



*Purity One™*

# *Biopharmaceutical Grade TPE Tubing*

## **The Ideal Choice For:**

- Aseptic Sealing Disconnections*
- Aseptic Welding Connections*
- Filtration*
- Sterile Filling and Transfer*
- Sampling*
- Single-Use Assemblies*



## Biopharmaceutical Grade TPE Tubing

### Introduction

Purity One One Biopharmaceutical grade TPE tubing has been formulated for demanding and critical fluid transfer applications in Biopharmaceutical processing. OneFlex is an excellent choice for applications that require heat sealing and sterile welding capabilities.

### Features

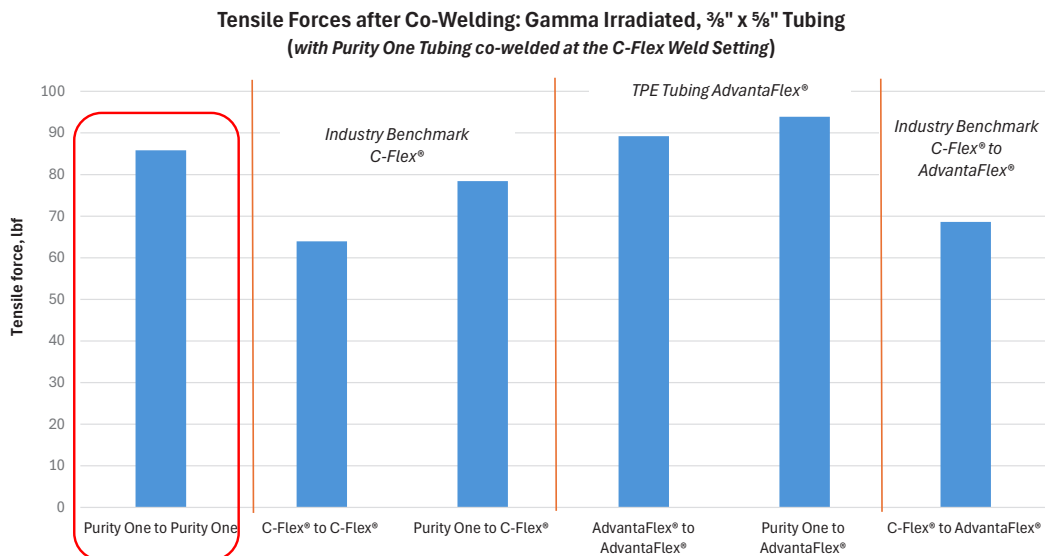
- Thermoplastic Elastomer (TPE)
- Hardness: 67D Shore A
- Moldable for Single-Use Assemblies
- USP 665 Extractable Testing
- Extensive Validation Testing



### Seal Integrity Testing



### Weld Burst and Tensile Testing



## Physical Properties

Test Standard	ASTM Method	Typical Value
Tensile Stress, 100% Strain, 73°F (psi)	D412	380
Tensile Stress, 300% Strain, 73°F (psi)	D412	680
Tensile Strength, Break, 73°F (psi)	D412	1180
Tensile Elongation Break, 73°F (%)	D412	600
Compression Set	D395B	72°F, 22hr 19%
		212°F, 22hr 69%
Specific Gravity	D792	0.89
Durometer	D2240	67

## Biocompatibility / Regulatory / Extractables

Test Standard	Test Item	Test Result
ISO 10993-4	Hemolysis	Pass
ISO 10993-5	Cytotoxicity	Pass
ISO 10993-11	Acute Systemic Toxicity Tests	Pass
USP<85>	Bacterial Endotoxin Tests	Pass
USP<87>	Biological Reactivity Tests, in vitro	Pass
USP<88>	Biological Reactivity Tests, in vitro, class VI	Pass
USP<665>	Extractables	Available Upon Request
USP<788>	Particulate Testing	Pass

## Sterilization Method

Test Standard	Test Result
High-Pressure Steam Sterilization	121°C/30min
Gamma Irradiation Sterilization	Up to 50kGy

PRODUCT NUMBER	I.D.		O.D		WALL THICKNESS		BURST PRESSURE AT 70°F (21.1°C)		CUT LENGTHS	
	(in.)	(mm)	(in.)	(mm)	(in.)	(mm)	(psi)	(bar)	(ft)	(m)
<b>(OneFlex)</b>										
OneFlex-0125-0250	0.125	3.2	0.250	6.4	0.063	1.6	CF*	CF*	50	15.2
OneFlex-0188-0313	0.188	4.8	0.313	8.0	0.063	1.6	CF*	CF*	50	15.2
OneFlex-0188-0375	0.188	4.8	0.375	9.5	0.094	2.4	CF*	CF*	50	15.2
OneFlex-0250-0375	0.250	6.4	0.375	9.5	0.063	1.6	CF*	CF*	50	15.2
OneFlex-0250-0438	0.250	6.4	0.438	11.1	0.094	2.4	CF*	CF*	50	15.2
OneFlex-0250-0500	0.250	6.4	0.500	12.7	0.125	3.2	CF*	CF*	50	15.2
OneFlex-0375-0500	0.375	9.5	0.500	12.7	0.063	1.6	CF*	CF*	50	15.2
OneFlex-0375-0563	0.375	9.5	0.563	14.3	0.094	2.4	CF*	CF*	50	15.2
OneFlex-0375-0625	0.375	9.5	0.625	15.9	0.125	3.2	CF*	CF*	50	15.2
OneFlex-0500-0688	0.500	12.7	0.688	17.5	0.094	2.4	CF*	CF*	50	15.2
OneFlex-0500-0750	0.500	12.7	0.750	19.1	0.125	3.2	CF*	CF*	50	15.2
OneFlex-0625-0875	0.625	15.9	0.875	22.2	0.125	3.2	CF*	CF*	50	15.2
OneFlex-0750-1000	0.750	19.1	1.000	25.4	0.125	3.2	CF*	CF*	50	15.2

\*For information, please contact the factory directly.

*Purity One™ manufactures single-use and custom hose solutions that are critical to improving quality of life and overall wellness for people all around the world. With our combined technical expertise and cleanroom assembly capabilities, we focus on providing a level of service and quality-assurance that is unparalleled in the global life sciences, biopharmaceutical and pharmaceuticals industries.*

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IMPORTANT: Users are accountable for verifying that Purity One™ products are appropriate and safe for their intended purposes, and that the materials used conform to all relevant medical regulatory standards. Purity One™ disclaims any liability for product failures resulting from the improper use of materials supplied, whether in the design, construction, or application of the products in which these materials are utilized.