Improving Product Quality and Consistency

DESIGN validation production QUALITY ASSURANCE



RUBBER FAB
technologies group

www.rubberfab.com

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.
- **Food-Flex** is setting new standards for **purity and performance for the food and beverage industries**. Food-Flex will not absorb product, thus eliminating flavor transfer and reducing the need for costly gasket changeouts. A contact surface of PTFE unitized to a Buna rubber inner core provides a PTFE gasket with the inert, **non-stick characteristics** and memory of an elastomer gasket **without pigmentation or spalling**. Unlike standard PTFE gaskets, once clamped (30 in./lb), **Food-Flex eliminates leaks** in ΔT situations and **out performs all standard elastomeric gaskets by providing 2-6x extended service life**.
- **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 -350°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 literature RF-170 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.

1 = Excellent 2 = Good 3 = Acceptable 4 = Marginal 5 = Poor X = Do Not Use

Gasket Comments	Continuous Steam	Intermittent Steam	Pure Water Ambient	Pure Water Hot	Process Fluids Ambient	Process Fluids Hot	Process Fluids Variable (<0°C->100°C)	Temp. Range
Tuf-Flex®/Ansi-Flex	1	1	1	1	1	1	1	-20°F to 300°F
Maintains seal with wide temperature variations. Has extended service life.*								
Food-Flex	X	2	1	2	1	2	2	-30°F to 250°F
Maintains seal. No pigmentation or spalling. Has extended service life.*								
Tuf-Steel®	1	1	1	1	1	1	1	-350°F to 550°F
Maintains seal with wide temperature variations. Has extended service life.*								
HPV	1	1	1	1	1	1	1	See Elastomer of choice
EPDM, FKM, Silicone†								
PTFE	1	1	1	1	1	1	3	-100°F to 500°F
Wide temperature variations and may cause leakage at ΔT.								
Silicone (platinum)	2	2	2	2	2	2	1	-40°F to 450°F
Very flexible low temperature.								
FKM Fluoroelastomer	2	2	2	2	2	2	2	-30°F to 400°F
Acceptable for steam applications.								
EPDM (peroxide cured)	3	3	3	3	3	3	3	-20°F to 300°F
Low pressure steam only.								

* Application dependent. † 100 SIP steam cycle tested.

Smart Gaskets®



The Rubber Fab Smart Gasket® value is proven when **validating sterility** in a high-purity pharmaceutical system. A standard sanitary flange utilizing the Smart Gasket® Thermocouple Gasket obtains the critical **thermal mapping** information needed during the validation process. **Meter fluids in your process system** using a **peristaltic pump** or **withdraw samples** through our luer lock valve or syringe. Then, utilize Rubber Fab's Spore Trap Gasket to **securely retain spore test strips**.

AVAILABLE SIZES:
1/2" – 4" (excluding 2-1/2")

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

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 only 24 hours (versus the five to seven 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**.

AVAILABLE SIZES:
3/4" – 2"

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

Patent 6,927,058

Orifice Plates



Our innovative Orifice Plate line includes a complete selection of solid 316L Stainless Steel, in **standard** or **tabbed TC** and **vertical styles**, that can be custom drilled with an **eccentric or concentric bore**. **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 advance your system's performance, **adjust flow rates, balance backflow** and **equalize back pressure** during SIP procedures; achievable benefits while maintaining sanitary conditions.

