#### Rubber Fab's BIOLOGICAL BIOLOGICALOR BIOLOGI



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# **The Biological Indicator Gasket**

Rubber Fab is proud to introduce a new product that enables the use of a self contained biological indicator in sanitary process lines. This unique Rubber Fab Smart Gasket<sup>®</sup> permits either top loading or inline positioning of an EZTest<sup>®</sup> self contained biological indicator and/or a temperature probe.

The great advantage of a self contained biological indicator over the traditional spore strip in glassine is the time saved when confirming spore kill. Results are easily obtained in only 24 hours (versus the five to seven days required with a spore strip) and without problematic laboratory transfer. You can feel secure knowing that the biological indicator will not be lost down stream in the process. The fail-safe Rubber Fab Smart Gasket® holds the indicator in place for easy retrieval. Available for 3/4", 1.0", 1.5" and 2.0" Sanitary, Tri-Clamp process lines.

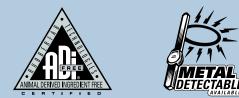
Rubber Fab'a Biological Indicator Hinge Clamp is required for use with this gasket.

#### Meets High Pharmaceutical Standards Biological Indicator Gasket

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.2600
- Traceability: Lot and Batch
- Certification: Lot and Batch
- ASME-BPE Standards
- USDA Standards
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Metal Detectable Elastomers available
- Animal Derived Ingredient Free

#### **EZTest**®

- U.S. Pharmacopeia
- ISO 11138
- European Norm 866



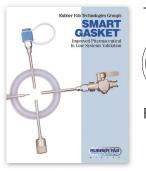




## Validation of Steam Systems

- Fermenters
- Sanitary Inline Pipe

## Smart Gasket Technology



Pharmaceutical Tanks

Pharmaceutical Hose

The Biological Indicator Gasket is also available with one (1) Smart Gasket® Thermocouple Port. See Rubber Fab's Smart Gasket literature on our website for more information on Rubber Fab's other inline system validation products.

® Smart Gasket and ADI Free are registered trademarks of Rubber Fab Technologies Group. Biological Indicator Gasket: United States Patent Number 6,927,058.

® EZTest is a registered trademark of SGM Biotech, Inc.

### **<u>CCM</u>**BIOTECH, INC.</u>

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