Guide to significantly increase efficacy of maintenance in biotech plants

How the right gasket selection reduces maintenance related costs and efforts

Our Mission Together

Our Mission Together:

- Partners with a high level of expertise
- Work closely together to serve verified market needs
- Serving special market needs

Up to the challenge:

- Keeping up with the pace
- Reduce Waste, Smaller Footprint
- Safer Products and Production
- Less Maintenance

Rubber Fab
a Garlock Hygienic Technologies company

Maintenance in Biotech plants

Industry trends

EXTENSIVE OUTSOURCING

FOCUS ON PREDICTIVE AND RELIABILITY-BASED MAINTENANCE

FOCUS ON ADVANCED TECHNOLOGY, AUTOMATION, MOBILE TECHNOLOGY

ACQUIRING SKILL AND TECHNOLOGY TO IMPROVE SERVICE CAPABILITY

SINGLE USE AND CONTINUOUS MANUFACTURING

Maintenance in Biotech plants

What does it take?

SPEED

EFFICIENCY

COST AWARENESS

INSPECTION

PROBLEM PREVENTION

The Average Manufacturer Faces 800 Hours of Downtime Annually!

Rubber Fab
a Garlock Hygienic Technologies company

One Common Misconception

Gasket Adhesion - And the impact on maintenance

- What cause a Gasket to adhere on a steel flange?
- Do all EPDM Compound Materials perform the same way?
- And what are the consequences for maintenance?

Problems of surface adhesion

- Loss of surface pressure
- Swelling of the gasket
- Excessive cleaning

Rubber Fab
a Garlock Hygienic Technologies company

One Common Misconception

What Causes Gasket Adhesion?

Gasket Adhesion and the impact on maintenance

- Blooming / Compound - "sweating of gasket"
- Physical Properties
- Curing (Over and Under Curing)
- Wrong application
- Chemicals, Temperature or Sterilization