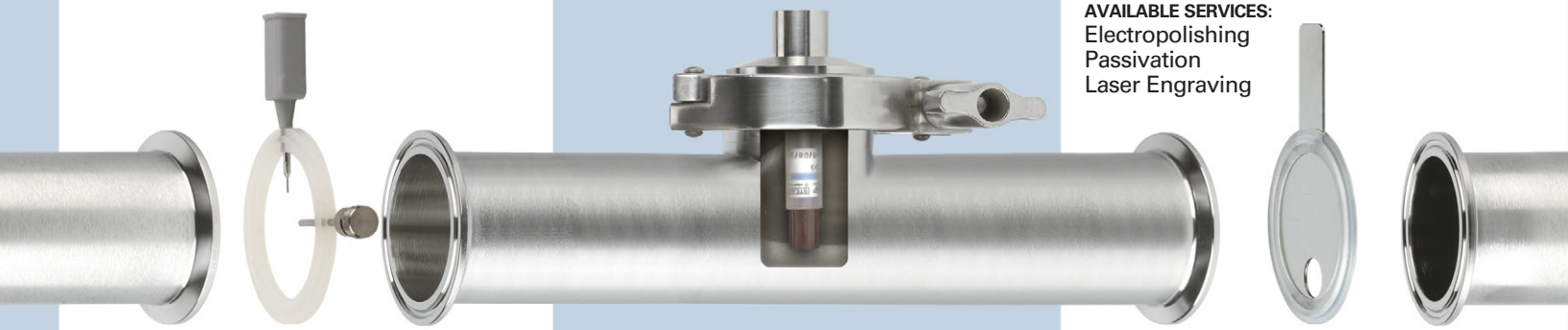
AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone, Buna*

AVAILABLE FLUOROPOLYMERS:
PTFE, Tuf-Steel®

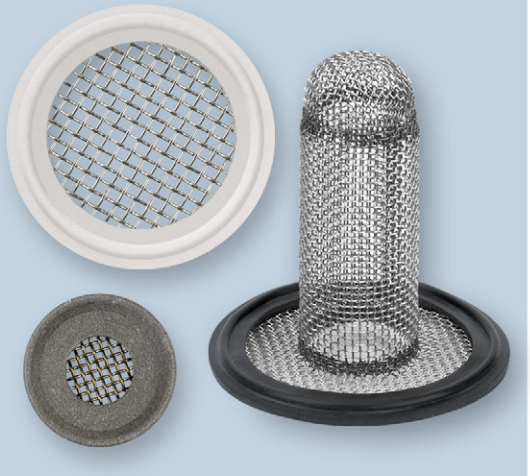
AVAILABLE SIZES:
1/2" – 4"
Consult factory for 6" and over

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 in a variety of mesh sizes, 10 micron through 4 mesh.

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 large amount of particulates are involved. Available in 10 mesh to 325 mesh with standard 16 mesh and 20 mesh in stock

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

AVAILABLE SERVICES:
Electropolishing

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.

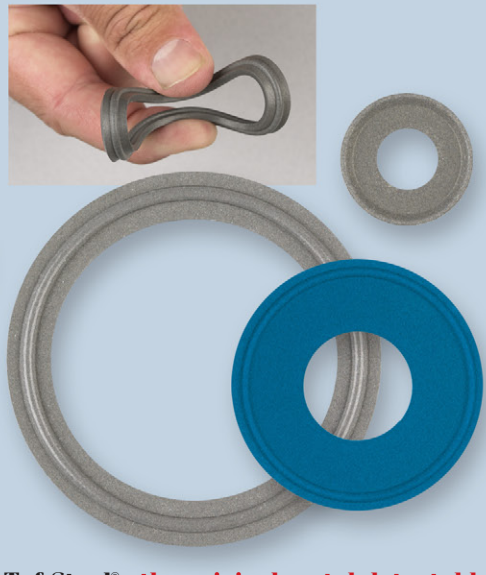
Gauge Guard Isolator Gasket

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**.





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 **-350°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
25" x 48" sheet

ALSO AVAILABLE:
Type II Flanged
Color Coded
DIN/ISO
Ansi Flange 1/8" thick
X-Ray Inspectable



PTFE Envelope Gaskets



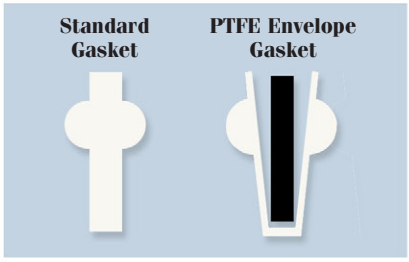
A PTFE Envelope gasket has the excellent chemical resistance and the enert characteristics of PTFE, and the EPDM or FKM elastomeric insert imparts memory. The PTFE Envelope gasket meets FDA and USP Class VI standards.

