Improving Product Quality and Consistency

DESIGN validation production

QUALITY ASSURANCE

RUBBER FAB technologies group
Rubber Fab’s Sanitary Gasket Guidelines

- **Tuf-Flex®** is the world’s first unitized gasket, setting new standards for purity, performance and flexibility. A Tuf-Flex® Gasket’s contact surface is PTFE unitized to an EPDM rubber inner core. This **totally bonded** construction provides a PTFE gasket with the mechanical characteristics, including memory, of an elastomer gasket. Designed to meet critical requirements in biopharmaceutical, ultra-pure water, WFI (water for injection) and difficult food and beverage processing.

- **Tuf-Steel®** is composed of a unique 50/50 blend of non-pigmented PTFE and 316L passivated and atomized stainless steel. **Testing and seven years of documented application usage** has demonstrated that Tuf-Steel® is the choice for **perfect surface performance, outstanding durability and extended service life** in both SIP (steam in place) and WFI (water for injection) applications. Tuf-Steel® is **ideal for sanitary steam pipe connections** in extreme temperatures ranging from -320°F to 550°F. The **superior strength** of Tuf-Steel® **eliminates creep and cold flow** providing a leak-free seal and preventing maintenance problems and system downtime.

- **PTFE** is the material of choice whenever low temperature flexibility or gasket memory is not required and can remain in service for longer periods of time in both water and steam applications. PTFE is not recommended with large temperature variations due to creep and cold flow. PTFE has minimal extractables, has a low absorption rate and excellent resistance to process fluids.

- **Platinum Cured Silicone** is the material of choice in sanitary water systems when PTFE is not feasible due to severely misaligned fittings, or if the cost of high pressure clamps does not outweigh the benefits of PTFE (extended service life). See Rubber Fab’s Platinum Silicone Hygienic Seal literature for more information.

- **FKM Fluoroelastomer** and **EPDM** compounds are specified by many of our process equipment manufacturers. They are generally suitable for these applications, however, service life must be considered and a preventative maintenance program be implemented to mitigate degradation.

- **Buna** is the last choice in most applications due to temperature limitations and does not pass U.S. Pharmacopeia Class VI Certification and Cytotoxicity.
**Smart Gaskets®**

The Rubber Fab Smart Gasket® value is proven when validating sterility in a high-purity pharmaceutical system. The Smart Gasket® Thermocouple Gasket obtains the critical thermal mapping information needed during the validation process. They can meter fluids in your process system using a peristaltic pump or withdraw samples through our lure lock valve or syringe. The Smart Gasket® requires a specifically designed thermocouple clamp but easily installs in any standard sanitary tri-clamp. Then, utilize Rubber Fab’s Spore Trap Gasket to securely retain spore test strips.

**AVAILABLE SIZES:**
- 1/2" – 4"

**AVAILABLE PORTS:**
- Thermocouple Gasket: 1 - 4 ports
- Spore Trap Gasket: 1 port

**ACCESSORIES AVAILABLE:**
- Sampling/Injection Tube
- Hole Plug
- Stopcock
- Teflon Coated Wire Probe
- Kapton Coated Wire Probe
- Thermometer
- Extension Lead – 3 ft & 6 ft
- Temperature Probes

**Biological Indicator**

Rubber Fab’s Biological Indicator Gasket enables the use of a self-contained biological indicator in sanitary process lines. This unique Smart Gasket® permits either top loading or inline positioning of an EZTest® 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 a few hours (versus several days required with a spore strip) and without problematic laboratory transfer. Feel secure knowing that the biological indicator will not be lost down stream in the process. This fail-safe Rubber Fab Smart Gasket® holds the indicator in place for easy retrieval. Biological Indicator Gaskets require a specifically designed thermocouple clamp but easily install in any standard tri-clamp.

**AVAILABLE SIZES:**
- 3/4" – 2"

**AVAILABLE PORTS:**
- 1 port in sizes 1", 1-1/2", 2"
- N/A in 3/4”

For more information on Rubber Fab’s Biological Indicator, please visit www.rubberfab.com.

Patent 6,927,058

**Orifice Plates**

Our innovative Orifice Plate line includes a complete selection of solid 316L Stainless Steel, in standard or tabbed tri-clamp that can be custom drilled with an eccentric or concentric bore. Vertical styles, which are funnel shaped for optimal vertical drainage, are also available. Steam trap mini orifice plates are an alternative to standard steam trap technology. Tabs help to acknowledge that an orifice plate is “in line” and can be laser engraved to indicate the hole diameter, gasket size or user specified information. A major safety consideration! Rubber Fab’s Orifice Plates can enhance your system’s performance, adjust flow rates, balance back flow and equalize back pressure during SIP procedures; achievable benefits while maintaining sanitary conditions.