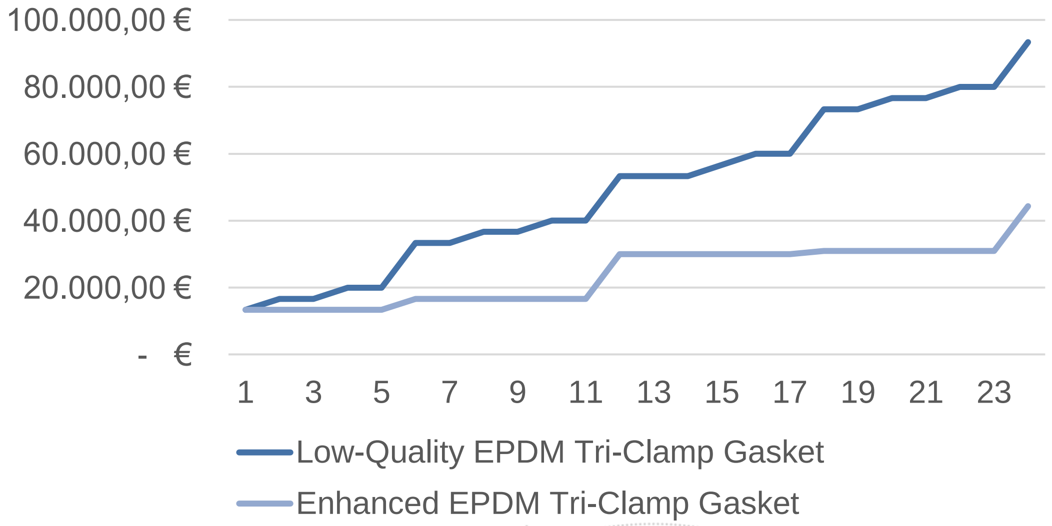
Maintenance Cost

Calculation of Installation Cost

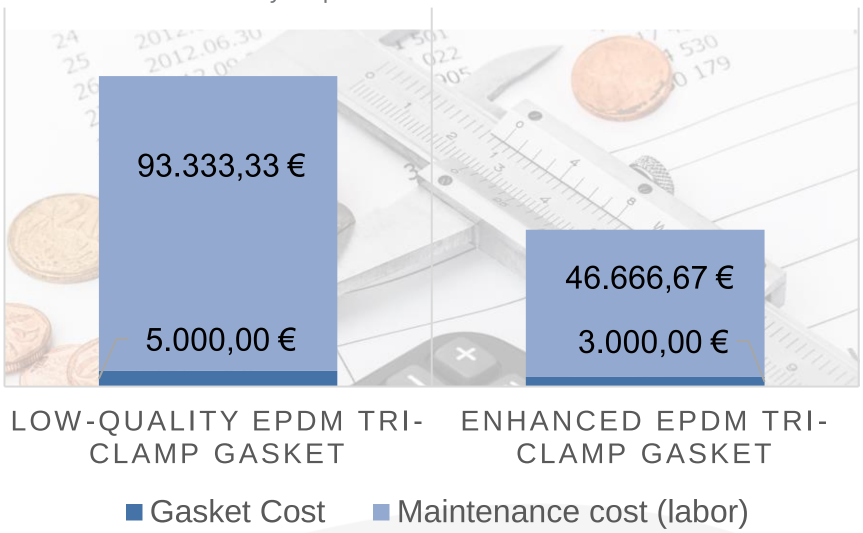
Maintenance time on hygienic connection

Number of connections in Biotech plant	1.000
Average intallation time to replace a gasket	20 min
Average time to re-torque a gasket	5 min

Maintenance costs over 2 year period



Estimated costs over 2 year period



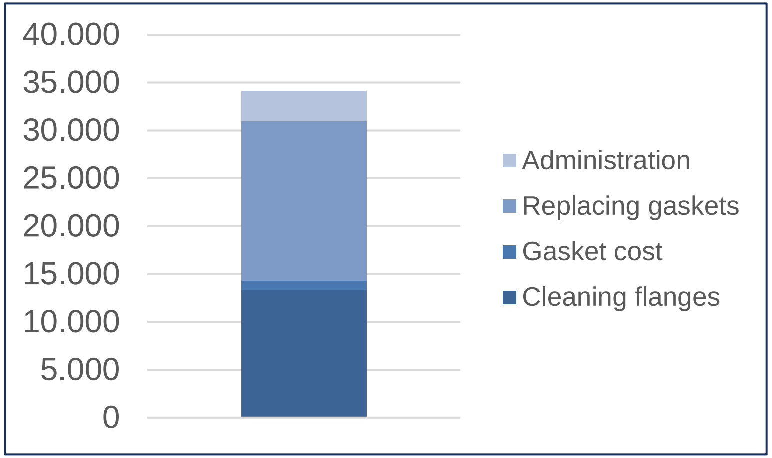
Maintenance Cost

Calculation of installation costs + Gaskets Sticking to Flanges

Cleaning flanges	Value
Number of connections in Biotech plant	1.000
Number of flanges	2.000
Time to clean 1 flange	10 min
Time to clean 2.000 flanges	333h
Labor costs	40 €/h*
Overall Costs Cleaning Flanges	**13.320 €**

**Labor costs considering staff qualification according to UBS-research prices and loans*

Gasket replacement	Value
Number of connections in Biotech plant	1.000
Purchase of new gaskets	1.000 €
Average intallation time to replace a gasket	20 min
Average time to re-torque a gasket	5 min
Time to replace & re-torque 1.000 connections	417h
Labor costs	40 €/h*
Overall Costs Gasket Replacement	**17.680 €**



Downtime	Value
Inspection (2 FTEs)	20 h
Procurement/Project Management (2 FTEs)	15 h
Cleaning Flanges / Gasket Replacement (10 FTEs)	75 h
Pressure tests + Passivation	80 h
Overall downtime	**190 h**

Rubber Fab
a Garlock Hygienic Technologies company

Maintenance Cost

Calculation of installation costs + Gaskets Sticking to Flanges + What else?

There is a Better Way

What if…

- You could reduce your maintenance efforts significantly by using biopharma grade gaskets, that do not stick to your stainless-steel flanges?
- By using these gaskets, you could eliminate the need of endlessly checking your sealing connections?
- Not only that, what if these high-purity gaskets could deliver a higher sealing performance, even in the most challenging hygienic applications?