AVAILABLE SIZES TYPE I:
1/2" – 12"

AVAILABLE SIZES TYPE II FLANGED:
1" – 4"

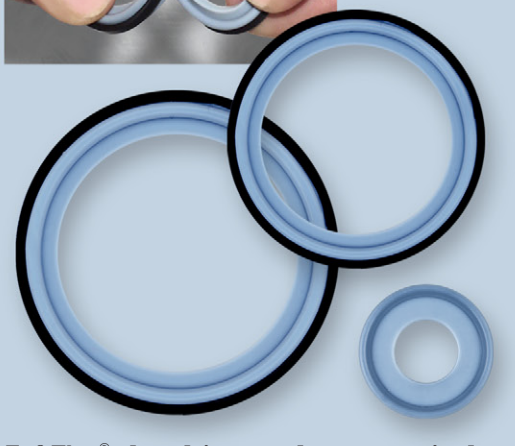
AVAILABLE INSERTS:
EPDM, FKM Fluoroelastomer

ALSO AVAILABLE:
Schedule V Envelope Gaskets



Tuf-Flex®

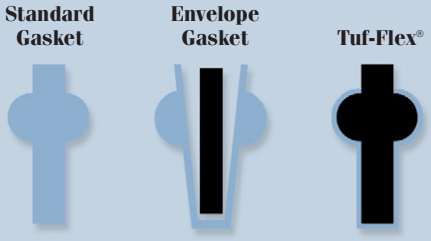




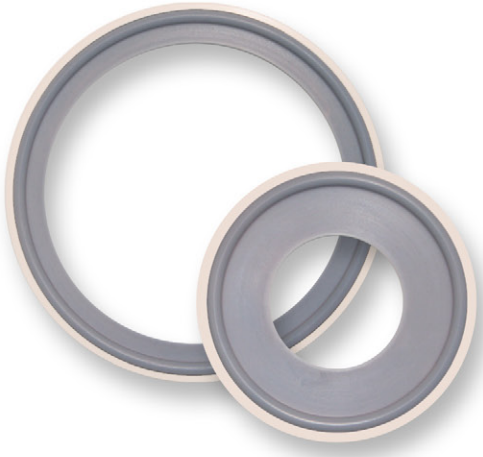
Tuf-Flex®, **the ultimate pharmaceutical sanitary gasket**, is setting new standards for **purity, performance, flexibility** and is the world's first **unitized gasket**. A Tuf-Flex® gasket's contact surface is PTFE unitized to an EPDM rubber inner core. **This totally bonded construction provides the 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**. Achieve higher performance under SIP/CIP conditions.

AVAILABLE SIZES:
1/2" – 6"

