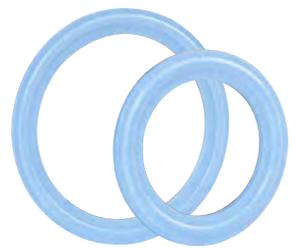
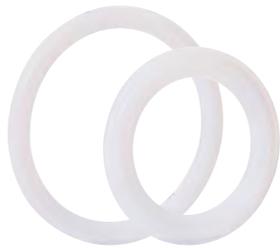


# Rubber Fab

a Garlock Hygienic Technologies company

## Portfolio of Validation Solutions for the Pharmaceutical Industry



*Engineered Products that Meet the  
Most Stringent Standards for Purity*



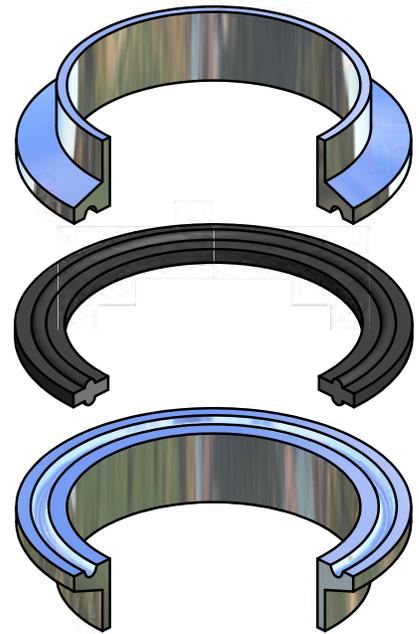
# What is a Tri-Clamp® Gasket?

Sanitary Tri-Clamp® Gaskets are used in the Food, Dairy, Beverage, Biotech, Pharmaceutical, and many other Sanitary Process industries to seal clamp connections in sanitary pipe lines.

The name Tri-Clamp® gasket comes from the Tri-Clover clamp which is used to hold a gasket in place.

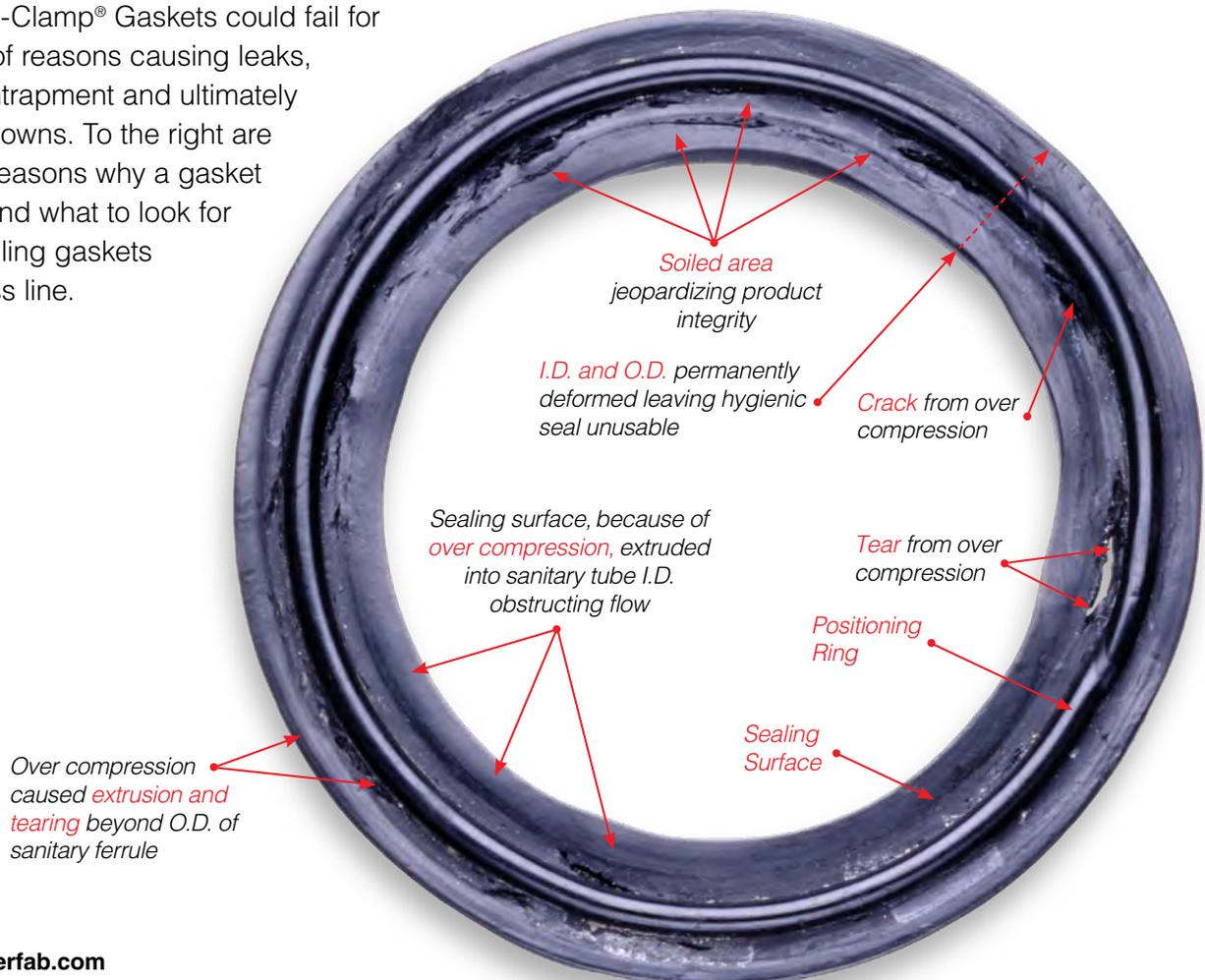
## Benefits of A Perfect Hygienic Seal

- Lower bacteria count
- Maintains/enhances product integrity
- Ensures that gasket I.D. matches pipe I.D.
- Conforms to CGMP
- Complies with USDA and 3-A Sanitary Standards



# Why do Gaskets Fail?

Sanitary Tri-Clamp® Gaskets could fail for a number of reasons causing leaks, bacteria entrapment and ultimately plant shutdowns. To the right are just a few reasons why a gasket could fail and what to look for when installing gaskets in a process line.



# Hygienic Seal Material Guidelines

This information has been carefully prepared to help in selecting the correct elastomer or perfluorocarbon utilized in high purity sanitary hygienic seals where critical pure water, process fluids (both ambient and hot), and SIP environments exist. The intention is to consider the different uses, applications and conditions to determine the most favorable hygienic seal material for each application.

The following criteria is used in determining correct hygienic seal materials:

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.1550
- CFR Title 21 Section 177.2600
- Traceability: Lot and Batch
- Certification: Lot and Batch
- ASME-BPE Standards
- USDA Standards
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Manufacturer data and specifications
- Consultation with various pharmaceutical users
- Animal Derived Ingredient Free

The gasket materials considered are Tuf-Steel® (PTFE/Stainless Steel), Tuf-Flex®, PTFE, Silicone (platinum), FKM Fluoroelastomer, EPDM and Buna.

The 3 main goals are:

- To protect products from contamination, spalling, particulates and TOCs resulting from the use of improper hygienic seal material.
- To protect facilities from unnecessary downtime associated with hygienic seal failure and replacement from use of improper hygienic seal material.
- To provide a standard of consistency for hygienic seal selection between multiple facilities.

Most decisions driving seal type selection are based on chemistry, temperature, exposure limits, USP, FDA qualifications, and curing methods. The following briefly addresses each of these issues.

## Exposure Limits

It is important to define the operating parameters of a new or existing processing sanitary system. The user specifications for exposure limits and reactivity to process fluids are compared with process operating parameters. All materials are acceptable for steam excluding Buna. All materials should meet process fluid reactivity parameters. Even though all compound exposure limits fall within operating parameters, the service life of some compounds will be different under certain conditions. This must be considered when selecting a compound.

## FDA and USP Qualifications

CFR's define the criteria for extractables and for compounds used in the manufacture of rubber and plastic articles. The two applicable categories are; rubber articles (Buna, EPDM, FKM Fluoroelastomer, Silicone) and perfluorocarbon resins (PTFE).

USP defines the criteria for testing biological reactivity and the amount/type of extractables. The hygienic seals in service must meet USP Class VI specifications, and be manufactured using the proper compounds as stated in the CFR, Title 21, Sections 177.1550 and 177.2600 respectively. Certificates are available from Rubber Fab verifying compliance with regulatory requirements, traceability lot and batch and certification lot and batch. Note: Not all hygienic seals meet these requirements.

## Curing Methods

Curing agents have an affect on the amount and type of extractables a material will emit. Typically, the hygienic seal group in service uses three methods; sulfur cured, peroxide cured and platinum cured. When dealing with elastomers, peroxide cured is the most favorable method. When dealing with silicone, platinum cured is the most favorable. All gaskets shall be post cured. Using these methods minimize potential reactions with the respective process fluid applications and can uphold pure water and process fluid standards. Sulfur cured elastomers can significantly alter a process

fluids integrity and negatively affect mammalian cell yields. Rubber Fab EPDM hygienic seals are all peroxide cured.

### What Material(s) Can Be Used

By reviewing manufacturer data and compiling information regarding regulatory requirements, it appears that any of the aforementioned compounds are suitable for both utility and process equipment use. However, you must ensure that all hygienic seals and compounds meet the CFR and USP requirements, and have a certificate to verify compliance.

### What Material(s) Should Be Used

- Tuf-Flex®, the world's first unitized gasket, has a contact surface that 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 & atomized stainless steel. Testing and 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.

- 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.

Material	Dot Description	Color Code
Tuf-Steel®	no dot	
Tuf-Flex®	no dot	
PTFE	no dot	
PTFE Envelope with FKM Fluoroelastomer Filler	one white & one yellow dot	
PTFE Envelope Style with EPDM Filler	three green dots	
FKM Fluoroelastomer	one white & one yellow dot	
EPDM - peroxide cured	three green dots	
Silicone - platinum cured	no dot	
Buna	one red dot	

# Gasket Certifications

It is Rubber Fab's policy to provide the highest quality products, which consistently meet the product specifications developed by Rubber Fab and their customers, both internal and external. We are committed to the continuous improvement of our quality system. We will meet and exceed the expectations of our customers. It is the responsibility of each of us to monitor and ensure the highest quality within our efforts in our organization. It is the responsibility of leadership to ensure that our policy and objectives are relevant to the business strategies and are executed throughout our organization. Rubber Fab certifies their gaskets based on the following certifications.

- 3-A Sanitary Standards - an independent, not-for-profit corporation dedicated to advancing hygienic equipment design for food, beverage and pharmaceutical industries. Prerequisite for 3-A approval is that the seal material already fulfills the FDA requirements.
- FDA - Government agency within the US Department of Health and Human Services responsible for enforcing the Federal Food, Drug and Cosmetic Act to ensure consumers' health and safety. Although the jurisdiction of the FDA is restricted to the United States, FDA regulations are commonly adopted as international control standards.
  - Title 21 is the portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration.
  - 21CFR177.2600 Rubber articles intended for repeated use
  - 21CFR177.1550 Perfluorocarbons (PTFE products and compounds, FEP, etc.)

ISSUE DATE: November 05, 2013

CERTIFICATE AUTHORIZATION NUMBER: 1727



THIS IS TO CERTIFY THAT

Rubber Fab, a Garlock Hygienic Technologies Company  
26 Brookfield Dr., Sparta, NJ 07871

is hereby authorized to continue to apply the  
3-A Symbol to the models of equipment, conforming to 3-A Sanitary Standards for:

Number 18-03  
18-03 (Multiple Use Rubber and Rubber-Like Materials)

set forth below

Both CIP and COP material compounds: CPO-196 Class IV; CPO-196XR Class III; CPO-296 Class III; CPO-3003/80 Class I; CPO-325 Class III; CPO-7D16 Class III; CPO-7F81 Class III; CPO-7N35 Class III; CPO-7S76 Class III; CPO-N7015FDA Class III; CPO-N7015FDAXR Class III; CPO-S70FDAXR Class IV; CPO-VT80FDAXR Class I.

VALID THROUGH: **December 31, 2018**

Timothy R. Rugh  
Executive Director  
3-A Sanitary Standards, Inc.