Safety Factor

For example:

- Steam-In-Place (SIP) and Cleaning-In-Place (CIP) media
- Temperature cycling, etc.

Sterilization

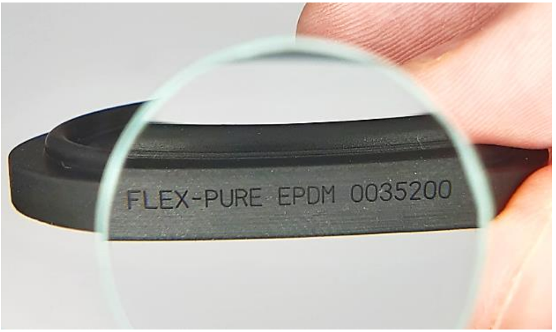
Temperature Range

Rubber Fab
a Garlock Hygienic Technologies company

Our Solution – Flex-Pure™ EPDM

Gaskets for hygienic clamp connection (Tri-Clamp)

NEW PRODUCTS



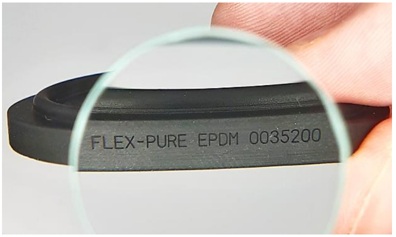
Rubber Fab
a Garlock Hygienic Technologies company

Our Solution – Flex-Pure™ EPDM

Gaskets for hygienic clamp connection (Tri-Clamp)

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



Our Solution - Flex-Pure™ EPDM

Gaskets for hygienic clamp connection (Tri-Clamp)

Regulatory Compliance

- FDA 21 CFR177.2600 (Formulation review & Extraction testing)
- USP Class VI <87>, <88> 121°C (In-Vivo and In-Vitro Biocompatibility Testing)
- 3A Sanitary Standard 18-03 (Multiple-Use Rubber as Product Contact Surfaces in Dairy Equipment)
- EC1935/2004 (Food Contact Regulation)
- ADI (Animal Derived Ingredient) Free (EMEA 410/01)
- Manufactured in compliance with FDA 21CFR174.5 (cGMP)
- Manufactured in compliance with EC 2023/2006 (GMP)

