

Unmatched Reliability in Demanding Bioprocess Applications

Product Description

The GORE™ STA-PURE™ Sanitary Gasket is made from 100% expanded PTFE (ePTFE), and engineered for sealing critical bioprocess piping systems. The STA-PURE™ gasket combines superior dimensional stability with the chemical inertness of PTFE to deliver an unmatched level of performance. Further, the STA-PURE™ gasket is optimized in its design to meet the latest ASME BPE specifications for sanitary fittings. These gaskets enable clean processing with virtually no particulation and extremely low extractable content.

Quality Assurance/Biocompatibility

The GORE™ STA-PURE™ Sanitary Gasket meets the most demanding requirements of biocompatibility. It is manufactured using materials that meet or exceed the test requirements of the following:

- USP Class VI for Plastics
- USP <661> Physiochemical tests
- FDA 21 CFR 177.1550

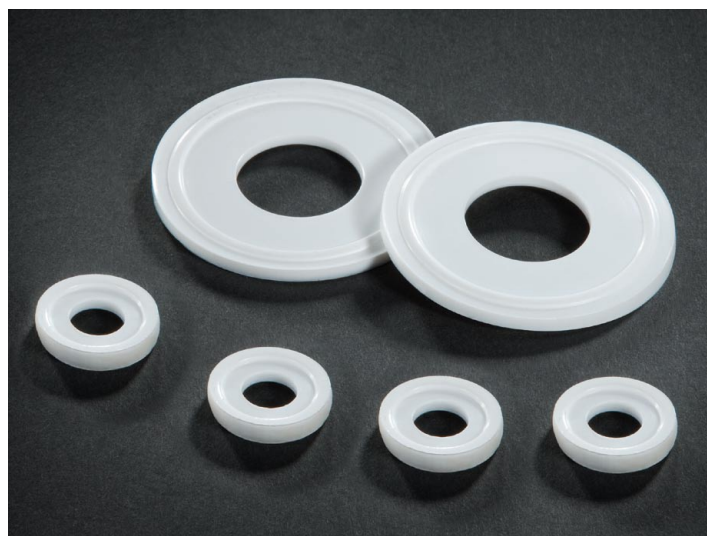
Critical properties are controlled throughout the manufacturing process, operating under a quality system based on appropriate current Good Manufacturing Practices (cGMP). Additionally, the STA-PURE™ gasket is manufactured with material that is animal derived component free (ADCF).

Materials of Construction

Expanded Polytetrafluoroethylene (ePTFE)

Typical Physical Properties

Property	Specifications
Specific Gravity	2.2
Tensile Strength, psi (ASTM F152)	7400
Temperature Range, °F (°C)	-450 to 600 (-268 to 316)
Bore Intrusion, in. (after 500 SIP)	Less than 0.008
Operating Pressures, psi	Vacuum to 3000
CIP Compatibility	Yes
Passivation Compatibility	Yes
Stability	Does not age
Color	White



Key Features

- Chemically inert
- Resistant to creep and cold flow
- Lowest bore intrusion
- Very low extractable content
- Withstands repeated SIP and CIP cycles
- Virtually no particulation
- Complete lot traceability
- Broad range of applications

Key Benefits

- Enables improved cleanability
- Promotes unobstructed fluid flow
- Maintains product integrity
- Ensures aseptic connections
- Protects against filter clogging
- Reduces validation costs

Typical Applications

- Process steam
- Upstream and downstream processing
- Ultra-pure water systems
- Sanitization (CIP) and passivation
- Process waste

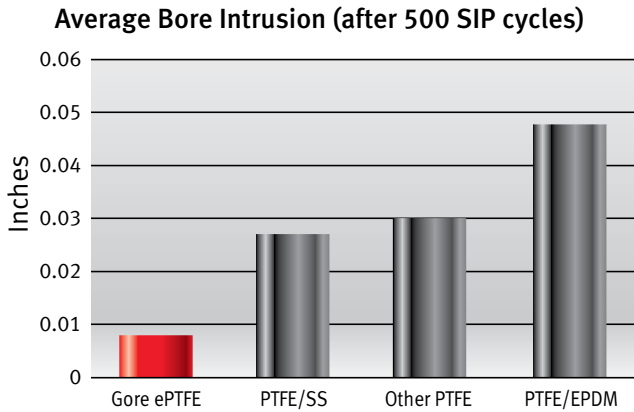


GORE™ STA-PURE™ Gasket

Expanded PTFE Sanitary Gaskets

Withstands Repeated SIP cycles

The STA-PURE™ gasket has the lowest bore intrusion of any commercially available sanitary gasket.



Results from testing conducted by the Sanitary Materials Testing Institute (SMTI) in March, 2009. Gaskets were retorqued after one SIP cycle to ensure initial seal.

Gasket Performance Evaluation

In testing conducted by SMTI, only the Gore gasket material passed all three testing requirements. All of the materials were torqued to at least 50 psi and exposed to 500 SIP cycles. The competitive gaskets did not pass the ASME BPE intrusion categories I and II and/or did not meet the one-hour pressure hold tests following every 100 SIP cycle interval.

Material	Pressure Hold	Intrusion Cat I	Intrusion Cat II
Gore ePTFE	Passed	Passed	Passed
Other PTFE	Passed	Passed	Failed
PTFE/SS	Passed	Passed	Failed
PTFE/EPDM	Failed	Failed	Failed

SMTI testing, March, 2009. Note: Based on maximum measured intrusion. Category I is defined as less than 0.025 in. intrusion. Category II is less than 0.008 in. intrusion.



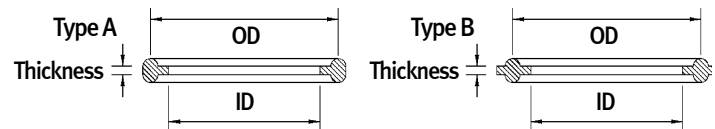
Customization Options

Building on a strong heritage of technical leadership and innovation, Gore continues to meet the demands of the marketplace by offering customers the ability to customize product offerings to meet specific needs. Customization options for GORE™ STA-PURE™ Gaskets include:

- Custom packaging including bagging and labeling
- Custom bulk quantities

Ordering Information

Part Number	ID (Nominal)	OD (Nominal)	Thickness (Nominal)	Description
SG050A		In Development		0.50" Sanitary Gasket, Type A
SG075A		In Development		0.75" Sanitary Gasket, Type A
SG100A		In Development		1.00" Sanitary Gasket, Type A
SG100B	0.870	1.984	0.080	1.00" Sanitary Gasket, Type B
SG150B	1.370	1.984	0.080	1.50" Sanitary Gasket, Type B
SG200B	1.870	2.516	0.080	2.00" Sanitary Gasket, Type B



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