

BioPure

High purity platinum-cured silicone gaskets

FEATURES AND BENEFITS

- High purity for bioprocess fluid path
- Low extractable profile
- Gamma stable and autoclavable
- Manufactured in accordance with ASME-BPE standards
- USP Class VI compliant and ADCF
- Compliant with FDA regulations CFR 21 177.2600
- Full material lot traceability
- Laser etched part coding available



COMPLIANCE

Production facilities:

- Components are manufactured and packed within an ISO14644-1 class 7 cleanroom

Post sterilised product was tested to a range of current USP and EP standards. These include:

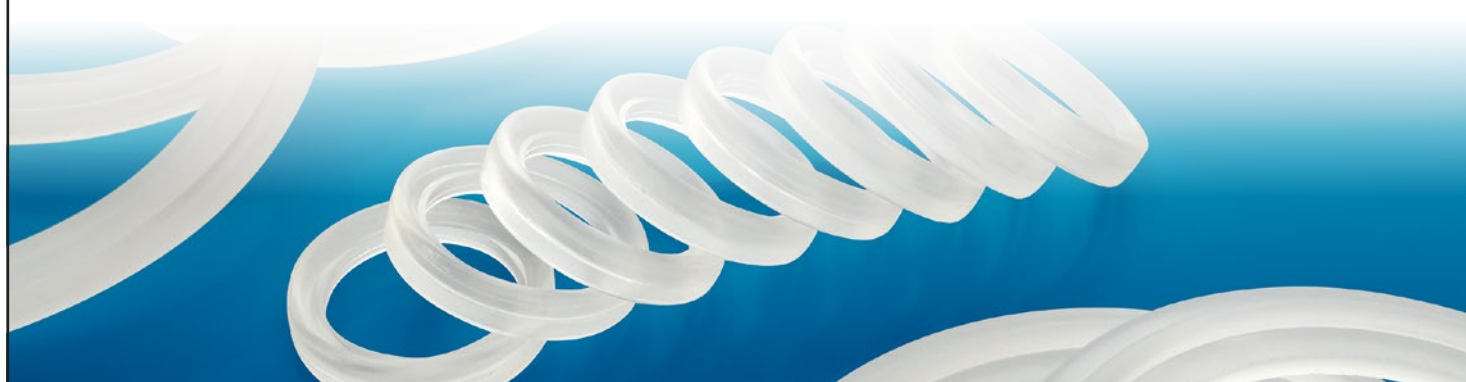
- USP <85> to determine the presence of bacterial endotoxin
- USP <88> and ISO 10993 Parts 6, 10 and 11 in vivo for biological reactivity
- USP <87> and ISO 10993 Part 5 for in vitro cytotoxicity
- USP <788> to determine the presence of particulates due to the manufacturing process
- EP 3.1.9 for physiochemical properties
- Extractables studies have been performed using a multi-solvent approach to BPOG guidelines

TECHNICAL DATA

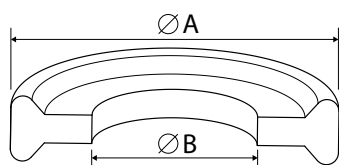
Operating temperature -65C to 254C (-85F to 490F)

Gamma irradiation up to 50kGY*

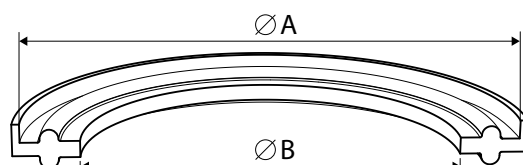
*Product is supplied non gamma irradiated