The issuance of this authorization for the use of the 3-A Symbol is based upon the voluntary certification, by the applicant for it, that the equipment listed above complies fully with the 3-A Sanitary Standard(s) designated. Legal responsibility for compliance is solely that of the holder of this Certificate of Authorization, and 3-A Sanitary Standards, Inc. does not warrant that the holder of an authorization at all times complies with the provisions of the said 3-A Sanitary Standards. This in no way affects the responsibility of 3-A Sanitary Standards, Inc. to take appropriate action in such cases in which evidence of nonconformance has been established.

NEXT TPV INSPECTION/REPORT DUE: **October 2018**

ISSUE DATE: April 01, 2014

CERTIFICATE AUTHORIZATION NUMBER: 1746



THIS IS TO CERTIFY THAT

Rubber Fab, a Garlock Hygienic Technologies Company  
26 Brookfield Dr., Sparta, NJ 07871

is hereby authorized to continue to apply the  
3-A Symbol to the models of equipment, conforming to 3-A Sanitary Standards for:

Number 20-27  
20-27 (Multiple Use Plastic Materials)

set forth below

Both CIP and COP material compounds: Tuf-Steel, Tuf-Flex, and CPO-8A.

VALID THROUGH: **December 31, 2018**

Timothy R. Rugh  
Executive Director  
3-A Sanitary Standards, Inc.

The issuance of this authorization for the use of the 3-A Symbol is based upon the voluntary certification, by the applicant for it, that the equipment listed above complies fully with the 3-A Sanitary Standard(s) designated. Legal responsibility for compliance is solely that of the holder of this Certificate of Authorization, and 3-A Sanitary Standards, Inc. does not warrant that the holder of an authorization at all times complies with the provisions of the said 3-A Sanitary Standards. This in no way affects the responsibility of 3-A Sanitary Standards, Inc. to take appropriate action in such cases in which evidence of nonconformance has been established.

NEXT TPV INSPECTION/REPORT DUE: **March 2019**

# Rubber Fab

a Garlock Hygienic Technologies company

## CERTIFICATE OF COMPLIANCE

### U.S.P. CLASS VI

Rubber Fab Technologies Group certifies that the material from which we manufacture the below mentioned parts has passed U.S.P. Class VI Cytotoxicity Testing and meets 3A and USDA Standards and are BSE/TSE compliant. Elastomer parts are FDA CFR 21, 177.2600 compliant, and PTFE, FEP, PFA and Tuf-Steel® parts are FDA CFR 21, 177.1550 compliant.

**CUSTOMER NAME:** Rubber Fab  
**CUSTOMER PO:** Sample  
**PART NO.:** Sample  
**DESCRIPTION:** Sample  
**MATERIAL:** Sample  
**LOT NUMBER:** Sample  
**CURE DATE:** Sample

*Sean Mayer*

Sean Mayer  
Quality Assurance Manager



The material used to manufacture our EPDM, FKM Fluoroelastomer, Silicone, PTFE, and Tuf-Steel® parts is Animal-Derived Ingredient-Free.



•Gaskets •Hose •Hose Assemblies •Tubing •Fittings •Pump and Replacement Parts  
26 Brookfield Drive, Sparta, NJ 07871 • Phone: 973-579-2959 • Fax: 973-579-7275  
[www.rubberfab.com](http://www.rubberfab.com)

- USP Class VI - Some Rubber Fab products meet the USP Class VI certification which means a plastic resin material is expected to be more likely to produce favorable biocompatibility results. Compounds must be made from ingredients with clear histories of biocompatibility that meet tight requirements for leachates. USP's drug standards are enforceable in the US by the Food and Drug Administration, and are also used in more than 140 countries. USP defines six plastics classes from I to VI with VI remaining the strictest.
- ADI® Free - Product compound that is manufactured with animal derived ingredients is Buna. All other elastomers are animal derived ingredient free. This was put into place as a sure way to remove any risk from the finished product, whether medication, food, or a component of another substance, to completely eliminate the potential for animal ingredient contact.

## Storage Procedures and Shelf Life of Elastomeric Gaskets

The shelf life of elastomeric, PTFE and FEP gaskets and O-Rings is dependent on many factors pertaining to their storage conditions. Products stored in their original packaging in a dry, cool environment away from direct sun light and artificial light should remain in optimal condition for 10 years. We do, however, recommend visual inspection of gaskets for discoloration, hardening and deformation after three years.

**Temperature:** In order to avoid certain forms of deterioration that may occur at higher temperatures, storage temperatures should be below 77°F (25°C). The effects of low temperatures are not permanently damaging, but articles may stiffen more than usual. Humidity Store in a dry environment to avoid condensation.

**Light:** Gaskets should be protected from light, especially direct sunlight and strong artificial light with high ultraviolet content.

**Oxygen and Ozone:** Whenever possible, gaskets should be protected from circulating air, ozone is very abrasive toward rubber, storage rooms should not contain any equipment capable of generating ozone such as mercury lamps, electric motors and any other equipment that produces electrical sparks and discharge.

**Deformation:** Whenever possible, gaskets should be stored in a relaxed condition free from tension, compression or other deformation.

**Contact with Liquid or Semi-Solid Materials:** Rubber should not come in contact with liquids or semi-solid materials, especially solvents, oils and greases at any time during storage.

**Rotation of Stocks:** Gaskets should remain in stores for as short of a period as possible. Therefore, articles should be issued from stores in strict rotation.

# Smart Gasket®

Rubber Fab's first ever validation product, the Smart Gasket®'s value is proven when validating sterility in a high-purity pharmaceutical system. The Smart Gasket® is used to obtain the critical thermal mapping information you need *during* the validation process.

Smart Gasket® easily installs between two sanitary standard flanges using the Rubber Fab sanitary Thermocouple Clamp to secure the flanges. Our clamp provides up to four internal ports for accepting the Smart Gasket® thermocouple samples or accessories. There is also a sampler device available that utilizes standard luer lock fittings. Meter fluids in your process system utilizing a peristaltic pump or withdraw samples utilizing our luer lock sampler and luer lock valve or syringe.

## Smart Gasket® Benefits:

- Use temporarily or permanently without custom thermowells or expensive custom fittings
- Easy to expand to multiple system sites
- Sanitary without a dead leg

## Smart Gasket® Features:

- Safe and user friendly
- Ease of installation
- 1, 2, 3 and 4 internal ports available
- Sensors seal with hygienic seal compression
- Reusable

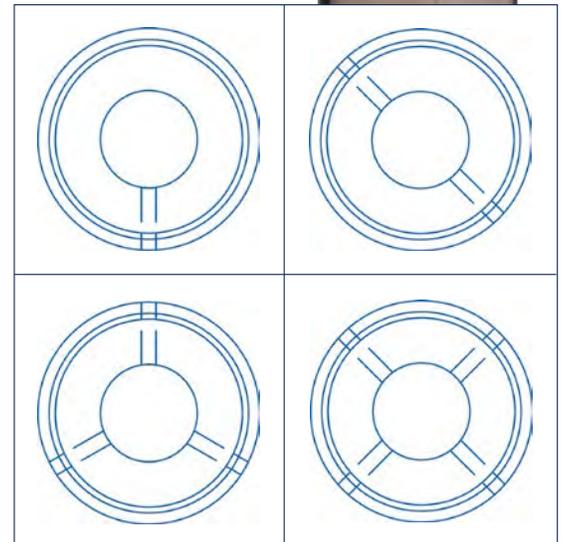
Smart Gasket® with a Thermocouple Clamp is available in 1/2", 3/4", 1", 1-1/2", 2", 3" and 4" sizes and fits standard sanitary flanges. Choose between EPDM, Platinum-Cured Silicone, and FKM.

## Meets High Pharmaceutical Standards

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.2600
- Traceability: Lot and Batch
- Certification: Lot and Batch
- USDA Standards
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Animal Derived Ingredient (ADI) Free



**Available Configurations for the Smart Gasket®**

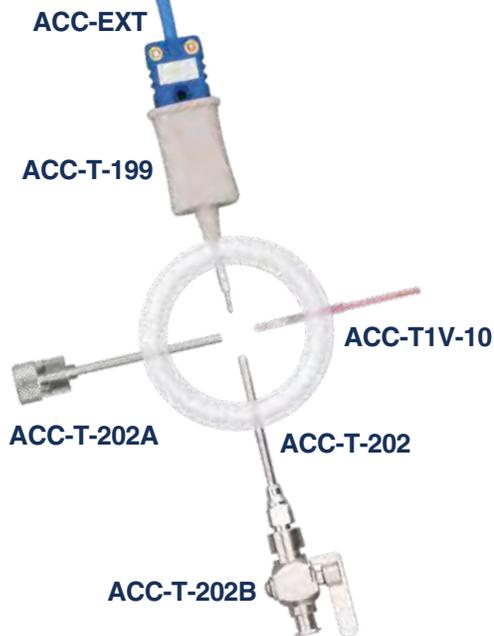


Part Number	Description
G-TH-XXX-SX	Platinum Silicone Thermocouple Smart Gasket®
G-TH-XXX-EX	EPDM Thermocouple Smart Gasket®
G-TH-XXX-VX	FKM Thermocouple Smart Gasket®

Smart Gasket® is a registered trademark of Rubber Fab

XXX = Size, X = Port number (1-4)

# Smart Gasket® Accessories



ACC-7001H



## Thermometer (ACC-7001H)

Temperature Range: -200° to +1370° C

Resolution: 0.1° C

Accuracy: ±0.2°C from -40°C to +200°C

Model ACC-7001H is a high-performance, precision handheld instrument for the measurement of temperature using type T, K, J, L, N, R or S thermocouple probes. This versatile instrument measures temperature in both °C and °F. The internal memory of the micro-computer stores the minimum and maximum measured temperature for instant recall via the LCD display.

## Extension Leads

ACC-EXT-3MM - 3 FEET

ACC-EXT-6MM - 6 FEET

ACC-EXT-12MM - 12 FEET

Male to male (sub-miniature type T connectors) 26 gauge. Stranded type to thermocouple wire with blue PVC insulation.

## Temperature Probe

ACC-K-199A-S or ACC-T-199A-S (short)

ACC-K-199A-L or ACC-T-199A-L (long)

Short and long temperature probe for thermocouple gasket. Copper Constantan female socket and bootie.

## Hole Plug (ACC-T-202A)

Chrome-plated brass head with stainless steel shaft 1-1/2" long .090 diameter. Also available in 316 Stainless Steel. ACC-T-202A-316

## Sampling/Injection Tube (ACC-T-202)

Chrome-plated brass female luer head with 1-1/2" long stainless hypodermic tube .090 O.D., .071 I.D.

## Stopcock (ACC-T-202B)

To fit sampling/injection tube. Chrome-plated brass construction female luer fitting to male luer lock. Also available in 316 Stainless Steel. ACC-T202B-316

## Thermocouple Wire (ACC-T1V-10, ACC-KV-10)

Coated thermocouple wire probe x 10' long with male mini quick disconnect connector for use with thermometer. Specify Kaptan or FEP when ordering.



# Spore Trap

You will never lose spore test strips in your process system again. The Rubber Fab Spore Trap is designed to securely retain and accurately expose spore challenge test strips for use in steam sterilization when validating. After each validation cycle, the spore trap, with its securely retained test strip, can easily be removed and rechallenged.

## Spore Trap Benefits

- Use in combination with Slotted Thermocouple Clamp for an accurate integration of sterilization and spore strip testing
- 1 internal port available when utilizing the spore strip
- No need for custom fittings or weldments and is easily installed into your sanitary systems
- Rubber Fab's Spore Trap Gasket is available with and without a thermocouple port

## 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 offers superior surface finish and elastomer purity in our finished hygienic seals.

After production, Rubber Fab seals 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.

*Spore strip is sold separately and is not part of the Rubber Fab product line. The spore strip can be purchased from Mesa Labs.*

Part Number	Description
G-SPR-XXX-S	Platinum Silicone Spore Trap Gasket

XXX = Size, Add -1 to the part number for 1 port



# Biological Indicator Gasket

Rubber Fab introduces an innovative product that enables the use of a self contained biological indicator in sanitary process lines. This unique Rubber Fab 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 24 hours (versus the five to seven days required with a spore strip) and without problematic laboratory transfer.