FDA BfR

USP CLASS VI

3A

EC 1935/2004

ADI FREE

2023/2006 EC

And more…

Our Solution - Flex-Pure™ EPDM

In-House Testing Capabilities

Chemical lab

Compound lab

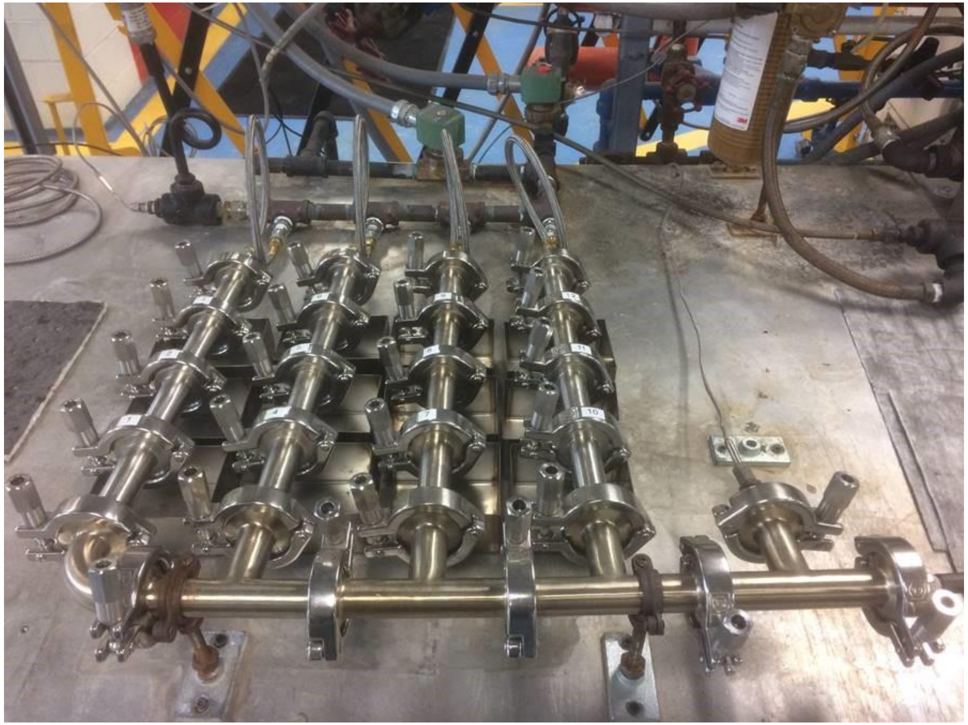
Physical lab

Functional lab

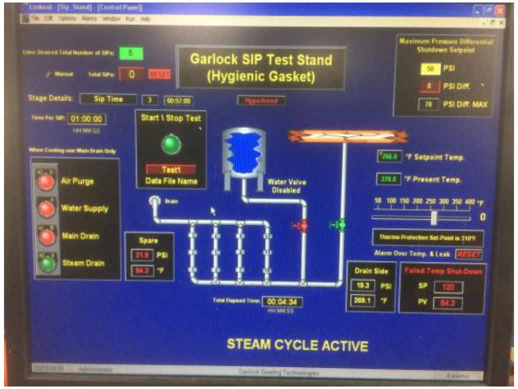
Rubber Fab
a Garlock Hygienic Technologies company

Our Solution - Flex-Pure™ EPDM

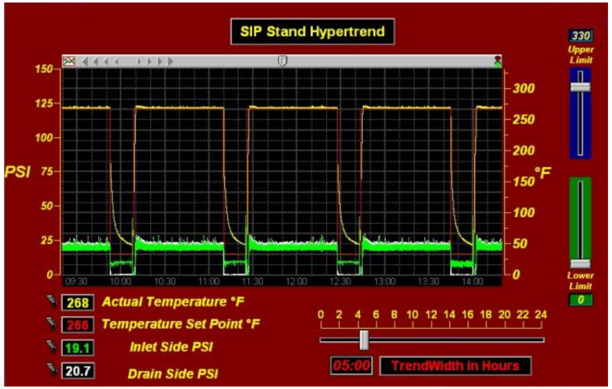
Steam-In-Place Testing



Steam-In-Place test stand for hygienic gaskets



SIP (Hygienic Gaskets) Test Control Panel



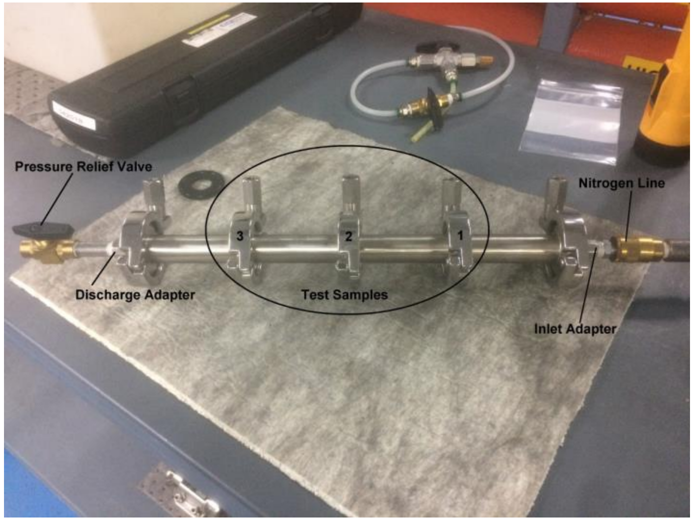
Plot of SIP (Hygienic Gaskets) Cycles in Series

Rubber Fab
a Garlock Hygienic Technologies company

Our Solution - Flex-Pure™ EPDM

Steam-In-Place Testing

- Open nitrogen supply valve and set pressure regulator to 100 psi / 6,9 bar.
- Submerge test spool in water tank. Hold for 1 minute to test shell.



Pressure

Acceptance Criteria:

No bubbles are permitted to break the surface of the water when the spool is immersed in water.

