DESIGN validation production

Sanitary validation products that meet the most stringent standards for purity



2" 1/2" hole ECC

a Garlock Hygienic Technologies company

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 or FKM 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 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.
- GYLON BIO-PRO[®] is a safe sealing solution with its modified and restructured PTFE material, pre-formed and stress controlled, for all Tri-Clamp[®] applications. It is also dimensionally stable and resists intrusion.

- GYLON[®] BIO-PRO PLUS[™] is manufactured from our proprietary GYLON[®] style 3522 modified PTFE. GYLON[®] BIO-PRO PLUS[™] delivers best in class performance across all critical factors such as compliance, chemical compatibility, seal-ability, creep and cold flow.
- **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).
- 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 Maintains seal with wide tempera	1 ature variations. H	1 Has extended se	1 rvice life**	1	1	1	1	-20°F to 300°F
Tuf-Steel ® Maintains seal with wide tempera	1 ature variations. H	1 Has extended se	1 rvice life**	1	1	1	1	-320°F to 550°F
GYLON BIO-PRO [®] Modified and restructured PTFE	1 material, pre-form	1 ned and stress o	1 controlled	1	1	1	1	-346°F to 500°F
GYLON [®] BIO-PRO PLUS™ Best in class performance for che	1 emical compatibi	1 lity, seal-ability,	1 creep and cold	1 flow	1	1	1	-450°F to 500°F
PTFE Wide temperature variations and	1 may cause leaka	1 ge at ∆T	1	1	1	1	3	-100°F to 500°F
Silicone (platinum) Very flexible low temperature	2	2	2	2	2	2	1	-40°F to 450°F
FKM Fluoroelastomer Acceptable for steam application:	2 S	2	2	2	2	2	2	-30°F to 400°F
EPDM (peroxide cured) Low pressure steam only	0	4	3	3	3	3	3	-30°F to 300°F
Buna* Not recommended for strong aci	0 ds and ozone	0	5	5	5	5	5	-30°F to 200°F

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

NOTE: Properties/applications shown throughout this brochure are typical. Your specific application should not be undertaken without independent study and evaluation for suitability. For specific application recommendations consult Rubber Fab. Failure to select the proper sealing products could result in property damage and/or serious personal injury. Performance data published in this brochure has been developed from field testing, customer field reports and/or in-house testing. While the utmost care has been used in compiling this brochure, we assume no responsibility for errors. Specifications subject to change without notice. This edition cancels all previous issues. Subject to change without notice Rubber Fab is a registered trademark for packings, seals, gaskets, and other products of Rubber Fab.

Smart Gasket®

Biological Indicator



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 connection.

AVAILABLE SIZES: 1/2" - 4" **AVAILABLE PORTS:** 1 - 4 ports

ACCESSORIES AVAILABLE:

Thermocouple Clamp with 1 - 4 ports Sampling/Injection Tube Hole Plug Stopcock Teflon Coated Wire Probe Kapton Coated Wire Probe Thermometer Extension Lead - 3 ft & 6 ft Temperature Probes Rubber Fab's Biological Indicator Gasket enables the use of a self-contained biological indicator in sanitary process lines. This unique 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 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 connection.

AVAILABLE SIZES: 3/4" - 2" AVAILABLE PORTS: 1 port 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 styles 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. This is 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 IN:

PTFE, Tuf-Steel[®], EPDM, FKM Fluoroelastomer, Silicone, and Buna* (Elastomer replacement gaskets are available) **AvaiLaBLE SIZES:**

1/2" – 8" (Platinum Silicone 8" not available) 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. These gaskets provide 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 IN:

 $\mathsf{PTFE}, \mathsf{Tuf}\text{-}\mathsf{Steel}^{\texttt{o}}, \mathsf{EPDM}, \mathsf{FKM}$ Fluoroelastomer, Silicone, and Buna^*

AVAILABLE SIZES:

1/2" – 8" (Platinum Silicone 8" not available) 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 IN: EPDM, FKM Fluoroelastomer, Silicone, and Buna^{*} ALSO AVAILABLE IN: 1 1/2" and 2" Tuf-Steel[®] AVAILABLE SERVICES: Electropolishing



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"

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

GYLON BIO-PRO®

GYLON BIO-PRO® sanitary seals offer a safe solution with its modified and restructured PTFE material, pre-formed and stress controlled, for all tri-clamp

connections. It is dimensionally stable and resists intrusion. GYLON BIO-PRO® has a temperature range of -346°F to 500°F and is highly resistant to most chemicals and temperature cycles. It also meets USP Class VI and is FDA compliant.

AVAILABLE SIZES: 1/2" – 12", DIN32676, ISO1127, SMS DIN1185

GYLON® BIO-PRO PLUS™

Manufactured from our proprietary GYLON® style 3522 modified PTFE, GYLON® BIO-PRO PLUS™ delivers best

in class performance across all critical factors such as compliance, chemical compatibility, sealability, creep and cold flow. Fulfilling ASME-BPE standards for dimensional consistency, this next generation sanitary gasket ensures ease of installation and long term operational integrity in the most challenging and critical applications. GYLON[®] BIO-PRO PLUS[™] has a temperature range of -450[°]F to 500[°]F.

available sizes: 1/2" – 12", DIN32676, ISO1127, SMS DIN1185

GYLON[®] Style 3504

GYLON® Style 3504 is a PTFE gasket with aluminosilicate microsphere filler. This style gasket is widely used in glass-lined flanges and other light-duty flanges where available torque is limited.

