



## Bottle & Flask Assemblies for Bioprocessing

Purity One™ bottles assemblies are engineered for aseptic fluid storage, sampling, and handling applications. Manufactured in an ISO Class 7 Cleanroom, Purity One's bottle assemblies are constructed from USP Class VI. Available in standard volumes ranging from 125mL - 2,000mL in 2 or 3 port configurations, our bottles are customizable with either OneFlex TPE or OneSil silicone tubing and molded bottle inserts.

SQUARE BOTTLE	CAP SIZE	PORTS	TUBING SIZE	MATERIAL	BOTTLE INSERT MATERIAL
125mL	38-430	2	1/8 x 1/4 (2)	PETG	OneFlex TPE or OneSil Silicone
250mL	38-430	2	1/8 x 1/4 (2)	PETG	OneFlex TPE or OneSil Silicone
500mL	38-430	2	1/8 x 1/4 (2)	PETG	OneFlex TPE or OneSil Silicone
1000mL	38-430	2	1/8 x 1/4 (2)	PETG	OneFlex TPE or OneSil Silicone
2000mL	53B	3	1/4 x 7/16 (2) and 1/8 x 1/4 (1)	PETG	OneFlex TPE or OneSil Silicone

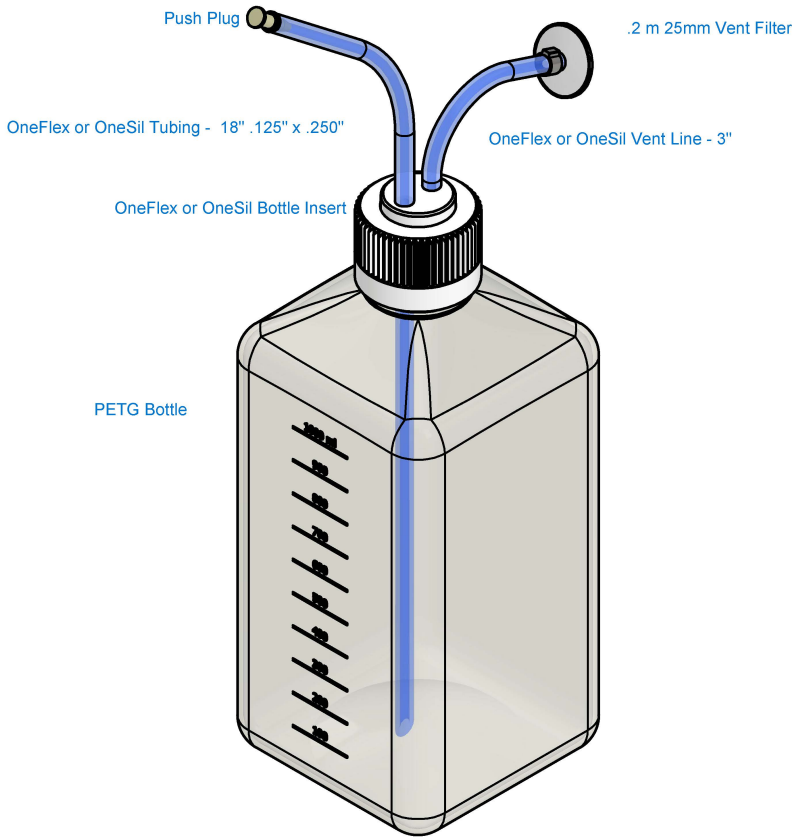
### Biocompatibility / Regulatory / Extractables

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, Class VI	Pass
USP<665>	Extractables	Available Upon Request
USP<788>	Particulate Testing	Pass

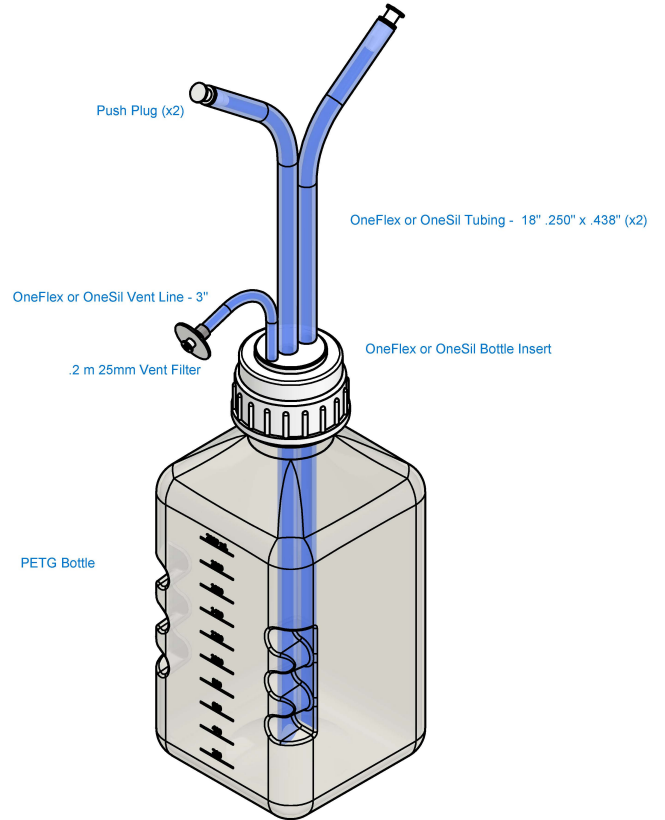
### Sterilization Method

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

38-430 bottle



53b bottle



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 pharmaceutical industries.

195 Industrial Drive  
Northampton MA 01060

(413)320-4650

sales@purityone.com

purityone.com



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.