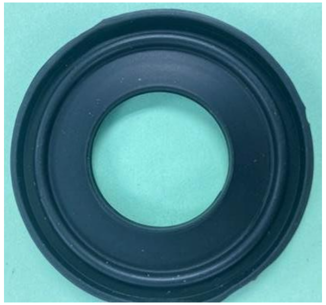
Rubber Fab
a Garlock Hygienic Technologies company

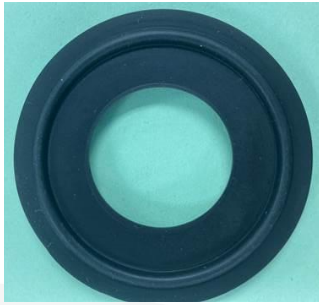
Our Solution - Flex-Pure™ EPDM

Steam-In-Place Testing

- After exposure to 500 SIP cycles: Comparison of stainless-steel flanges after removal of EPDM gaskets

Flex-Pure™ EPDM





EPDM-B

Our Solution - Flex-Pure™ EPDM

Physical Property testing

Physical Properties	Test method	Flex-Pure™ EPDM	EPDM - A	EPDM - B	EPDM - C	EPDM - D
Hardness (Shore A)	ASTM D 2240	**75 ±5**	76	77	71	77
Tensile Strength (MPa)	ISO 37 Type 1	**19,5 (2828 psi)**	16,4 (2379 psi)	12,9 (1880 psi)	7,1 (1030 psi)	16,2 (2350 psi)
Elongation (%)	ISO 37 Type 1	**205**	130	381	152	386
Specific Gravity (g/cm³)	ISO 2781 A	**1,14**	-	1,29	1,07	1,11
100% Modulus (MPa)	ISO 37 Type 1	**6,5 (943 psi)**	-	3,4 (488 psi)	4,5 (652 psi)	4,2 (612 psi)
Compression Set (%) 22 hours @ 100°C	ISO 815 / ASTM D 395/B	**6**	-	-	-	-
Compression Set (%) 22 hours @ 150°C	ISO 815 / ASTM D 395/B	**11,6**	-	25,7	13,6	13,6
Compression Set (%) 48 hours @ 100°C	ASTM D 395/B	**-**	4,2	-	-	-
Compression Set (%) 48 hours @ 150°C	ASTM D 395/B	**-**	10	-	-	-

