Improving Product Quality and Consistency

DESIGN validation production

QUALITY ASSURANCE

RUBBER FAB
technologies group

Rubber Fab's Sanitary Gasket Guidelines

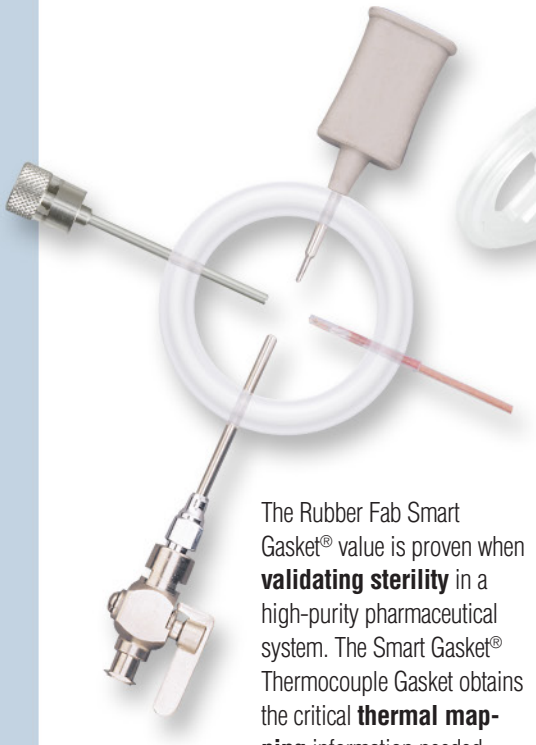
- **Tuf-Flex®** is the world's first **unitized gasket**, setting new standards for purity, performance and flexibility. A Tuf-Flex® Gasket's contact surface is PTFE unitized to an EPDM rubber inner core. This **totally bonded** construction provides a PTFE gasket with the mechanical characteristics, 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.

1 = Excellent 2 = Good 3 = Acceptable 4 = Marginal 5 = Poor 0 = 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.**								
Tuf-Steel®	1	1	1	1	1	1	1	-320°F to 550°F
Maintains seal with wide temperature variations. Has extended service life.**								
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	-30°F to
Low pressure steam only.								
Buna*	0	0	5	5	5	5	5	-30°F to 200°F
Not recommended for strong acids and ozone								

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

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.

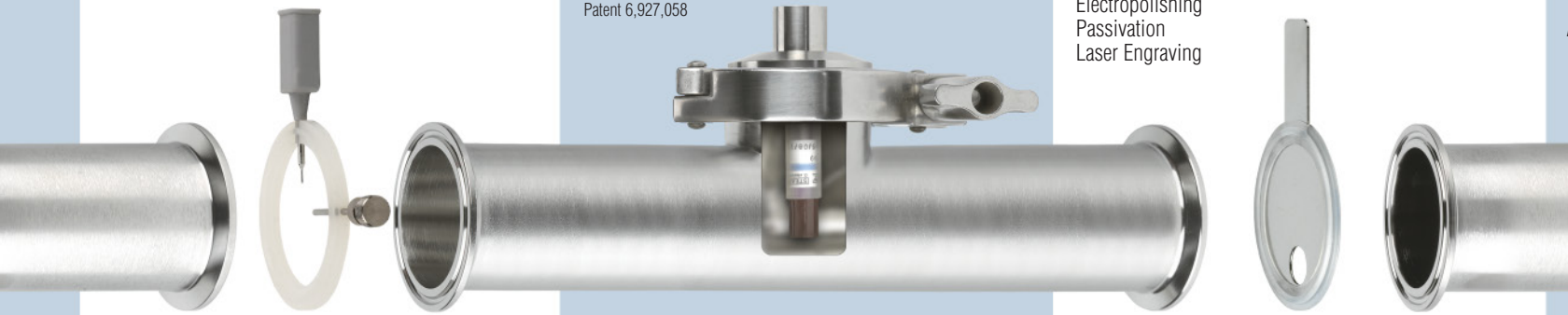
AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone, Buna*
(Elastomer replacement gaskets are available)

