

Rubber Fab's High Purity

PLATINUM SILICONE HYGIENIC SEALS



Rubber Fab

a Garlock Hygienic Technologies company

Rubber Fab Purity: The Complete Platinum Cured Silicone Program

High purity platinum cured silicone hygienic seals are the ideal choice for use in production facilities of fine pharmaceutical, biotechnology, high-purity water, injectables, food and beverage products. Rubber Fab's platinum cured silicone seals withstand temperature extremes, radiation, corona, ozone exposure*, moisture and steam. Due to its smooth finish, platinum cured silicone resists product adhesion. These odorless, tasteless, non-toxic hygienic seals maintain product integrity and can be autoclaved, irradiated and gas sterilized. And because there is no Benzoic Acid residue, Rubber Fab's platinum cured silicone hygienic seals provide you with the ultimate, high pure, contact surface.

The Choice is "Clear"

- Eliminates particulates
- Non-pyrogenic
- No pigmentation
- No plasticizers
- No Benzoic Acid
- Non-toxic
- High/low temperature range: -100°F to 450°F
- S.I.P. up to 30 psi @123°C
- No reversion
- Smooth bore
- Non leaching
- Odorless and tasteless
- Superior tear resistance
- Metal Detectable Elastomers available

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

* Check with Rubber Fab for specifics.

The Platinum Cured Silicone Hygienic Seal

When considering silicone seals, platinum cured is the most favorable over peroxide cured. The curing method used on the silicone has a direct affect on the amount and type of extractables the hygienic seal will emit.

Peroxide curing will always have residuals from the curing additive. Its conversion, Benzoic Acid, will result in an unwanted surface condition causing product contamination. Platinum curing eliminates this problem and minimizes reactions with the respective process fluids. All Rubber Fab silicone hygienic seals are post cured and will not cause cell mutation or growth retardation. They maintain and uphold ultra-pure water and CGMP process fluid standards. **WHAT YOU PUT IN, YOU GET OUT.**

Superior Tear Resistance

Rubber Fab manufactures all platinum silicone hygienic seals from milled gum silicone. When compared to LIM (liquid injection molding) silicone, milled gum silicone seals have superior resistance to tearing and deformation.

Complete Choice in Platinum Cured Silicone Products

Rubber Fab's platinum cured silicone seals are available in all designs. They are interchangeable with standard sanitary clamp seals and work with Rubber Fab's Torque-Rite® (see below). Additional product lines are also available, including Smart Gasket®, platinum cured silicone sheets, O-Rings and platinum cured silicone tubing.



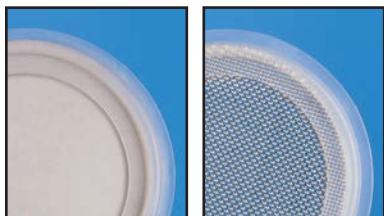
TORQUE-RITE®

The Torque-Rite retrofits all sanitary clamps, mini through 6" and is available in 30 or 50 inch/pound models. No torque wrench or special training required.

**MODEL TR-30
is the recommended
model for Platinum Cured
Silicone Hygienic Seals.**

Fluid Conditioning Hygienic Seals

Rubber Fab's line of fluid conditioning seals provide particulate elimination to protect fill and finish sterile products.



A full range of stainless steel mesh and filter cloth is available (20 micron through mesh). Metallic screens are in stock for all particulate removal needs in your injectable filled product, chromatography, columns, filtration, downstream or upstream particulate removal. Perforated, screen and orifice fluid conditioning seals, removable discs and holders are also available.

Self-Draining Orifice Plates

The Rubber Fab Orifice Plate is offered in a concentric or self draining eccentric bore configuration. Designed to prevent dead legs, volume hold up and maintain flow while assuring drainage, the Orifice Plate eliminates the potential for soil retention. Manufactured from 316L stainless steel, Rubber Fab's Orifice Plates adjust flow rates, balance backflow and equalize pressure during SIP procedures while maintaining sanitary conditions. Tabbed Orifice Plates are also available. All orifice plates can be electropolish finished.



