

DESIGN
validation
production
QUALITY
ASSURANCE

Improving Product Quality and Consistency



Smart Gasket®



Rubber Fab's Smart Gasket's® 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. Then, utilizing the Smart Gasket® Spore Trap securely retains spore challenge test strips. **Meter fluids in your process system** utilizing a **peristaltic pump** or **withdraw samples** utilizing our luer lock valve or syringe.

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

AVAILABLE PORTS:
1 - 4 ports

Biological Indicator



Rubber Fab's Biological Gasket enables the use of a **self-contained biological indicator in sanitary process lines**. This unique Rubber Fab Smart Gasket® permits either top loading or inline positioning of an EZTest® self-contained 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 48 hours (versus the five to seven days required with a spore strip) and without problematic laboratory transfer. You can feel secure knowing that the biological indicator **will not be lost** down stream in the process. The 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"

patented

Orifice Plates



Our innovative Orifice Plate line includes a complete selection of solid 316L Stainless Steel that can be custom drilled with an **eccentric or concentric bore**. Tabbed Orifice Plates and slotted clamps are also available. Tabs help to acknowledge that an orifice plate in **"in the line"** and can be **laser engraved** to indicate the hole diameter, gasket size or with 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:
Buna, EPDM, FKM Fluoroelastomer, PTFE, Silicone, Tuf-Steel®

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

ALSO AVAILABLE :
Slotted Clamps

Screen Gaskets

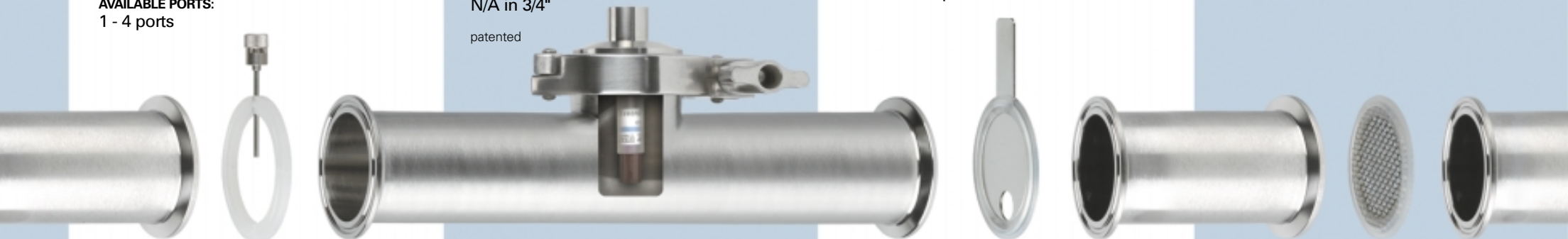


Rubber Fab manufactures fluid conditioning screen gaskets in **10 micron through 4 mesh**. Screen gaskets provide **prefiltration** for critical membrane filters, **coalescence of water vapor** from process exhaust lines, **particulate removal** before fill and finish and more. Also available:

- Perforated plate fluid conditioning gaskets
- Complete elastomer selection
- Removable sanitary gasket holders for all discs
- Screen disc inserts
- Perforated plate disc inserts
- Orifice plate disc inserts

AVAILABLE ELASTOMERS:
Buna, EPDM, FKM Fluoroelastomer, PTFE, Silicone, Tuf-Steel®

AVAILABLE SIZES:
1/2" - 4"
Consult factory for over 6"
Consult factory for custom meshes



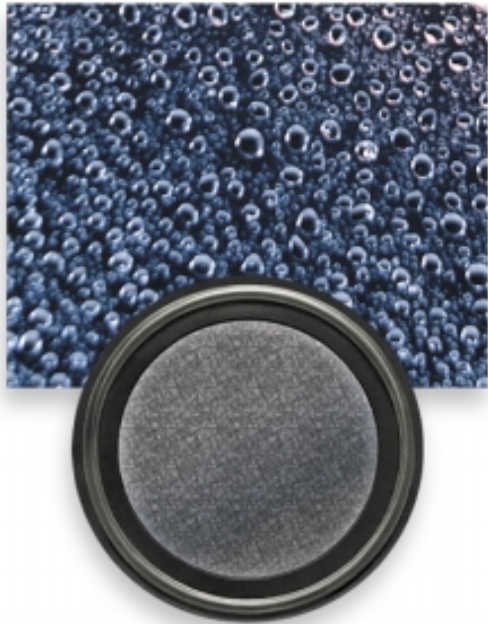
For additional information,
please refer to Rubber Fab literature #RF-100.