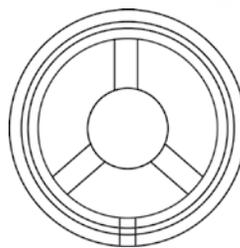
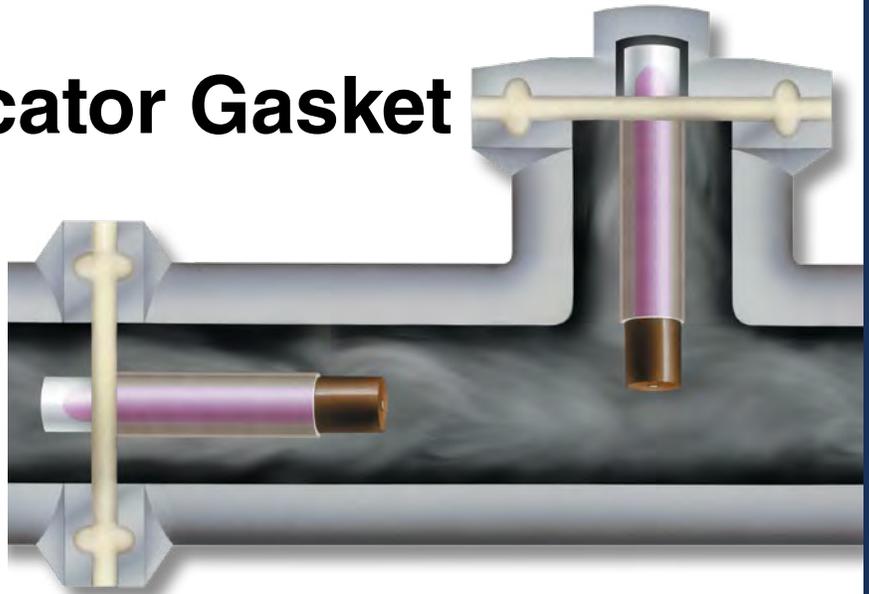
You can feel secure knowing that the biological indicator will not be lost down stream in the process. This fail-safe gasket holds the indicator in place for easy retrieval. Available for 3/4", 1", 1.5" and 2" Sanitary Tri-Clamp process lines. Biological Indicator Gaskets can be purchased with one (1) Thermocouple Port.

## Meets High Pharmaceutical Standards

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.2600
- Traceability: Lot and Batch
- Certification: Lot and Batch
- USDA Standards
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Animal Derived Ingredient (ADI) Free

## Validation of Steam Systems

- Fermenters
- Pharmaceutical Tanks
- Sanitary Inline Pipe
- Pharmaceutical Hose



*EZ-Test® strips and Incubator not included and may be purchased through Mesa Labs.*

Part Number	Description
42RXPX-BI-075	3/4" Platinum Silicone Biological Indicator
40RXPX-BI-100	1" Platinum Silicone Biological Indicator
40RXPX-BI-150	1 1/2" Platinum Silicone Biological Indicator
40RXPX-BI-200	2" Platinum Silicone Biological Indicator

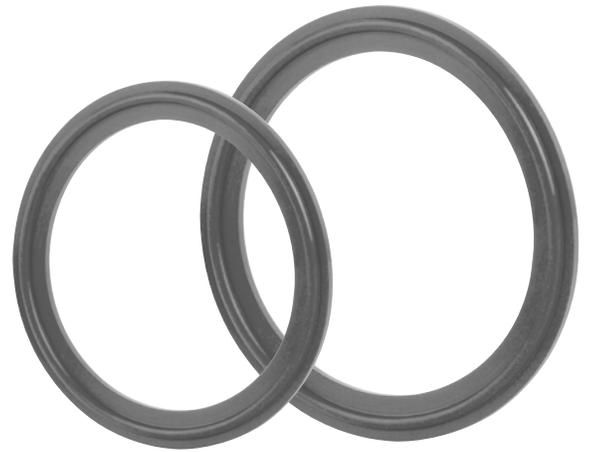
Add a -1 for a One Port Biological Indicator

*Biological Indicator Gasket: United States Patent #6,927,058.*



# Kalrez® Tri-Clamp® Gasket - LS390

Kalrez® is a sealing product for use in food, beverage and pharmaceutical processing applications where FDA and Class VI compliance is required. Kalrez® Tri-Clamp® gasket LS390 is designed to address thermal and chemical resistance, compression set issues and high static friction, which can cause intrusion in the process line. The Kalrez® gasket can address these problems by offering high hardness, low stiction and a high temperature resistance. These properties enable increased MTBR (Mean Time Between Repair). Because of its unique grey color, LS390 seals are easy to identify for proper material selection and application. Kalrez® LS390 Tri-Clamp® gasket is available from 1/2" to 6" and has a maximum application temperature of 428°F (220°C).



## Applications

- Food Processing
- Beverage Processing
- Pharmaceutical Application
- Chemical Applications

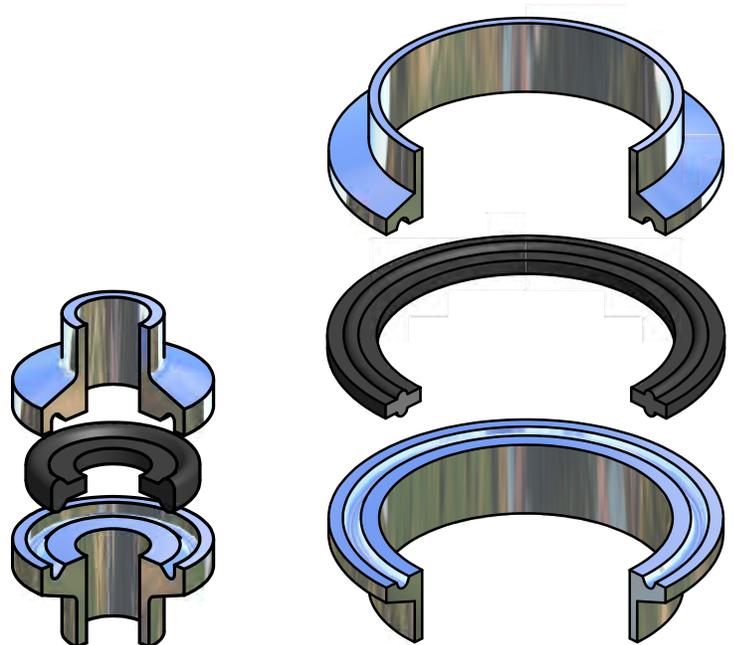
## Features

- Low Stiction Performance
- WFI and SIP/CIP Process
- High Hardness/Modulus
- Ease of Identification (Grey color)

## Certifications

- FDA
- USP Class VI, Chapter 88 at 121°C
- USP Chapter 87
- Japanese Pharmacopeia Edition 16

*Kalrez® is a registered trademark of  
E.I. duPont de Nemours and Company*



Part Number	Description
40MP-KZ-LS390-XXX	Kalrez® LS390 Tri-Clamp® Gasket

XXX = Size

# Torque-Rite® and Torque Tee

Another Rubber Fab innovation is the Torque-Rite® Nut. This nut allows you to control compression and expansion while maintaining constant inch/pounds force insuring a controlled compression I.D. Torque-Rite® eliminates the problems associated with over- or under-tightening a seal 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 hygienic seal (if emergency conditions arise, the Torque-Rite® has a built-in manual override feature). Torque-Rite® works with any of Rubber Fab's clamps to control compression.

## Rubber Fab Torque Tee

The Torque Tee also allows you to control compression and expansion while maintaining constant inch/pounds force insuring a controlled compression I.D. This eliminates the problems associated with over- or under-tightening a seal which can lead to an unsanitary system.

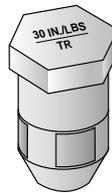
The Torque Tee and universal torque socket are designed to aid in clamp installation and removal. The Torque Tee handle creates effective tightening leverage and aids in reaching tight spaces, including over head and behind tanks.

## Torque-Rite® Specifications

- Material: 440C Stainless Steel
- Hardness: 48 Rockwell
- Overall Height: 1.670"
- Driving Hex: .875 (7/8")
- Body Diameter: .875"
- Override Flats: .8125 (13/16")
- Lot Traceable



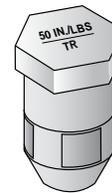
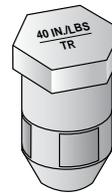
## Torque-Rite® is stocked in 3 models



### Model TR-30 (and TR-40)

*Recommended for use with*

- Buna
- Silicone
- FKM Fluoroelastomer
- EPDM
- Tuf-Flex®



### Model TR-50

*Recommended for use with*

- PTFE
- Tuf-Steel®
- PTFE Envelope

### TR-30-TEE-CP and TR-40-TEE-CP

*Recommended for*

- Buna
- Silicone
- FKM Fluoroelastomer
- EPDM
- Tuf-Flex®

### TR-50-TEE-CP

*Recommended for*

- PTFE
- Tuf-Steel®

### TR-70-TEE-CP

*Recommended for*

- GYLON BIO-PRO®
- GYLON® BIO-PRO PLUS™



TR-30-TEE-CP



TR-40-TEE-CP



TR-50-TEE-CP



TR-70-TEE-CP



Universal Socket

# Tuf-Flex® Unitized Gasket

## Introducing a Technologically Advanced Sanitary Gasket

Tuf-Flex®, a revolutionary sanitary gasket from Rubber Fab, is the world's only unitized seal setting new standards for purity, performance and flexibility. Designed to meet critical requirements in pharmaceutical, biotechnology, ultra-pure water, WFI (water-for-injection) and difficult food and beverage processing, Tuf-Flex® outperforms other sanitary hygienic seals and increases uptime by helping eliminate costly process interruptions.

## Performance Based on a Revolutionary Composition

A Tuf-Flex® sanitary gasket's contact surface is a layer of PTFE grafted to an EPDM rubber inner core. This totally bonded construction provides an exceptionally pure and incredibly flexible seal.

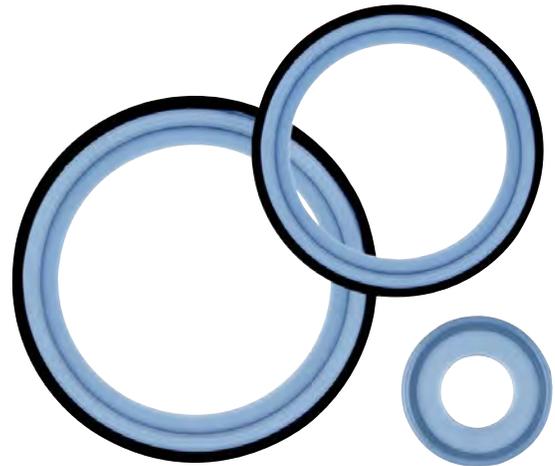
By grafting the elastomer with a layer of PTFE, Tuf-Flex® will behave like an elastomer but will prevent product contamination, service interruptions and clean-up costs associated with traditional elastomer seals.

## Product Purity Without Changeout

With standard CIP cleaning, Tuf-Flex® sanitary gaskets will NOT impart taste or odor. Because there's no cross flavor contamination, Tuf-Flex increases processing uptime by minimizing need for changeout.

## High Performance With Exceptional Purity

Because its elastomer core is protected by a unitized layer of PTFE, a Tuf-Flex® sanitary gasket will not release elastomer extractables or particulates totally eliminating



spalling. The result is an exceptionally maintained sanitary tubing I.D. with no I.D. invasiveness or system contamination.

## Achieve Higher Results Under SIP/CIP Conditions

- Superior resistance to cold flow and creep
- Excellent chemical resistance
- Minimal thermal expansion
- Exceptional flexibility

## Ultra-Pure

- Will not impart taste or odor – no cross flavor contamination
- No extractables, TOCs or particulates to contaminate product stream
- No-pigment
- No gasket I.D. invasion
- Exceptional cleanability response
- Non-stick surfaces
- Available in 1/2" - 12"

## Prevents Process Interruptions

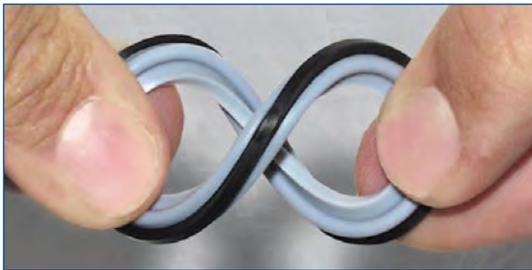
- Perfect cleanability
- No re-torquing
- Up to 500 SIP cycles guaranteed
- Outstanding service life
- Reusable
- Extended uptime
- Maintains seal @ 30 in./lbs.
- Temperature Range: -20°F to 300°F (-29°C to 149°C)



*Tuf-Flex® is a registered trademark of Rubber Fab*

### Meets Stringent Standards

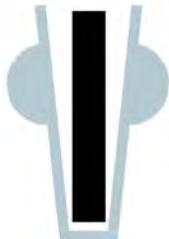
- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- Title 21 CFR 177.2600 and 177.1550
- 3-A Certified
- USDA Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Animal Derived Ingredient (ADI) Free



### Type I and Type III Envelope Gaskets vs Tuf-Flex®



A Solid PTFE Type I gasket is guaranteed to fail in SIP conditions. They will creep, cold flow and leak at  $\Delta T$ .