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

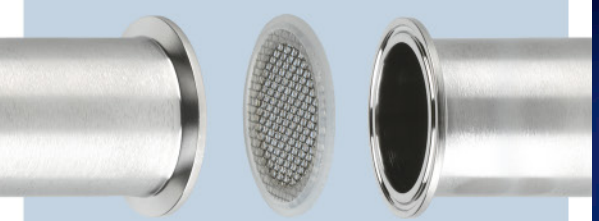
AVAILABLE SERVICES:
Electropolishing
Passivation
Laser Engraving

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



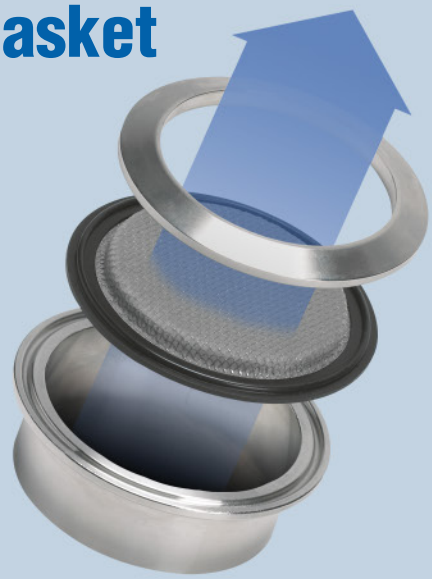
Inline Strainers & Overscreens

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

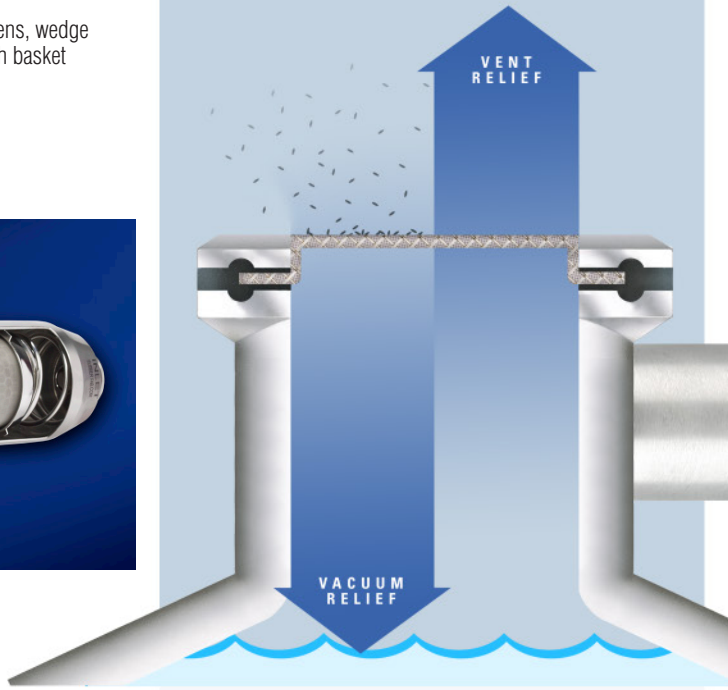
V²B Vent Gasket



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 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.

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.