GYLON[®] Style 3504 creates a tighter seal with improved performance over conventional PTFE which reduces product loss and emissions.

AVAILABLE SIZES: 1/2" - 12" in 1/16" and 1/8" thicknesses, and Ansi-150# Style

Gauge Guard Protector



The Gauge Guard Protector Gasket protect expensive gauge diaphragms and instruments from damage. When moving, storing or being autoclaved, the Gauge Guard Protector protects the gauge's fragile diaphragm from damage, when not in use. The easy attach ring slips effortlessly onto the gauge keeping the Gauge Guard Protector 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.



Tuf-Steel[®]



Tuf-Steel[®] – the original metal detectable 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 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 36" x 36" sheets ALSO AVAILABLE:

Type II Flanged DIN/ISO Ansi Flange 1/16" & 1/8" thick

TUF-STEEL® Type II Flanged AVAILABLE!

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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 or FKM 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 and out performs other gaskets by eliminating costly process interruptions.



International Dairy Fittings Also Available!

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"

GYLON[®] STRESS SAVER[®]

The new style 3504 GYLON[®] STRESS SAVER[®] combines the proven sealing advantages with the performance characteristics of the industry recognized GYLON[®] 3504.

The molded raised ribs help to create a tighter seal by concentrating the compressive load, ideal for lightweight piping.

AVAILABLE SIZES: 1" - 8"

Detectomer® METAL DETECTABLE/ X-RAY INSPECTABLE PRODUCTS



Detectomer[®] is a full line of Metal Detectable/X-ray Inspectable products designed to work with any existing conveyor, pipe line or free fall detection system. Detectomer® products are available in 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.

AVAILABLE ELASTOMERS:

EPDM, FKM Fluoroelastomer, Silicone, Buna* and Tuf-Steel $^{\ensuremath{\circ}}$

AVAILABLE PRODUCTS:

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

ALSO AVAILABLE:

Ansi-Flange in $\ 1/16"$ and $\ 1/8"$ thick Tuf-Steel $^{\circ}$ material

PLASTIC MATERIAL (METAL DETECTABLE ONLY): UHMW, Acetal

SHEET MATERIAL AVAILABLE: Polyurethane



Metal Detectable Patent #7,390,580 X-ray Inspectable Patent #9,701,827

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 DIN 32676, DIN11850, DIN10357, and ISO 1127.

AVAILABLE ELASTOMERS:

PTFE, Tuf-Flex[®], Tuf-Steel[®], GYLON BIO-PRO[®], GYLON[®] BIO-PRO PLUS[™], Platinum Silicone, FKM Fluoroelastomer, EPDM, Buna^{*}

O-Rings & Cord

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

AS 568 Dash Numbers & Metric O-Rings available in Standard, FDA, Class VI, and Detectomer®

AVAILABLE ELASTOMERS:

PTFE, Tuf-Steel[®], Silicone, EPDM, FKM Fluoroelastomer, and Buna^{*}

O-Ring Cord

Vulcanize your own O-rings from our selection of O-ring cord stock, offered in both inch or metric sizes. Cord is available in Standard, FDA, Class VI, and Detectomer[®].

For cord diameters, please consult factory

Torque-Rite[®]

For Standard Gasket and Specialty Gasket Applications



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® selflimiting 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 and 40 in/lbs for all elastomers and Tuf-Flex[®] 50 in/lbs for PTFE, PTFE Envelope and Tuf-Steel[®] 70 in/lbs for GYLON BIO-PRO[®] and GYLON[®] BIO-PRO PLUS[™]

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 & 70 in/lbs. Consult factory for other torques up to 80 in/lbs.

Standard Gaskets

Rubber Fab standard tri-clamp sanitary gaskets are manufactured using FDA compliant compounds. 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
- DIN/ISO
- Envelope
- Full Face Flange Gaskets 150# & 300#
- Gauge Guard Isolators
- I-Line
- John Perry
- Manway

- Orifice Plates
- O-Rings Perforated Plates
- Q-Line
- Quad Rings
- Schedule V
- Screen Gaskets and Socks
- 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.

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, applicationspecific 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.

Etching on Tabbed Orifice Plate Gaskets:

Tabs protrude from clamp and can be laser etched for easy line identification.







Rubber Fab REAT . FEP LINED

RF.SV

Rubber Fab

Jer Fab

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

Golden Bridge Hose Support

Fittings & Adapters: 316L, Special Alloys & Non Metallic 3A Standard Number 62-02







- U.S. Pharmacopeia Class VI Certification*
- Cytotoxicity Criteria*
- Title 21 CFR 177.2600 and 177.1550
- USDA and 3-A Sanitary Standards
- ASME-BPE Standards
- Animal Derived Ingredient Free*
 Buna does not pass U.S. Pharmacopeia Class VI Certification
 and Cytotoxicity and is not ADI free.

Rubber Fab

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