

Rubber Fab Technologies Group's

SMART GASKET[®]

Improved Pharmaceutical
In Line Systems Validation



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west

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Our Commitment is Certified

Rubber Fab Technologies Group successfully meets the goals and standards set forth by the U.S. Pharmacopeia, Class VI certification, passes cytotoxicity criteria and complies with Title 21 CFR 177.2600 standards. Our certification is an endorsement of our commitment to provide you with quality products that meet the highest sanitary standards and purity criteria.

NAMSA, a world leader in testing services for the medical device industry, has certified our PTFE, fluoroelastomers, platinum silicone and EPDM hygienic seals. You can be assured of our continuous commitment to our superior quality.

Meets High Pharmaceutical Standards

- 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)
- Animal Derived Ingredient Free
- Metal Detectable Elastomers available

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Rubber Fab Technologies Group's Metal Detectable products are patent pending.



Smart Gasket®

Rubber Fab's Smart Gasket's value is proven when validating sterility in a high-purity pharmaceutical system. Your standard sanitary flange utilizing the Smart Gasket is used to obtain the critical thermal mapping information you need during the validation process.

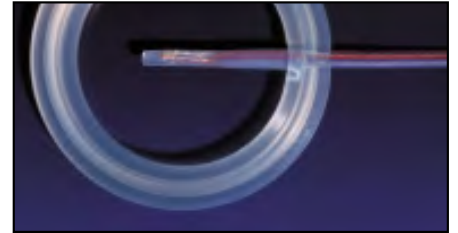
Smart Gasket easily installs between two sanitary standard flanges using the Rubber Fab sanitary Smart Clamp to secure the flanges. Our clamp provides up to four internal ports for accepting the Smart Gasket thermocouple samples or accessories; i.e. ACC-T or K-199-S-Short Temperature Probe; ACC-L or K-199A-L-Long Temperature Probe.

Choose between Rubber Fab's Thermocouple hygienic seal or select the Smart Gasket Spore Trap to securely retain spore challenge test strips. There is also a sampler device available that utilizes standard luer lock fittings.

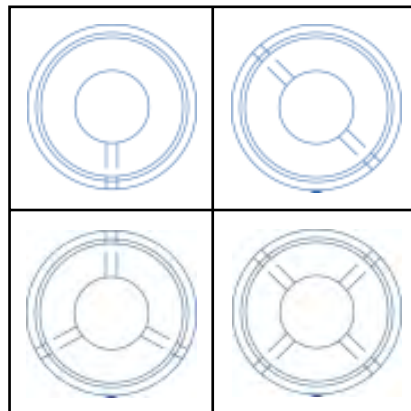
Meter fluids in your process system utilizing a peristaltic pump or withdraw samples utilizing our luer lock sampler and luer lock valve or syringe.

Smart Gasket Benefits:

- Use temporarily or permanently without custom thermowells or expensive custom fittings.
- Easy to expand to multiple system sites.
- Sanitary without a dead leg.



Available Configurations for the Smart Gasket®



Smart Gasket® Features:

- Safe to use.
- Ease of installation.
- 1, 2, 3 and 4 internal ports available.
- Sensors seal with hygienic seal compression.
- User friendly.
- Reusable.

Smart Gasket with Smart Clamp is available in 1/2", 3/4", 1", 1-1/2", 2", 3" and 4" sizes and fits standard sanitary flanges. Choose between EPDM, platinum-cured silicone, FKM and other elastomers.



Spore Trap

You will never lose spore test strips in your process system again. The Rubber Fab Smart Gasket with the Spore Trap is designed to securely retain and accurately expose spore challenge test strips for use in steam sterilization when validating. After each validation cycle, the spore trap, with its securely retained test strip, can easily be removed and rechallenge.

Spore Trap Benefits:

- Use in combination with the Smart Gasket Thermocouple Hygienic Seal for an accurate integration of sterilization and spore strip testing.
- 1 internal port available when utilizing the spore strip Smart Gasket.
- No need for custom fittings or weldments and is easily installed into your sanitary systems.
- Rubber Fab's Smart Gasket with Spore Trap holder is available with and without a thermocouple port.

Our Promises to Purity

Our state-of-the-art facility assures superior quality control and purity of material with rigorous standards during each critical step of production. Rubber Fab Technologies Group offers superior surface finish and elastomer purity in our finished hygienic seals.

