

SterilEnz



Samplers

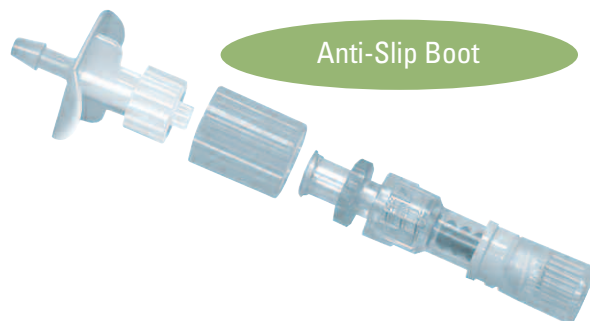
Maintain the Sterility of Critical Sampling Points on your Single-Use Products

SterilEnz® Samplers were designed for single-use bags, bioreactors and sampling systems. A common area of sample contamination (false positives) occurs directly at the injection site. SterilEnz Samplers protect this location with a rugged overwrap pouch. Durable, yet easy to remove, the pouch also serves as a tamper evident closure.



Each SterilEnz Sampler is assembled using PAW's innovative Anti-Slip Boot which insures the luer components do not unscrew during shipping or routine handling. SterilEnz Samplers provide the following benefits:

- ✓ **Ease-of-Use:** Our 3-in-1 design incorporates a needle-less valve access system, however, it can also be used with standard male and female luer components.
- ✓ **Security:** The Anti-Slip Boot maintains integrity of the luer fitting assembly. This simple solution prevents loss and contamination of your valuable process due to accidental disconnection of luer parts.
- ✓ **Sterility:** The overwrap pouch keeps the critical surfaces of your injection site sterile until time of use, thus reducing or eliminating contamination which can lead to false positive test results.



Quality & Integrity by Design

All components are USP Class VI Compliant. SterilEnz Samplers are suitable for sterilizing via gamma irradiation or autoclave.



PAW BioScience

Products for the BioTech & BioPharmaceutical Manufacturing Industries



Samplers

Technical Specifications

SterilEnz Samplers have been qualified under the most stringent test regimes. Biological, chemical and physical tests provide users of SterilEnz Samplers with data representing a variety of processing conditions. All testing was performed on finished articles POST-gamma processing.

SterilEnz Samplers are tested for compliance to:

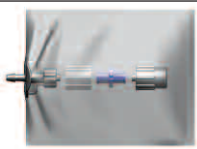
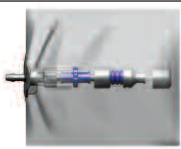



USP <87>: Cytotoxicity, MEM Elution, in vitro

USP <88>: Class VI Biological reactivity tests, in vivo

USP <661>: Physicochemical Test for Plastics

All SterilEnz Samplers are assembled inside a certified ISO 5 (Class 100) environment to insure they are free from contamination.

Material Of Construction

Description:	Standard Needle Injection Site	SmartSite® Sampler	Female Luer & Cap	Anti-Slip Boot	1/8" x MLL Flange
					
Male Luer Base Fitting	HDPE	HDPE	HDPE	N/A	HDPE
Female Luer Coupler	Polycarbonate	Polycarbonate	Polypropylene	N/A	N/A
Injection Site	PC/Polyisoprene	Acrylic/Polyurethane/ Silicone	N/A	N/A	N/A
Cap	N/A	Polypropylene	Polypropylene	N/A	N/A
Boot Material	Silicone	Silicone	Silicone	Silicone	N/A
Pouch	PET/LLDPE	PET/LLDPE	PET/LLDPE	N/A	N/A

Ordering Information

Part Number	Hose Barb	Injection Site Style	Qty/Case	Operating Temp Range	Sterilize*
CH-2ML-PCIJ-3X4	1/8"	Needle	200	-20C to 50C	G
CH-2ML-PCSS-3X4	1/8"	SmartSite®	200	-20C to 50C	G
CH-2ML-PPXX-3X4	1/8"	Female Luer	200	-20C to 50C	G
CH-MLL-GASKET.75	N/A	N/A	100	-20C to 50C	G or A
CH-2MLL (Base Only)	1/8"	Male Luer	100	-20C to 50C	G

*G = Gamma irradiate, 25-40kGy

*A = Autoclave, 123C 30 minutes

Member of BPSA 

Bio-Process Systems Alliance
Advancing Single-Use Worldwide



PAW BioScience

Products for the BioTech & BioPharmaceutical Manufacturing Industries
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Protected by U.S. Patent # 6,893,428 other patents pending.
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