Platinum Silicone Properties

Formulation

CPO-3003/80
70 Durometer Platinum Cure
Silicone Elastomer

Specific Gravity

1.200 Lower Limit
1.240 Upper Limit

Durometer Shore A

65.0 Lower Limit
75.0 Upper Limit

Tensile (PSI)

Min. 700

Elongation (5)

Min. 800

Modulus 100% (PSI)

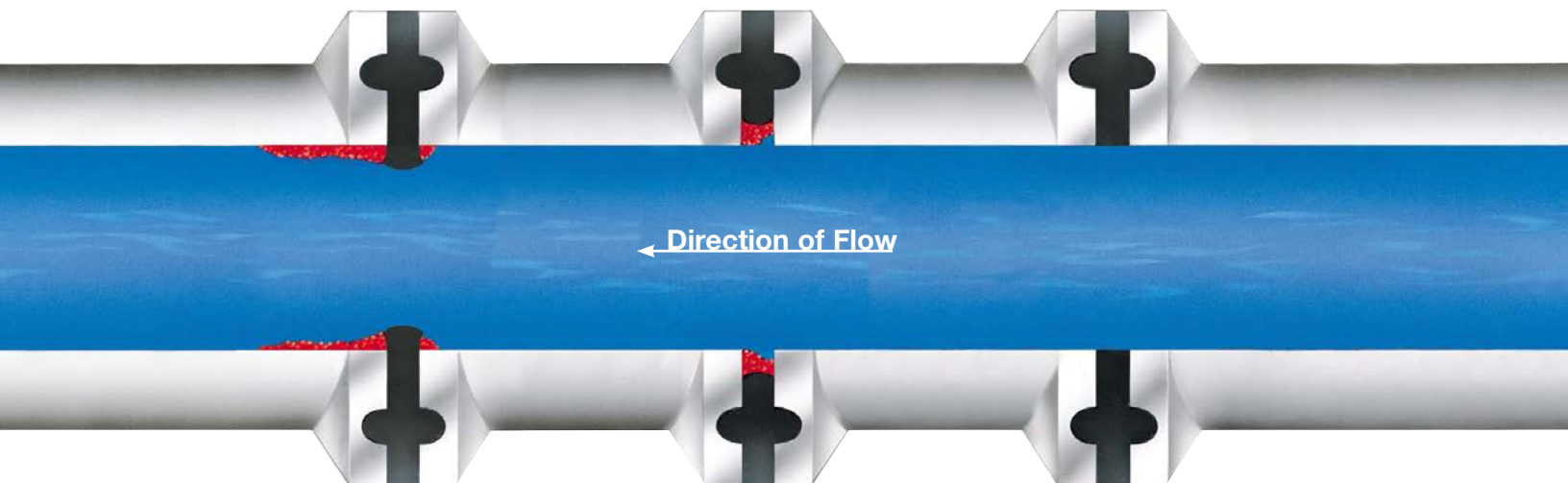
0.0 Lower Limit
2000 Upper Limit

Tear B (PPI)

Min. 200

Compression Set

87% (Not post-cured)
50% (Post-cured)



