

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

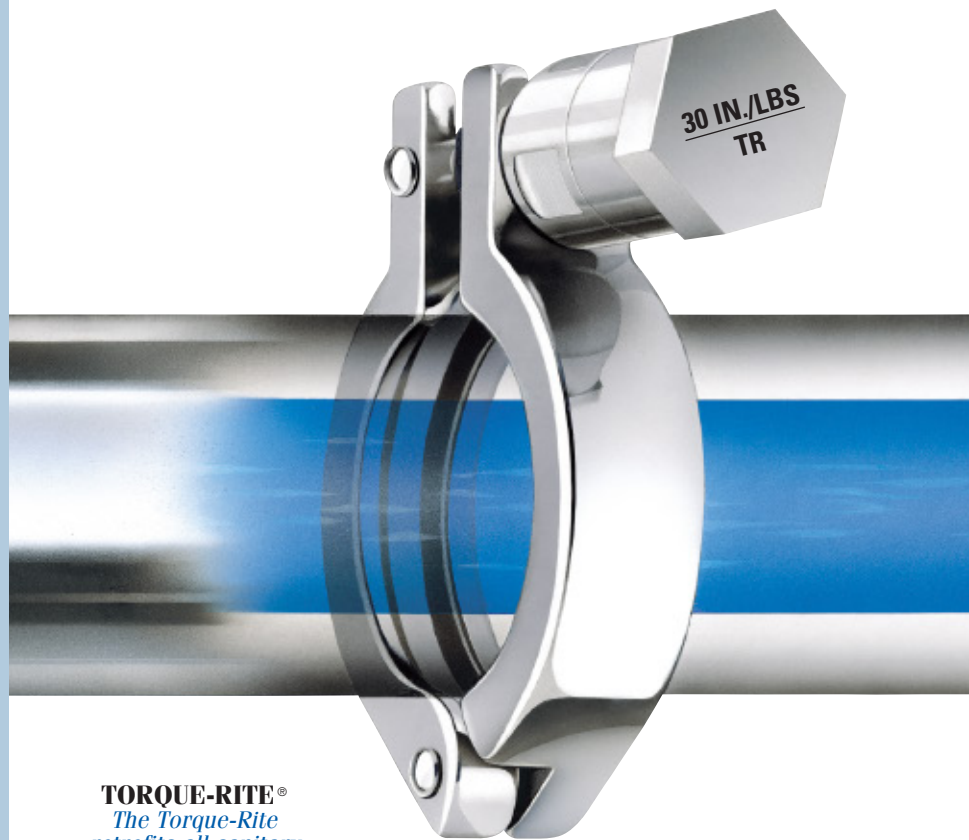
When considering silicone seals, **platinum cured** is the most favorable over peroxide cured. The curing method used on the silicone has a direct affect on the amount and type of extractables the hygienic seal will emit. Peroxide curing will always have residuals from the curing additive. Its conversion, **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**.

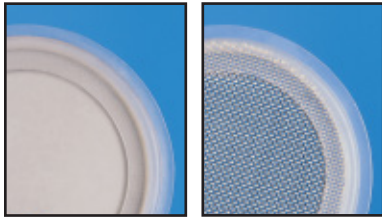


**TORQUE-RITE®**  
*The Torque-Rite retrofits all sanitary clamps, mini through 6" and is available in 30 or 50 inch/pound models. No torque wrench or special training required.*

**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

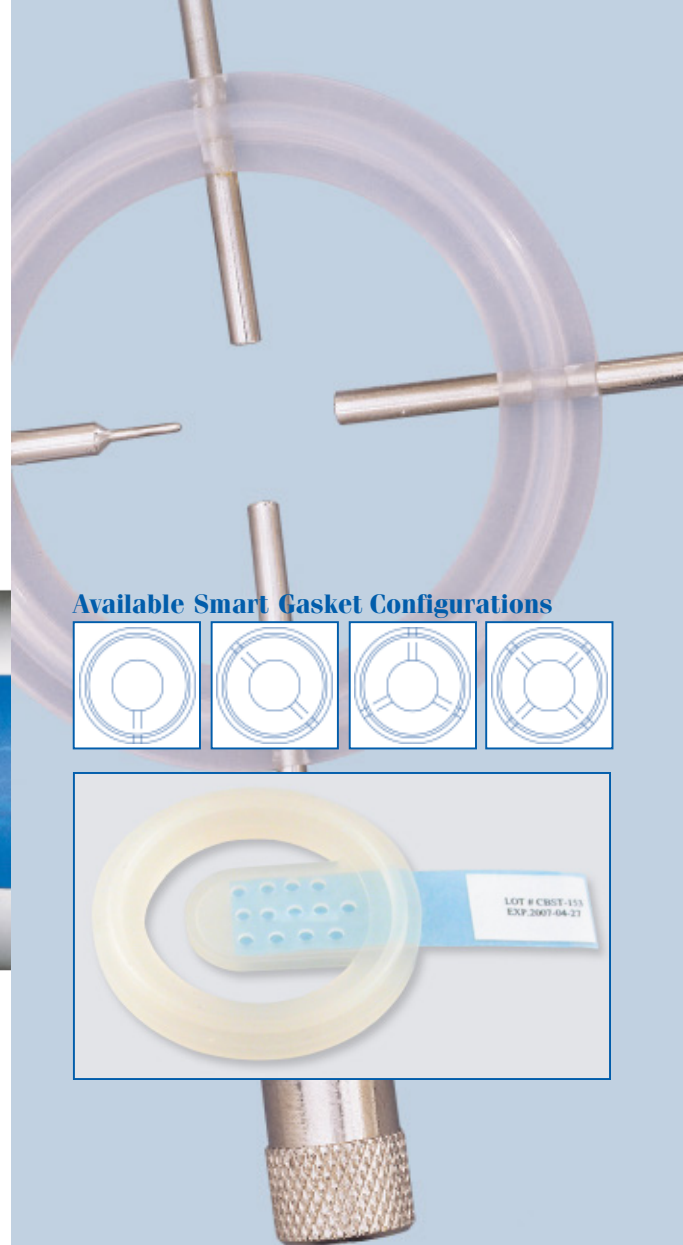
The Rubber Fab Orifice Plate is offered in a **concentric or self draining eccentric bore configuration**. Designed to prevent dead legs, volume hold up and **maintain flow while assuring drainage**, the Orifice Plate eliminates the potential for soil retention. Manufactured from 316L stainless steel, 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.