TUF-FLEX® SHEET AVAILABLE:
1/16" & 1/8" thick and 13-3/4" square

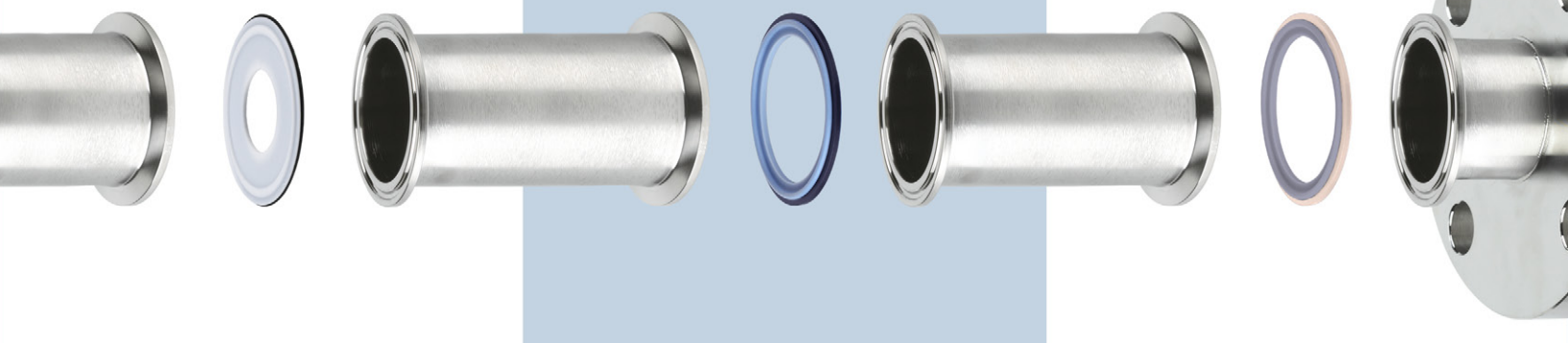


Eco-Flex



Eco-Flex, the next generation in **unitized gasket** technology, was **designed specifically for purity and performance in critical phamaceutical, food and beverage applications**. An Eco-Flex Gasket's contact surface is PTFE unitized to a Buna rubber inner core. This **totally bonded** construction provides a PTFE gasket with the inert, **non-stick characteristics** and memory of an elastomer gasket **without pigmentation or spalling**. Eco-Flex will not absorb product, thus eliminating flavor transfer and **reducing need for costly gasket changeouts resulting in increased up-time**. Unlike standard PTFE gaskets, once clamped (30 in./lb), **Eco-Flex eliminates leaks** in ΔT situations and **resists all CIP (Clean in Place) media**. Eco-Flex **out performs all standard elastomeric gaskets by providing 2-6x extended service life** and helps **eliminate costly process interruptions**. Eco-Flex is suitable for use in homogenizers, carbo coolers, filtration housings and pasteurizers. Meets FDA, 3A and USDA requirements.

AVAILABLE SIZES:
1" – 6"



Ansi-Flex 150# Ansi Flange Gasket



An Ansi-Flex 150# Ansi Flange 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 with **exceptional steam resistance.** An Ansi-Flex 150# Ansi Flange Gasket is ideal for applications, such as **PVC piping and glass lining piping**, where low seating stress is required. The Ansi-Flex 150# Ansi Flange Gasket has **superior and extended service life** over standard flange gaskets. Achieve higher performance under SIP/CIP conditions.

AVAILABLE SIZES:
1/2" – 12"
Consult factory for sizes over 12"