**AVAILABLE ELASTOMERS:**
- EPDM, FKM Fluoroelastomer, Silicone, Buna
  (Elastomer replacement gaskets are available)

**AVAILABLE FLUOROPOLYMERS:**
- PTFE, Tuf-Steel®

**AVAILABLE SIZES:**
- 1/2” – 4”
  - Consult factory for 6” and over

**ALSO AVAILABLE:**
- Slotted Clamps for Tabbed style orifice plates

**AVAILABLE SERVICES:**
- Electropolishing
- Passivation
- Laser Engraving
Screen Gaskets

Rubber Fab’s fluid filtration screen gaskets provide the most comprehensive range of stainless steel mesh and filter cloth which provide for particulate elimination to protect fill and finish sterile products, spray balls and spray nozzles. You can choose a screen gasket in a USP Class VI elastomer or Fluoroelastomer and are available in a variety of mesh sizes including 10 micron through 4 mesh. Custom screens are also available.

AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone, Buna*

AVAILABLE FLUOROPOLYMERS:
PTFE, Tuf-Steel®

AVAILABLE SIZES:
1/2” – 6” (Consult factory for 6” and over)
Consult factory for custom meshes

AVAILABLE SERVICES:
Electropolishing
Passivation
Laser Engraving

Sock Screens

The extended sock shaped mesh gasket offers up to 300% more open area for 300% more soil collection capability than conventional screens. They provide greater flow for situations where a large amount of particulates are involved. Available in 10 mesh to 325 mesh with standard 10 & 16 mesh in stock.

AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone, Buna*

AVAILABLE SERVICES:
Electropolishing

Inline Strainers & Overscreens

Today’s processing pipe lines require strainers with an increased capacity to meet production needs of state-of-the-art Food, Beverage and Pharmaceutical manufacturing facilities. Rubber Fab’s sanitary strainers and overscreens protect valuable processing equipment (pumps, spray nozzles, needle valves, heat exchangers and homogenizers) and have been specifically designed to meet the most stringent process requirements. Our sanitary strainer products are manufactured using 316L stainless steel and are designed for maximum installation flexibility, sanitary construction, and unrestricted flow.

AVAILABLE:
Inline Sanitary Strainers, Hi-Capacity Sanitary Strainers, Side Inlet Sanitary Strainers and Custom Fabricated Sanitary Strainers

ALSO AVAILABLE:
Wire mesh overscreens, hygienic overscreens, wedge wire, disposable filter socks, wire and mesh basket liners, 10 mesh to 200 mesh overscreen

V²B Vent Gasket

The Rubber Fab V²B Vent Gasket provides vacuum and pressure relief for pharmaceutical and food/beverage processing tank venting when airborne particulate removal is required. A 200 mesh screen combined with a 14 mesh screen of sintered construction creates a cost effective alternative to expensive vacuum breakers and venting systems.

The V²B System is attached/connected the same way a standard vacuum breaker is installed. Installation can be horizontal, vertical or in single or multiple port configurations (i.e. manifolds) without special fabrication or expensive tooling. The V²B screen will fit perfectly into the I.D. of a sanitary pipe and can be used for inflow fluid conditioning filtration.

AVAILABLE SIZES:
1-1/2” – 6”
**Gauge Guard Protector**

The Gauge Guard Isolator and Protector Gaskets protect expensive gauge diaphragms and instruments from damage. When moving, storing or being autoclaved, the Gauge Guard Protector Gasket protects the gauge’s fragile diaphragm from damage. The easy attach ring slips effortlessly onto the gauge keeping the Protector Gasket ready for use.

**AVAILABLE IN:**
Platinum Silicone only and Sizes 3/4” - 2”  
(3/4” protectors can be used with 1/2” isolators)

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**Gauge Guard Isolator Gasket**

By combining a Rubber Fab sanitary gasket with a thin membrane, the Isolator Gasket isolates CIP and corrosive solutions from instrumentation without affecting performance, a necessary and cost-effective step in assuring long life and accurate results.