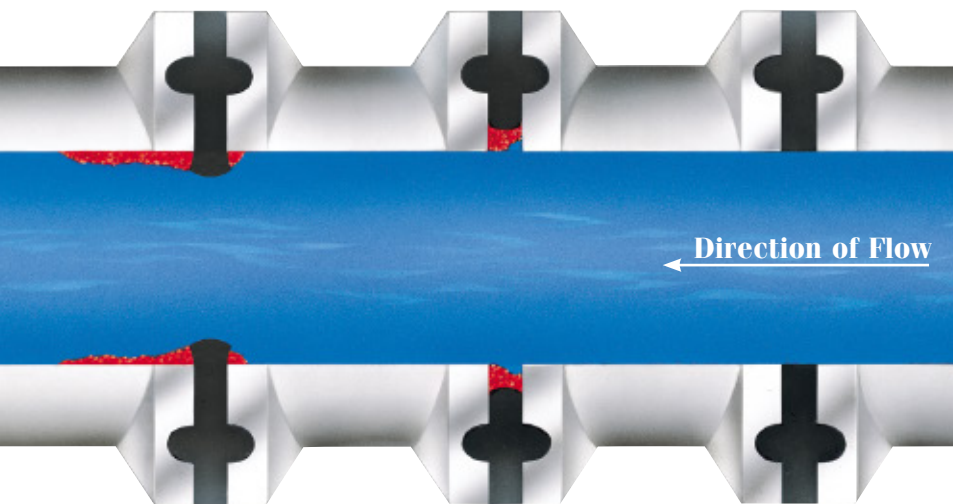
## Platinum Cured Silicone: Your "Smart" Choice

**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



#### 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 Silicone Properties

### Formulation

CPO-296  
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)

© Smart Gasket, Torque-Rite and ADI Free are registered trademarks of Rubber Fab.

Torque-Rite: United States Patent Number 6,082,941.



## Add some color...

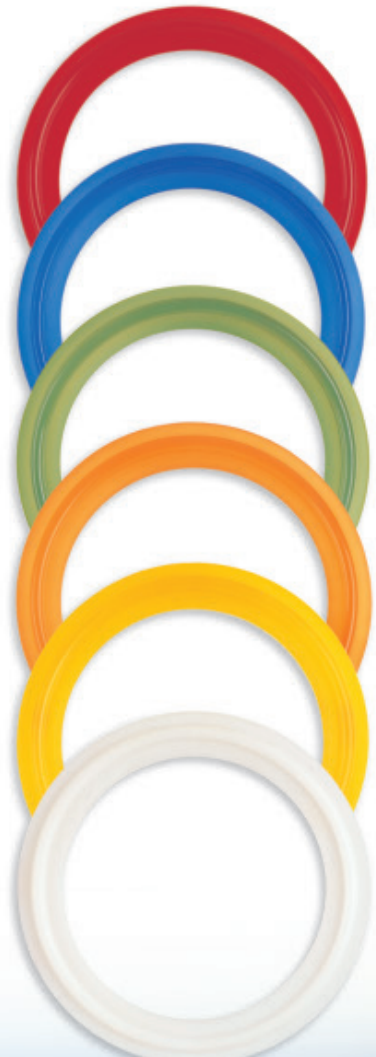
Platinum Cured Silicone hygienic seals are also available in different colors. **Colorized seals** can provide a unique way of **identifying a dedicated product line** while establishing the opportunity for a **dating mechanism and change out discipline**.

Stocked colors available include **translucent, red, and opaque white**. Consult factory for additional colors.

Note: Non stock custom colors are available and subject to minimum run quantities.

### Color coding uses include:

- Identify dedicated product lines
- Identify specific process lines
- Create a color coded change out program



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#### SANITARY CLAMP HYGIENIC SEAL

PART NO: 42 RXPX 050  
TYPE: PLATINUM CURED  
MATERIAL: SILICONE  
SIZE: 1/2"  
LOT#: HBA497B  
REORDER: 42 RXPX 050  
QUANTITY: 50

#### High Purity Pharmaceutical Gaskets

Passes - USP CLASS VI  
Passes - CYTOTOXICITY TESTING  
Meets - FDA 21 CFR, 177.2600  
Meets - 3-A STANDARDS  
---- MADE IN USA ----

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[www.rubberfab.com](http://www.rubberfab.com)

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