ALSO AVAILABLE:
Ansi-Flange in 1/8" thick Tuf-Steel® material

Detectomers™

X-RAY INSPECTABLE AND METAL DETECTABLE PRODUCTS



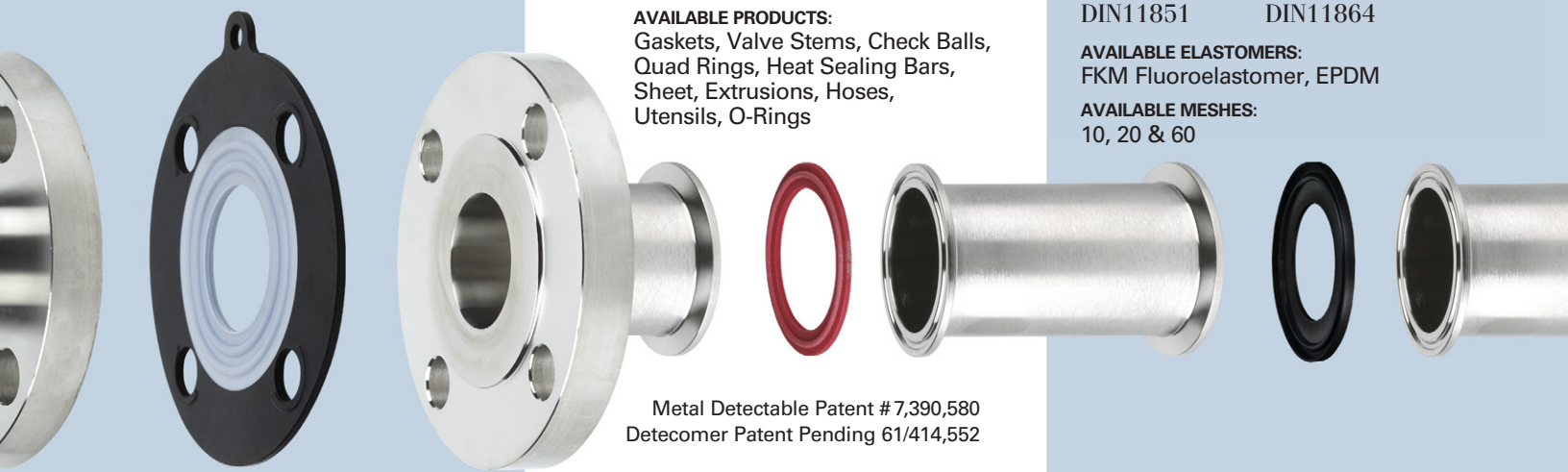
Detectomers™ is a **full line of x-ray inspectable and metal detectable products** designed to work with any existing conveyor, pipe line or free fall detection system – sanitary gaskets, o-rings, sanitary screens, sheet, rod, hose, tubing, extrusions, cam & groove gaskets, scoops, scrapers, pump and valve parts. Detectomers™ help **eliminate product recall, lower product loss and decrease the risk of components consumed in a finished product**. They insure 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®

AVAILABLE PRODUCTS:
Gaskets, Valve Stems, Check Balls, Quad Rings, Heat Sealing Bars, Sheet, Extrusions, Hoses, Utensils, O-Rings



Metal Detectable Patent # 7,390,580
Detecomer Patent Pending 61/414,552

DIN/ISO NEW!

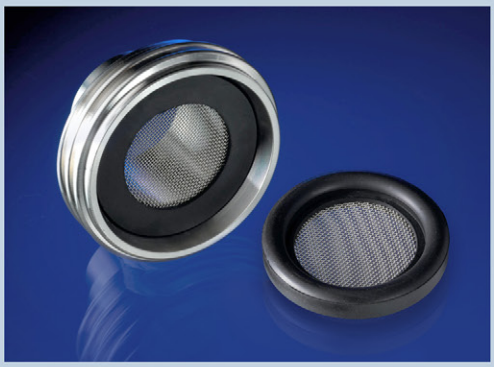


Rubber Fab's DIN/ISO gaskets are manufactured in compliance with FDA, USP Class VI requirements to **insure the highest purity sealing product available worldwide**. We offer the following line of European standard sanitary gaskets

DIN32676	DIN11851
DIN11864	ISO1127
ISO2852	SMS1149

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

AVAILABLE FLUOROPOLYMERS:
PTFE, Tuf-Steel®



DIN/ISO Screen Gaskets

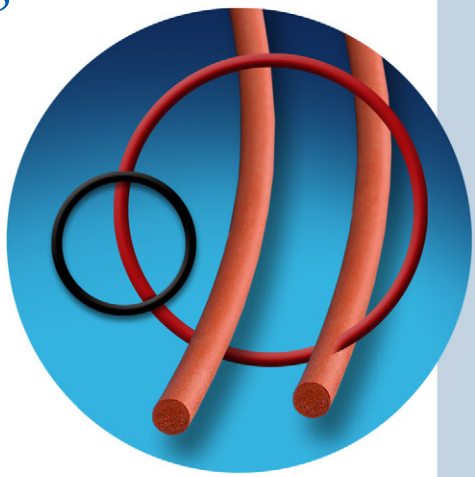
DIN11851 DIN11864

AVAILABLE ELASTOMERS:
FKM Fluoroelastomer, EPDM

AVAILABLE MESHES:
10, 20 & 60

O-Rings & O-Ring Cord

The O-Ring is an exceptionally versatile sealing device. Countless applications make it the world's most popular seal.



