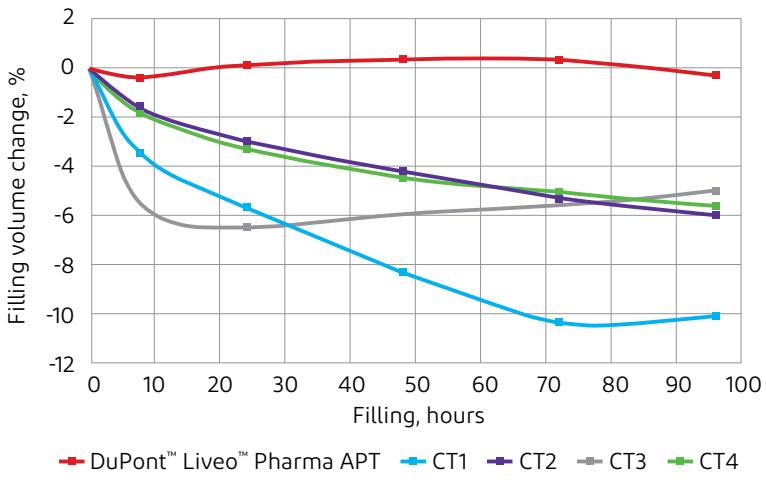
Comparative filling accuracy for silicone tubing in peristaltic pump applications

High quality and mechanical memory characteristics of the tubing are important for accurate, consistent dispensing to eliminate costly underfilling or overfilling. For these reasons, silicone tubing is used widely in peristaltic pumps. These figures describe a recent study investigating the filling accuracy of five silicone tubing products designed for peristaltic pumping applications. The testing protocol was validated with a global fill/finish equipment manufacturer.

Tubing pump life data



Filling accuracy change over time



The graphs on this page compare the tubing pump life and filling accuracy of five tested tubing products, including DuPont™ Liveo™ Pharma Advanced Pump Tubing (APT) and four leading silicone pump tubing products (labeled as CT1, CT2, CT3 and CT4).

Tubing pump life offers the measure of the durability of the tubing under peristaltic conditions, which statistically is indifferent for the tested products. The filling accuracy test results show that DuPont™ Liveo™ Pharma Advanced Pump Tubing delivers precise filling volume throughout the duration of the filling process, while the filling volume drifts for the other tubing products.

Test conditions:

- 1.6 mm I.D. (inner diameter) tubing products
- Filtered deionized water for recirculation
- Double line dosing Flexicon "pulsation-free" peristaltic pump
- 3 batches of tubing tested in triplicate, with 2 ml fluid delivery at each dispense; filtered deionized water was circulated

The test results demonstrate that DuPont™ Liveo™ Pharma Advanced Pump Tubing provides the highest filling accuracy over an extended dispensing time when compared to four other leading silicone tubing products recommended for peristaltic pump applications.

DuPont™ Liveo™ Pharma Advanced Pump Tubing is the most reliable choice for maintaining accurate filling volume throughout the duration of filling processes.

DuPont™ Liveo™ Pharma Advanced Pump Tubing (APT) options *(continues on next page)*

Material no.	Product name	I.D., inches	O.D., inches	Wall, inches	I.D., mm	O.D., mm	Wall, mm	Typical burst pressure, bar	Working pressure calculated with safety factor of 1/3, bar	Packaging information
4089982	PHARMA-APT ST TBG .8MMX4MM,FT,50FT-S	0.03	0.16	0.06	0.8	4.0	1.6			50 feet/coil, 1 coil/box
12098126	PHARMA-APT ST TBG 0.8MMX4.2MM,FT,50FT-S	0.03	0.17	0.07	0.8	4.2	1.7			50 feet/coil, 1 coil/box
4103806	PHARMA-APT ST TBG 1.20MMX4.38MM,FT,50FT	0.05	0.17	0.06	1.2	4.4	1.6			50 feet/coil, 1 coil/box
12098127	PHARMA-APT ST TBG 1.2MMX4.6MM,FT,50FT-S	0.05	0.18	0.07	1.2	4.6	1.7			50 feet/coil, 1 coil/box
4074016	PHARMA-APT ST TBG 1.6MMX4.8MM,M,15M-S	0.06	0.19	0.06	1.6	4.8	1.6			50 feet/coil, 1 coil/box
12098144	PHARMA-APT ST TBG 1.6MMX5.1MM,FT,50FT-S	0.06	0.20	0.07	1.6	5.1	1.8			50 feet/coil, 1 coil/box
4075999	PHARMA-APT ST TBG 1.6MMX6.4MM,FT,50FT-S	0.06	0.25	0.09	1.6	6.4	2.4			50 feet/coil, 1 coil/box
12098143	PHARMA-APT ST TBG 1.6MMX6.7MM,FT,50FT-S	0.06	0.26	0.10	1.6	6.7	2.6			50 feet/coil, 1 coil/box
4103807	PHARMA-APT ST TBG 2.40MMX5.60MM,FT,50FT-	0.09	0.22	0.06	2.4	5.6	1.6			50 feet/coil, 1 coil/box
12098128	PHARMA-APT ST TBG 2.4MMX5.9MM,FT,50FT-S	0.09	0.23	0.07	2.4	5.9	1.8			50 feet/coil, 1 coil/box
4066816	PHARMA-APT ST TBGMK 2.4MMX7.2MM,M,15M-S	0.09	0.28	0.09	2.4	7.2	2.4			15 meter/coil, 1 coil/box
12098160	PHARMA-APT ST TBG 2.4MMX7.5MM,FT,50FT-S	0.09	0.30	0.10	2.4	7.5	2.6			50 feet/coil, 1 coil/box
4040492	PHARMA-APT ST TBG .125X.250,FT,50FT-S	0.13	0.25	0.06	3.2	6.4	1.6	5.4	1.8	50 feet/coil, 1 coil/box
4089983	PHARMA-APT ST TBG 3.2MMX6.8MM,FT,50FT-S	0.13	0.27	0.07	3.2	6.8	1.8			50 feet/coil, 1 coil/box
4076000	PHARMA-APT ST TBG 3.2MMX8MM,FT,50FT-S	0.13	0.31	0.09	3.2	8.0	2.4			50 feet/coil, 1 coil/box
4077165	PHARMA-APT ST TBG .188X.313,FT,50FT-S	0.19	0.31	0.06	4.8	8.0	1.6	3.8[1]	1.3	50 feet/coil, 1 coil/box
4076620	PHARMA-APT ST TBG .188X.375,FT,50FT	0.19	0.38	0.09	4.8	9.5	2.4	4.8	1.6	50 feet/coil, 1 coil/box
4088134	PHARMA-APT ST TBG .188X.438,FT,50FT-S	0.19	0.44	0.13	4.8	11.1	3.2			50 feet/coil, 1 coil/box