The Envelope gasket construction provides inconsistent results between the two materials. It will also creep, cold flow and leak over time.



The PTFE grafted elastomer in a Tuf-Flex® gasket will maintain I.D. without re-torquing or leaking.

Part Number	Description
A40MPGR-TF-XXX-E	PTFE/EPDM Unitized Tuf-Flex® Gasket
FF-AF-E-XXX-150#-.197	PTFE/EPDM Ansi-Flex Full Faced Gasket

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"

## Ansi-Flex Full Faced Gasket

An Ansi-Flex 150# Full Faced 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 elastomeric gasket with steam resistance. The Ansi-Flex 150# Full Faced Gasket has superior and extended service life over standard flange gaskets. Ansi-Flex is available in 1/2" - 8".

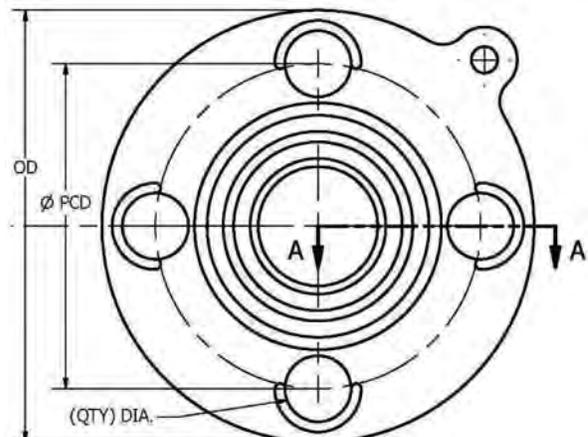
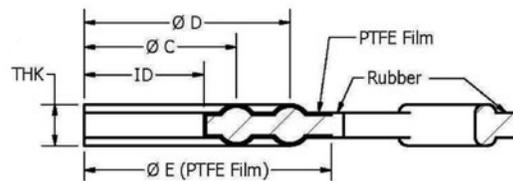


### Applications

- PVC Piping
- Glass Lining Piping

### Meets Stringent Standards

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



# Tuf-Steel® Family of Products

The original Tuf-Steel® gasket, a Rubber Fab product innovation, is the strongest gasket in the food, beverage, pharmaceutical and biotech industries. Whatever your application, there's a gasket in the Tuf-Steel® family ready to do the job.

Composed of a unique proprietary blend of non-pigmented PTFE and 316L passivated and atomized Stainless Steel, you can bet on any Tuf-Steel® seal for leak-proof performance and outstanding durability. There is no beating the Tuf-Steel® family in SIP, WFI and hot oil applications because Tuf-Steel® maintains seal integrity in applications with large temperature variations. With a 500 steam cycle guarantee, this metal detectable gasket will easily outperform any elastomeric or perfluoroelastomer gasket and will remain in service for extended periods of time. It is the material of choice when chemical and heat resistance are required. With minimum creep and cold flow, non-stick, ultra-low absorption, and no pigmentation, Tuf-Steel® will not revert, eliminating creep and cold flow, resulting in a leak free seal. This gasket is tough!

Testing and a decade of documented application usage has demonstrated that Tuf-Steel® is the choice for perfect surface performance and extended service life. Tuf-Steel® is ideal for extreme temperature applications, such as steam, hot oil and friers, where temperatures range from -325°F to 550°F. Because of the superior strength and chemical resistance of Tuf-Steel®, it can go the distance, significantly reducing maintenance and system downtime by staying in place when cleaning and validating a system. 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® Stands Up to Rigorous Conditions and Delivers Leak-Proof Performance

- 500 CIP/SIP cycles guaranteed
- Excellent expansion/contraction stability with minimal thermal expansion
- Excellent chemical resistance
- Stops leaks when correctly torqued (50 in./lbs. with Torque-Rite® Model TR-50)
- Tuf-Steel® is a compression control gasket
- No gasket intrusion into the sanitary tube I.D.
- No obstruction of flow
- Maintains sealing stability in  $\Delta T$  processes

## Tuf-Steel® Offers Rugged Composition for Demanding Challenges

- Proprietary PTFE and Stainless Steel blend
- Metal detectable
- Rouging eliminated
- Non-pigmented
- Non-stick surfaces
- I.D. Pharmaceutical finish



### Tuf-Steel® Meets Stringent Standards

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- FDA CFR 21 177.1550
- 3-A Certified
- USDA
- Current Good Manufacturing Practices (CGMP)
- Animal Derived Ingredient (ADI) Free

### Tuf-Steel® is available in:

- Type I Standard Tri-Clamp® Gasket
- Type II Flanged
- O-rings
- Tri-Clamp® Screen Gasket
- Tri-Clamp® Orifice Plate Gasket
- Steam Trap Orifice Plate Gasket
- Sheet
- Solid Rod
- Ansi Flange
- Custom Gaskets
- Please visit [www.rubberfab.com](http://www.rubberfab.com) for a complete list of part numbers



Orifice Plates



**Tuf-Steel® sheet material can be waterjet cut into custom patterns.**  
**Available Sheet Size: 36" x 36"**  
**Available Thickness: 1/16" & 1/8"**



**Tuf-Steel® Solid Rod can be machined into custom parts and adapters**

**AVAILABLE ROD DIAMETER: 1/8" – 2"**



Screen Gaskets

# Tuf-Steel® Family of Products

## Tuf-Steel® Type I Tri-Clamp® Gasket

The original Tuf-Steel® Type I Tri-Clamp® style sanitary gasket is widely used in sanitary processing pipeline systems for Pharmaceutical, Biopharmaceutical, Food, Beverage and Dairy industries. Specifically designed for demanding steam applications, high temperatures and hot oil applications.

Available Sizes: 1/2" – 12"

Part Number	Description
40MPG-TS-XXX	Tuf-Steel® Tri-Clamp® Gasket

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"

## Tuf-Steel® Orifice Plate

Rubber Fab's innovative Tuf-Steel® Orifice Plate line includes a complete selection of Tuf-Steel® 316 Stainless Steel Orifice Plate gaskets in standard or tabbed style that can be custom drilled with an eccentric or concentric bore. Orifice Plate 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. Orifice plates can advance your system's performance, adjust flow rates, balance backflow and equalize back pressure during SIP procedures.

Available Sizes: 1/2" – 6"

Part Number	Description
A80MPG-TS-XXX	Tuf-Steel® Orifice Plate Gasket

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"

## Tuf-Steel® Tri-Clamp® 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.

Available Sizes: 1/2" – 6"

Part Number	Description
40MPGTSSXX-XXSS	Tuf-Steel® Screen Gasket

XXX = Size, XXSS = Mesh Size, 42 is the Part Designation Number for 1/2" and 3/4"



**Bevel Seat Gaskets**

## Tuf-Steel® Full Face Flange and Ring Gaskets

Rubber Fab offers a complete size range of standard Full Face 150# and 300# Ansi Flange gaskets, as well as, Ring Gaskets specifically designed for demanding steam applications.

Available Sizes: 1" – 8"

Part Number	Description
XX-TS-XXX-150#-.125	Tuf-Steel® Full Faced & Ring

XX = FF for flanged face & RG for ring gasket, XXX = Size

## Tuf-Steel® I-Line Gaskets

Available Sizes: 1" – 8"

Part Number	Description
40IT-TS-XXX	Tuf-Steel® I-Line Gasket

XXX = Size

## Tuf-Steel® John Perry Gaskets

Available Sizes: 1" – 4"

Part Number	Description
40JPG-TS-XXX	Tuf-Steel® John Perry Gasket

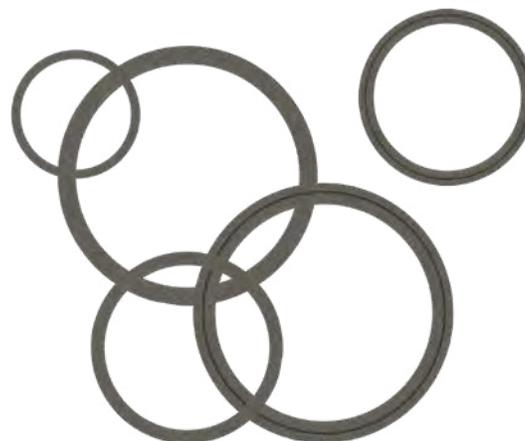
XXX = Size

## Tuf-Steel® Bevel Seat Gaskets

Available Sizes: 1" – 4"

Part Number	Description
40BSS-TS-XXX	Tuf-Steel® Bevel Seat Gasket

XXX = Size



**I-Line Gaskets**

# Case Study: Aloe Vera Juice Processing

## Tuf-Steel® Gaskets



### INDUSTRY

Beverage Manufacturing - Aloe Vera Juice

### CUSTOMER

A large US beverage manufacturer, producing natural juices at their production plant in Texas.

### BACKGROUND

This customer was using standard PTFE tri-clamp gaskets on their hygienic pipe connections, but was facing ongoing problems with gasket failure. In order to avoid severe leaks throughout their process, they were replacing gaskets on a weekly basis which was not only expensive but also time-consuming for the maintenance crews.

### CHALLENGES FACED

Production of aloe vera juice is challenging, and requires careful process control – not only to preserve the biological integrity of the active ingredient, but also to maintain the delicate flavour of the finished product. Mechanical extraction processes (crushing, grinding or pressing of the leaf) create debris, which can damage soft process components and requires frequent cleaning and sterilization cycles between each batch. Additionally, various stages of filtration and stabilization introduce rapid temperature fluctuations from near-boiling point down to flash-cooling, which create physical stresses on hygienic connections as they expand and contract.

### OPERATING CONDITIONS

1. Size: 1" to 4" Tri-Clamp (ASME-BPE)
2. Temperature: -5°C (23°F) to 95°C (203°F)
3. Application: All hygienic process pipe/vessel connections

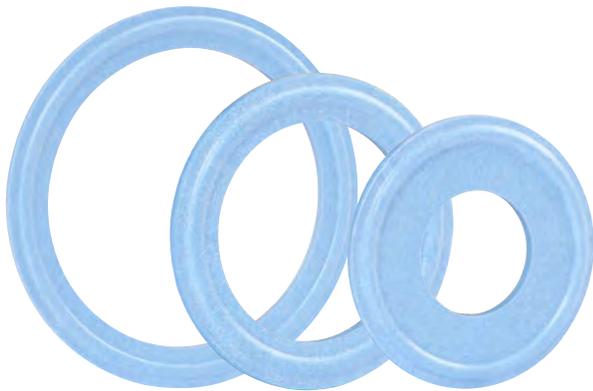
4. Media : Raw extract and purified aloe vera juice
5. Pressure: 120 PSI (8.3 bar)

### SOLUTION AND BENEFITS

The customer provided full access to the plant and their processing conditions so that Rubber Fab could carry out detailed trouble-shooting and recommend the best possible improvements. Taking into account the need for mechanical strength, chemical compatibility, and resilience in temperature cycling conditions, it was recommended that the standard PTFE gaskets were replaced with Tuf-Steel® sanitary gaskets which would not exhibit the creep and cold-flow (and hence leakages) normally associated with PTFE. The unique blend of virgin PTFE and passivated 316L stainless steel provides possibly the most robust gasket material for hygienic applications, which would have no problem to provide a long-lasting and effective seal in these process conditions. Additionally, Rubber Fab's experience in other sensitive food & beverage applications re-assured the customer that these gaskets would not impart any flavour into the juice.

