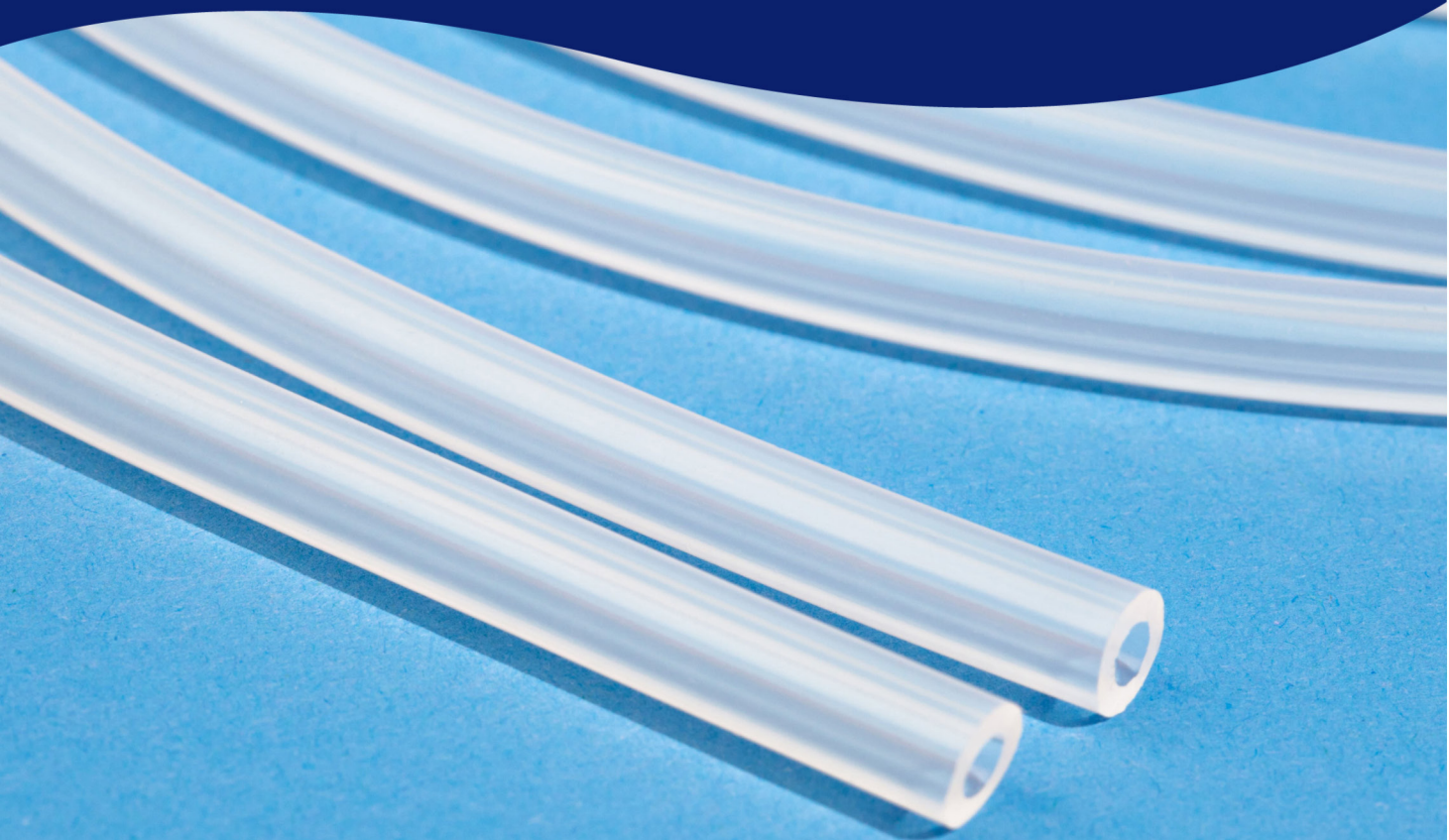


The Single-Use Expert for the Biopharma Market



Datasheet
**AS-PTC-DF - 50 Shore
Platinum-Cured Silicone Tubing**

For more information, please contact us :

sales@aseptic-group.com

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Parc du Puy d'Or, 539 allées des frênes, 69760 Limonest, FRANCE