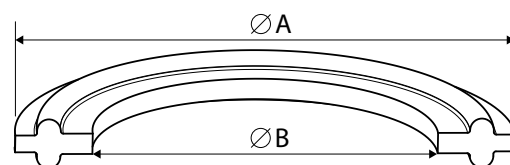
ORDER INFORMATION



Unflanged type gasket for sizes
<3/4" flange OD



Flanged type gasket



Unflanged type gasket for sizes >3/4" flange OD

BioPure High Purity Platinum-Cured Silicone Unflanged Gasket—Laser Etched

Part number	Size inch	O.D inch (ØA)	I.D inch (ØB)	Quantity
5001.0050.025	1/2	0.85 (21.6)	0.43 (10.9)	25
5001.0075.025	3/4	0.85 (21.6)	0.63 (16.0)	25
5001.0100.025	1	1.98 (50.3)	0.90 (22.9)	25
5001.0150.025	1 1/2	1.98 (50.3)	1.40 (35.6)	25
5001.0200.025	2	2.52 (64.0)	1.90 (48.3)	25
5001.0250.025	2 1/2	3.05 (77.5)	2.40 (61.0)	25
5001.0300.025	3	3.58 (90.9)	2.90 (73.7)	25
5001.0400.025	4	4.68 (118.9)	3.87 (98.3)	25
5001.0600.025	6	6.51 (165.4)	5.82 (147.8)	25

BioPure High Purity Platinum-Cured Silicone Flanged Gasket—Laser Etched

Part number	Size inch	O.D inch (ØA)	I.D inch (ØB)	Quantity
5101.0100.025	1	1.98 (50.3)	0.91 (23.1)	25
5101.0150.025	1 1/2	1.98 (50.3)	1.41 (35.8)	25
5101.0200.025	2	2.52 (64.0)	1.91 (48.5)	25
5101.0300.025	3	3.58 (90.9)	2.91 (73.9)	25
5101.0400.025	4	4.68 (118.9)	3.88 (98.6)	25

BioPure High Purity Platinum-Cured Silicone Unflanged Gasket

Part number	Size inch	O.D inch (ØA)	I.D inch (ØB)	Quantity
5201.0050.025	1/2	0.85 (21.6)	0.43 (10.9)	25
5201.0075.025	3/4	0.85 (21.6)	0.63 (16.0)	25
5201.0100.025	1	1.98 (50.3)	0.90 (22.9)	25
5201.0150.025	1 1/2	1.98 (50.3)	1.40 (35.6)	25
5201.0200.025	2	2.52 (64.0)	1.90 (48.3)	25
5201.0250.025	2 1/2	3.05 (77.5)	2.40 (61.0)	25
5201.0300.025	3	3.58 (90.9)	2.90 (73.7)	25
5201.0400.025	4	4.68 (118.9)	3.87 (98.3)	25
5201.0600.025	6	6.51 (165.4)	5.82 (147.8)	25

BioPure High Purity Platinum-Cured Silicone Flanged Gasket

Part number	Size inch	O.D inch (ØA)	I.D inch (ØB)	Quantity
5301.0100.025	1	1.98 (50.3)	0.91 (23.1)	25
5301.0150.025	1 1/2	1.98 (50.3)	1.41 (35.8)	25
5301.0200.025	2	2.52 (64.0)	1.91 (48.5)	25
5301.0300.025	3	3.58 (90.9)	2.91 (73.9)	25
5301.0400.025	4	4.68 (118.9)	3.88 (98.6)	25

To download the validation information visit wmftg.com/validation/summary-guides/

Disclaimer: The information contained in this document is believed to be correct but Watson-Marlow Limited accepts no liability for any errors it contains and reserves the right to alter specifications without notice. It is the users responsibility to ensure product suitability for use within their application. Watson-Marlow and pure are registered trademarks of Watson-Marlow Limited. Bio Y, BioClamp, BioBarb, FlatBioEndCap, BioEndCap, BioValve and BioTube applicator are Trademarks of BioPure Technology Limited. Tri-Clamp is a registered trademark of Alfa Laval Corporate AB. Q-Clamp is used under licence.



wmftg.com
info@wmftg.com
+44 (0) 2392 499000