**AVAILABLE IN:**
Platinum Silicone, PTFE, Tuf-Steel®, FKM and EPDM

**AVAILABLE SIZES:**
1/2” - 2”  
Consult Factory for sizes per material.

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**Tuf-Steel®**

Tuf-Steel® – the original metal detectable and x-ray inspectable gasket, a Rubber Fab market innovation, is composed of a unique proprietary blend of non-pigmented PTFE and 316L passivated and atomized stainless steel. Testing and many years of documented application usage has demonstrated that Tuf-Steel® is the choice for perfect surface performance, outstanding durability, extended service life and increased up-time in both SIP (steam in place) and WFI (water for injection) applications. Tuf-Steel® is ideal for sanitary steam and extreme temperature processes, specifically fryer and hot oil applications, with temperatures ranging from -320°F up to 550°F. The superior strength of Tuf-Steel® eliminates creep and cold flow providing a leak-free seal.

**AVAILABLE SIZES:**
1/2” – 12”

**TUF-STEEL® SHEET AVAILABLE:**
1/16” & 1/8” thick  
12” x 12”, 24” x 24”, and 36” x 36”

**ALSO AVAILABLE:**
Type II Flanged  
DIN/ISO  
Ansi Flange 1/8” thick  
X-Ray Inspectable  
150# Flanged Screen Gaskets

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**Tuf-Flex®**

Tuf-Flex®, the ultimate pharmaceutical sanitary gasket, is setting new standards for purity, performance, flexibility and is the world’s first unitized gasket. A Tuf-Flex® gasket’s contact surface is PTFE unitized to an EPDM rubber inner core. This totally bonded construction provides the inert, non-stick benefits of PTFE with the memory of an elastomeric gasket without fear or risk of pigmentation or spalling. Designed to meet critical requirements in biopharmaceutical, ultra-pure water, WFI (water for injection) and difficult aseptic processing applications. Tuf-Flex’s® extended service life increases up-time by out performing other gaskets by eliminating costly process interruptions.

**AVAILABLE SIZES:**
1/2” – 6”

**TUF-FLEX® SHEET AVAILABLE:**
1/16” & 1/8” thick and 13-3/4” square
Detectomer® is a full line of metal detectable and x-ray inspectable products designed to work with any existing conveyor, pipe line or free fall detection system – sanitary gaskets, o-rings, sanitary screens, sheet, rod, hose, tubing, extrusions, cam & groove gaskets camlock screen gaskets, scoops, and scrapers. Detectomer® products help eliminate product recall, lower product loss and decrease the risk of components consumed in a finished product by insuring that a worn off piece of elastomer material migrating through your system will be detected and rejected by an in-line x-ray system, metal detector or removed by a mag bar. Searching for and locating fragmented component parts has traditionally been a costly, time consuming and inconclusive process. Not locating a worn and detached part can have an even costlier outcome!

Meets USDA Hazard Analysis and Critical Control Points.

AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone, Buna*

AVAILABLE FLUOROPOLYMERS:
PTFE, Tuf-Steel®

DIN/ISO

Rubber Fab's DIN/ISO gaskets are manufactured in compliance with FDA, USP Class VI requirements to insures the highest purity sealing product available worldwide. We offer the following line of European standard sanitary gaskets DIN32676, DIN11851, DIN11864, ISO1127, ISO2852, SMS1149

AVAILABLE ELASTOMERS:
Platinum Silicone, FKM Fluoroelastomer, EPDM, Buna*

AVAILABLE FLUOROPOLYMERS:
PTFE, Tuf-Steel®

Lock & Label

Lock & Label tags provide sanitary system safety, security and identification. When properly installed, they cannot be opened, reducing the risk of accidental steam or product release. Lock & Label tags will work with most hinge clamps. Customer specified labeling is available.

AVAILABLE IN:
Blue, Green, Red, Yellow and White

Metal Detectable Patent # 7,390,580
Detectomer® Patent Pending 61/414,552
Rubber Fab Technologies Group is pleased to announce a new division! Rubber Fab The O-Ring Group offers a full line of AS 568 Dash Numbers, metric and specialty O-Ring sizes in many materials including Detectomer® Metal Detectable and X-Ray Inspectable materials. Our proprietary compounds are designed to perform in a wide range of applications with varying chemical exposures, pressures and temperatures.

**Products**
- O-Rings
- O-Ring Kits
- O-Ring Cord

**Materials Available**
- Buna*
- Silicone
- FKM Fluoroelastomer
- EPDM
- PTFE
- Tuf-Steel®

**Available AS 568 Dash Numbers and Metric O-Rings**
- Standard
- FDA
- Class VI
- Detectomer® Metal Detectable/X-Ray Inspectable

**O-Ring Cord**
Vulcanize your own O-rings from our selection of O-ring cord stock, offered in both inch or metric sizes.