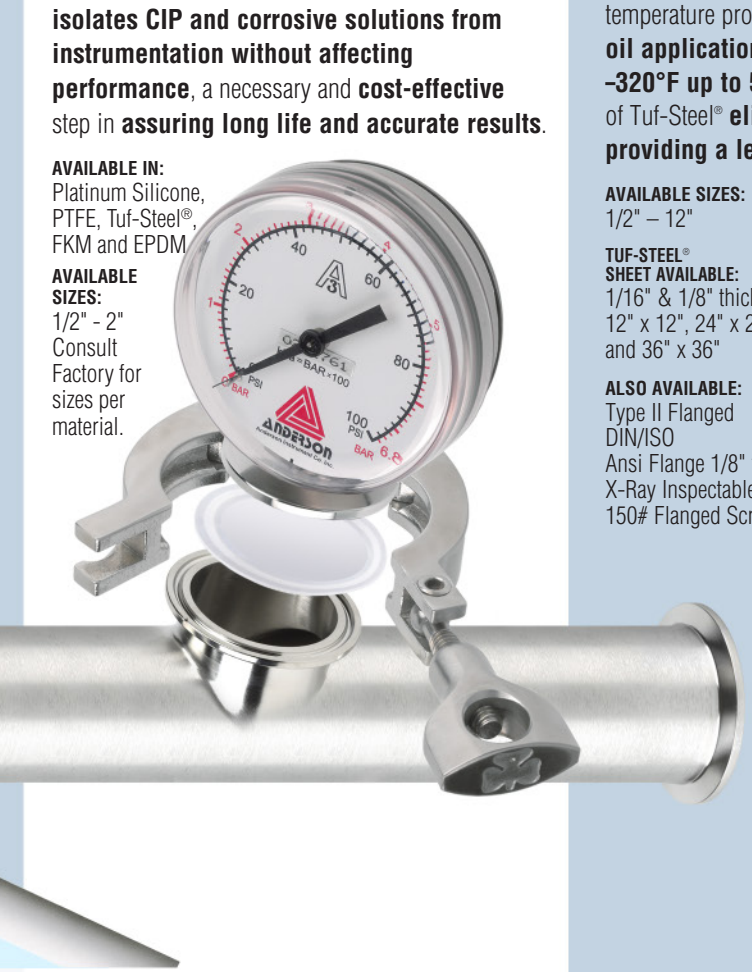
AVAILABLE IN:
Platinum Silicone only and Sizes 3/4" - 2"
(3/4" protectors can be used with 1/2" isolators)

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.



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"

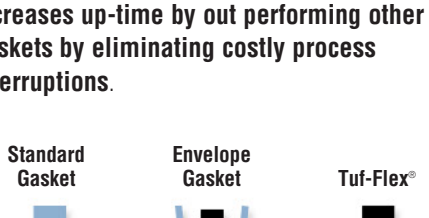
TUF-STEEL® Type II Flanged AVAILABLE!

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

Tuf-Flex®

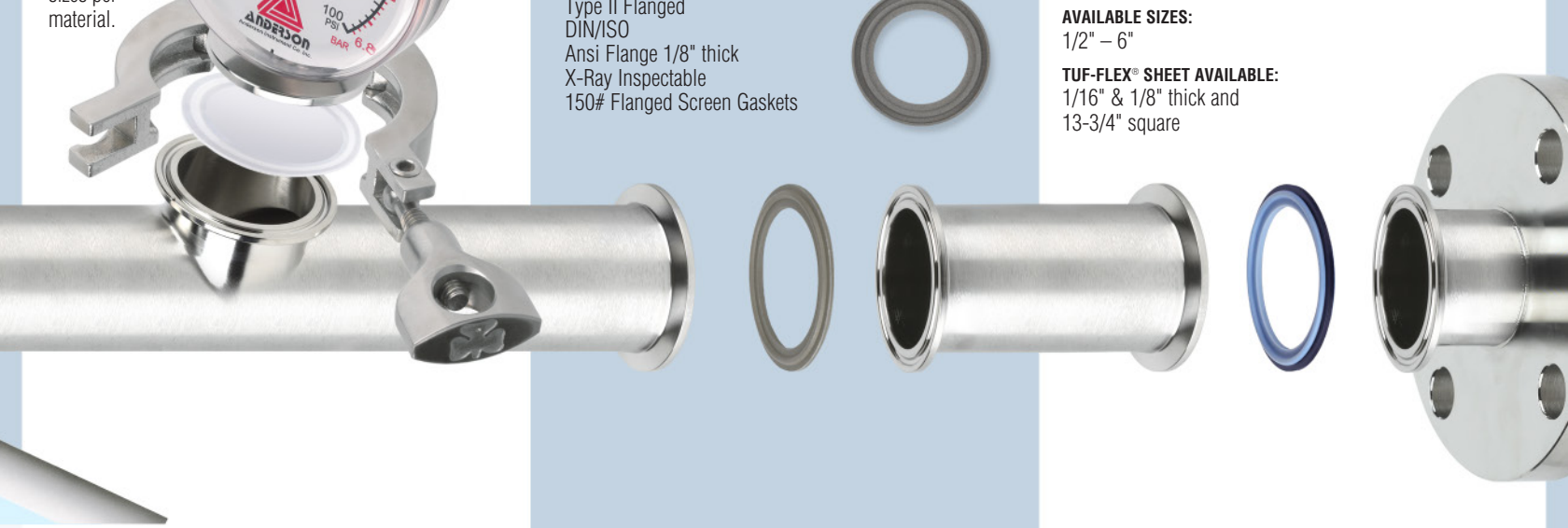
International Dairy Fittings Also Available!