Our Solution - Flex-Pure™ EPDM

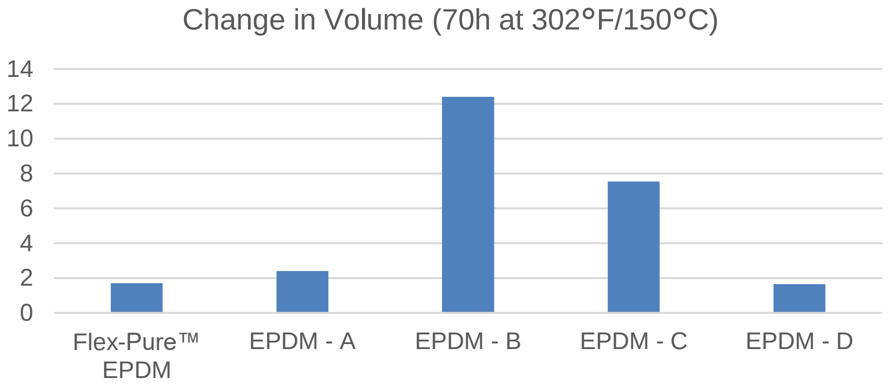
Steam Immersion Testing

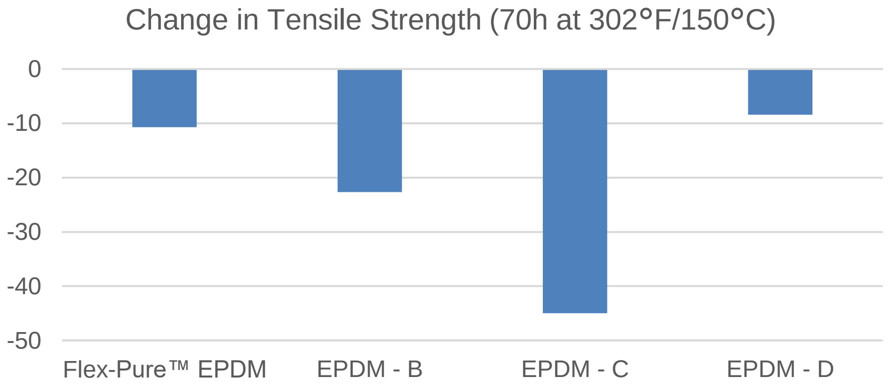
- Steam Immersion Testing (or Steam Aging) is part of our Gate 1 Screening procedures, when developing and validating new compounds.
- Besides testing physical properties, we have performed extensive steam testing utilizing Parr bombs (pressure equipment) and glass tubes.
- EPDM materials are exposed to steam (liquid and gas phase) at 302°F(150°C) for duration of 70h. After exposure time, the key physical properties are measure again and a “before/after” comparison is made. The results are displayed on following slide.