Rubber Fab offers a full line of AS 568 Dash Numbers, metric and specialty O-Ring sizes in many materials including X-Ray Inspectable and Metal Detectable materials. Our proprietary compounds are designed to perform in a wide range of applications with varying chemical exposures, pressures and temperatures.

O-Ring Products

- O-Rings
- O-Ring kits
- Splicing kits
- Cord

Materials Available

- Tuf-Steel®
- Buna-N
- Silicone
- FKM Fluoroelastomer
- EPDM
- PTFE

Available

AS 568 Dash Numbers and Metric O-Rings available in:

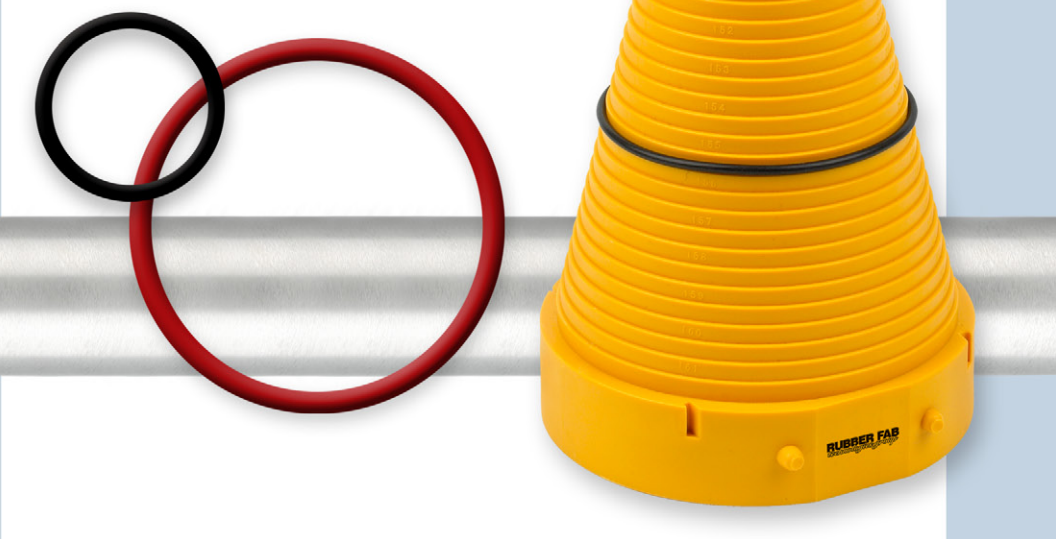
- Standard
- FDA
- Class VI

NOW AVAILABLE!
Class VI O-Rings in Platinum Silicone, EPDM and FKM!

O-Ring Cord

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

For cord diameters and available materials, please consult Rubber Fab's sales office.



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**.

- APC
- Bevel Seat
- Camlock
- Compression Control
- Detectomers™
- Diffuser
- DIN/ISO
- Envelope
- Flapper
- Full Face 150#, 300#
- Gauge Guard
- I-Line
- John Perry
- Manway
- Metal Detectable
- Orifice Plates
- O-Rings
- Perforated Plates
- Eco-Flex
- Q-Line
- Quad Rings
- Ring 150#, 300#
- Schedule V
- Screen
- Smart Gaskets®
- Tuf-Flex®
- Tuf-Steel®
- Tri-Clamp® Type I
- Tri-Clamp® Type II
- V^2B Vent Breaker
- Valve Body
- X-Ray Inspectable