For additional information,
please refer to Rubber Fab literature #RF-185.

For additional information,
please refer to Rubber Fab literature #RF-130.

For additional information,
please refer to Rubber Fab literature #RF-110.

Sanitary Diffuser



Diffuser aeration systems provide **increased oxygen content** to high purity water systems. Diffusers can also be used to **diffuse digester gases** such as hydrogen sulfide and sulphur dioxide; to **introduce ozone** for oxidizing and destroying bacterial and organic chemical contaminants, also for **carbon dioxide injection** for carbonization and **ph adjustment**.

AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone

AVAILABLE SIZES:
1/2" - 3"
Consult factory for other sizes

AVAILABLE MICRON:
1/2 - 2 micron
2 micron is standard stock,
all other micron is custom

Standard Gaskets



All Rubber Fab standard sanitary gaskets are molded from **FDA compliant** compounds. Our Tri-Clamp® gaskets have all **passed 3A testing**. Rubber Fab's EPDM, FKM Fluoroelastomer, Silicone and PTFE Tri-Clamp® gaskets have all **passed U.S.P. Class VI testing**. Rubber Fab gaskets are molded in the U.S.A.

AVAILABLE ELASTOMERS:
Buna, EPDM, FKM Fluoroelastomer, PTFE, Platinum & Peroxide-Cured Silicone, Tuf-Steel®, Tuf-Flex®

AVAILABLE SIZES:
1/2" - 12"
Available in all Sanitary Gasket configurations

Metal Detectable Elastomers

By manufacturing any standard gasket with a **3A, FDA approved** metal filler, a worn off piece of elastomer material **can be located** by an in-line metal detector. Detectables **eliminate product recall** and **lowers product loss**.

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

AVAILABLE PRODUCTS:
Gaskets, Valve Stems, Check Balls

Controlled Compression



The Controlled Compression Gasket (CCG) **cannot be over-tightened!** The CCG is composed of the elastomer of your choice with a ring of ultem® vulcanized inside the gasket from the ring O.D. to the locating ring of the gasket. This non-compressible ring **controls clamp compression** to exactly the correct amount, allowing the properly positioned gasket to make a **perfect surface I.D. seal** with the ferrules. No torque restrictions are necessary. CCG is also available in a tabbed gasket making it more user friendly while isolating it from unnecessary human contact. Helps with position control and speeds up the installation process.

AVAILABLE ELASTOMERS:
EPDM, FKM Fluoroelastomer, Silicone

AVAILABLE SIZES:
1" - 3"

CCG'S MEET ASME BPE SPECIFICATIONS

patent number
6,857,638

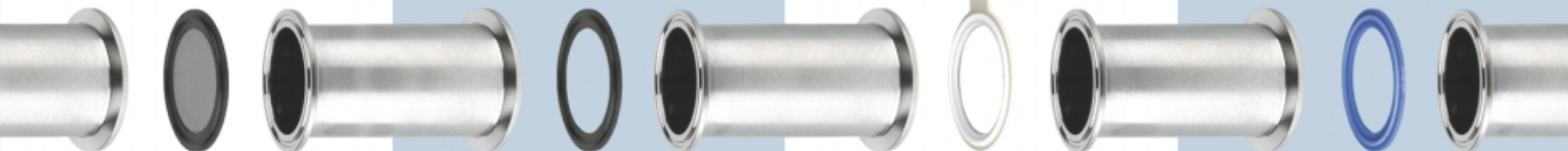
Laser Engraved



Laser Engraved Gaskets, Screen and Orifice Plates **insure permanent batch and lot traceability**. Engraving remains readable throughout the service life of the gasket. Compound type and/or special application markings can also be laser engraved on gaskets at the customer's request.

AVAILABLE ELASTOMERS:
Available on all Rubber Fab gaskets

NOTE:
Consult factory for spacing and size limitations.



For additional information,
please refer to Rubber Fab literature #RF-135.

For additional information,
please refer to www.rubberfab.com.

For additional information,
please refer to Rubber Fab literature #RF-800.