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



Ansi-Flex150# 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"

Detectomer®

METAL DETECTABLE AND X-RAY INSPECTABLE PRODUCTS

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:
Tuf-Steel®

AVAILABLE PRODUCTS:
Gaskets, Quad Rings, Heat Sealing Strips, Sheet, Extrusions, Hoses, Utensils, O-Rings

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

PLASTIC MATERIAL (METAL DETECTABLE ONLY):
UHMW, Acetal

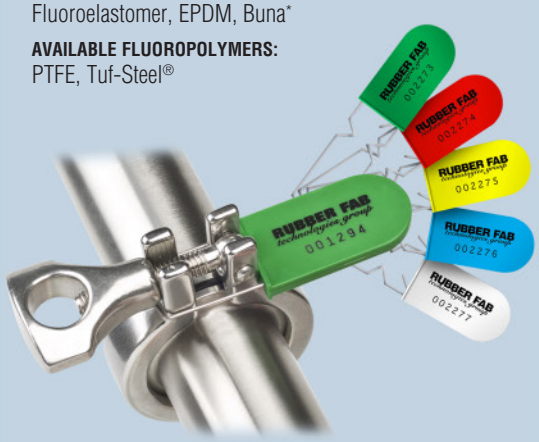
SHEET MATERIAL AVAILABLE:
Polyurethane

DIN/ISO

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®



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
The O-Ring Group

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 available in:

- Standard
- FDA
- Class VI
- Detectomer® Metal Detectable/X-Ray Inspectable

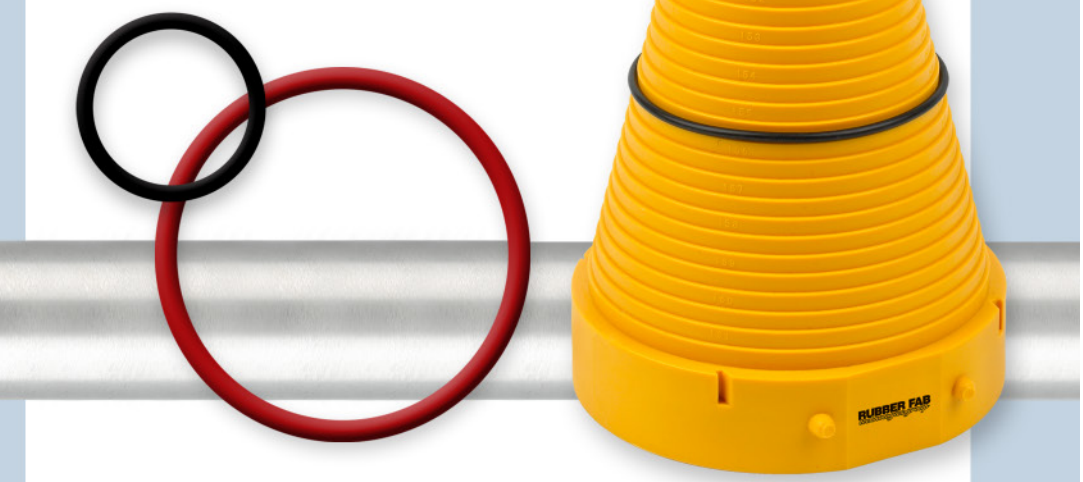
O-Ring Cord

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

Materials Available

- Standard
- Class VI
- Detectomer® Metal Detectable/X-Ray Inspectable
- FDA
- Metal Detectable

