

SterilEnz



Generation II/H

Hermetically Sealed Sanitary Connectors with Pre-Attached Silicone Gaskets



SterilEnz®-II/H BioProcess Connectors are specifically intended for single-use container systems. For ultimate convenience, each fitting is equipped with a medical grade silicone gasket pre-attached to the fitting face. The fitting and gasket are safely sealed inside a rugged over-wrap pouch, which maintains the sterility of the single-use system until time of use. SterilEnz-II/H fittings provide the following benefits:

- ✓ **Sterility:** Your process remains guarded by the rugged over-wrap pouch.
- ✓ **Tamper Proof:** The pouch must be removed to access the fitting.
- ✓ **Validation:** Cleaning validation and cross-contamination issues are eliminated.
- ✓ **Convenience:** The built-in sterile gasket saves time, money & eliminates gasket preparation by the end-user.

Quality & Integrity by Design

100% of all SterilEnz-II/H fittings are integrity tested to guarantee your bag and process solutions maintain their sterility. All components are USP Class VI Compliant and ADCF (animal derived component free). SterilEnz-II/H fittings are suitable for sterilizing via gamma irradiation.

Pre-Attached Gaskets



PAW BioScience

Products for the BioTech & BioPharmaceutical Manufacturing Industries

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Technical Specifications

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

SterilEnz-II/H Connectors 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

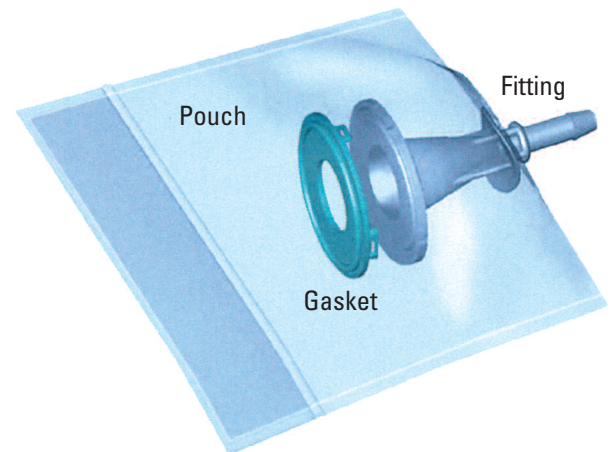
USP <1207>: Sterile Product Packaging - Integrity Evaluation, via microbial immersion

ASTM F756-00 : Rabbit Blood Cell Hemolysis

SterilEnz-II/H are certified ADCF (animal derived component free).

All SterilEnz-II/H products are assembled inside a certified ISO 5 (Class 100) environment to insure they are free from contamination.

All SterilEnz products are 100% integrity tested during manufacture.



Materials of Construction

Part	Material
Fitting	HDPE
Pouch	LLDPE/PET
Gasket	Silicone, medical grade

Ordering Information

Part Number	Hose Barb	Flange	Qty/Case	Pressure Rating*	Operating Temp Range	Gamma Cycle**
2H-408-TC-4X4	1/4"	Mini	200	75 psi	-20C to 50C	25-40kGy
2H-608-TC-4X4	3/8"	Mini	200	75 psi	-20C to 50C	25-40kGy
2H-812-TC-4X4	1/2"	Mini	100	75 psi	-20C to 50C	25-40kGy
2H-416-TC-5X5	1/4"	1"/1.5"	100	75 psi	-20C to 50C	25-40kGy
2H-616-TC-5X5	3/8"	1"/1.5"	100	75 psi	-20C to 50C	25-40kGy
2H-816-TC-5X5	1/2"	1"/1.5"	100	75 psi	-20C to 50C	25-40kGy
2H-1216-TC-5X5	3/4"	1"/1.5"	100	75 psi	-20C to 50C	25-40kGy

*Maximum operating pressure at ambient temperature.

**SterilEnz-II/H fittings are not suitable for autoclaving. If autoclaving is required, please use SterilEnz-II/AT fittings.



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Member of BPSA 

Bio-Process Systems Alliance
Advancing Single-Use Worldwide

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