For additional information,
please refer to Rubber Fab literature #RF-195.

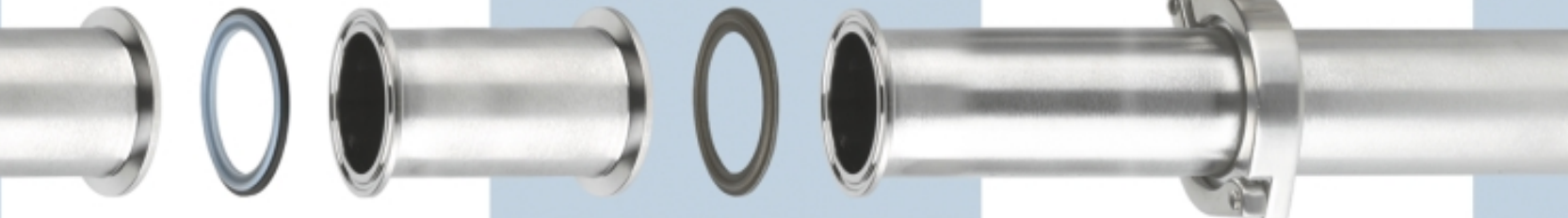
Tuf-Flex®



Tuf-Flex®, the revolutionary gasket from Rubber Fab is the world's only **unitized gasket**, setting new standards for purity, performance and flexibility. A Tuf-Flex® Gasket's contact surface is a layer of 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-Flex® **out performs other gaskets** while eliminating costly process interruptions. Achieve higher performance under SIP/CIP conditions.

AVAILABLE SIZES:
1/2" - 4"

Type I and Type III Envelope Gaskets vs TUF-FLEX



For additional information, please refer to Rubber Fab literature #RF-600.

Tuf-Steel®



PTFE and Stainless Steel deliver **leak-proof performance** composed of a unique 50/50 blend on non-pigmented PTFE and 316L: passivated and atomized stainless steel. Tuf-Steel® is the choice for leak-proof, perfect surface performance and **outstanding durability** in SIP (steam in place) and WFI (water for injection) applications. Tuf-Steel® is **ideal for sanitary steam pipe connections** in extreme temperatures ranging from -100°F to 500°F. The **superior strength** of Tuf-Steel® **eliminates cold flow and creep** to prevent maintenance problems and system downtime.

AVAILABLE SIZES:
1/2" - 12"

For additional information, please refer to Rubber Fab literature #RF-600.

Torque-Rite®



Torque-Rite® allows you to **control compression and expansion** while maintaining constant inch/pounds force insuring a Perfect Surface I.D. when used with a Perfect Surface Gasket. Torque-Rite® **eliminates the problems associated with over- or under-tightening** a gasket which can lead to an unsanitary system. Compression control is easy! When tightened, the Torque-Rite's® **self-limiting** internal mechanism will make an audible "click" signaling the user 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).

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

patent number
6,082,941



For additional information, please refer to Rubber Fab literature #RF-150.

SANITARY GASKET GUIDELINES

- **Tuf-Flex®**: Tuf-Flex® is the world's only **unitized gasket**, setting new standards for purity, performance and flexibility. A Tuf-Flex® Gasket's contact surface is a layer of 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-Flex® **out performs other gaskets** while eliminating costly process interruptions. Achieve higher performance under SIP/CIP conditions.
- **Tuf-Steel®**: A unique 50/50 blend of non-pigmented PTFE and 316L, water atomized and passivated, delivers **leak-proof performance**. Tuf-Steel® is the choice for leak-proof, perfect surface performance and **outstanding durability** in SIP (steam in place) and WFI (water for injection) applications. Tuf-Steel® is **ideal for sanitary steam pipe connections** in extreme temperatures ranging from -100°F to 500°F. The **superior strength** of Tuf-Steel® **eliminates cold flow and creep** to prevent maintenance problems and system downtime.
- **PTFE** is the material of choice whenever low temperature flexibility or gasket memory is not required (not recommended where large temperature variations occur frequently, leakage can occur). PTFE has almost no extractables, has a low absorption rate and excellent resistance to process fluids. It can remain in service for longer periods of time in both water and steam for continuous use, high pressure clamps are recommended to prevent leakage resulting from temperature variations. PTFE envelope gaskets with a FKM Fluoroelastomer inner core should be used if slight misalignment is observed.
- **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. They are acceptable, but not recommended for continuous use in SIP procedures.