For cord diameters, please consult Rubber Fab's o-ring department.



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
- 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

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.

Torque-Rite®

For Standard Gasket and Specialty Gasket Applications

Patent 6,082,941

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**. 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®

Torque Tee

Rubber Fab's Torque Tee and universal torque socket are designed to aid in clamp installation & removal. Available with a family of components, the Torque Tee handle creates effective tightening leverage & aids in reaching tight spaces.

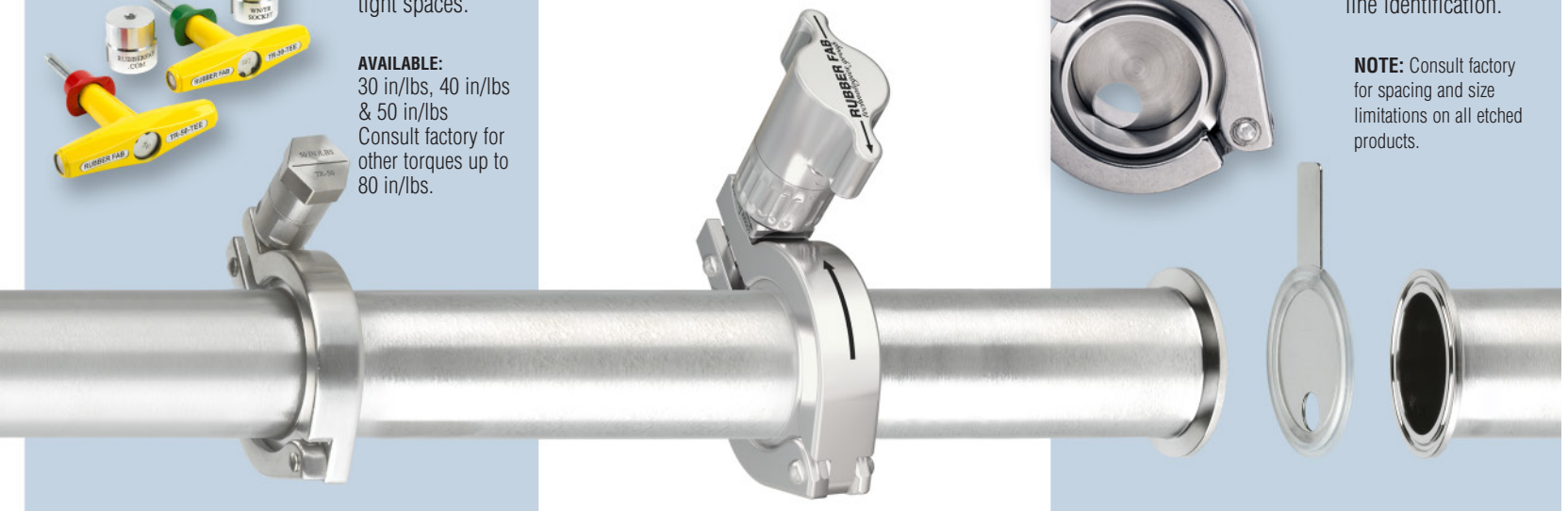
AVAILABLE:
30 in/lbs, 40 in/lbs & 50 in/lbs
Consult factory for other torques up to 80 in/lbs.

Smart Clamp™

The "Half-Turn" Sanitary Smart Clamp

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

3A® Standard Number 62-02

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.

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Detectomer® 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

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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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