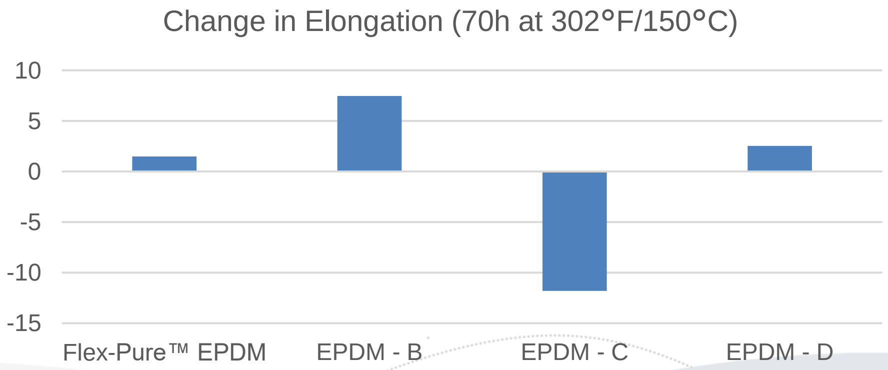
Picture Credit: Parr Instrument Company

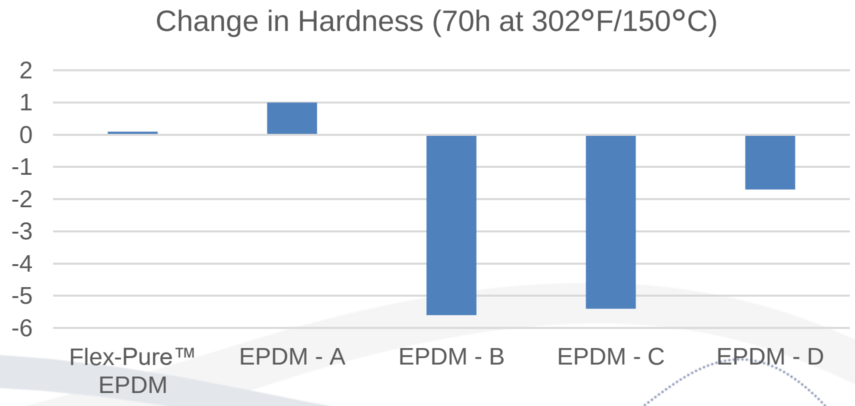
Our Solution - Flex-Pure™ EPDM

Steam Immersion Testing









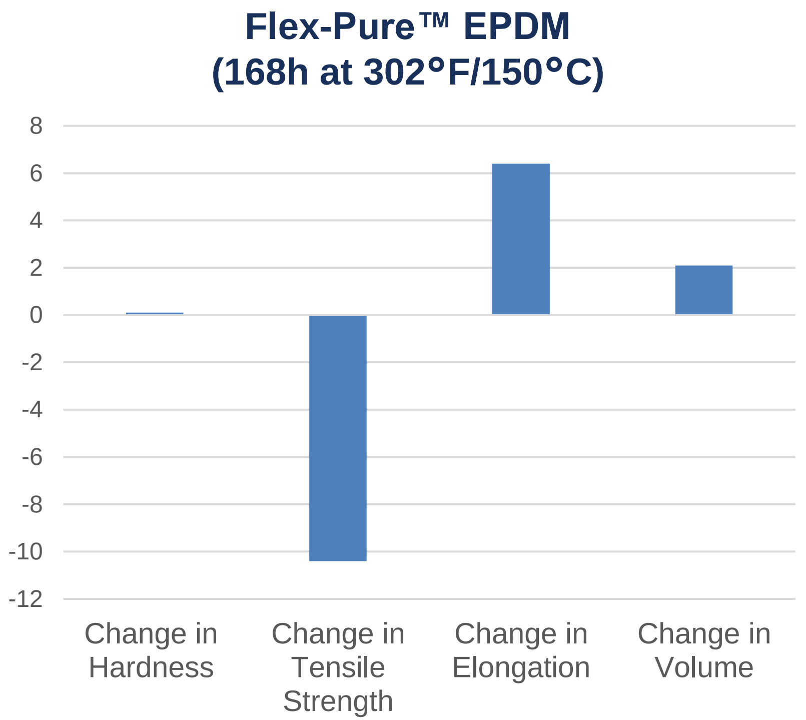
Rubber Fab
a Garlock Hygienic Technologies company

Our Solution - Flex-Pure™ EPDM

Steam Immersion Testing

- Rubber Fab Flex-Pure™ EPDM shows best in class resistance to steam exposure (see previous slide)

- Even after prolonged exposure to steam (168h), our Flex-Pure™ EPDM shows only minimal change of physical properties.

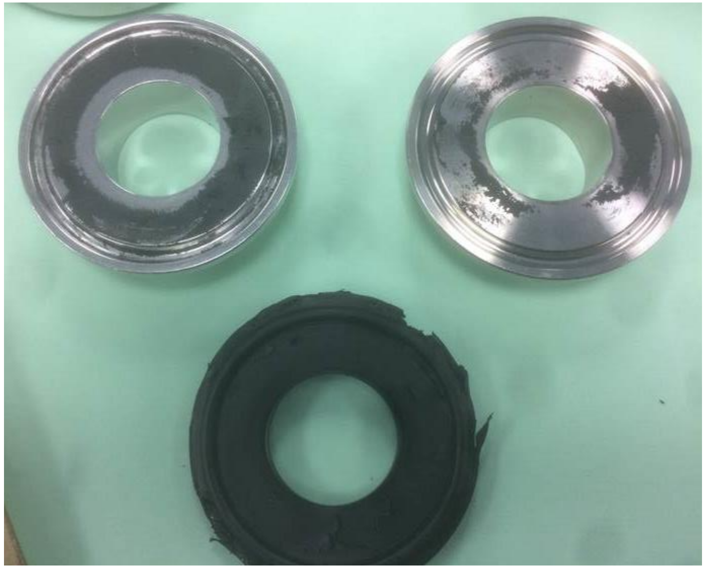


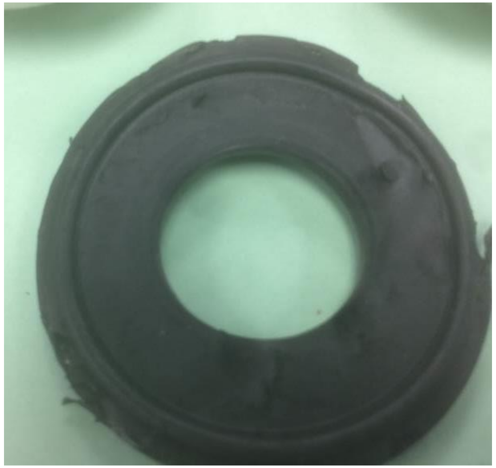
Our Solution - Flex-Pure™ EPDM

Dry Heat - Surface Adhesion

EPDM gasket and stainless-steel flanges after exposure to dry heat (24h @ 130°C/266°F):