Following a successful trial in one part of the process, Tuf-Steel® was quickly adopted across the whole plant and eliminated all of the leaks that previously caused so many problems. Instead of urgently replacing gaskets on a weekly basis, the customer is now replacing Tuf-Steel® gaskets every 2-3 months as part of scheduled maintenance.

# GYLON® Family of Gaskets



## GYLON BIO-PRO®

Tri-Clamp® connections are the standard connection in the pharmaceutical industry. Seals of varying quality and materials are often used regardless of their suitability for constantly increasing operating parameters. GYLON BIO-PRO® seals offer a safe solution with its modified and restructured PTFE material, pre-formed and stress controlled, for all Tri-Clamp® standards. It is dimensionally stable and resists intrusion. Rubber Fab is proud to offer GYLON BIO-PRO® in Tri-Clamp® gaskets with sizes ranging from 1/2" to 4" and also in ring gaskets.

### Features

- No extrusion and cold flow
- Temperature Range of -346°F to 500°F (-210°C to 260°C)
- High resistance to most chemicals & temperature cycles

### Certifications

- USP Class VI
- FDA compliant
- EN 1935/2004
- KTW approved

## 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™ is pre-formed and stress controlled with high manufacturing precision, helping to eliminate critical and costly contamination issues often associated with gasket recession or intrusion within hygienic couplings. With a smooth surface finish, the GYLON® BIO-PRO PLUS™ is ideal for product contact applications and is a top performer relative to both CIP and SIP cycle life, regardless of cleaning media or sterilization procedure. Our GYLON® 3522 material of construction is 100% pure PTFE, and provides full compliance with all industry standards. GYLON® BIO-PRO PLUS is available in 1/2" - 6".

### Features

- Sealing integrity - proprietary GYLON® resists creep and cold flow
- Temperature Range of -450°F to 500°F (-268°C to 260°C)
- Eliminates gasket recession and intrusion into the process flow
- Ease of removal with zero gasket residue
- Exceptional chemical and thermal cycling capabilities

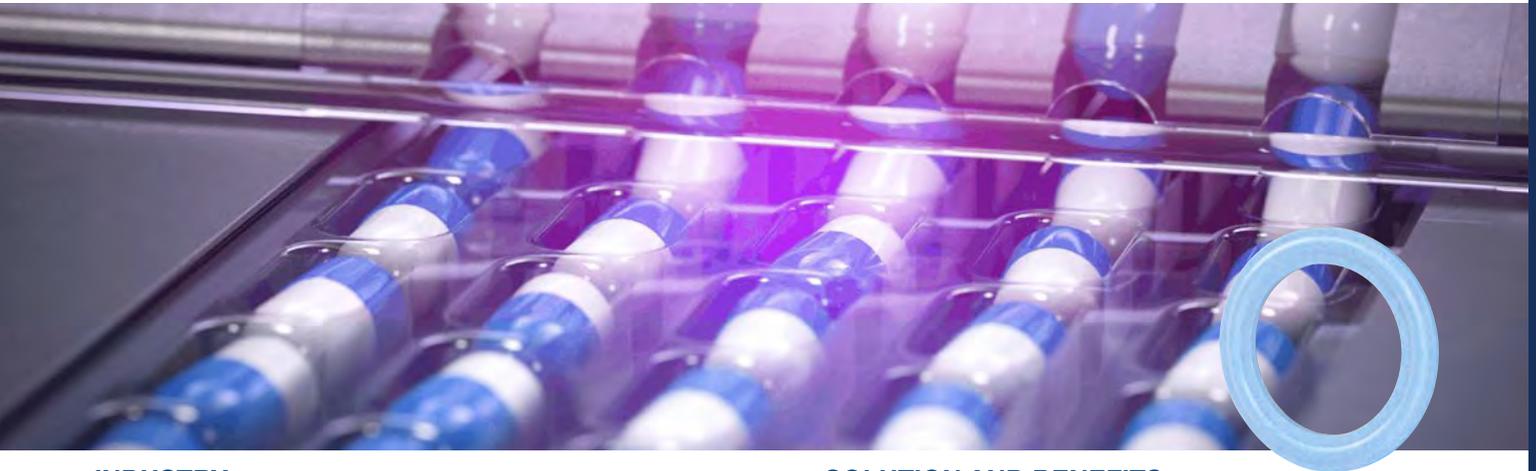


Part Number	Description
40MP-BIO-PRO-XXX	GYLON BIO-PRO®
40MP-BIO-PRO-PLUS-XXX	GYLON® BIO-PRO PLUS™

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"

# Case Study: Pharmaceutical Gel Caps

## GYLON BIO-PRO®



### INDUSTRY

Pharmaceutical Processing - Excipients

### CUSTOMER

A global manufacturer of pharmaceutical-grade gelatin for capsules.

### BACKGROUND

The customer's USA facility was using both EPDM and PTFE sanitary gaskets throughout their process, but they had encountered issues over the years with both materials. The EPDM gaskets were typically over-tightened which created gasket intrusion and physical degradation, and upon replacement they were also found to be stuck to the ferrules, creating further problems when maintenance technicians had to use hard tools to scrape away any residue. The PTFE gaskets were easier to remove, but showed considerable evidence of creep and cold flow which created process leaks, resulting in build-up of crystallised gelatin around the tri-clamp connections. Worryingly, in both cases, there was evidence of downstream contamination from gasket fragments which frequently led to un-scheduled downtime, additional cleaning, as well as batch quarantine and disposal.

### OPERATING CONDITIONS

1. Media (process): Liquid Gelatin
2. Media (cleaning): 3% Caustic Solution @180°C
3. Size: Various 1" to 6"
4. Temperature: 392°F (200°C)
5. Pressure: 200PSI (13.8 bar) with spikes up to 800PSI (55.2 bar)

### SOLUTION AND BENEFITS

Production of pharmaceutical-grade gelatin involves some challenging process conditions – alkaline or acid extraction, deionization, sterilization, concentration – as well as harsh cleaning regime to ensure that the process cleanliness and sterility is maintained. In order to meet these conditions and overcome the ongoing problems with both standard EPDM and PTFE materials, GYLON BIO-PRO® sanitary gaskets were recommended as a universal solution across the entire plant. Despite some initial reluctance to specify a more expensive component, the customer's extensive testing program demonstrated that the modified PTFE used in GYLON BIO-PRO® solved all their problems and thus provided much higher value than the commodity gaskets they had been using. Superb compatibility with all process and cleaning conditions, elimination of process leaks without the need to re-torque, and easy installation were all factors that support the customer's decision to change their long-standing specification.

Since the whole plant was converted to BIO-PRO® sanitary gaskets, the customer has not experienced a single contamination event and is enjoying the benefits of longer service life and reliable performance. As an example, in one area of the plant they were replacing EPDM gaskets due to failure every 6-8 weeks, but the maintenance program has already been extended to more than one year with GYLON BIO-PRO® gaskets without any problems.

# Case Study: Oncology Injectables

## GYLON® BIO-PRO PLUS™



### INDUSTRY

Pharmaceutical production- Oncology injectables

### CUSTOMER

Cytostatic injection manufacturer to treat oncological diseases

### BACKGROUND

The customer struggled with a very short life time of the gaskets installed in his tri-clamp connections. The gaskets showed high creep and cold-flow behavior and needed to be re-tightened after every single SIP (Sterilization In Place) cycle. The previously used gaskets were either made from virgin PTFE or envelope gaskets consisting of FKM core and outer virgin PTFE layer. The lifetime of these gaskets was approximately 2 weeks.

### CHALLENGES FACED

The aseptic production process for cytostatic injectables underlies strict rules concerning the systems hygienic design. Good cleanability and sterilizability of all system components are of decisive importance. The end products are directly injected into the human body. Due to strict compatibility tests only pure PTFE gaskets without any additives, fillers or pigments can be approved for the process-line. Virgin PTFE gaskets and envelope gaskets only had a very short lifetime (approx. 2 weeks) due to their very high creep. All connections had to be re-tightened after every SIP cycle and exchanged after 3 cycles. One cycle consists of: 1. CIP (Cleaning In Place), 2. Re-torquing with 2 Nm, 3. SIP – re-torquing with 2Nm,

4. Leak test, 5. Production. This procedure takes about 4 hours.

### SERVICE CONDITIONS

1. Product: Cytostatic injections
2. Cleaning Media: SIP process (30 min-Steam at 121° C (250° F)) and CIP (WFI-Water for Injection at 75° C (167° F))
3. Size: 34/DN15; 50.5/DN15; 50.5/DN25; 50.5/DN40
4. Temperature: Up to 131° C (268° F)
5. Pressure: 2 bar (29 psi) SIP and 3 bar (44 psi) CIP

### SOLUTION AND BENEFITS

Since the installation of GYLON® BIO-PRO PLUS™ the re-torquing of connections is no longer necessary. The lifetime of the gaskets has increased significantly assuring a reliable performance at all times. After more than 100 cycles ran with GYLON® BIO-PRO PLUS™ the customer extended the gasket replacement period from 3 to 6 months. Even after 6 months in use the gaskets still looked very good so that the gasket replacement period can be prolonged in the future. Most importantly with GYLON® BIO-PRO PLUS™ the customer increased the plants productivity gaining 4 additional product batches per month which they were losing in the past due to gasket replacement and re-torquing efforts. GYLON® BIO-PRO PLUS™ with a very high density and low porosity easily passed the systems pressure/leak-testing cycle. During this test GYLON® BIO-PRO PLUS™ showed a steady result where previously used envelope gaskets showed a 10 times higher pressure drop.

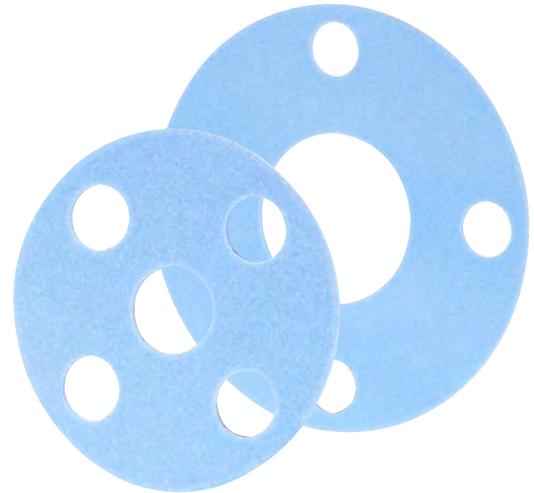
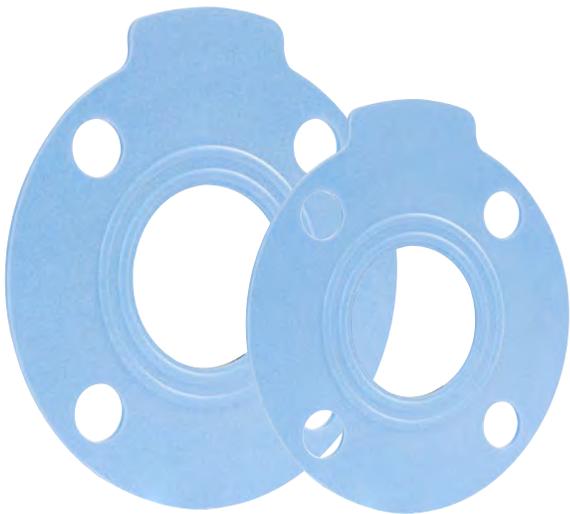
# GYLON® Family of Gaskets

## GYLON® STRESS SAVER®

The new Style 3504 GYLON® STRESS SAVER® combines these 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. The combination of these two time-tested configurations make Style 3504 GYLON® STRESS SAVER® the ultimate sealing solution.

### Features

- Suitable for both metallic and non-metallic piping with either flat or raised face flanges
- GYLON® 3504 is ideal for a wide range of caustics and acids, helping to simplify the selection process
- Limited Creep and Cold-Flow – Greatly reduces the leakage after installation and system cycling
- Available in 1" - 8"



## 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. The unique manufacturing process minimizes cold flow problems typical of skived and expanded PTFE sheets and has excellent bolt torque retention. GYLON® Style 3504 can withstand a wide range of chemicals for extended service life in a wide variety of applications.

### Features

- Improved performance over conventional PTFE
- Unique manufacturing process minimizes cold flow problems
- Withstands a wide range of chemicals for extended service life in a wide variety of applications
- Ideal for wavy, warped, pitted, or scratched flanges, and for many types of flat faced flanges.