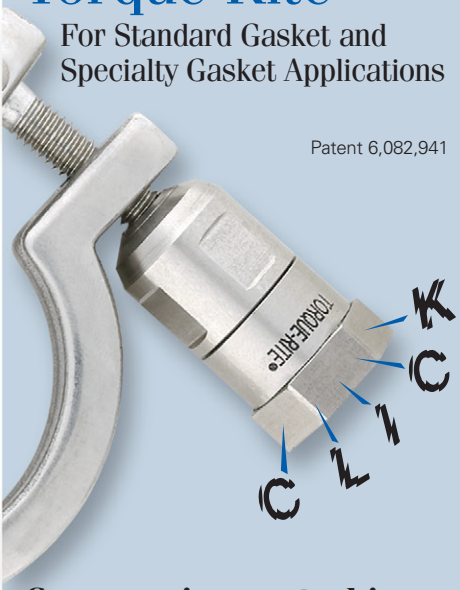
Rubber Fab also offers Sanitary Sheet Material, profiles and cord in Class VI and FDA compliant materials.



Torque-Rite®

For Standard Gasket and Specialty Gasket Applications

Patent 6,082,941



Compression control is easy!

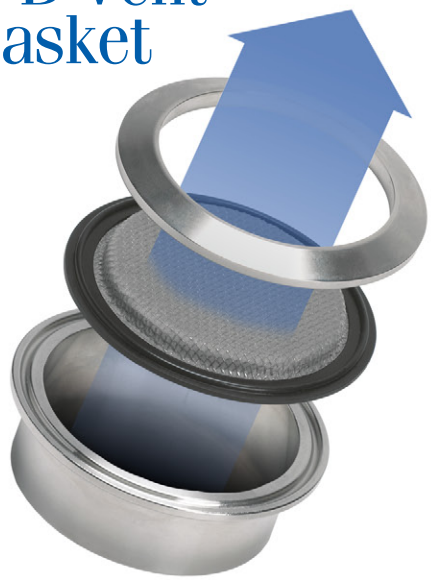
Torque-Rite® allows you to **control compression and expansion** while maintaining constant inch/pounds force insuring a Perfect Surface I.D. Torque-Rite® **eliminates sanitary problems associated with over- or under-tightening a gasket.** When tightened, the Torque-Rite's® **self-limiting** internal 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** (if emergency conditions arise, the Torque-Rite® has a built-in manual override feature). 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, Tuf-Flex® and Eco-Flex

50 in/lbs for PTFE and Tuf-Steel®

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 in 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.

System Identification

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: Gaskets, Hose assemblies, Stainless Fittings & Adapters insure process line identification and provide complete cradle to grave lot and batch traceability.

NOTE: Consult factory for spacing and size limitations.



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



Color Identification: Colored Tuf-Steel® and Colored PTFE gaskets and Gold Spot fittings, adapters and clamps assist in sanitary process line identification, and change out procedures, as well as, application segregation.



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

ADI FREE ANIMAL DERIVED INGREDIENT FREE CERTIFIED

NAHAD MEMBER THE ASSOCIATION FOR HOSE AND ACCESSORIES DISTRIBUTION

METAL DETECTABLE



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
- ISO 9001:2000 and QS-9000:1998
- Animal Derived Ingredient Free*

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

Smart Gasket®, Tuf-Steel®, Tuf-Flex® and Torque-Rite® are registered trademarks of Rubber Fab Technologies Group.
Detectomers™ is a trademark of Rubber Fab Technologies Group.
EZTest® is a registered trademark of SGM Biotech, Inc.
Tri-Clamp® is a registered trademark of The Ladish Company.
Ultem® is a registered trademark of GE.
Kalrez® is a registered trademark of Du Pont Performance Elastomers LLC

RUBBER FAB technologies group

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Rubber Fab Technologies Group is a member of:

ISPE

International Association of Food Industry Suppliers

fisa Distributors Serving Sanitary Processing

3A

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