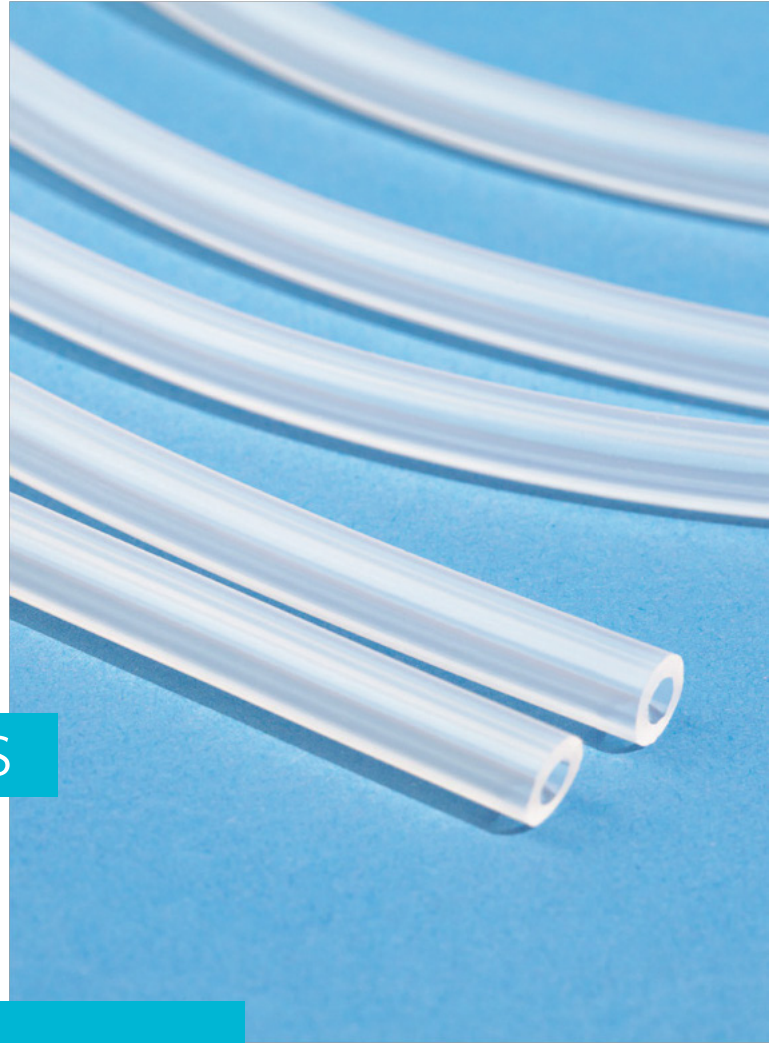
AS-PTC-DF is a pharmaceutical grade silicone tubing for safe and secure transferring of ultra-pure liquids, in pharmaceutical and biotechnological manufacturing processes.

TYPICAL APPLICATIONS

Designed for applications that require the transfer of high purity fluids where contamination is a concern.

KEY FEATURES

- Excellent flexibility
- Low extractables
- Stable over a wide temperature range
- No impaired taste or odor
- Non-wetting (hydrophobic) surface
- ISO 7 - Cleanroom manufactured
- 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"
- Manufactured to the principles of FDA 21 CFR 210/211 cGMPs for Pharmaceutical products
- High purity quality (USP 788 Particulate matter for Injection, USP 85 Bacterial Endotoxins, ISO 11737-1 Bioburden)
- FDA 21 CFR 177.2600 and USP 661 Physico-chemical tests - Plastics
- Reduces risk of contaminating ultra-pure liquids
- Complete traceability



Tubing

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Filling Needles

Sampling
systems

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PRODUCT SPECIFICATIONS

Inside Diameter (mm)	Outside Diameter (mm)	Wall (mm)	Burst Pressure (bar)
1.6	4.7	1.6	6.5*
3.2	6.4	1.6	5.5
4.8	8.0	1.6	4.5*
4.8	9.5	2.4	7
6.4	9.5	1.6	3.5*
6.4	11.1	2.4	4.9*
6.4	12.7	3.2	5.9
8.0	12.7	2.4	4*
9.5	12.7	1.6	2*
9.5	14.3	2.4	3.5*
9.5	15.9	3.2	4.1
12.7	17.5	2.4	2.4*
12.7	19.1	3.2	3.3
15.9	22.2	3.2	2.6
19.1	25.4	3.2	2.3

* Predicted burst pressure : a regression formula was used to calculate burst pressure of these tubing sizes not actually tested for burst strength.

MECHANICAL PROPERTIES ELASTOMERS

Shore A hardness	50	ASTM D 2240
Stress at 200% strain, die D	2 ₁ MPa	ASTM D 412
Stress at break, die D	9 ₁ MPa	ASTM D 412
Strain at break, die D	>300 ₁ %	ASTM D 412
Tear strength, die B	47 kN/m	ASTM D 624

1 tested on tubes

CHEMICAL MEDIA RESISTANCE

Sterilisation methods Gamma		
Autoclave Steam, 30min at 121°C	Radiation, 50 kGy	Ethylene Oxyde

Possibly resistant. Defined as: Supplier has sufficient indication that contact with chemical can be potentially accepted under the intended use conditions and expected service life. Criteria for assessment have to be indicated (e.g. surface aspect, volume change, property change).

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LIMITATIONS AND SAFETY : It is the user's responsibility to ensure the suitability and safety of Aseptic Group products for all intended uses. Products must be used in accordance with applicable regulatory requirements defined in datasheet.

Aseptic Group assumes no obligations or liability for any advice furnished by it, or for results obtained with respect to these products. The data supplied is given and accepted at the buyer's risk.

This product is neither tested or approved for any hospital or patient care use such as for temporary insertion or any in vivo procedures. This product is not to be used in human implantation, or human contraceptive, reproductive, obstetrical or gynecological applications. The user shall hold Aseptic Group harmless from any and all damages resulting from use of this product. It is the sole responsibility of the user to determine the safety and efficacy of this product for any specific use. This product is not tested for specific pharmaceutical or medical device use(s). Should you wish to use this product in a specific pharmaceutical or medical device application, please contact us to discuss such potential use. It remains the User's responsibility to ensure the safety, efficacy and legal and regulatory compliance in each relevant jurisdiction (including targeted geographic regions of manufacture and supply) of these materials for its intended uses. Aseptic Group makes no representation concerning the suitability of these products for any particular medical or pharmaceutical application. Under no circumstances should these materials be considered for implantation into the human body for periods that exceed 30 days in duration.

Before handling, please consult the corresponding material safety data sheets. These are available upon request.

WARRANTY: Aseptic Group products are warranted to be free from defects in materials and workmanship. Any products found to carry such defects will be replaced without charge. This warranty is limited only to the replacement of Aseptic Group products. Aseptic Group specifically disclaims any other liability.

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