Part Number	Description
FF-SS-3504-XXX-150#-.125	GYLON® STRESS SAVER®
FF-3504-XXX-150#-.0625	GYLON® Style 3504 1/16" thick
FF-3504-XXX-150#-.125	GYLON® Style 3504 1/8" thick

XXX = Size

# Gauge Guard Isolators

The Rubber Fab Gauge Guard Isolator gasket protects expensive stainless steel diaphragms and instruments from damage without affecting instrument performance. By combining a quality Rubber Fab hygienic seal with a membrane, the Gauge Guard Isolator hygienic seal isolates corrosive solutions from the stainless steel diaphragm. A necessary and cost effective step in assuring long life and accurate results from your gauges.

As some manufacturers will suggest the use of a gauge guard seal, others note that the failure to use a gauge guard seal can void most instrument and gauge warranties.

## All the Rubber Fab Benefits in a Gauge Guard Hygienic Seal

- Seal membrane protects stainless steel diaphragm from corrosive solutions
- Will not interfere with gauge operation or accuracy
- Works with most industry standard instruments
- Helps extend the life of gauges
- Available in:
  - Platinum Silicone
  - PTFE
  - EPDM
  - FKM Fluoroelastomer
- 1/2" and 3/4" – .015 membrane thickness
- 1", 1-1/2" and 2" – .010 membrane thickness

## All Rubber Fab Hygienic Seals Meet the Stringent Standards For Purity

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



Part Number	Description
40GGI-E-XXX	EPDM Gauge Guard Isolator
40GGI-SFY-XXX	FKM Gauge Guard Isolator
40GGI-PX-XXX	Plat. Silicone Gauge Guard Isolator
40GGI-G-XXX	PTFE Gauge Guard Isolator

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"



# Gauge Guard Protectors

Rubber Fab's Gauge Guard Protector gasket protects expensive, fragile gauge diaphragms and other similar instruments from damage during calibration, routine maintenance and during autoclave procedures. The Gauge Guard Protector is available in 3/4", 1", 1-1/2" and 2" and is manufactured using U.S.P. Class VI Platinum Cured Silicone and 316 Stainless Steel.

Combine the Gauge Guard Protector with a quality Rubber Fab Gauge Guard Isolator Gasket to achieve complete diaphragm protection. This is a necessary and cost effective step in assuring maximum service life and accurate results from your instruments and gauges. Rubber Fab's Gauge Guard Protectors are also designed to snap onto sanitary Tri-Clamp® hose connections, protecting the ferrule face from damage while breaking down or storing hoses.

## All Rubber Fab Hygienic Seals Meet the Stringent Standards For Purity

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- USDA
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Animal Derived Ingredient Free (ADI Free)



Part Number	Description
40GGP-PX-XXX	Plat. Silicone Gauge Guard Protector

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"

[sales@rubberfab.com](mailto:sales@rubberfab.com)

# Platinum Cured Silicone Gaskets

High purity platinum cured silicone hygienic seals are the ideal choice for use in production facilities of fine pharmaceutical, biotechnology, and injectables. Rubber Fab's platinum cured silicone seals withstand temperature extremes, radiation, corona, moisture and steam. Due to its smooth finish, platinum cured silicone resists product adhesion. These odorless, tasteless, non-toxic hygienic seals maintain product integrity and can be autoclaved, irradiated and gas sterilized. And because there is no Benzoic Acid residue, Rubber Fab's platinum cured silicone hygienic seals provide you with the ultimate, high pure, contact surface.

## The Platinum Cured Silicone Hygienic Seal

When considering silicone seals, platinum cured is the most favorable over peroxide cured. The curing method used on the silicone has a direct affect on the amount and type of extractables the hygienic seal will emit. Peroxide curing will always have residuals from the curing additive. Its conversion, Benzoic Acid, will result in an unwanted surface condition causing product contamination. Platinum curing eliminates this problem and minimizes reactions with the respective process fluids. All Rubber Fab silicone hygienic seals are post cured and will not cause cell mutation or growth retardation. They maintain and uphold ultra-pure water and CGMP process fluid standards.

## Superior Tear Resistance

Rubber Fab manufactures all platinum silicone hygienic seals from milled gum silicone. When compared to LIM (liquid injection molding) silicone, milled gum silicone seals have superior resistance to tearing and deformation.

## Complete Line of Platinum Cured Silicone Products

Rubber Fab's platinum cured silicone seals are available in Type I, 1/2" - 6" and Type II Flanged, 1" - 12". They are interchangeable with standard sanitary clamp seals and work with Rubber Fab's Torque-Rite®. Additional product lines are also available, including O-Rings and tubing.

Part Number	Description
40RXPX-XXX	Platinum Cured Silicone Clear Tri-Clamp® Gaskets
40RXPX-F-XXX	Platinum Cured Silicone Clear Tri-Clamp® Flanged Gaskets

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4"



## The Choice is "Clear"

- Eliminates particulates
- Non-pyrogenic
- No pigmentation
- No plasticizers
- High/low temperature range: -100°F to 450°F (-73°C to 232°C)
- S.I.P. up to 30 psi @ 253°F (123°C)
- No reversion
- Non leaching
- Odorless, tasteless and non-toxic
- Superior tear resistance
- Detectomer® Silicone Gaskets available

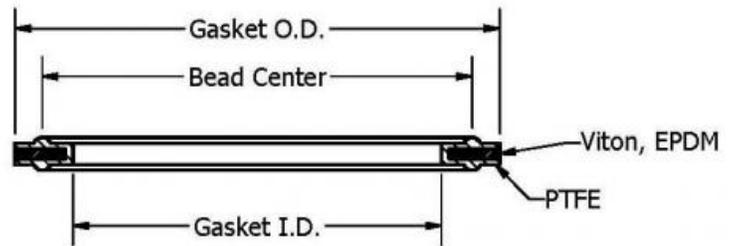
## Meets High Pharmaceutical Standards

- U.S. Pharmacopeia Class VI Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.2600
- Traceability: Lot and Batch
- Certification: Lot and Batch
- USDA Standards
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Animal Derived Ingredient (ADI) Free



# Envelope Tri-Clamp<sup>®</sup> Gaskets

A PTFE envelope gasket has the chemical resistance of PTFE and the elastomeric characteristics of EPDM or FKM Fluoroelastomer. Envelope Gaskets have an outer shell of white PTFE and the option of either an EPDM filler or a FKM filler, depending on the application need. The PTFE envelope gasket meets FDA and USP Class VI standards. Envelope gaskets are available in 1/2" - 12" and Flanged, 1" - 4".



Part Number	Description
A40MPGR-XXX-E	PTFE Envelope Gasket with EPDM Filler
A40MPGR-XXX-V	PTFE Envelope Gasket with FKM Filler

XXX = Size, 42 is the Part Designation Number for 1/2" and 3/4", add a F for Flanged

sales@rubberfab.com

## Are You On The List?

### Be in the Know with Rubber Fab's Email Newsletter

Rubber Fab is growing and new ideas are being generated to solve customer problems all the time. Want to keep up with what is going on, and new products before they hit the market? Subscribe to our newsletter!

The Rubber Fab E-Newsletter is a monthly newsletter FULL of information about Rubber Fab and our products. We have product spotlights, our trade show schedule and links to great resources.

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# DIN and ISO Gaskets



Rubber Fab sanitary gaskets for hygienic clamp connections are now available in DIN and ISO dimensions.

Our sanitary gaskets are widely used in Pharmaceutical, Biotech, Food, and Beverage applications. Rubber Fab's sanitary gaskets are in full compliance with FDA and USP Class VI regulations ensuring highest purity, process safety and sealing performance.

In addition to our proprietary products such as Tuf-Flex<sup>®</sup>, Tuf-Steel<sup>®</sup> and the GYLON BIO-LINE<sup>®</sup>, our new range of DIN and ISO gaskets are also available in additional elastomers, fluoroelastomers and PTFE.

The new range of Rubber Fab sanitary gaskets are designed to meet DIN 32676, DIN 11850, DIN 10357 and ISO 1127 specifications.

All of our DIN and ISO gaskets come with a Certificate of Compliance indicating the applicable lot number and all relevant order information to ensure full traceability at all times.

Upon request the batch number and other desired information can also be applied directly to the gasket using specially developed laser marking techniques. Our laser etching service further supports and simplifies the traceability process for our customers on site.



## MATERIALS AVAILABLE

- Tuf-Flex<sup>®</sup>
- Tuf-Steel<sup>®</sup>
- GYLON BIO-LINE<sup>®</sup>
- EPDM
- Silicone
- FKM
- PTFE
- PTFE Envelope Style

## SIZES AVAILABLE

- DIN 32676 size range
- DIN11850 size range
- DIN10357 size range
- ISO 1127 size range



# Elastomer Resistance and Temperature Overview

## KEY

1 = Excellent    2 = Good    3 = Acceptable    4 = Marginal    5 = Poor    0 = Do not use

Gasket Elastomer	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®	1	1	1	1	1	1	1	-20°F to 300°F (-29°C to 149°C)
Tuf-Steel®	1	1	1	1	1	1	1	-325°F to 550°F (-198°C to 288°C)
Kalrez®	1	1	1	1	1	1	1	-4°F to 428°F (-20°C to 220°C)
GYLON BIO-PRO®	1	1	1	1	1	1	1	-346°F to 500°F (-210°C to 260°C)
GYLON® BIO-PRO PLUS™	1	1	1	1	1	1	1	-450°F to 500°F (-267°C to 260°C)
PTFE	1	1	1	1	1	1	3	-100°F to 500°F (-73°C to 260°C)
Silicone (platinum)	2	2	2	2	2	2	1	-40°F to 450°F (-40°C to 232°C)
FKM	2	2	2	2	2	2	2	-30°F to 400°F (-34°F to 204°C)
EPDM	0	4	3	3	3	3	3	-30°F to 300°F (-34°C to 149°C)
Buna	0	0	5	5	5	5	5	-30°F to 200°F (-34°C to 93°C)

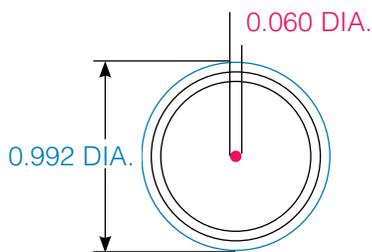
**NOTE:** Properties/applications shown throughout this brochure are typical. Your specific application should not be undertaken without independent study and evaluation for suitability. For specific application recommendations consult Rubber Fab. Failure to select the proper sealing products could result 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.

# Tri-Clamp® Gasket Sizing Guide

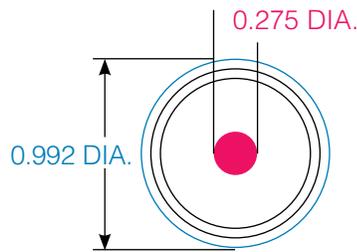
These actual size drawings are provided to eliminate sizing errors when specifying sanitary fittings. The outside diameter is the same for 1/8", 1/4", 3/8", 1/2", and 3/4" ID, "mini" sizes (0.992" OD). The same holds true for the 1"

and 1-1/2" ID sizes (1.984" OD). The 2", 2-1/2", 3", 4", and 6" ID have specific OD diameters.

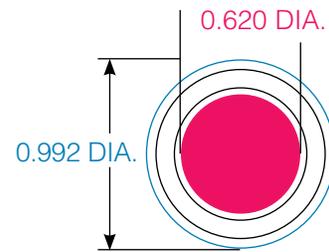
For your convenience and ordering accuracy, all of these drawings may be used as sizing ID and OD patterns.



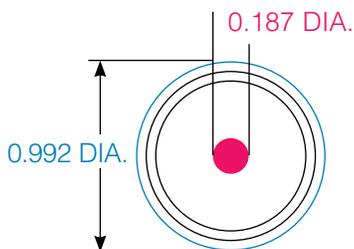
1/8" MINI TC



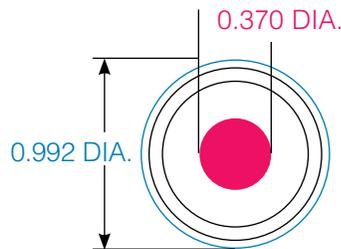
3/8" MINI TC



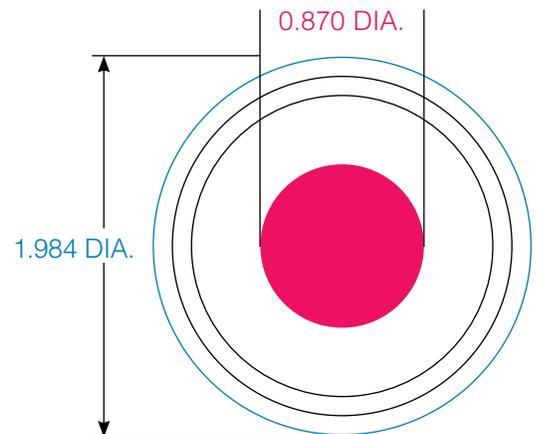
3/4" MINI TC



1/4" MINI TC



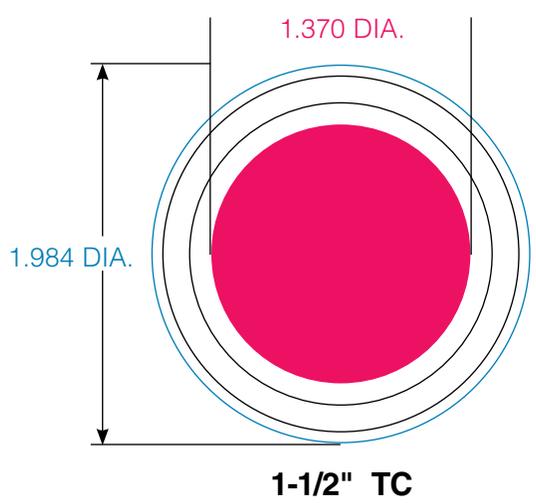
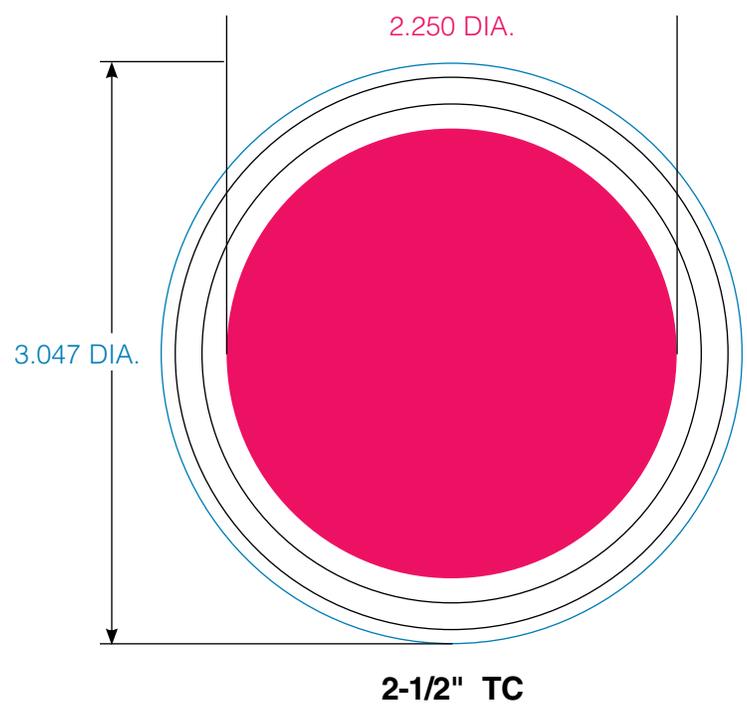
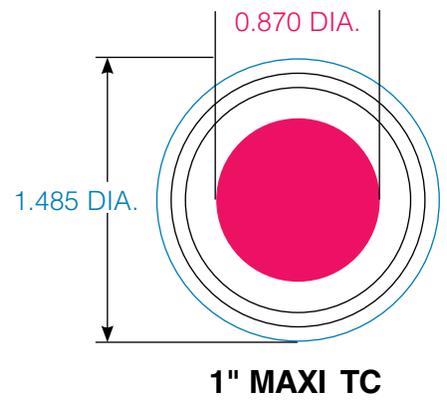
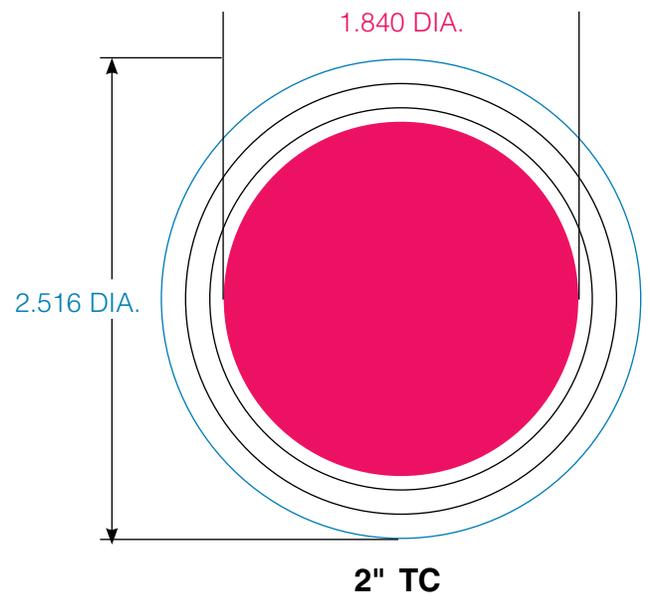
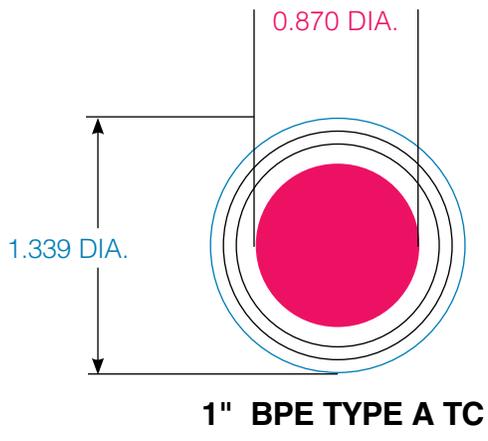
1/2" MINI TC

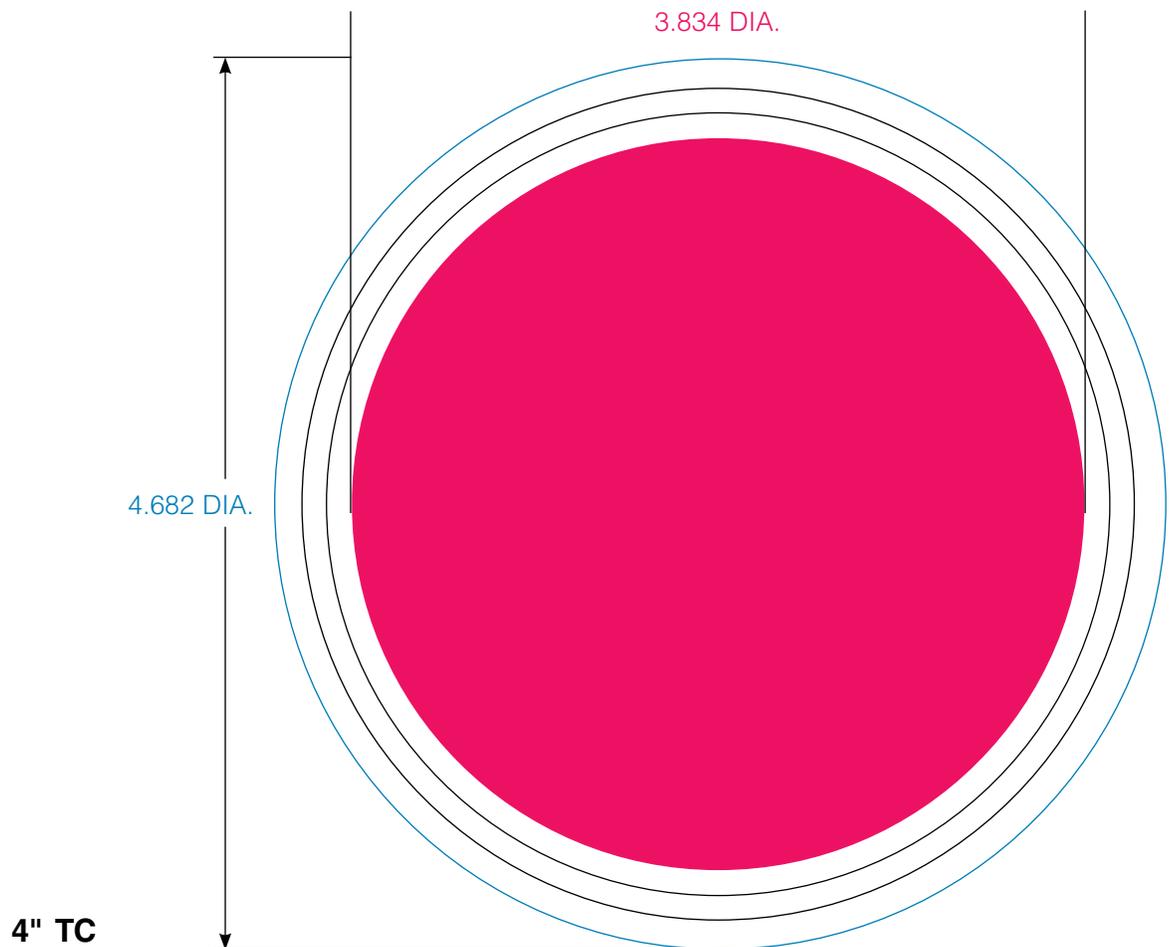
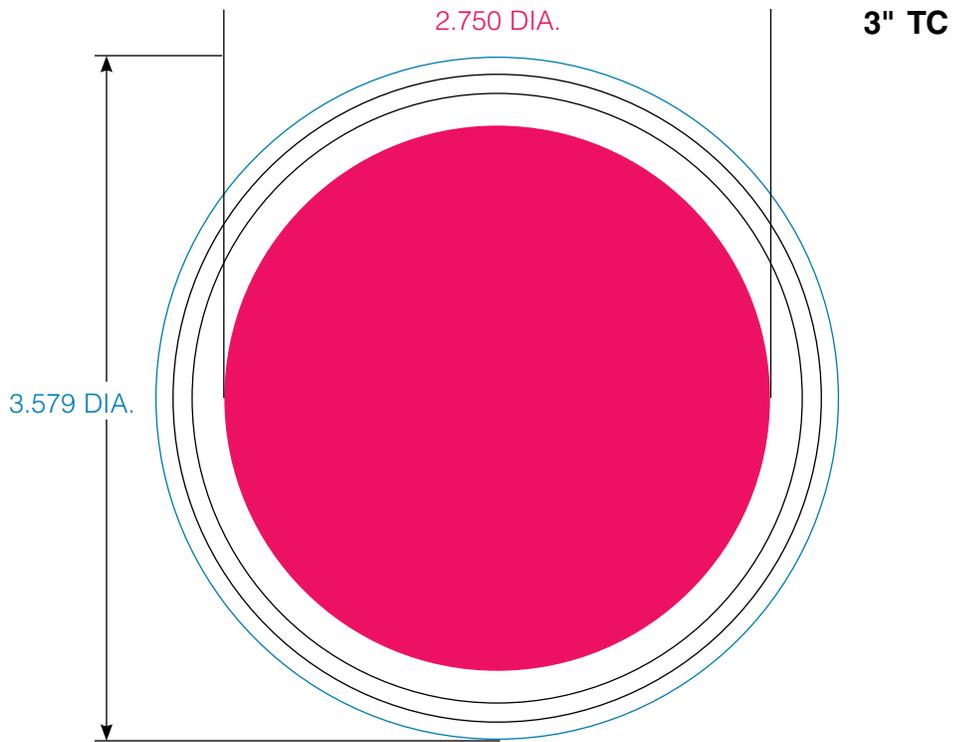


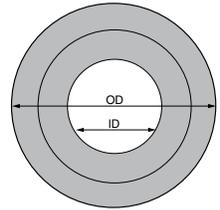
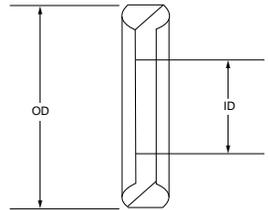
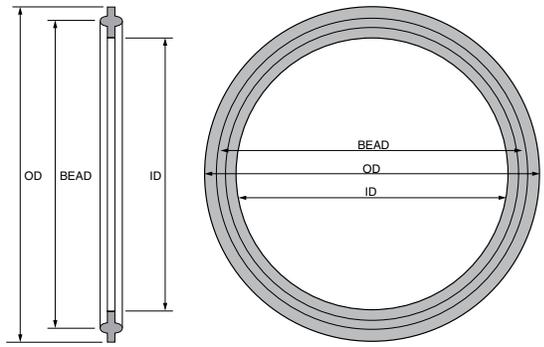
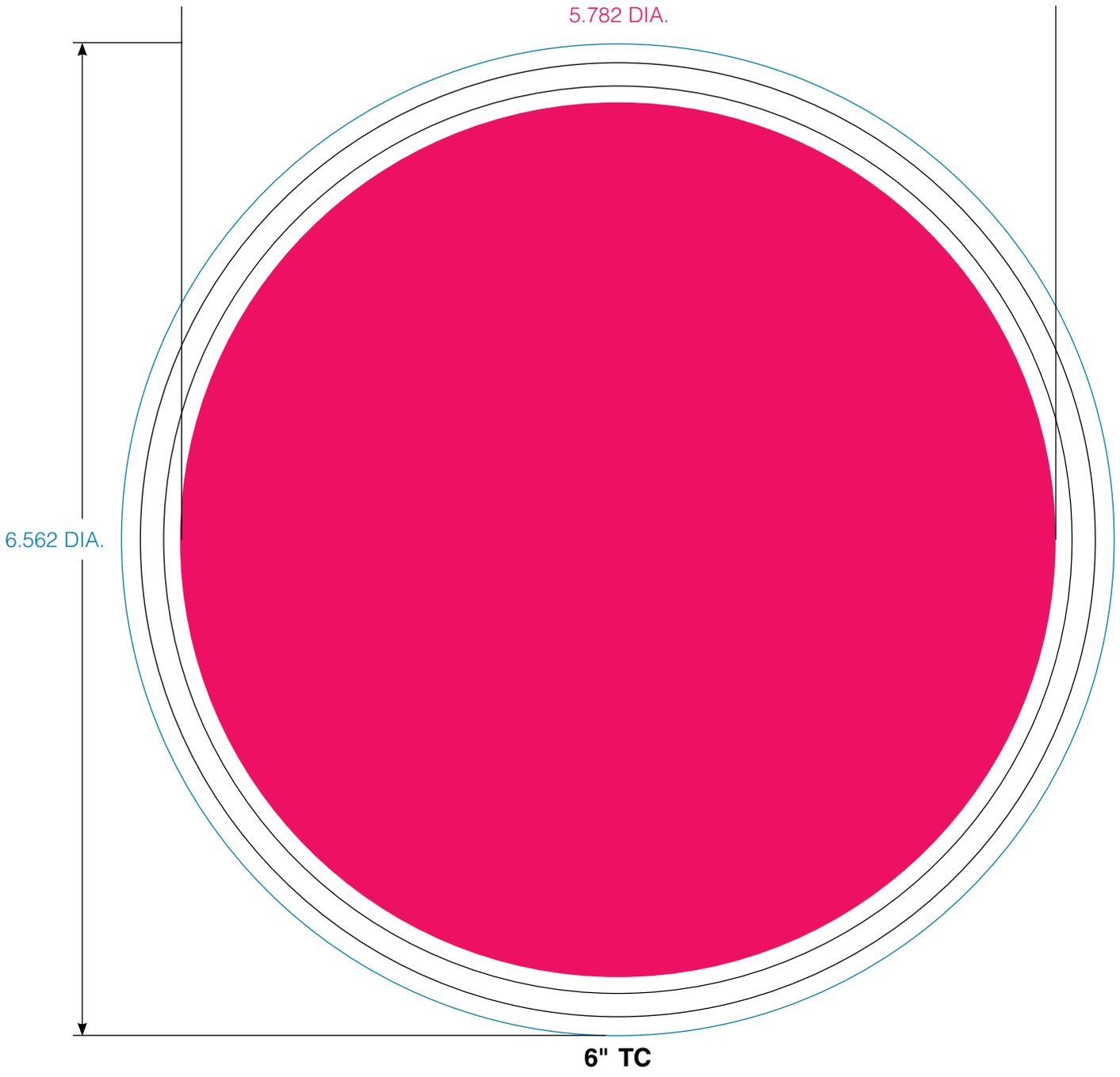
1" LADISH® TC

**NOTE:**

ID measurements are indicated in red  
OD measurements are indicated in blue







# Dimensional Chart for Tri-Clamp® Gaskets

ID		OD		Bead		Series A DIN32676	Series B ISO1127	Series C ASME BPE	ISO 2852	SMS 3019	BS 4825-3	SCH 5 BS	Special Size
inch	mm	inch	mm	inch	mm								
0.17	4.20	0.86	21.80	0.80	20.20								X
0.19	4.80	0.86	21.80	0.80	20.20			1/4"					
0.24	6.20	0.86	21.80	0.80	20.20	DN06							
0.28	7.20	0.86	21.80	0.80	20.20		DN06						
0.31	8.00	0.86	21.80	0.80	20.20			3/8"					
0.32	8.20	0.86	21.80	0.80	20.20	DN08							
0.38	9.60	0.86	21.80	0.80	20.20			1/2"			1/2"		
0.41	10.50	0.86	21.80	0.80	20.20		DN08						
0.48	12.20	0.86	21.80	0.80	20.20								X
0.56	14.20	0.86	21.80	0.80	20.20		DN10						
0.63	16.00	0.86	21.80	0.80	20.20			3/4"			3/4"		
0.88	22.30	1.34	34.00	0.80	20.20			1" Type A					
* 21.8mm gaskets do not have a ferrule bead (Including 1" Type A). 21.8mm sizes utilize size: 13MHMM-304-050/075													
0.39	10.00	1.34	34.00	1.08	27.50					DN12			
0.40	10.20	1.34	34.00	1.08	27.50	DN10			DN12				
0.41	10.50	1.34	34.00	1.08	27.50								X
0.43	10.90	1.34	34.00	1.08	27.50				DN12.7				
0.56	14.20	1.34	34.00	1.08	27.50								X
0.61	15.40	1.34	34.00	1.08	27.50				DN17.2				
0.64	16.20	1.34	34.00	1.08	27.50	DN15				DN18			
0.72	18.30	1.34	34.00	1.08	27.50								X
0.77	19.50	1.34	34.00	1.08	27.50				DN21.3				
0.80	20.20	1.34	34.00	1.08	27.50	DN20							
0.88	22.30	1.34	34.00	1.08	27.50								X
Above sizes utilize clamp size: 13MHMM-304-34mm (Including 1" Type A)													
0.40	10.20	2.00	50.50	1.71	43.50								X
0.56	14.20	2.00	50.50	1.71	43.50								X
0.64	16.20	2.00	50.50	1.71	43.50								X
0.72	18.30	2.00	50.50	1.71	43.50		DN15						
0.80	20.20	2.00	50.50	1.71	43.50								X
0.88	22.30	2.00	50.50	1.71	43.50			1"					
0.90	22.80	2.00	50.50	1.71	43.50				DN25	DN25			
0.94	23.90	2.00	50.50	1.71	43.50		DN20						
1.03	26.20	2.00	50.50	1.71	43.50	DN25							
1.18	29.90	2.00	50.50	1.71	43.50		DN25						
1.20	30.50	2.00	50.50	1.71	43.50							1"	
1.24	31.50	2.00	50.50	1.71	43.50				DN33.7	DN33.7			
1.27	32.50	2.00	50.50	1.71	43.50	DN32							
1.38	35.00	2.00	50.50	1.71	43.50							1.5"	
1.41	35.80	2.00	50.50	1.71	43.50				DN38	DN38			
1.50	38.20	2.00	50.50	1.71	43.50	DN40							
1.52	38.60	2.00	50.50	1.71	43.50								X
Above sizes utilize clamp size: 13MHMM-304-100/150													
1.49	37.80	2.52	64.00	2.22	56.50				DN40				
1.52	38.60	2.52	64.00	2.22	56.50		DN32						
1.75	44.50	2.52	64.00	2.22	56.50		DN40						
1.78	45.30	2.52	64.00	2.22	56.50							1.5"	
1.88	47.70	2.52	64.00	2.22	56.50							2"	
1.92	48.80	2.52	64.00	2.22	56.50				DN51	DN51			
1.98	50.20	2.52	64.00	2.22	56.50	DN50							
Above sizes utilize clamp size: 13MHMM-304-200													

ID		OD		Bead		Series A DIN32676	Series B ISO1127	Series C ASME BPE	ISO 2852	SMS 3019	BS 4825-3	SCH 5 BS	Special Size
inch	mm	inch	mm	inch	mm								
2.22	56.50	3.05	77.50	2.78	70.50		DN50						
2.26	57.40	3.05	77.50	2.78	70.50							2"	
2.38	60.40	3.05	77.50	2.78	70.50			2.5"			2.5"		
2.38	60.50	3.05	77.50	2.78	70.50				DN63.5	DN63.5			
Above sizes utilize clamp size: 13MHHM-304-250													
2.61	66.20	3.58	91.00	3.29	83.50	DN65							
2.64	67.00	3.58	91.00	3.29	83.50				DN70				
2.72	69.00	3.58	91.00	3.29	83.50							2.5"	
2.85	72.30	3.58	91.00	3.29	83.50		DN65						
2.88	73.10	3.58	91.00	3.29	83.50			3"	DN76.1	DN76.1	3"		
Above sizes utilize clamp size: 13MHHM-304-300													
3.20	81.20	4.17	106.00	3.82	97.00	DN80							
3.33	84.50	4.17	106.00	3.82	97.00		DN80						
3.35	85.10	4.17	106.00	3.82	97.00				DN88.9	DN88.9		3"	
Above sizes utilize clamp size: 13MHHM-V-304-300													
3.84	97.60	4.67	119.00	4.33	110.00			4"			4"		
3.85	97.80	4.67	119.00	4.33	110.00				DN101.6	DN101.6			
3.94	100.20	4.67	119.00	4.33	110.00	DN100							
Above sizes utilize clamp size: 13MHHM-304-400													
4.33	109.90	5.12	130.00	4.80	122.00		DN100						
4.35	110.50	5.12	130.00	4.80	122.00				DN114.3	DN114.3		4"	
Above sizes utilize clamp size: 13MHHM-V-304-400													
4.86	123.50	5.68	144.20	5.29	134.30			5**					
Above sizes utilize clamp size: 13MHHM-304-500													
4.93	125.20	6.10	155.00	5.75	146.00	DN125							
5.30	134.70	6.10	155.00	5.75	146.00		DN125						
5.35	135.90	6.10	155.00	5.75	146.00				DN139.7	DN139.7		5**	
Above sizes utilize clamp size: 13MHHM-V-304-500													
5.79	147.10	6.57	167.00	6.16	156.50			6"					
Above sizes utilize clamp size: 13MHHM-304-600													
5.91	150.20	7.20	183.00	6.85	174.00	DN150							
6.43	163.30	7.20	183.00	6.85	174.00		DN150		DN168.3	DN168.3		6"	
Above sizes utilize clamp size: 13MHHM-V-304-600													
7.78	197.60	8.56	217.40	8.15	207.00			8**					
Above sizes utilize clamp size: 13MHHM-304-800													
7.88	200.20	9.19	233.50	8.86	225.00	DN200							
8.43	214.10	9.19	233.50	8.86	225.00		DN200		DN219.1	DN219.1		8"	
Above sizes utilize clamp size: 13MHHM-V-304-800													
9.77	248.20	10.66	271.00	10.14	257.60	DN250*		10**					
Above sizes utilize clamp size: 13MHHM-304-1000													
10.49	266.50	11.32	287.60	11.00	279.40							10"	
Above sizes utilize clamp size: 13MHHM-V-304-1000													
11.81	300.00	12.56	319.00	12.17	309.00	DN300*		12**					
Above sizes utilize clamp size: 13MHHM-304-1200													
12.44	316.00	13.31	338.10	12.93	328.42							12"	
Above sizes utilize clamp size: 13MHHM-V-304-1200													

\* Not included in the sanitary standard