EPDM-B



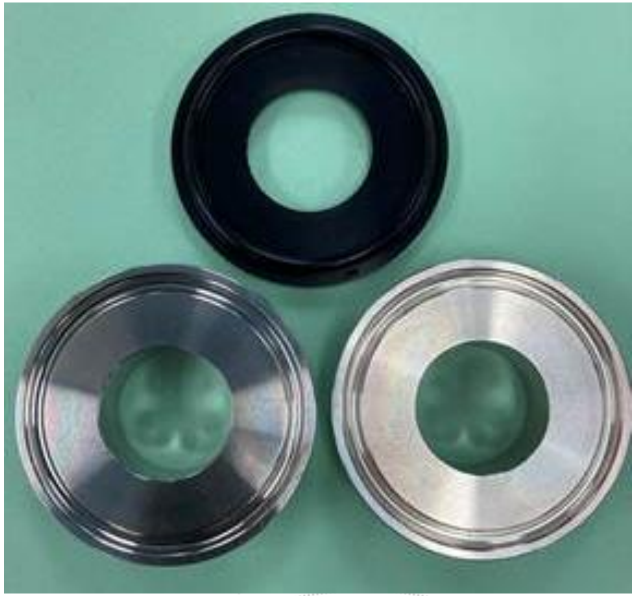


Our Solution - Flex-Pure™ EPDM

Dry Heat - Surface Adhesion

EPDM gasket and stainless-steel flanges after exposure to dry heat (24h @ 130°C/266°F):

Flex-Pure™ EPDM



Rubber Fab
a Garlock Hygienic Technologies company

Our Solution - Flex-Pure™ EPDM

CIP Detergent (Alkaline and Acid) exposure testing

Flex-Pure™ EPDM

CIP 100®* (4% by volume in de-ionized water)	Unit	4 weeks at 60°C/140°F
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.*

CIP 200®* (4% by volume in de-ionized water)	Unit	**4 weeks at 60°C/140°F**
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

CIP 100® (4% by volume in de-ionized water)	Unit	4 weeks at 60°C/140°F
Hardness Change	IRHD	-2
Tensile Change	%	-9,7
Elongation Change	%	-7
Volume Change	%	2,6

CIP 200® (4% by volume in de-ionized water)	Unit	**4 weeks at 20°C/68°F**
Hardness Change	IRHD	0
Tensile Change	%	-24
Elongation Change	%	-16
Volume Change	%	0,1

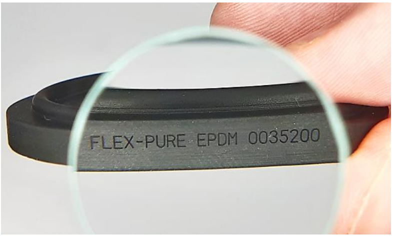
Rubber Fab
a Garlock Hygienic Technologies company

Our Solution – Flex-Pure™ EPDM

Gaskets for hygienic clamp connection (Tri-Clamp)

Key Benefits

- Laser marked by default with Lot number and material name
- Full and Easy Traceability
- Highest Purity of Products – Peroxide Cured
- Clean and Easy Removal of gaskets - No sticking to the flanges
- 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
- Low Extractable values
- Excellent Dimensional Stability
- Very low Compression Set for best Sealing Performance



Rubber Fab
a Garlock Hygienic Technologies company

Rubber Fab - Flex-Pure™ Gaskets

Flex-Pure™ NEW PRODUCTS

Silicone - Platinum cured

Sanitary Tri-Clamp® gasket

Flex-Pure™ NEW PRODUCTS

EPDM - Peroxide-cured

Sanitary Tri-Clamp® gasket

Flex-Pure™ NEW PRODUCTS

FKM - Peroxide cured

Sanitary Tri-Clamp® gasket

Thank you for your attention!

Do you have any questions?

Get in touch with our team!

Sascha Butter
Product Manager Europe

Mobile +49 160 92388039
sbutter@rubberfab.com | www.rubberfab.com

Christoph Neuffer
Application Engineer

Mobile +49 176 56668135
cneuffer@rubberfab.com | www.rubberfab.com

Dominik Wiese
Area Sales Manager Europe

Mobile +49 160 91769096
dwiese@rubberfab.com | www.rubberfab.com

European Warehouse - PSI Products GmbH - Ulrichstrasse 25 - 72116 Mössingen / Germany - Office +49 7473 3781 731 rubberfab.europe@rubberfab.com

Visit us

Rubber Fab on Twitter   Rubber Fab on Youtube   Rubber Fab on Linkedin

Rubber Fab
a Garlock Hygienic Technologies company