After production, Rubber Fab seals are inspected and packaged in our cosmetic particulate free box. A step ahead of standard packaging, our box is made with cosmetic quality material that gives you a product free of particulates. Each box is clearly labeled with product information for clear inventory control. Lot and batch numbers provide traceability at all times.

Thermocouple Program

Thermometer

ACC-7001HT

ACC-7001HK

Temperature Range:

-90° to +400° C

130° to +752° F

Resolution/Accuracy:

0.1° C, 0.2° F $\pm 0.05\%$ of reading

$\pm 0.7^\circ$ C or 1.3° F.

Accuracy is specified for operating ambient temperature of 23° C $\pm 5^\circ$ C.

Cold junction error for thermocouples:

For operating ambient temperature for 0° C to $+18^\circ$ C and $+28^\circ$ C to 50° C, and an additional error of $\pm 0.03^\circ$ C/per degree C, or $\pm 0.03^\circ$ F/per degree F.

Model ACC-7001H is a high-performance, precision hand-held instrument for the measurement of temperature using type T thermocouple probes.

This versatile instrument measures temperature in both $^\circ$ C and $^\circ$ F. The internal memory of the micro-computer stores the minimum and maximum measured temperature for instant recall via the LCD display.

Extension Leads

ACC-EXT-3MM-OAL-3 FEET

ACC-EXT-6MM-OAL-6 FEET

ACC-EXT-12MM-OAL-12 FEET

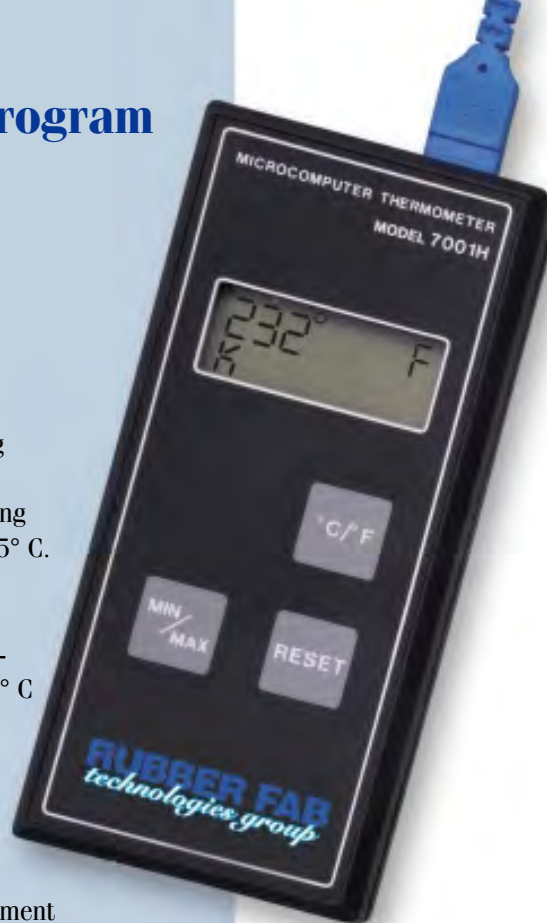
Male to male (sub-miniature type T connectors) 26 gauge. Stranded type to thermocouple wire with blue PVC insulation.

Temperature Probe

ACC-K or T-199A-S (short)

ACC-K or T-199A-L (long)

Short and long temperature probe for thermocouple gasket. Copper Constantan female socket and bootie.



ACC-7001H

ACC-EXT

ACC-T-199

ACC-T202A

ACC-T202

ACC-T1V-10

ACC-T202B

Hole Plug

ACC-T202A

Chrome-plated brass head with stainless steel shaft
1-1/2" long .095 diameter.

Stopcock

ACC-T202B

To fit sampling/injection tube. Chrome-plated brass construction female luer fitting to male luer lock.

Sampling/Injection Tube

ACC-T202

Chrome-plated brass female luer head with 1-1/2" long stainless hypodermic tube .095 O.D., .071 I.D.

Thermocouple Wire

ACC-T1V-10

ACC-KV-10

Coated thermocouple wire probe x 10' long with male mini quick disconnect connector for use with thermometer. Specify Kaptan or FEP when ordering.

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