

SterilEnz



II/A Assemblies

A Complete End Fitting System - Fully Assembled & Pressure Tested

SterilEnz II/A Assemblies are designed for single use applications that require the highest level of end fitting protection. Each assembly is delivered pre-assembled and fully pressure tested with end caps, gaskets and clamps. All include the SterilEnz hermetically sealed protective overwrap pouch which protects and maintains the sterility of all the components parts contained inside.

Single-use systems that use unprotected end-fittings or simple poly-pouch covers subject the process to the follow risks:

- X Risk:** Leaks due to mis-aligned parts or flange gaskets.
- X Risk:** Contamination of fluid path from adjacent non-sterile exterior surfaces.
- X Risk:** Contamination during use as a result of dropped and/or mis-aligned gaskets.
- ✓ Solution:** All SterilEnz assemblies are pressure tested to insure the parts were assembled correctly & will not leak. PAW's pre-attached gasket system (patent pending) and handle-equipped end-caps are easier for operators to handle, disassemble and reconnect. This results in cleaner connections and less chance for operator-error and contamination.

Quality & Integrity by Design

100% of all SterilEnz-II/A Assemblies are integrity tested to guarantee your clients bag and process solutions maintain their sterility. The pouch also provides a tamper-evident means of security. It must be opened using the tear-notches provided, thus indicating the bag contents have been accessed. All fluid contact materials are Class VI compliant & animal derived component free (ADCF). SterilEnz-II/A Assemblies are suitable for sterilizing via gamma irradiation.



A Complete End Fitting System



PAW BioScience

Products for the BioTech & BioPharmaceutical Manufacturing Industries



II/A Assemblies

Technical Specifications

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

SterilEnz-II/A Assemblies 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/A are certified ADCF (animal derived component free)

All SterilEnz-II/A products are assembled inside a certified ISO 5 (Class 100) environment

All SterilEnz products are 100% integrity tested during manufacture

Materials of Construction

Part	Material
Fitting	LDPE
Pouch	LLDPE/PET
Gasket	Silicone, medical grade
End-Cap	Polypropylene
Clamp	Nylon, borosilicate reinforced

Ordering Information

Part Number	Hose Barb	Flange	Qty/Case	Pressure Rating*	Operating Temp Range	Gamma Cycle**
2A-408-TC-5X5	1/4"	Mini	50	60 psi	-20C to 50C	25-40kGy
2A-608-TC-5X5	3/8"	Mini	50	60 psi	-20C to 50C	25-40kGy
2A-812-TC-5X5	1/2"	Mini	50	60 psi	-20C to 50C	25-40kGy
2A-416-TC-6X8	1/4"	1"/1.5"	50	40 psi	-20C to 50C	25-40kGy
2A-616-TC-6X8	3/8"	1"/1.5"	50	40 psi	-20C to 50C	25-40kGy
2A-816-TC-6X8	1/2"	1"/1.5"	50	40 psi	-20C to 50C	25-40kGy
2A-1216-TC-6X8	3/4"	1"/1.5"	50	40 psi	-20C to 50C	25-40kGy

*Maximum operating pressure at ambient temperature.

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

Member of BPSA



PAW BioScience

Products for the BioTech & BioPharmaceutical Manufacturing Industries
28 Eaton Road • Eatontown, NJ 07724
www.pawbio.com

Bio-Process Systems Alliance
Advancing Single-Use Worldwide

Protected by U.S. Patent # 6,893,428 other U.S. & International Patents Pending.

SterilEnz is a registered trademark of



Call now 732-460-0088

PAW BioScience Products, Inc. All rights reserved 2010