**Materials Available**
- Standard
- FDA
- Metal Detectable
Standard Gaskets

Rubber Fab standard Tri-Clamp® sanitary gaskets are manufactured using FDA compliant compounds, and according to CGMP guidelines. Our 1/2” – 4” Type I EPDM, FKM Fluoroelastomer, Silicone and PTFE, Tuf-Flex®, & Tuf-Steel® Tri-Clamp® gaskets are USP Class VI and FDA CFR 177.2600 & 177.1550 and ADI (Animal Derived Ingredient Free) certified.

Rubber Fab offers a variety of:
- APC
- Bevel Seat
- Camlock
- Detectomer® Metal Detectable/ X-ray Inspectable
- Diffuser
- DIN/ISO
- Envelope
- Full Face Flange Gaskets 150# & 300#
- Gauge Guard
- I-Line
- John Perry
- Manway
- Orifice Plates

In addition to standard gaskets Rubber Fab offers custom Screen Gaskets, Custom Gaskets, and Custom Tooling. We also offer Sanitary Sheet Material, profiles and cord in Class VI and FDA compliant materials.

- O-Rings
- Perforated Plates
- Q-Line
- Quad Rings
- Schedule V
- Screen
- Smart Gaskets®
- Tuf-Flex®
- Tuf-Steel®
- Tri-Clamp® Type I
- Tri-Clamp® Type II
- V2B Vent Gasket
- Valve Body
Torque-Rite® allows you to control compression and expansion while maintaining constant inch/pounds force ensuring a Perfect Surface I.D. Torque-Rite® eliminates sanitary problems associated with over- or under-tightening a gasket. When tightened, the Torque-Rite’s® self-limiting internal mechanism will make an audible “click” signaling the user that they have reached proper inch/pounds force. If further tightening is attempted, there will be more “clicks” but no additional application of force on the gasket. Because Torque-Rite® does not require any special tools or training, exact torque is reached faster and on the first try!

AVAILABLE:
30 in/lbs for all elastomers and Tuf-Flex®
50 in/lbs for PTFE and Tuf-Steel®

Rubber Fab is proud to introduce the next generation of sanitary hinge clamps – the one-piece, completely unitized Smart Clamp™. With features that include half-turn installation and faster uptime, the benefits of Rubber Fab’s Smart Clamp™ far exceeds any other sanitary clamp.
- Dramatically increased uptime
- Supports ASME-BPE seal performance
- Half-turn installation
- Repetitive stress and ergonomic benefits
- Multiple compression settings for sanitary gaskets, no over or under tightening of gasket
- Extends gasket’s service life
- Deeper clamp channel nests ferrules and evenly distributes force over the gasket’s face
- Single unitized unit - no additional parts
- Threadless system minimizes soil and bacterial entrapment
- Clamp hinge and locking arm will not collapse
- Manufactured in 304 Stainless Steel
- No tools required
- User-friendly

Services
What really sets Rubber Fab apart from other manufacturers are our value added services.

Coding & Labeling:
Time is money. Don’t waste valuable time searching for sanitary components in your process line. “Identify” your system components using one of Rubber Fab’s System Identification products.

Laser Engraved Products & Bar Coding:
Gaskets, hose assemblies, stainless fittings & adapters insure process line identification and provide complete cradle to grave lot and batch traceability.

Laser Engraved Products & Bar Coded Collars present a sharp legible, professional image. Include your company name, application-specific information such as serial numbers or maintenance codes, and more. Use etched collars to communicate your most critical information. Part numbers, sizes, service dates, and usage recommendations are just a few examples.

Tabbed Orifice Plate Gaskets:
Tabs protrude from clamp and can be laser etched for easy line identification.

NOTE: Consult factory for spacing and size limitations on all etched products.
Hose, Hose Assemblies, Tubing, Fittings and Adapters

High Purity Platinum Silicone Hose, Tubing, Sanitary Molded Ends
PTFE & FEP Lined Smooth Bore & Convoluted Hose
Metal Hose
FDA Rubber Hose
FDA PVC Hose, Tubing, Sanitary Molded Ends
Sight Gauges: PTFE & Polysulfone
Fittings & Adapters: 316L, Special Alloys & Non Metallic
3A Standard Number 62-02

Rubber Fab Gaskets Meet the Most Stringent Standards For Purity

- U.S. Pharmacopeia Class VI Certification*
- Cytotoxicity Criteria*
- Title 21 CFR 177.2600 and 177.1550
- USDA and 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- ASME-BPE Standards
- Animal Derived Ingredient Free*

* Buna does not pass U.S. Pharmacopeia Class VI Certification and Cytotoxicity and is not ADI free.