Note: Burst pressure values are typical values and are not intended for writing specifications. Test method is based on ASTM D380-14.
[1] Predicted burst pressure: A regression formula was used to calculate burst pressure of these tubing sizes not actually tested for burst pressure.

DuPont™ Liveo™ Pharma Advanced Pump Tubing (APT) options *(continued)*

Material no.	Product name	I.D., inches	O.D., inches	Wall, inches	I.D., mm	O.D., mm	Wall, mm	Typical burst pressure, bar	Working pressure calculated with safety factor of 1/3, bar	Packaging information
4089984	PHARMA-APT ST TBG 4.8MMX8.8MM,FT,50FT-S	0.19	0.35	0.08	4.8	8.8	2.0			50 feet/coil, 1 coil/box
4076001	PHARMA-APT ST TBG 4.8MMX9.6MM,FT,50FT-S	0.19	0.38	0.09	4.8	9.6	2.4			50 feet/coil, 1 coil/box
4076619	PHARMA-APT ST TBG .250X.375,FT,50FT	0.25	0.38	0.06	6.4	9.5	1.6	2.8[1]	0.9	50 feet/coil, 1 coil/box
4076981	PHARMA-APT ST TBG .250X.4375,FT,50FT-S	0.25	0.44	0.09	6.4	11.1	2.4	4.1[1]	1.4	50 feet/coil, 1 coil/box
4040491	PHARMA-APT ST TBG .250X.500,FT,50FT-S	0.25	0.50	0.13	6.4	12.7	3.2	5.2	1.7	50 feet/coil, 1 coil/box
4071215	PHARMA-APT ST TBG 8MMX12MM,M,15M-S	0.31	0.47	0.08	8.0	12.0	2.0			50 feet/coil, 1 coil/box
4085725	PHARMA-APT ST TBG .3125X.500,FT,50FT-S	0.31	0.50	0.09	7.9	12.7	2.4	3.4[1]	1.1	50 feet/coil, 1 coil/box
4085723	PHARMA-APT ST TBG .375X.500,FT,50FT-S	0.38	0.50	0.06	9.5	12.7	1.6	1.6[1]	0.5	50 feet/coil, 1 coil/box
4090087	PHARMA-APT ST TBG .375X.5625,FT,50FT-S	0.38	0.56	0.09	9.5	14.3	2.4	2.9[1]	1.0	50 feet/coil, 1 coil/box
4040286	PHARMA-APT ST TBG .375X.625,FT,50FT-S	0.38	0.63	0.13	9.5	15.9	3.2	3.4	1.1	50 feet/coil, 1 coil/box
4076992	PHARMA-APT ST TBG .375X.655,FT,50FT	0.38	0.66	0.14	9.5	16.6	3.6			50 feet/coil, 1 coil/box
4090085	PHARMA-APT ST TBG .500X.6875,FT,50FT-S	0.50	0.69	0.09	12.7	17.5	2.4	2.0[1]	0.7	50 feet/coil, 1 coil/box
4040490	PHARMA-APT ST TBG .500X.750,FT,50FT-S	0.50	0.75	0.13	12.7	19.1	3.2	2.6	0.9	50 feet/coil, 1 coil/box
4085722	PHARMA-APT ST TBG .500X.875,FT,50FT-S	0.50	0.88	0.19	12.7	22.2	4.8			50 feet/coil, 1 coil/box
4038450	PHARMA-APT ST TBG .625X.875,FT,50FT-S	0.63	0.88	0.13	15.9	22.2	3.2	2.3	0.8	50 feet/coil, 1 coil/box
4050914	PHARMA-APT ST TBG .625X1.00,FT,50FT-MP	0.63	1.00	0.19	15.9	25.4	4.8			50 feet/coil, 4 coils/box
4090086	PHARMA-APT ST TBG .750X1.00,FT,50FT-S	0.75	1.00	0.13	19.1	25.4	3.2	1.7	0.6	50 feet/coil, 1 coil/box
4078666	PHARMA-APT ST TBG .750X1.125,25FT,FT-S	0.75	1.13	0.19	19.1	28.6	4.8			25 feet/coil, 1 coil/box

Note: Burst pressure values are typical values and are not intended for writing specifications. Test method is based on ASTM D380-14.
[1] Predicted burst pressure: A regression formula was used to calculate burst pressure of these tubing sizes not actually tested for burst pressure.

About DuPont™ Liveo™

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 solutions.

For more information about DuPont™ Liveo™ Biopharmaceutical Processing Solutions

Visit **liveo.dupont.com** – or scan the QR code to be taken directly to our biopharma processing web page, where you'll find details on our 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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