OVER TIGHTENED GASKET

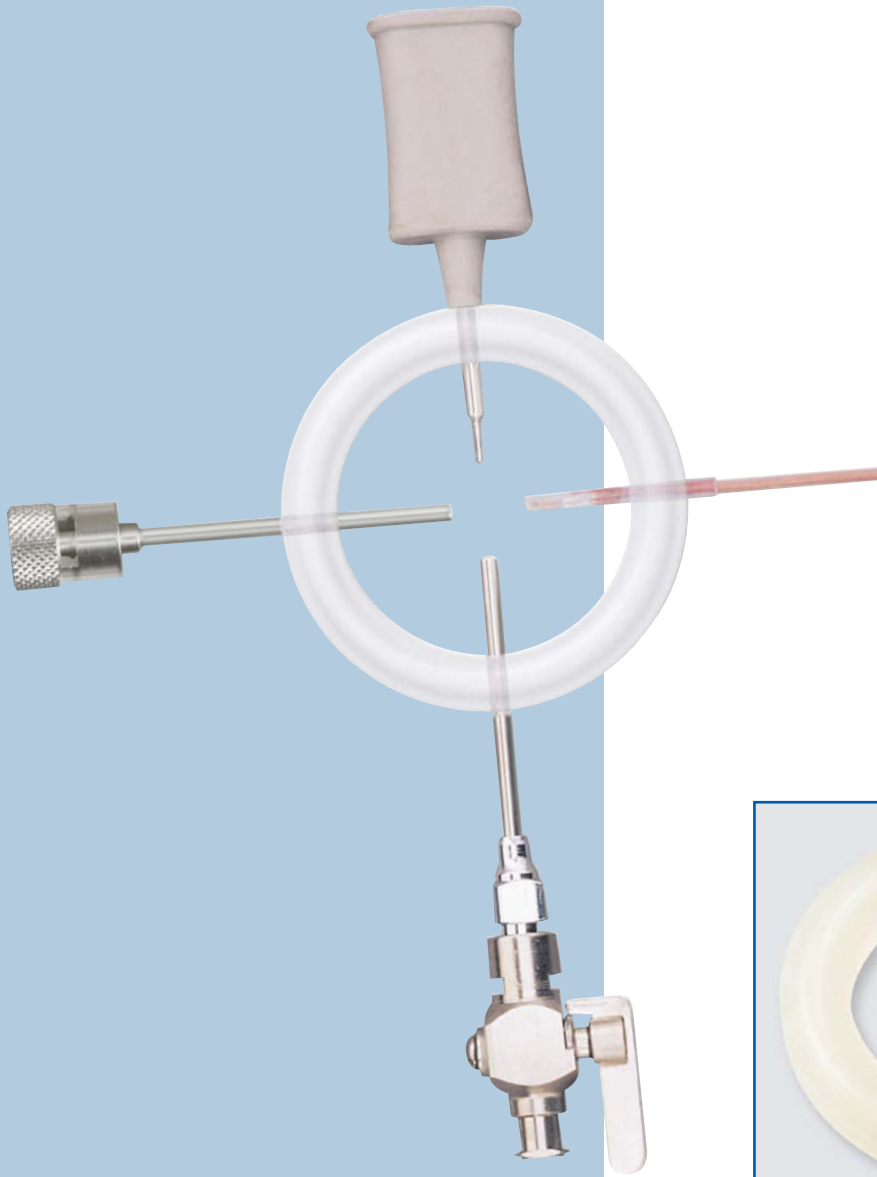
An over-tightened gasket extrudes into the pipe, prevents draining, and allows deposits to build up behind the seal.

UNDER TIGHTENED GASKET

May allow leakage. Can form concave surfaces at the product side of the seal affecting free drainage and cleaning.

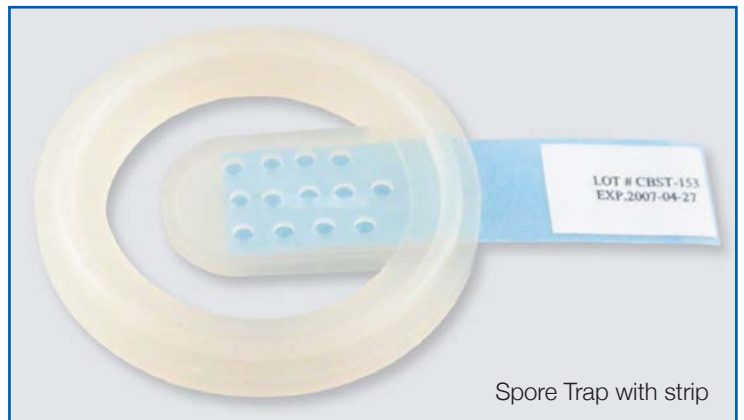
PERFECT SURFACE HYGIENIC SEAL

Torque-Rite and a Platinum Cured Perfect Surface Hygienic Seal assures that seal I.D. matches pipe I.D.

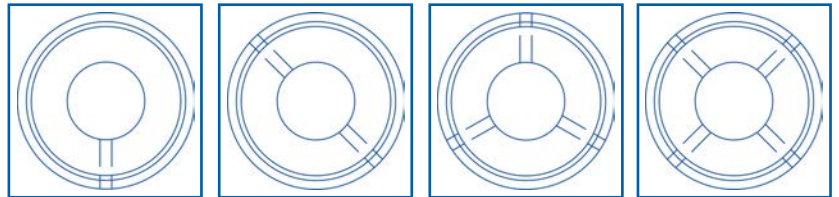


Platinum Cured Silicone: Your "Smart" Choice

It's value is proven when validating for 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. Our clamp provides up to four internal ports for accepting the Smart Gasket® thermocouple sampler or accessories. Choose between Rubber Fab's Thermocouple Hygienic Seal or select the Smart Gasket® Spore Trap to securely retain spore challenge test strips. Meter fluids in your process system utilizing a peristaltic pump (feeds in or out), syringe, sampler, valve, with optional luer lock.



Available Smart Gasket Configurations



1 Port

2 Ports

3 Ports

4 Ports



- Smart Gasket, Torque-Rite and ADI Free are registered trademarks of Rubber Fab.
- Torque-Rite: United States Patent Number 6,082,941.

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