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

Gasket Comments	Continuous Stream	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® Maintains seal with wide temperature variations. Has extended service life.*	1	1	1	1	1	1	1	-100°F to 350°F
Tuf-Steel® Maintains seal with wide temperature variations. Has extended service life.*	1	1	1	1	1	1	1	-100°F to 500°F
PTFE Wide temperature variations and may cause leakage at ΔT.	1	1	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 applications.	3	2	2	2	2	2	2	-30°F to 400°F
EPDM (peroxide cured) Low pressure steam only.	3	3	3	3	3	3	3	-30°F to 300°F

* Application dependent.

Our Commitment is Certified

Rubber Fab Technologies Group successfully meets the goals and standards set forth by the U.S. Pharmacopoeia, Class VI certification, passes cytotoxicity criteria and complies with Title 21 CFR 177.2600 and 177.1550 standards. Our certification is an endorsement of our commitment to provide you with quality products that meet the highest sanitary standards and purity criteria.

NAMSA, a world leader in testing services for the medical device industry, certified our PTFE, FKM fluoroelastomer, platinum cured silicone and EPDM gaskets. You can be assured of our continuous commitment to our superior quality.

Our Promises to Purity

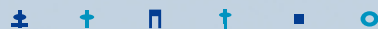
Our state-of-the-art facility assures superior quality control and purity of material with rigorous standards during each critical step of production. Rubber Fab Technologies Group offers superior surface finish and elastomer purity in our finished sanitary gaskets.

After production, Rubber Fab sanitary gaskets are inspected and packaged in our cosmetic particulate free box. A step ahead of standard packaging, our box is made with cosmetic quality material that gives you a product free of particulates. Each box is clearly labeled with product information for clear inventory control. Lot and batch numbers provide traceability at all times.

Meeting the Stringent Standards For Purity

- U.S. Pharmacopeia Class VI Certification*
- Cytotoxicity Criteria*
- Title 21 CFR 177.2600
- USDA and 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- ASME-BPE Standards
- ISO 9001:2000 and QS-9000:1998
- European Pharmacopeia 3.1.9*
- Animal Derived Ingredient Free*
- All Gaskets are Made in the USA*

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



Rubber Fab Technologies Group
Limecrest Road

P.O. Box 626 • Andover, NJ 07821
phone: 973-579-2959 fax: 973-579-7275

www.rubberfab.com

Rubber Fab Technologies Group
HOSE, FITTINGS AND ACCESSORIES

Silicone, Metal, FDA PVC,
FDA Rubber,
Smooth Bore PTFE,
Smooth Bore FEP and
Convuluted PTFE

Features:

- Fitting sizes available from .25" to 6"
- Heat trace number for traceability on all sanitary Tri-Clamps*
- Fittings are manufactured in 316L, stainless steel
- Standard BPA surface finish on Tri-Clamps*
- Material test reports (MTRs) are available upon request
- Electropolishing of fittings available
- Fittings available in non-metallic materials such as Kynar®/PVDF
- Fittings available in special alloys include:
Hastelloy C22 & C276, Alloy 20, Titanium and Monel

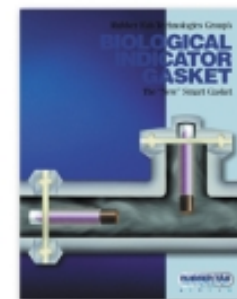
Also Available:
Rubber Fab offers a full line of high purity gaskets. As a demonstration of our quality a set of compatible gaskets will be included with every hose order.

Hose Accessories • Molded Ends • Sight Gauges

RUBBER FAB technologies group

The Tri-Clamp is a registered trademark of Ladish Company.
Kynar is a registered trademark of ECP America.

www.rubberfab.com



Rubber Fab Technologies Group, a Material Science Company, is a leading innovator of high quality sanitary gaskets, hose assemblies, valve, pump and filler machine components in a wide range of high purity elastomer materials. For additional information, contact Rubber Fab at 973-579-2959 or visit us at www.rubberfab.com.

Smart Gasket®, Tuf-Steel®, Tuf-Flex® and Torque-Rite® are registered trademarks 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.

Rubber Fab Technologies Group is a member of:

