



# Flex-Pure<sup>®</sup> Enhanced EPDM Gaskets



Traditional EPDM gaskets have been in the pharmaceutical processing industry for many years. While they have solved the problem of needing a seal that can handle temperatures between -30°F to 300°F, they have their shortcomings; one of which is gasket adhesion.

Gasket adhesion is when the gasket sticks to the stainless steel flanges, causing loss of surface pressure, swelling of the gasket and excessive cleaning. This problem can become very costly for a number of reasons.

- Difficulty cleaning due to intrusion or surface roughness
- Damage to ferrules from excessive adhesion
- Time consuming maintenance
- Poor gasket performance which could lead to contamination

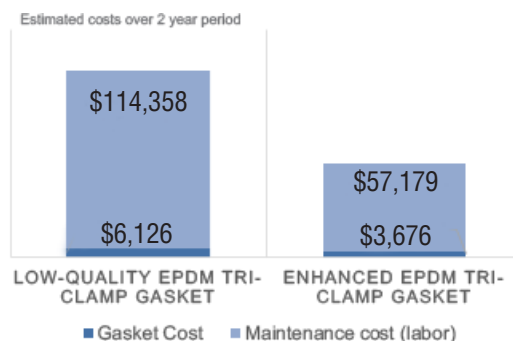
## WHAT IF THERE WAS A BETTER WAY?

What if...

- You could reduce your maintenance efforts significantly by using pharmaceutical grade gaskets that do not stick to the flanges?
- You could eliminate the need for endlessly checking your sealing connection
- There was a high-purity gasket that delivers a higher sealing performance, even in the most challenging hygienic applications such as SIP and CIP, as well as temperature cycling



*Stainless steel flanges with an EPDM Tri-Clamp<sup>®</sup> Gasket adhered to it*



*This graph is based on a 2 year period with 1,000 connections, an average time to replace gasket at 20 minutes, and the average time to re-torque gasket at 5 minutes*

## Introducing Rubber Fab's Flex-Pure<sup>™</sup> Enhanced EPDM Gasket

## FLEX-PURE® ENHANCED EPDM TRI-CLAMP® GASKET

Rubber Fab's Flex-Pure® EPDM gasket has a good temperature resistance from -29°F to 300°F (-34°C to 149°C) and has excellent media resistance to hot water, steam, acids and alkalis. Due to its very good resistance to steam, acids and alkalis, Flex-Pure® is compatible with most CIP (Cleaning in Place) and SIP (Sterilization in Place) cleaning media. Flex-Pure® is therefore suitable for use in sterilizable bioreactors and in many synthesis processes for active pharmaceutical ingredients. You don't need to spend a lot more to get a quality EPDM gasket with great sealing characteristics and low maintenance costs.

### KEY BENEFITS

- Laser marked by default with lot number and material name
- Full and easy traceability
- Highest purity of products – peroxide cured
- Suitable for SIP and CIP
- Good steam resistance - very low swell and minimal loss of physical properties after repeated steam cycling
- Good chemical resistance - very low swell and minimal loss of physical properties after long-term exposure to CIP media
- Clean and easy removal of gaskets - no sticking to the flanges
- Low extractable values
- Excellent dimensional stability
- Very low compression set for best sealing performance

### AVAILABLE SIZES

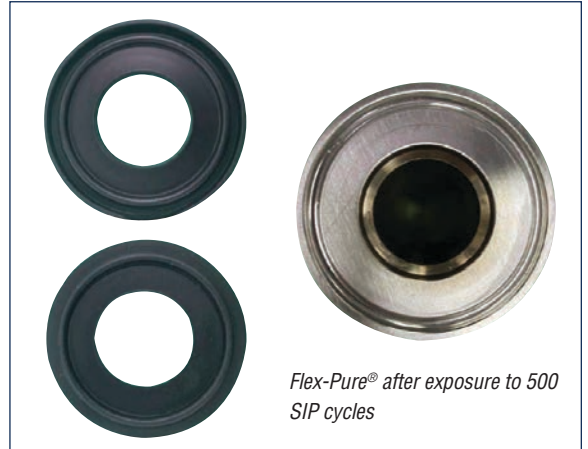
- 1/4" - 12"

### CERTIFICATIONS

- USP Class VI <87>, <88> (250°F, 121°C)
- 3A Sanitary Standard 18 03 Class II
- FDA 21 CFR177.2600 (Formulation & Extraction)
- Simulated SIP Testing (500 Cycles) in accordance with ASME BPE 2019 (SG 4.2 Static Seal Performance)
- EC1935/2004 (EU Food Contact Regulation)
- Manufactured in compliance with EC2023/2006 (GMP)
- Manufactured in compliance with FDA 21 CFR174.5 (cGMP)
- ADI free (EMEA 410/01)



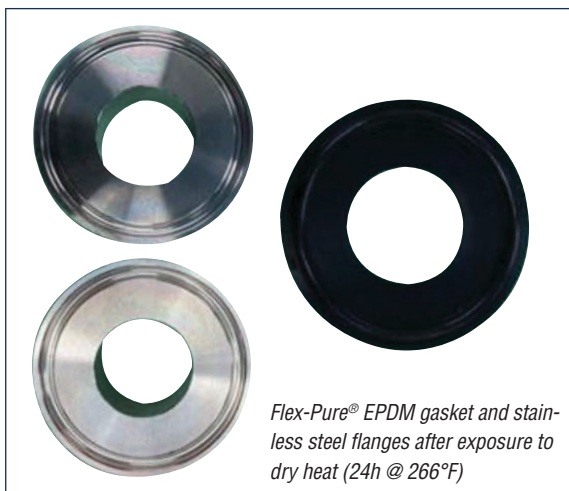
Flex-Pure® EPDM gasket laser etched with lot number and material name.



Flex-Pure® after exposure to 500 SIP cycles



EPDM B after exposure to 500 SIP cycles



Flex-Pure® EPDM gasket and stainless steel flanges after exposure to dry heat (24h @ 266°F)



EPDM gasket B and stainless steel flanges after exposure to dry heat (24h @ 266°F)

# FLEX-PURE® TEST RESULTS

## PHYSICAL PROPERTY TESTING

Physical Properties	Test Method	Flex-Pure™ EPDM Gasket	EPDM-A
Hardness (Shore A)	ASTM D 2240	75±5	76
Tensile Strength (MPa)	ISO 37 Type 1	19.5 (2828 psi)	16.4 (2379 psi)
Elongation (%)	ISO 37 Type 1	205	130
Specific Gravity (g/cm <sup>3</sup> )	ISO 2781 A	1.14	–
100% Modulus (MPa)	ISO 37 Type 1	6.5 (943 psi)	–
Compression Set (%) 22 hours @ 212°F (100°C)	ISO 815/ASTM D 395/B	6	–
Compression Set (%) 22 hours @ 302°F (150°C)	ISO 815/ASTM D 395/B	11.6	–
Compression Set (%) 48 hours @ 212°F (100°C)	ASTM D 395/B	–	4.2
Compression Set (%) 48 hours @ 302°F (150°C)	ASTM D 395/B	–	10

EPDM-A is an enhanced EPDM currently on the market

## CIP DETERGENT (ALKALINE AND ACID) EXPOSURE TESTING

### Flex-Pure® EPDM Gasket

CIP 100®* (4% by volume in de-ionized water)	Unit	4 weeks at 140°F/60°C
Hardness Change	IRHD	-0.9
Tensile Change	%	1.9
Elongation Change	%	-3.3
Volume Change	%	0.53

\*Based on potassium hydroxide. CIP 100® is a registered trademark of Steris Corporation

### EPDM-A Gasket

CIP 100® (4% by volume in de-ionized water)	Unit	4 weeks at 140°F/60°C
Hardness Change	IRHD	-2.0
Tensile Change	%	-9.7
Elongation Change	%	-7.0
Volume Change	%	2.6

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### Flex-Pure® EPDM Gasket

CIP 200®* (4% by volume in de-ionized water)	Unit	4 weeks at 140°F/60°C
Hardness Change	IRHD	-1.8
Tensile Change	%	2.7
Elongation Change	%	-2.9
Volume Change	%	0.61

\*Based on phosphoric acid. CIP 200® is a registered trademark of Steris Corporation

### EPDM-A Gasket

CIP 100® (4% by volume in de-ionized water)	Unit	4 weeks at 68°F/20°C
Hardness Change	IRHD	0.0
Tensile Change	%	-24.0
Elongation Change	%	-16.0
Volume Change	%	0.1

EPDM-A is an enhanced EPDM currently on the market

# Rubber Fab

a Garlock Hygienic Technologies company

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